รายงานฉบับสมบูรณ์

การศึกษากฎระเบียบการขึ้นทะเบียนผลิตภัณฑ์ยา ในประเทศเวียดนาม ประจำปีงบประมาณ 2563

พลอยศรี อมรวัฒนา

กรกฎาคม 2563

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บรรณานุกรม
ภาคผนวก
แบบสอบถามผู้ประกอบการ

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บทสรุปผู้บริหาร

โครงการการศึกษากฎระเบียบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ที่ได้รับการรับรองจากสำนักงานคณะกรรมการอาหารและยา (อย.) ประจำปีงบประมาณ พ.ศ. 2562 เป็นการดำเนินงานโดยมีวัตถุประสงค์หลัก คือ การศึกษากฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ซึ่งจะนำไปสู่ผลการศึกษาข้อมูลกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม รวมถึงเอกสารต่าง ๆ ที่ต้องใช้ประกอบการขึ้นทะเบียนผลิตภัณฑ์ เพื่อเป็นข้อมูลประกอบการจัดทำแนวทางการขึ้นทะเบียนผลิตภัณฑ์สุขภาพสำหรับเผยแพร่แก่ผู้ประกอบการ ผลการวิเคราะห์และจัดลำดับกฎระเบียบที่อาจเป็นอุปสรรคในการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม และข้อเสนอแนะเพื่อนำไปใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาของภูมิภาคอาเซียน เพื่อสร้างความสามารถในการแข่งขันให้แก่ผู้ประกอบการไทย

ตามขอบเขตการดำเนินงาน ผู้วิจัยได้ทำการรวบรวมและศึกษาข้อมูลการกำกับดูแลผลิตภัณฑ์ยาในประเทศเวียดนาม และกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม โดยหน่วยงานกำกับดูแลหลักในด้านผลิตภัณฑ์ยาของประเทศเวียดนาม คือ Drug Administration of Vietnam (DAV) สังกัดกระทรวงสาธารณสุข ซึ่งหลักเกณฑ์การกำกับดูแลจะเป็นไปตามที่กำหนดในกฎหมายว่าด้วยเภสัชกรรม (Law on Pharmacy No. 105/2016/QH13) ที่มีผลบังคับใช้เมื่อวันที่ 1 มกราคม 2560 และกฎหมายลำดับรองที่ออกภายใต้กฎหมายว่าด้วยเภสัชกรรมดังกล่าว

จากการวิเคราะห์กฎระเบียบของประเทศเวียดนาม พบว่ากฎระเบียบของประเทศเวียดนามก่อให้เกิดอุปสรรคทางการค้าที่สำคัญกับผู้ประกอบการไทยหลายประการ โดยสามารถแบ่งออกได้เป็น (1) อุปสรรคจากเนื้อหาของกฎระเบียบ เช่น ข้อกำหนดเกี่ยวกับผู้ที่สามารถยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา และข้อกำหนดเกี่ยวกับรายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาแต่ละประเภท และ (2) อุปสรรคด้านขั้นตอนกระบวนการขึ้นทะเบียนผลิตภัณฑ์ เช่น ความไม่แน่นอนของการบังคับใช้กฎระเบียบ ข้อมูลเกี่ยวกับกฎระเบียบยังไม่ได้รับการตีพิมพ์หรือเผยแพร่อย่างเพียงพอ

ในการจัดลำดับข้อกฎหมายที่เป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ผู้วิจัยได้อาศัยข้อมูลที่ได้จากการศึกษา ข้อมูลที่ได้จากการสัมภาษณ์ผู้บริหารของ อย. ประกอบกับข้อมูลที่ได้จากการจัดประชุมหารือร่วมกับผู้ประกอบการภาคเอกชนและการสำรวจข้อมูลผ่านแบบสอบถามจากผู้ประกอบการภาคเอกชน โดยสามารถสรุปการจัดลำดับข้อกฎหมายที่เป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ในด้านเนื้อหาของกฎระเบียบได้ดังนี้ อุปสรรคลำดับที่ 1 คือ ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมสำหรับยาต่างประเทศ อุปสรรคลำดับที่ 2 คือ ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมกรณียาที่ผลิตภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี (pharmaceutical technology transfer) โดยยาต้นแบบ (source drug of transfer) และอุปสรรคลำดับที่ 3 คือ ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการต่ออายุ

ทะเบียนผลิตภัณฑ์ ทั้งนี้ ในบรรดาข้อกำหนดย่อยของทุกข้อกำหนด ประเด็นที่เป็นอุปสรรคต่อผู้ประกอบการเอกชนมากที่สุด คือ หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) ซึ่งอยู่ในส่วนของข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมสำหรับยาต่างประเทศ เนื่องจากประเทศเวียดนามมีการกำหนด CPP ที่มีรายละเอียดแตกต่างจาก CPP ตามข้อกำหนดของ World Health Organization (WHO) หรือของประเทศไทย ทำให้ประเทศเวียดนามไม่ยอมรับ CPP ที่ผู้ประกอบการไทยยื่นเพื่อประกอบการคำขอขึ้นทะเบียนผลิตภัณฑ์ยาหรือคำขอต่ออายุทะเบียน

นอกจากนี้ ผู้ประกอบการภาคเอกชนมีความเห็นว่าอุปสรรคที่สำคัญอีกประการหนึ่งที่เกิดจากเนื้อหากฎระเบียบของประเทศเวียดนามนอกเหนือจากกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม คือ กฎระเบียบที่เกี่ยวข้องกับการประกวดราคาในการจัดซื้อยาของภาครัฐหรือที่ใช้งบประมาณจากภาครัฐ ที่มีการแบ่งกลุ่มของผลิตภัณฑ์ยาโดยให้ความสำคัญกับผลิตภัณฑ์ยาที่เป็นไปตามมาตรฐาน EU-GMP หรือผลิตภัณฑ์ยาที่ผลิตในประเทศที่เป็นทั้งสมาชิก PIC/S และสมาชิก ICH หรือยาที่ผลิตในประเทศเวียดนาม มากกว่าผลิตภัณฑ์จากประเทศอื่น

สำหรับอุปสรรคด้านขั้นตอนกระบวนการขึ้นทะเบียนผลิตภัณฑ์ สามารถสรุปการจัดลำดับได้ดังนี้ อุปสรรคลำดับที่ 1 คือ ความไม่แน่นอนของการบังคับใช้กฎระเบียบ อุปสรรคลำดับที่ 2 คือ การที่กฎระเบียบมักไม่จัดทำเป็นภาษาอังกฤษ และความล่าช้าในการดำเนินการของเจ้าหน้าที่ที่เกี่ยวข้อง และอุปสรรคลำดับที่ 3 คือ ข้อมูลเกี่ยวกับกฎระเบียบที่ยังไม่ได้รับการตีพิมพ์หรือเผยแพร่อย่างเพียงพอ

ในส่วนของความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุนนั้น ผู้ประกอบการประสงค์จะได้รับความช่วยเหลือหรือสนับสนุนจากภาครัฐ ดังนี้ ความต้องการลำดับที่ 1 คือ การจัดทำสรุปข้อกฎหมายของกลุ่มประเทศสมาชิกอาเซียนที่เกี่ยวกับผลิตภัณฑ์ยา ความต้องการลำดับที่ 2 คือ การกำหนดมาตรการด้านแรงจูงใจ อาทิ มาตรการลดหย่อนภาษี ความต้องการลำดับที่ 3 คือ การส่งเสริมภาพลักษณ์ และความน่าเชื่อถือในคุณภาพ และมาตรฐานของผลิตภัณฑ์ส่งออกของประเทศไทย ความต้องการลำดับที่ 4 คือ การจัดทำคู่มือเกณฑ์ความตกลงอาเซียนที่เข้าใจง่าย และสามารถนำไปปฏิบัติได้จริง ความต้องการลำดับที่ 5 คือ การให้ความช่วยเหลือด้านการถ่ายทอดเทคโนโลยี เช่น การจัดอบรม ความต้องการลำดับที่ 6 คือ การจัดศึกษาดูงานด้านผลิตภัณฑ์ยาของกลุ่มประเทศสมาชิกอาเซียน ความต้องการลำดับที่ 7 คือ การสนับสนุนด้านการวิจัยพัฒนาผลิตภัณฑ์ ทั้งในรูปตัวเงิน และไม่เป็นตัวเงิน และความต้องการลำดับที่ 8 คือ การจัดหาแหล่งเงินทุนในอัตราดอกเบี้ยต่ำ

จากการศึกษา นำไปสู่การจัดทำข้อเสนอแนะใน 2 ประเด็นหลัก ดังนี้ (1) ข้อเสนอแนะเพื่อนำไปใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาของภูมิภาคอาเซียน ได้แก่ การส่งเสริมความร่วมมือระหว่างหน่วยงานภาครัฐทั้งระหว่างหน่วยงานภาครัฐในประเทศเอง และระหว่างหน่วยงานภาครัฐในประเทศกับต่างประเทศ การเจรจาหรือขอความร่วมมือให้ประเทศสมาชิกอาเซียนจัดทำคู่มือการขึ้นทะเบียนผลิตภัณฑ์ซึ่งระบุถึงขั้นตอนและเอกสารที่ต้องใช้ประกอบ รวมถึงข้อกำหนดในกฎระเบียบที่ชัดเจนและเข้าใจ

ง่ายเป็นภาษาอังกฤษ การสนับสนุนความร่วมมือด้านวิจัยและพัฒนา และการพัฒนาศักยภาพทีมเจรจาด้านต่างประเทศของ อย. และ (2) แนวทางส่งเสริมผลิตภัณฑ์ยาภายใต้การกำกับดูแลของ อย. ให้สามารถแข่งขันได้ในระดับสากล ได้แก่ การพัฒนาศักยภาพของผู้ประกอบการไทยโดยเฉพาะที่เกี่ยวข้องกับการผลิตยานวัตกรรม การพัฒนาศักยภาพของเจ้าหน้าที่ที่เกี่ยวข้องให้มีความรู้ความเข้าใจเกี่ยวกับกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในต่างประเทศ และการให้ความช่วยเหลือผู้ประกอบการไทยในต่างประเทศ

บทที่ 1
บทนำ

1.1 หลักการและเหตุผล

ปัจจุบันกระแสการดูแลสุขภาพ และความต้องการผลิตภัณฑ์ของไทยในตลาดต่างประเทศมีแนวโน้มสูงขึ้น จากการศึกษาผลิตภัณฑ์สุขภาพที่มีความสามารถในการแข่งขันในช่วงปีงบประมาณ 2560-2561 จำนวน 5 ผลิตภัณฑ์ ได้แก่ อาหาร ยา เครื่องสำอาง ยาแผนโบราณ และผลิตภัณฑ์เสริมอาหาร ตลอดจนการหารือกับผู้ประกอบการ พบว่า ผลิตภัณฑ์ยาของประเทศไทยเป็นผลิตภัณฑ์ที่มีศักยภาพในการแข่งขันในกลุ่มประเทศ CLMV เนื่องจากได้รับความเชื่อมั่นในด้านคุณภาพ และกลุ่มประเทศดังกล่าวได้นำเข้าผลิตภัณฑ์ยาจากประเทศไทยมาเป็นระยะเวลานาน อย่างไรก็ตาม การเปลี่ยนแปลงกฎระเบียบด้านผลิตภัณฑ์ยา โดยเฉพาะที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาของกลุ่มประเทศเหล่านี้ส่งผลกระทบต่อความสามารถในการแข่งขันของผลิตภัณฑ์ยาจากประเทศไทย ดังนั้น สำนักงานคณะกรรมการอาหารและยา (อย.) โดยกองแผนงานและวิชาการได้วางแผนส่งเสริมผู้ประกอบการแบบมุ่งเป้าเพื่อสนับสนุนผลิต ภัณฑ์ยาของประเทศไทย ซึ่งจากการหารือร่วมกับผู้ประกอบการ เห็นควรศึกษากฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม เพื่อช่วยให้ผู้ประกอบการไทยสามารถรักษาฐานการตลาดในประเทศเวียดนาม และเพื่อให้เป็นข้อมูลในการเจรจาต่อรองประเด็นที่อาจเป็นปัญ หาอุปสรรคต่อการแข่งขันของผู้ประกอบการไทยในเวทีการเจรจาที่เกี่ยวข้องต่อไป

ทั้งนี้ แผนการดำเนินงานดังกล่าวสอดคล้องกับยุทธศาสตร์ที่ 3 ของ อย. ซึ่งมุ่งพัฒนางานบริการสู่ความเป็นเลิศและให้ผู้ประกอบการมีความสามารถในการแข่งขัน กลยุทธ์ที่ 2 พัฒนาศักยภาพและเตรียมความพร้อมผู้ประกอบการรองรับกฎระเบียบใหม่และส่งเสริมการส่งออก

1.2 วัตถุประสงค์

เพื่อศึกษากฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

1.3 ขอบเขตการดำเนินงาน

1.3.1 ผู้รับจ้างจัดทำกรอบการดำเนินงานการศึกษากฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ประจำปีงบประมาณ พ.ศ. 2563 และเสนอต่อผู้ที่เกี่ยวข้องเพื่อรับฟังความคิดเห็น

1.3.2 ผู้รับจ้างรวบรวมและศึกษาข้อมูลแนวทางการขึ้นทะเบียน

1.3.3 ผู้รับจ้างวิเคราะห์กฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

1.3.4 ผู้รับจ้างจัดทำ (ร่าง) รายงานการศึกษากฎระเบียบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ที่มีข้อมูลประกอบด้วยประกอบด้วย

- ภาพรวมการกำกับดูแลผลิตภัณฑ์ยาในประเทศเวียดนาม
- รายการกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม
- รายการกฎระเบียบ/ข้อกฎหมายที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

พร้อมทั้งนำเสนอแก่ผู้ที่เกี่ยวข้องเพื่อรับฟังความคิดเห็น

1.3.5 ผู้รับจ้างสำรวจข้อมูล

- เพื่อจัดทำขั้นตอนและเอกสารสำหรับประกอบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม
- จัดลำดับข้อกฎหมายที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม
- ข้อเสนอแนะเพื่อนำไปใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาของภูมิภาคอาเซียน

1.3.6 ผู้รับจ้างจัดทำ (ร่าง) รายงานการศึกษากฎระเบียบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ที่มีข้อมูลประกอบด้วย

- ภาพรวมการกำกับดูแลผลิตภัณฑ์ยาในประเทศเวียดนาม
- รายการกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม
- สรุปกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม
- ขั้นตอนและเอกสารสำหรับประกอบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม
- รายการกฎระเบียบ/ข้อกฎหมายที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม
- ข้อเสนอแนะเพื่อนำไปใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาระหว่างประเทศ

พร้อมทั้งนำเสนอแก่ผู้ที่เกี่ยวข้องเพื่อรับฟังความคิดเห็น

1.3.7 ผู้รับจ้างจัดทำรายงานการศึกษากฎระเบียบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม (ฉบับสมบูรณ์)

1.4 กรอบแนวคิดในการดำเนินงาน

1.4.1 สำรวจแนวคิด รวมทั้งนโยบาย และการดำเนินงานด้านผลิตภัณฑ์ยาที่ครอบคลุมมิติต่าง ๆ อาทิ มิติด้านเศรษฐกิจ และมิติด้านการกำกับดูแลโดยหน่วยงานที่เกี่ยวข้อง

1.4.2 ศึกษา และรวบรวมข้อมูลกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม โดยแหล่งข้อมูลจะแบ่งออกเป็น (1) แหล่งข้อมูลปฐมภูมิ อาทิ อาทิ กฎหมาย (Law) ซึ่งออกโดยสภานิติบัญญัติ กฤษฎีกา (Decree) ซึ่งออกโดยรัฐบาลของประเทศเวียดนาม และหนังสือเวียน (Circular) ซึ่งเป็นกฎหมายลำดับรองที่ออกโดยกระทรวงที่เกี่ยวข้องและ (2) แหล่งข้อมูลทุติยภูมิ อาทิ บทวิเคราะห์กฎหมาย และข่าว

1.4.3 วิเคราะห์กฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามซึ่งจะดำเนินการโดยนำข้อมูลกฎระเบียบที่ได้ในข้อ 1.4.2 มาวิเคราะห์เพื่อระบุข้อกำหนด และ/หรือ เงื่อนไขต่าง ๆ ที่ผู้ประกอบการไทยต้องปฏิบัติตามเมื่อต้องการส่งออกผลิตภัณฑ์ยาไปยังประเทศเวียดนาม รวมถึงระบุข้อกฎหมายที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ทั้งนี้ ในการวิเคราะห์ดังกล่าวจะคำนึงถึงศักยภาพของผู้ประกอบการไทยในปัจจุบันประกอบด้วย

1.4.4 สำรวจข้อมูลร่วมกับกองแผนงานและวิชาการ โดยการสัมภาษณ์หรือการประชุมเชิงปฏิบัติการร่วมกับหน่วยงานภาครัฐที่เกี่ยวข้อง อาทิ อย. รวมไปถึงการสัมภาษณ์หรือประชุมเชิงปฏิบัติการร่วมกับผู้ประกอบการภาคเอกชนจำนวนประมาณ 7-8 ราย เพื่อจัดทำรายละเอียด ได้แก่ (1) ขั้นตอนและเอกสารสำหรับประกอบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม (2) ลำดับข้อกฎหมายที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม และ (3) ข้อเสนอแนะเพื่อนำไปใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาของภูมิภาคอาเซียน

1.4.5 จัดทำ (ร่าง) รายงานการศึกษากฎระเบียบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม พร้อมทั้งนำเสนอแก่ผู้ที่เกี่ยวข้องเพื่อรับฟังความคิดเห็นก่อนการส่งมอบรายงานฉบับสมบูรณ์

1.5 ระยะเวลาและแผนการดำเนินงาน

ระยะเวลาในการดำเนินโครงการศึกษาทั้งสิ้น 8 เดือน (229 วัน) นับจากวันที่ลงนามในสัญญา (16 ธันวาคม 2562 – 31 กรกฎาคม 2563)

ตารางที่ 1.1 แผนการดำเนินงานรายงานการศึกษากฎระเบียบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ประจำปีงบประมาณ พ.ศ. 2563

กิจกรรม	ระยะเวลา (เดือน)							
	1	2	3	4	5	6	7	8
1. การเตรียมและวางแผนการดำเนินงาน	→							
1.1 ประสานงานเพื่อขอข้อมูลเบื้องต้น อาทิ สถานการณ์ปัจจุบันของการค้าผลิตภัณฑ์ยาในประเทศเวียดนาม บทบาทการเจรจา	→							
1.2 วิเคราะห์ข้อมูลเบื้องต้น	→							
2. การศึกษา และรวบรวมข้อมูลกฎระเบียบของประเทศเวียดนาม		→	→	→				
2.1 รวบรวมข้อมูลกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม		→						
2.2 รวบรวมข้อมูลทุติยภูมิที่เกี่ยวข้องกับการกำกับดูแลผลิตภัณฑ์ยาและวิธีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม		→						
2.3 จัดหาผู้แปลกฎระเบียบภาษาเวียดนาม (แล้วแต่กรณี)		→						
2.4 จัดทำรายการกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม		→	→					
2.5 จัดทำสรุปกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม				→				
2.6 วิเคราะห์ข้อกฎหมายที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม				→				
3. การจัดทำ (ร่าง) รายงานครั้งที่ 1		→	→	→				
3.1 นำเสนอ (ร่าง) รายงาน				★				
4. การสำรวจข้อมูลร่วมกับกองแผนงานและวิชาการ					→	→	→	→
4.1 ดำเนินการสัมภาษณ์หรือประชุมเชิงปฏิบัติการ							→	→
4.2 จัดทำรายละเอียดขั้นตอนและเอกสารสำหรับประกอบการขึ้นทะเบียนผลิตภัณฑ์อาหารประเภทเครื่องดื่ม							→	→
4.3 จัดทำลำดับข้อกฎหมายที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยา							→	→
4.4 จัดทำข้อเสนอแนะ							→	→
5. การจัดทำ (ร่าง) รายงานครั้งที่ 2						→	→	→
5.1 นำเสนอ (ร่าง) รายงาน								★
6. การจัดทำรายงาน ฉบับสมบูรณ์								→

1.6 ประโยชน์ที่คาดว่าจะได้รับ

1.6.1 ผลการศึกษาข้อมูลกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม รวมถึงเอกสารต่าง ๆ ที่ต้องใช้ประกอบการขึ้นทะเบียนผลิตภัณฑ์ เพื่อเป็นข้อมูลประกอบการจัดทำแนวทางการขึ้นทะเบียนผลิตภัณฑ์สุขภาพสำหรับเผยแพร่แก่ผู้ประกอบการ

1.6.2 ผลการวิเคราะห์และจัดลำดับกฎระเบียบที่อาจเป็นอุปสรรคในการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

1.6.3 ข้อเสนอแนะเพื่อนำไปใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาของภูมิภาคอาเซียน เพื่อสร้างความสามารถในการแข่งขันให้แก่ผู้ประกอบการไทย

1.7 ผู้รับผิดชอบโครงการศึกษา

นางสาวพลอยศรี อมรวัฒนา

บทที่ 2

การกำกับดูแลผลิตภัณฑ์ยาในประเทศเวียดนาม

2.1 หน่วยงานภาครัฐที่เกี่ยวข้องกับการกำกับดูแลผลิตภัณฑ์ยาในประเทศเวียดนาม

หน่วยงานภาครัฐที่เกี่ยวข้องกับการกำกับดูแลผลิตภัณฑ์ยาในประเทศเวียดนามประกอบไปด้วยหลายหน่วยงาน โดยสามารถสรุปบทบาทหน้าที่ของแต่ละหน่วยงานที่เกี่ยวข้องกับการกำกับดูแลผลิตภัณฑ์ยาในประเทศเวียดนามได้ดังนี้

2.1.1 **กระทรวงสาธารณสุข** (Ministry of Health) เป็นหน่วยงานหลักในการกำกับดูแลผลิตภัณฑ์ยาในประเทศเวียดนาม โดยกระทรวงสาธารณสุขมีบทบาทหน้าที่ในการออกนโยบาย กลยุทธ์ แผนพัฒนาหรือกฎระเบียบต่าง ๆ ที่เกี่ยวกับผลิตภัณฑ์ยา และกระทรวงสาธารณสุขยังมีบทบาทหลักในการประสานงานกับกับกระทรวงอื่นเพื่อดำเนินการในด้านต่าง ๆ ที่เกี่ยวข้องกับการกำกับดูแลผลิตภัณฑ์ยา ได้แก่ กระทรวงศึกษาและฝึกอบรม กระทรวงทรัพยากรธรรมชาติและสิ่งแวดล้อม กระทรวงอุตสาหกรรมและการค้า กระทรวงเกษตรและพัฒนาชนบท และกระทรวงวิทยาศาสตร์และเทคโนโลยี ทั้งนี้ หน่วยงานภายใต้กระทรวงสาธารณสุขที่รับผิดชอบเกี่ยวกับผลิตภัณฑ์ยา คือ Drug Administration of Vietnam (DAV)

2.1.2 **กระทรวงศึกษาและฝึกอบรม** (Ministry of Education and Training) มีหน้าที่ร่วมมือกับกระทรวงสาธารณสุขเพื่อจัดทำแผนการพัฒนาและฝึกอบรมทรัพยากรบุคคลด้านวิจัยและการผลิตยาชนิดต่าง ๆ รวมถึงยาแผนโบราณ

2.1.3 **กระทรวงทรัพยากรธรรมชาติและสิ่งแวดล้อม** (Ministry of Natural Resources and Environment) มีบทบาทหลักในการออกนโยบายเกี่ยวกับพันธุกรรมของทรัพยากรที่ใช้ผลิตยา และมีหน้าที่ร่วมมือกับกระทรวงสาธารณสุขเพื่อจัดทำแผนเกี่ยวกับทรัพยากรการผลิต

2.1.4 **กระทรวงอุตสาหกรรมและการค้า** (Ministry of Industry and Trade) มีหน้าที่ร่วมมือกับกระทรวงสาธารณสุขเพื่อออกกฎระเบียบและแผนพัฒนาอุตสาหกรรมยา

2.1.5 **กระทรวงเกษตรและพัฒนาชนบท** (Ministry of Agriculture and Rural Development) มีบทบาทหน้าที่หลักในการศึกษาวิจัยทางวิทยาศาสตร์ ร่วมกับกระทรวงสาธารณสุข และกระทรวงวิทยาศาสตร์และเทคโนโลยี เพื่อคัดเลือกหรือเพาะสายพันธุ์ต่าง ๆ ที่ใช้เป็นส่วนผสมของผลิตภัณฑ์ยา รวมถึงการออกนโยบายเกี่ยวกับพันธุ์พืชและจัดทำรายการทะเบียนพันธุ์พืชเพื่อพัฒนาการผลิตยา

2.1.6 **กระทรวงวางแผนและการลงทุน** (Ministry of Planning and Investment) มีบทบาทหน้าที่ในการจัดสรรทรัพยากรการลงทุนเพื่อพัฒนาอุตสาหกรรมยา รวมถึงร่วมมือกับกระทรวงการคลังเพื่อออกกฎระเบียบและนโยบายส่งเสริมการลงทุนเพื่อสนับสนุนอุตสาหกรรมยา

2.1.7 **กระทรวงการคลัง** (Ministry of Finance) มีบทบาทหน้าที่หลักในการพัฒนาเครื่องมือทางการเงินที่ใช้สำหรับการดำเนินการตามแผนพัฒนาด้านอุตสาหกรรมยา รวมถึงร่วมมือกับกระทรวงอุตสาหกรรมและการค้า กระทรวงกลาโหม กระทรวงสาธารณสุข และคณะกรรมการประชาชน (People's Committees) ในการบริหารจัดการและควบคุมการนำเข้าผลิตภัณฑ์ยาหรือส่วนผสมของยาที่ยังไม่ได้รับอนุญาตให้จำหน่ายในประเทศเวียดนาม

2.1.8 **กระทรวงวิทยาศาสตร์และเทคโนโลยี** (Ministry of Science and Technology) มีหน้าที่ในการเสนอหน่วยงานที่มีอำนาจเพื่อจัดสรรงบประมาณในการจัดทำวิจัยทางวิทยาศาสตร์ และร่วมมือกับกระทรวงเกษตรและพัฒนาชนบทและกระทรวงสาธารณสุขในการจัดทำวิจัยต่าง ๆ รวมไปถึงร่วมมือกับกระทรวงสาธารณสุขในด้านทรัพย์สินทางปัญญาของยาแผนโบราณ

2.1.9 **คณะกรรมการประชาชนระดับจังหวัด** (Provincial-level People's Committees) มีบทบาทหน้าที่ในการจัดทำแผนพัฒนาอุตสาหกรรมยาในระดับท้องถิ่นให้สอดคล้องกับแผนพันฒนาระดับประเทศ

2.2 นโยบายและมาตรการเพื่อส่งเสริมผลิตภัณฑ์ยาของประเทศเวียดนาม

แผนยุทธศาสตร์ ระยะ 5 ปี หรือ Plan for People's Health Protection, Care, and Promotion 2016-2020 ซึ่งจัดทำโดยกระทรวงสาธารณสุข ได้บรรจุเรื่องผลิตภัณฑ์ยาไว้ในยุทธศาสตร์ที่ 4.7 การปรับปรุงโครงสร้างองค์กรด้านการบริหารจัดการ เพื่อความปลอดภัยของอาหาร ยา วัคซีน เครื่องมือทางชีวภาพ และเครื่องมือแพทย์ (To renew the organizational structure of the management apparatus to guarantee the safety of foods, drugs, vaccines, biologicals and medical equipment) ทั้งนี้ยุทธศาสตร์ที่ 4.7 ครอบคลุมถึง (1) การปรับปรุงวิธีบริหารจัดการคุณภาพของผลิตภัณฑ์ยา (2) การจัดให้มีผลิตภัณฑ์ยาในราคาที่เหมาะสมและตรงกับความต้องการของประชาชน (3) พัฒนาอุตสาหกรรมยาในประเทศโดยมีเป้าหมายให้การผลิตยาในประเทศอยู่ที่ร้อยละ 80 ของปริมาณการใช้ยาทั้งหมดภายในปี 2563 (4) การบริหารจัดการ และใช้ประโยชน์จากผลิตภัณฑ์ยาอย่างเหมาะสม ปลอดภัยและมีประสิทธิภาพ (5) ทบทวนและออกกฎระเบียบเกี่ยวกับการจัดหายาแบบศูนย์กลาง (centralized procurement) ทั้งในระดับประเทศและระดับท้องถิ่น และจัดตั้งศูนย์กลางเพื่อเป็นตัวแทนในการจัดหายาของหน่วยงานภาครัฐและเจรจาราคาผลิตภัณฑ์ยา

ทั้งนี้ แผนยุทธศาสตร์ ระยะ 5 ปีของกระทรวงสาธารณสุขนี้ เป็นส่วนหนึ่งของโมเดลการขับเคลื่อนประเทศเวียดนามสู่การเป็นประเทศอุตสาหกรรมที่ทันสมัย (Modern industrialized country) ในปี 2563 ภายใต้แผนพัฒนาสังคม-เศรษฐกิจแห่งชาติ ปี 2559-2563 (The Five Year Socio-Economic Development Plan)

2.3 กฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

กฎหมายว่าด้วยเภสัชกรรม (Law on Pharmacy No. 105/2016/QH13) ออกโดยสภานิติบัญญัติตามที่กระทรวงสาธารณสุขเสนอ เมื่อวันที่ 5 เมษายน 2559 และมีผลบังคับใช้ตั้งแต่วันที่ 1 มกราคม 2560 เป็นกฎหมายแม่บทที่กำกับดูแลเรื่องเภสัชกรรมในประเทศเวียดนามทุกด้าน

กฎหมายว่าด้วยเภสัชกรรมประกอบไปด้วย 116 มาตรา แบ่งออกเป็น 14 หมวด สรุปบทบัญญัติที่สำคัญได้ดังนี้

<u>หมวด 1</u> บทบัญญัติทั่วไป (มาตรา 1-6)

มาตรา 1 กำหนดขอบเขตของกฎหมาย โดยกฎหมายว่าด้วยเภสัชกรรมจะกำหนดหลักเกณฑ์เกี่ยวกับนโยบายของรัฐเกี่ยวกับเภสัชกรรมและการพัฒนาอุตสาหกรรมยา วิธีปฏิบัติทางเภสัชกรรม ธุรกิจยา การขึ้นทะเบียนผลิตภัณฑ์/จัดจำหน่าย/เรียกคืนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา ใบสั่งยาและการใช้ยา การโฆษณาผลิตภัณฑ์ยา การตรวจสอบผลิตภัณฑ์ยา การศึกษาทางคลินิกของผลิตภัณฑ์ยา การบริหารจัดการคุณภาพยา รวมไปถึงการควบคุมราคาผลิตภัณฑ์ยา

มาตรา 2 กำหนดนิยามศัพท์ที่ใช้ในกฎหมายฉบับนี้ โดย “ยา” หมายถึงวัตถุที่มุ่งใช้ในการป้องกัน วินิจฉัย รักษา หรือบรรเทาโรคของมนุษย์หรือมุ่งหมายให้เกิดผลแก่การกระทำหน้าที่ใด ๆ ของร่างกายมนุษย์ ทั้งนี้ “ยา” ให้รวมถึง เภสัชเคมีภัณฑ์ ยาสมุนไพร ยาแผนโบราณ วัคซีน และยาชีวภาพด้วย

<u>หมวด 2</u> นโยบายรัฐด้านเภสัชกรรมและการพัฒนาอุตสาหกรรมยา (มาตรา 7-10)

มาตรา 7 นโยบายรัฐด้านเภสัชกรรมมีวัตถุประสงค์คือ

(1) ให้ประชาชนเข้าถึงยาที่มีคุณภาพได้อย่างทั่วถึงในราคาที่เหมาะสม

(2) ส่งเสริมการใช้ยาอย่างสมเหตุสมผล ปลอดภัยและมีประสิทธิภาพ

(3) ส่งเสริมการลงทุนด้านการผลิตยาและวัตถุดิบเกี่ยวกับยา

(4) กรณีการจัดซื้อยาโดยใช้งบประมาณของรัฐ หรือกองทุนประกันสุขภาพ ให้ความสำคัญกับการจัดซื้อยาดังต่อไปนี้ก่อน 1) ยาสามัญที่ผลิตในประเทศเวียดนามและขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม 2) ยาสมุนไพรและยาแผนโบราณที่ผลิตจากวัตถุดิบในประเทศ 3) ยาที่มีส่วนผสมของเภสัชเคมีภัณฑ์ ยาเสริม (adjuvant) แคปซูล หรือบรรจุภัณฑ์ปฐมภูมิ ที่ผลิตโดยผู้ประกอบการในประเทศ 4) วัตถุดิบเกี่ยวกับยา ยาสมุนไพร และยาแผนโบราณ ที่ผลิตขึ้นภายใต้พันธกิจด้านวิทยาศาสตร์และเทคโนโลยีของประเทศ กระทรวง หรือระดับจังหวัด นอกจากนี้ ให้หลีกเลี่ยงการจัดซื้อหรือคัดเลือกยาที่นำเข้าจากการประกวดราคา หากยาดังกล่าวสามารถผลิตได้ในประเทศเวียดนามและคุณภาพ/ราคาที่ยอมรับได้

(5) สนับสนุนกระบวนการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาเพื่อจัดจำหน่ายโดยเฉพาะยาหรือวัคซีนที่หายาก (rare drug and vaccines)

(6) รัฐร่วมสนับสนุนการลงทุนเพื่อพัฒนาอุตสาหกรรมยา

(7) สนับสนุนการค้นคว้า การศึกษาทางคลินิก และการขึ้นทะเบียนทรัพย์สินทางปัญญาของผลิตภัณฑ์ยาโดยเฉพาะยาแผนโบราณ และยาสมุนไพร

(8) รักษาความลับเกี่ยวกับการจัดเตรียมและการดำเนินการศึกษาทางคลินิกของยาแผนโบราณ

(9) ส่งเสริมการถ่ายทอดทางเทคโนโลยีที่ใช้ผลิตยา รวมถึงการพัฒนาเครือข่ายการจำหน่ายยา

(10) ส่งเสริมให้สถานพยาบาลของทหารออกหน่วยแพทย์เคลื่อนที่ไปยังพื้นที่ทุรกันดาร เช่น พื้นที่ตามเขาที่ชนเผ่าหรือชาวเขาอยู่

(11) ยกระดับคุณภาพทรัพยากรบุคคลทางด้านเภสัชกรรม

มาตรา 10 กำหนดบทบาทหน้าที่ของหน่วยงานรัฐที่เกี่ยวข้องกับการกำกับดูแลผลิตภัณฑ์ยาในประเทศเวียดนาม ได้แก่ กระทรวงสาธารณสุข กระทรวงอุตสาหกรรมและการค้า กระทรวงเกษตรและพัฒนาชนบท กระทรวงทรัพยากรธรรมชาติและสิ่งแวดล้อม กระทรวงวางแผนและการลงทุน กระทรวงการคลัง กระทรวงวิทยาศาสตร์และเทคโนโลยี และคณะกรรมการประชาชนระดับจังหวัด

<u>หมวด 3</u> ใบประกอบวิชาชีพเภสัชกรรม (มาตรา 11-31)

<u>หมวด 4</u> ธุรกิจยา (มาตรา 32-53)

มาตรา 32 การประกอบธุรกิจยาแบ่งออกได้เป็น 2 ประเภท คือ 1) การประกอบธุรกิจเกี่ยวกับยา เช่น การค้า การให้บริการเกี่ยวกับยา และ 2) การจัดตั้งสถานประกอบการเกี่ยวกับยา เช่น โรงงานผลิตยาและวัตถุดิบเกี่ยวกับยา บริษัทนำเข้า/ส่งออกยาและวัตถุดิบเกี่ยวกับยา บริษัทจำหน่ายยา บริษัทซึ่งให้บริการทดสอบยาและวัตถุดิบเกี่ยวกับยา

มาตรา 33 กำหนดเงื่อนไขในการออกใบอนุญาตประกอบธุรกิจยา (Certificate of eligibility for pharmaceutical business) ซึ่งประกอบด้วยคุณสมบัติด้านสถานที่และพนักงาน

มาตรา 35 สถานประกอบการที่ได้รับยกเว้นไม่ต้องขอใบอนุญาตประกอบธุรกิจยา ได้แก่ สถานประกอบการที่ประกอบธุรกิจยาที่ไม่ได้มีวัตถุประสงค์เพื่อการค้า สถานประกอบการที่มีชั้นวางยา (drug shelf)

มาตรา 37 ผู้ที่มีอำนาจพิจารณาออก/แก้ไข/เพิกถอนใบอนุญาตการประกอบธุรกิจยา คือ รัฐมนตรีว่าการกระทรวงสาธารณสุข (ทุกประเภท) และผู้อำนวยการของหน่วยงานสาธารณสุขส่วนจังหวัด (เฉพาะใบอนุญาตจัดตั้งสถานประกอบการเพื่อขายส่งหรือขายปลีกยา)

มาตรา 38 กำหนดรายการเอกสารที่ใช้ประกอบการขอใบอนุญาตการประกอบธุรกิจเกี่ยวกับยา

มาตรา 39 กำหนดกระบวนการในการพิจารณาคำขอใบอนุญาตการประกอบธุรกิจเกี่ยวกับยาของกระทรวงสาธารณสุข

มาตรา 40 กำหนดเหตุในการเพิกถอนใบอนุญาตการประกอบธุรกิจยา

<u>หมวด 5</u> การขึ้นทะเบียน การจัดจำหน่าย และการเรียกคืนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา (มาตรา 54-65)

มาตรา 54 ผู้ประกอบการต้องขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยาก่อนวางจำหน่ายในประเทศเวียดนาม ยกเว้น ยาตามใบสั่งแพทย์ที่จำหน่ายที่ร้านขายยาและยาที่ผลิตขึ้นเพื่อวัตถุประสงค์ในการทดสอบ ยานำเข้าบางประเภท (เช่น ยาที่มีความจำเป็นต้องใช้เพื่อประโยชน์ทางด้านความปลอดภัยของชาติหรือเพื่อป้องกัน/ควบคุมโรคระบาด ยาหายาก ยาที่ได้รับบริจาคเพื่อความช่วยเหลือของประเทศ ยาที่ไม่ได้มีวัตถุประสงค์เพื่อการค้า) ยาแผนโบราณที่ใช้เพื่อวัตถุประสงค์ในการทดสอบหรือที่ผลิตโดยโรงพยาบาล

มาตรา 56 กำหนดรายการเอกสารที่ใช้ประกอบการขอขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา

มาตรา 61 กำหนดรายละเอียดที่ต้องมีในฉลากของผลิตภัณฑ์ยา เช่น ชื่อของยา/วัตถุดิบเกี่ยวกับยา ส่วนผสม ชื่อและที่อยู่ของผู้ผลิต เลขที่การผลิต วันหมดอายุ ทั้งนี้ รายละเอียดดังกล่าวต้องจัดทำเป็นภาษาเวียดนาม โดยมีข้อยกเว้นไม่ต้องใช้ภาษาเวียดนามสำหรับข้อมูลที่ไม่สามารถแปลเป็นภาษาเวียดนามได้หรือข้อมูลที่ถ้าแปลเป็นภาษาเวียดนามแล้วจะไม่สามารถเข้าใจได้

<u>หมวด 6</u> ยาสมุนไพร และยาแผนโบราณ (มาตรา 66-73)

มาตรา 71 คำขอขึ้นทะเบียน ต่ออายุทะเบียน แก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ยาประเภทยาแผนโบราณ

<u>หมวด 7</u> ใบสั่งยาและการใช้ยา (มาตรา 74-75)

มาตรา 74 กระทรวงสาธารณสุขมีหน้าที่ในการกำหนดรายละเอียดของเอกสารกำกับยา

มาตรา 75 กำหนดหลักเกณฑ์การใช้ยาสำหรับการทดสอบหรือรักษา และการใช้ยาในกรณีอื่น ๆ

<u>หมวด 8</u> ข้อมูลเกี่ยวกับผลิตภัณฑ์ยาและการโฆษณาผลิตภัณฑ์ยา (มาตรา 76-79)

มาตรา 79 การโฆษณาผลิตภัณฑ์ยาต้องมีเนื้อหาที่ได้รับการรับรองจากกระทรวงสาธารณสุขและกฎหมายว่าด้วยการโฆษณา

<u>หมวด 9</u> เภสัชกรรมคลินิก (มาตรา 80-83)

<u>หมวด 10</u> การบริหารจัดการยาเพื่อการทดสอบหรือรักษาโรค (มาตรา 84-85)

<u>หมวด 11</u> การศึกษาทางคลินิกของผลิตภัณฑ์ยา (มาตรา 86-101)

มาตรา 87 วิธีการศึกษาทางคลินิกของผลิตภัณฑ์ยาทั้งก่อนและหลังการขึ้นทะเบียนผลิตภัณฑ์เพื่อวางจำหน่ายในประเทศเวียดนาม

มาตรา 89 ประเภทยาที่ต้องมีการศึกษาทางคลินิก ได้แก่ ยาใหม่ ยาสมุนไพรซึ่งมีส่วนผสมจากวัตถุดิบที่เคยใช้ผลิตยาในประเทศเวียดนามและใช้รักษาโรค และวัคซีนที่มีการใช้ครั้งแรกในประเทศเวียดนาม

<u>หมวด 12</u> กฎระเบียบและมาตรฐานด้านคุณภาพของผลิตภัณฑ์ยา วัตถุดิบเกี่ยวกับยา และบรรจุภัณฑ์ของยา (มาตรา 102-105)

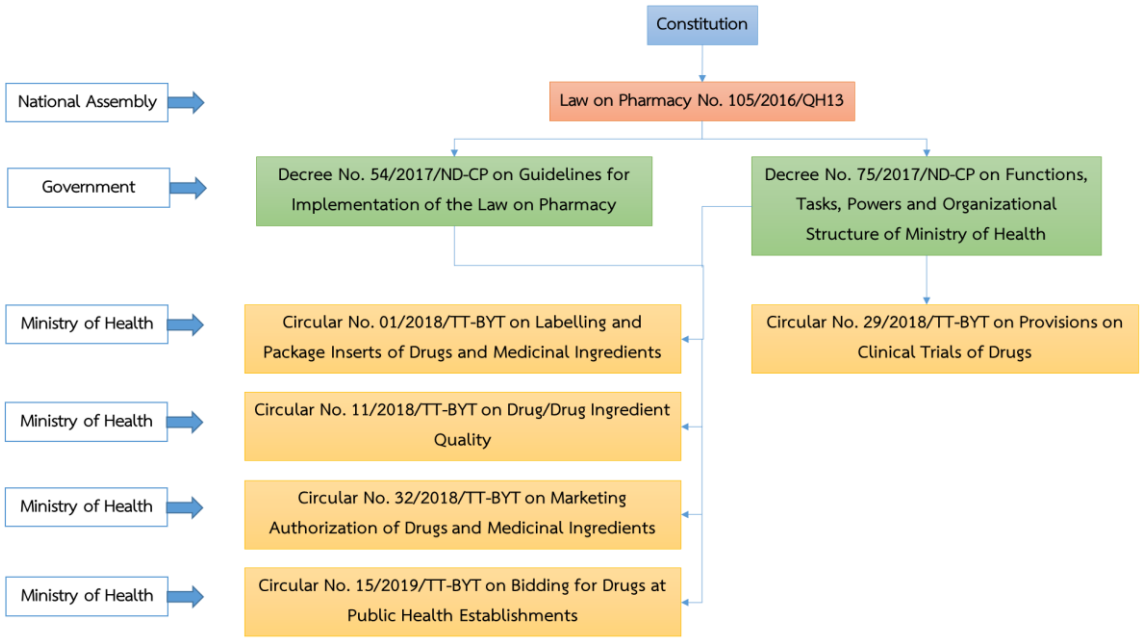
<u>หมวด 13</u> การควบคุมราคายา (มาตรา 106-114)

<u>หมวด 14</u> การบังคับใช้กฎหมาย (มาตรา 115-116)

มาตรา 115 บทเฉพาะกาล โดยสถานประกอบการที่ได้รับใบอนุญาตการประกอบธุรกิจยาตามกฎหมายว่าด้วยเภสัชกรรม เลขที่ 34/2005/QH11 สามารถดำเนินการต่อไปได้จนกว่าใบอนุญาตจะหมดอายุ และคำขอขึ้นทะเบียนผลิตภัณฑ์ยาที่ยื่นก่อนวันที่ 1 มกราคม 2560 ซึ่งเป็นวันที่กฎหมายมีผลบังคับใช้นั้น จะอยู่ภายใต้กฎหมายว่าด้วยเภสัชกรรม เลขที่ 34/2005/QH11 เว้นแต่ผู้ประกอบการประสงค์จะอยู่ภายใต้บังคับของกฎหมายว่าด้วยเภสัชกรรม เลขที่ 105/2016/QH13 นี้

นอกจากนี้ รัฐบาลและกระทรวงสาธารณสุขได้มีการออกกฎระเบียบโดยอาศัยอำนาจจากกฎหมายว่าด้วยเภสัชกรรม เลขที่ 105/2016/QH13 เพื่อกำหนดรายละเอียดเพิ่มเติมเกี่ยวกับผลิตภัณฑ์ยาในประเทศเวียดนาม ดังนี้

ภาพที่ 2.1 ภาพรวมกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม



(1) **Decree No. 54/2017/ND-CP on Guidelines for Implementation of the Law on Pharmacy** ออกโดยรัฐบาลเมื่อวันที่ 8 พฤษภาคม 2560 และมีผลบังคับใช้วันที่ 1 กรกฎาคม 2560 ซึ่งถูกแก้ไขเพิ่มเติมโดย Decree No. 155/2018/ND-CP on Amendments to Some Articles Related to Business Conditions under State Management of the Ministry of Health ลงวันที่ 12 พฤศจิกายน 2561 และมีผลบังคับใช้วันที่ 12 พฤศจิกายน 2561 กฤษฎีกาฉบับนี้กำหนดหลักเกณฑ์เกี่ยวกับการดำเนินธุรกิจด้านเภสัชกรรมในประเทศเวียดนาม ซึ่งรวมถึงขั้นตอนและเอกสารที่ต้องใช้เพื่อนำเข้าผลิตภัณฑ์ยา

Decree No. 54/2017/ND-CP ประกอบไปด้วย 145 มาตรา แบ่งออกเป็น 9 หมวด โดยสามารถสรุปบทบัญญัติที่สำคัญได้ดังนี้

<u>หมวด 1</u> บทบัญญัติทั่วไป (มาตรา 1-2)

มาตรา 1 กฤษฎีกาฉบับนี้จะใช้บังคับกับองค์กรหรือบุคคลในประเทศเวียดนามและในต่างประเทศที่ดำเนินการเกี่ยวข้องกับเภสัชกรรมในประเทศเวียดนาม โดยกฤษฎีกานี้กำหนดหลักเกณฑ์เกี่ยวกับใบประกอบวิชาชีพด้านเภสัชกรรม ธุรกิจยา การนำเข้าและส่งออกผลิตภัณฑ์ยา การขึ้นทะเบียนสมุนไพร/สารเพิ่มปริมาณ/แคปซูลนิ่ม การประเมินผู้ผลิตยาในต่างประเทศ กระบวนการในการเรียกคืนวัตถุดิบเกี่ยวกับยา กระบวนการออกใบรับรองโฆษณาผลิตภัณฑ์ยา และการควบคุมราคายา

มาตรา 2 กำหนดคำนิยามศัพท์ที่ใช้ในกฤษฎีกาฉบับนี้

<u>หมวด 2</u> ใบประกอบวิชาชีพด้านเภสัชกรรม (มาตรา 3-30)

<u>หมวด 3</u> ธุรกิจยา (มาตรา 31-56)

มาตรา 31 กำหนดคุณสมบัติของผู้ที่ประสงค์จะประกอบธุรกิจเกี่ยวกับยาแผนโบราณ เช่น สถานที่จัดเก็บ อุปกรณ์ที่ใช้จัดเก็บ ยานพาหนะ ระบบควบคุมคุณภาพ รวมไปถึงพนักงานของผู้ให้บริการจัดเก็บยาแผนโบราณต้องเป็นไปตามมาตรฐาน Good Storage Practice for Pharmaceuticals (GSP)

มาตรา 32 กำหนดรายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอใบอนุญาตการประกอบธุรกิจยา (Certificate of eligibility for pharmacy business)

มาตรา 33 กำหนดกระบวนการออกใบอนุญาตการประกอบธุรกิจยาของกระทรวงสาธารณสุข

มาตรา 42 กำหนดคุณสมบัติของผู้ที่มีสิทธิทำการค้ายาควบคุมพิเศษ

มาตรา 49 รายการเอกสารที่ต้องใช้ประกอบการขออนุญาตทำการค้ายาควบคุมพิเศษ

<u>หมวด 4</u> การส่งออกและนำเข้าผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา (มาตรา 57-92)

มาตรา 65 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้าผลิตภัณฑ์ยาที่มีสารออกฤทธิ์ (active ingredients) เป็นส่วนประกอบ ซึ่งไม่ได้มีการขึ้นทะเบียนผลิตภัณฑ์ยา และการขออนุญาตนำเข้าผลิตภัณฑ์ยาที่มีสมุนไพรเป็นส่วนประกอบซึ่งใช้ในประเทศเวียดนามเป็นครั้งแรก

มาตรา 66 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้าผลิตภัณฑ์ยาที่มีสารออกฤทธิ์เป็นส่วนประกอบซึ่งได้มีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามแล้วแต่มีจำนวนไม่เพียงพอ และการขออนุญาตนำเข้าผลิตภัณฑ์ยาที่มีสมุนไพรเป็นส่วนประกอบซึ่งเคยใช้ในประเทศเวียดนามแล้วแต่มีจำนวนไม่เพียงพอ

มาตรา 67 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้าผลิตภัณฑ์ยากรณีเร่งด่วนเพื่อประโยชน์ทางด้านความปลอดภัยของประเทศหรือควบคุมโรคระบาดหรือบรรเทาภัยพิบัติ

มาตรา 68 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้าผลิตภัณฑ์ยาเพื่อรักษาโรคเป็นการเฉพาะ (special treatment)

มาตรา 69 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้ายาหายาก (rare drug)

มาตรา 70 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้ายาที่มีชื่อทางการค้า สารออกฤทธิ์ ปริมาณ เช่นเดียวกับยาที่เคยได้ขึ้นทะเบียนในประเทศเวียดนามแล้ว

มาตรา 71 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้ายาที่เกี่ยวข้องกับโครงการสุขภาพของภาครัฐ

มาตรา 72 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้ายาที่ได้รับการช่วยเหลือจากประเทศอื่น (emergency aid หรือ humanitarian aid)

มาตรา 73 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้ายาเพื่อวัตถุประสงค์ในการศึกษาทางคลินิก

มาตรา 74 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้ายาเพื่อการจัดแสดงนิทรรศการ

มาตรา 75 กำหนดเงื่อนไขและรายการเอกสารที่ต้องใช้ประกอบการขออนุญาตนำเข้ายาที่ไม่ได้มีวัตถุประสงค์เพื่อการค้า

<u>หมวด 5</u> การขึ้นทะเบียนสมุนไพร/สารเพิ่มปริมาณ/แคปซูลนิ่ม (มาตรา 93-100)

<u>หมวด 6</u> การเรียกคืนวัตถุดิบเกี่ยวกับยา (มาตรา 101-104)

<u>หมวด 7</u> กระบวนการออกใบรับรองโฆษณาผลิตภัณฑ์ยา (มาตรา 105-129)

<u>หมวด 8</u> การควบคุมราคายา (มาตรา 130-139)

<u>หมวด 9</u> การบังคับใช้กฤษฎีกาฉบับนี้ (มาตรา 140-145)

มาตรา 145 กระทรวงสาธารณสุขมีหน้าที่กำหนดแนวปฏิบัติและบังคับใช้กฤษฎีกานี้

(2) **Circular No. 01/2018/TT-BYT on Labelling and Package Inserts of Drugs and Medicinal Ingredients** ออกโดยกระทรวงสาธารณสุขเมื่อวันที่ 18 มกราคม 2561 และมีผลบังคับใช้วันที่ 1 มิถุนายน 2561 หนังสือเวียนฉบับนี้กำหนดหลักเกณฑ์เกี่ยวกับฉลาก เอกสารกำกับยา และบรรจุภัณฑ์ของผลิตภัณฑ์ยา ซึ่งครอบคลุมถึงข้อมูลขั้นต่ำที่ต้องแสดงบนฉลากและบรรจุภัณฑ์ อาทิ ชื่อผลิตภัณฑ์ วันหมดอายุ ชื่อผู้ผลิต และเลขที่หรือรอบที่ผลิต โดยข้อมูลดังกล่าวต้องแสดงเป็นภาษาเวียดนามด้วย

Circular No. 01/2018/TT-BYT ประกอบไปด้วย 40 มาตรา แบ่งออกเป็น 4 หมวด โดยสามารถสรุปบทบัญญัติที่สำคัญได้ดังนี้

<u>หมวด 1</u> บทบัญญัติทั่วไป (มาตรา 1-6)

มาตรา 1 หนังสือเวียนฉบับนี้กำหนดหลักเกณฑ์เกี่ยวกับรายละเอียดบนฉลาก วิธีการติดฉลาก เอกสารกำกับยาแบบ Package insert โดยหนังสือเวียนฉบับนี้ไม่ใช้บังคับกับฉลากของผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาที่มีวัตถุประสงค์เพื่อการส่งออกและไม่ได้ขึ้นทะเบียนในประเทศเวียดนาม ยาที่นำเข้าโดยไม่มีวัตถุประสงค์ทางการค้า และยาที่มีความจำเป็นต้องนำเข้าเพื่อประโยชน์ทางด้านความปลอดภัยของชาติหรือเพื่อป้องกัน/ควบคุมโรคระบาด

<u>หมวด 2</u> รายละเอียดบนฉลากและเอกสารกำกับยาแบบ Package insert (มาตรา 7-13)

มาตรา 7 กำหนดรายละเอียดขั้นต่ำที่ต้องระบุบนฉลากของบรรจุภัณฑ์ทุติยภูมิ (secondary package label) ของผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา

มาตรา 8 กำหนดรายละเอียดขั้นต่ำที่ต้องระบุบนฉลากของบรรจุภัณฑ์ที่อยู่ระหว่างบรรจุภัณฑ์ปฐมภูมิและบรรจุภัณฑ์ทุติยภูมิ (intermediate package label)

มาตรา 9 กำหนดรายละเอียดขั้นต่ำที่ต้องระบุบนฉลากของบรรจุภัณฑ์ปฐมภูมิ (primary package label) ของผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา

มาตรา 12 กำหนดรายละเอียดขั้นต่ำที่ต้องระบุบนเอกสารกำกับยาแบบ Package insert

<u>หมวด 3</u> การนำเสนอรายละเอียดของฉลากและเอกสารกำกับยาแบบ Package insert (มาตรา 14-35)

<u>หมวด 4</u> การบังคับใช้ (มาตรา 36-40)

มาตรา 40 Drug Administration of Vietnam, Traditional Medicine Administration และหน่วยงานอื่น ๆ ที่สังกัดกระทรวงสาธารณสุข สาธารณสุขส่วนจังหวัด รวมไปถึงผู้ประกอบธุรกิจยา เช่น ผู้ผลิตยา ผู้ส่งออก/นำเข้ายา ต้องปฏิบัติตามหนังสือเวียนฉบับนี้

(3) **Circular No. 11/2018/TT-BYT on Drug/Drug Ingredient Quality** ออกโดยกระทรวงสาธารณสุขเมื่อวันที่ 4 พฤษภาคม 2561 และมีผลบังคับใช้เมื่อวันที่ 20 มิถุนายน 2561 และถูกแก้ไขเพิ่มเติมโดย Circular No. 03/2020/TT-BYT on Amendments to Some Articles of the Circular No. 11/2018/TT-BYT ซึ่งออกโดยกระทรวงสาธารณสุขเมื่อวันที่ 22 มกราคม 2563 และมีผลใช้บังคับเมื่อวันที่ 16 มีนาคม 2563

หนังสือเวียนฉบับนี้กำหนดหลักเกณฑ์เกี่ยวกับการนำมาตรฐานด้านคุณภาพมาใช้กับผลิตภัณฑ์ยา รวมไปถึงการทดสอบผลิตภัณฑ์ยา ทั้งนี้ Circular No. 11/2018/TT-BYT ประกอบไปด้วย 19 มาตรา แบ่งออกเป็น 5 หมวด โดยสามารถสรุปบทบัญญัติที่สำคัญได้ดังนี้

<u>หมวด 1</u> บทบัญญัติทั่วไป (มาตรา 1-2)

มาตรา 1 หนังสือเวียนฉบับนี้กำหนดหลักเกณฑ์เกี่ยวกับการนำมาตรฐานคุณภาพยาและวัตถุดิบเกี่ยวกับยามาใช้ การทดสอบยาและวัตถุดิบเกี่ยวกับยา รวมถึงการเรียกคืนยาที่ไม่ได้มาตรฐาน

<u>หมวด 2</u> การนำมาตรฐานคุณภาพยาและวัตถุดิบเกี่ยวกับยามาใช้ (มาตรา 3-6)

มาตรา 4 กำหนดวิธีการนำตำรายา (Pharmacopia) มาใช้

<u>หมวด 3</u> การทดสอบยาและวัตถุดิบเกี่ยวกับยา (มาตรา 7-11)

<u>หมวด 4</u> หลักเกณฑ์ในการเรียกคืนหรือดำเนินการกับยาที่ไม่ได้มาตรฐาน (มาตรา 12-16)

<u>หมวด 5</u> การบังคับใช้ (มาตรา 17-19)

มาตรา 19 Director General of the Drug Administration of Vietnam, Director of the Ministry Office, Chief Ministerial Inspector และหัวหน้าของหน่วยงานอื่น ๆ ที่สังกัดกระทรวงสาธารณสุข สาธารณสุขส่วนจังหวัด รวมไปถึงผู้ประกอบธุรกิจยาต้องปฏิบัติตามหนังสือเวียนฉบับนี้

(4) **Circular No. 29/2018/TT-BYT on Provisions on Clinical Trials of Drugs** ออกโดยกระทรวงสาธารณสุขเมื่อวันที่ 29 ตุลาคม 2561 หนังสือเวียนฉบับนี้กำหนดกระบวนการศึกษาทางคลินิกและการประเมินกระบวนการศึกษาทางคลินิก

Circular No. 29/2018/TT-BYT ประกอบไปด้วย 30 มาตรา แบ่งออกเป็น 8 หมวด โดยสามารถสรุปบทบัญญัติที่สำคัญได้ดังนี้

<u>หมวด 1</u> บทบัญญัติทั่วไป (มาตรา 1-3)

มาตรา 1 หนังสือเวียนฉบับนี้กำหนดหลักเกณฑ์เกี่ยวกับกระบวนการศึกษาทางคลินิกและการประเมินกระบวนการศึกษาทางคลินิกตาม Good Clinical Practice (GCP) ทั้งนี้ ขั้นตอนต่าง ๆ ที่เกี่ยวข้องกับกระบวนการศึกษาทางคลินิกนอกจากจะต้องเป็นไปตามหนังสือเวียนฉบับนี้แล้ว ยังต้องเป็นไปตามกฎหมายว่าด้วยการวินิจฉัยและรักษาโรค (Law on Examination and Treatment) ด้วย

<u>หมวด 2</u> การนำ GCP มาใช้ (มาตรา 4-5)

<u>หมวด 3</u> หลักทั่วไปในการประเมินความสอดคล้องกับ GCP (มาตรา 6-7)

<u>หมวด 4</u> การประเมินความสอดคล้องกับ GCP (มาตรา 8-11)

มาตรา 8 กำหนดรายการเอกสารที่ต้องใช้ยื่นประกอบการประเมินความสอดคล้องกับ GCP

มาตรา 10 กำหนดกระบวนการประเมินความสอดคล้องกับ GCP

<u>หมวด 5</u> การรักษาความสอดคล้องกับ GCP (มาตรา 12-15)

<u>หมวด 6</u> ผู้มีหน้าที่ประเมินความสอดคล้องกับ GCP (มาตรา 16-17)

<u>หมวด 7</u> รายการเอกสารและกระบวนการศึกษาทางคลินิก (มาตรา 18-25)

มาตรา 18 กำหนดขั้นตอนของกระบวนการศึกษาทางคลินิก

มาตรา 19 กำหนดรายการเอกสารที่ต้องใช้ประกอบการศึกษาทางคลินิก

<u>หมวด 8</u> การบังคับใช้ (มาตรา 26-30)

มาตรา 30 Director of Department of Science, Technology and Training, Director of Drug Administration, Director of Ministry Offices, Chief Ministerial Inspector และหัวหน้าของหน่วยงานอื่น ๆ ที่สังกัดกระทรวงสาธารณสุข รวมไปถึงผู้ประกอบธุรกิจยาต้องปฏิบัติตามหนังสือเวียนฉบับนี้

(5) **Circular No. 32/2018/TT-BYT on Marketing Authorization of Drugs and Medicinal Ingredients** ออกโดยกระทรวงสาธารณสุขเมื่อวันที่ 12 พฤศจิกายน 2561 และมีผลบังคับใช้เมื่อวันที่ 1 กันยายน 2562 หนังสือเวียนฉบับนี้กำหนดขั้นตอนและเอกสารที่ต้องใช้ประกอบการขึ้นทะเบียนและการต่อทะเบียนผลิตภัณฑ์ยา

Circular No. 32/2018/TT-BYT ประกอบไปด้วย 50 มาตรา แบ่งออกเป็น 7 หมวด โดยสามารถสรุปบทบัญญัติที่สำคัญได้ดังนี้

<u>หมวด 1</u> บทบัญญัติทั่วไป (มาตรา 1-12)

มาตรา 1 หนังสือเวียนฉบับนี้กำหนดขั้นตอนและเอกสารที่ต้องใช้ประกอบการขึ้นทะเบียน การต่อทะเบียน หรือการแก้ไขเนื้อหาในทะเบียนของผลิตภัณฑ์ยา ซึ่งรวมถึงวัคซีน วัตถุดิบเกี่ยวกับยา และวัตถุดิบสมุนไพร ที่ใช้สำหรับมนุษย์และใช้ในประเทศเวียดนาม

มาตรา 8 ทะเบียนผลิตภัณฑ์ยามีอายุ 5 ปีนับแต่วันขึ้นทะเบียนหรือวันต่ออายุทะเบียน เว้นแต่ผลิตภัณฑ์ยาดังต่อไปนี้ให้มีอายุทะเบียน 3 ปี ได้แก่ ยาใหม่หรือวัคซีนใหม่ที่ขึ้นทะเบียนผลิตภัณฑ์เป็นครั้งแรก ยาที่มีสารออกฤทธิ์หรือส่วนผสมเหมือนยาใหม่ ยาอื่น ๆ ที่ไม่ได้ยื่นรายงานความปลอดภัยและความมีประสิทธิภาพประกอบการขอต่ออายุทะเบียนผลิตภัณฑ์ และยาที่ยังต้องติดตามดูแลด้านความปลอดภัยและความมีประสิทธิภาพอย่างต่อเนื่อง

<u>หมวด 2</u> การยืนยันความปลอดภัยและความมีประสิทธิภาพโดยกระบวนการศึกษาทางคลินิก (มาตรา 13-22)

<u>หมวด 3</u> การขึ้นทะเบียนผลิตภัณฑ์ (มาตรา 23-33)

มาตรา 23 กำหนดรายละเอียดในเอกสารที่ต้องใช้ยื่นประกอบการขอขึ้นทะเบียน ต่ออายุทะเบียน แก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา เช่น เอกสารที่ออกโดยหน่วยงานรัฐต่างประเทศต้องมีการรับรองเอกสาร (Consular legalization)

มาตรา 24 กำหนดภาพรวมรายการเอกสารที่ต้องใช้ยื่นประกอบการขอขึ้นทะเบียน ต่ออายุทะเบียน แก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา

มาตรา 25 กำหนดรายละเอียดที่ต้องมีในเอกสารแสดงคุณภาพผลิตภัณฑ์ยาประเภทยาแผนปัจจุบัน วัคซีน หรือยาชีวภาพ

มาตรา 28 คำขอขึ้นทะเบียน ต่ออายุทะเบียน แก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ยาประเภทยาแผนปัจจุบัน วัคซีน หรือยาชีวภาพ

มาตรา 29 กำหนดรายละเอียดที่ต้องมีในเอกสารแสดงคุณภาพผลิตภัณฑ์ยาประเภทยาสมุนไพร

มาตรา 30 คำขอขึ้นทะเบียน ต่ออายุทะเบียน แก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ยาประเภทยาสมุนไพร

มาตรา 32 กำหนดรายละเอียดที่ต้องมีในเอกสารแสดงคุณภาพวัตถุดิบเกี่ยวกับยา

มาตรา 33 คำขอขึ้นทะเบียน ต่ออายุทะเบียน แก้ไขเนื้อหาในทะเบียนวัตถุดิบเกี่ยวกับยา

<u>หมวด 4</u> กระบวนการขึ้นทะเบียน ต่ออายุทะเบียน และการแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา (มาตรา 34-41)

มาตรา 38 กำหนดกระบวนการของ Drug Administration ในการพิจารณาขึ้นทะเบียนผลิตภัณฑ์ยา

มาตรา 39 กำหนดกระบวนการของ Drug Administration ในการพิจารณาต่ออายุทะเบียนผลิตภัณฑ์ยา

มาตรา 40 กำหนดกระบวนการของ Drug Administration ในการพิจารณาแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ยาที่ยังไม่หมดอายุ

<u>หมวด 5</u> การเพิกถอนทะเบียน (มาตรา 42-43)

มาตรา 42 กำหนดรายการเอกสารและขั้นตอนในการเพิกถอนทะเบียน

มาตรา 43 การเพิกถอนทะเบียนชั่วคราว

<u>หมวด 6</u> หลักเกณฑ์ในการดำเนินงานของ Marketing Authorization Advisory Board (มาตรา 44-45)

มาตรา 44 Marketing Authorization Advisory Board จัดตั้งขึ้นโดยรัฐมนตรีว่าการกระทรวงสาธารณสุข คณะกรรมการดังกล่าวประกอบด้วยผู้เชี่ยวชาญที่มีคุณสมบัติและประสบการณ์เกี่ยวกับการพิจารณาคำขอ โดยคณะกรรมการจะมีหน้าที่ให้คำแนะนำต่อรัฐมนตรีว่าการกระทรวงสาธารณสุขเกี่ยวกับกฎหมายว่าด้วยเภสัชกรรม เอกสารต่าง ๆ ที่เกี่ยวข้องกับผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา การขึ้นทะเบียน การต่ออายุทะเบียน และการแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์

<u>หมวด 7</u> การบังคับใช้ (มาตรา 46-50)

มาตรา 50 เพื่อให้สอดคล้องกับ roadmap for ASEAN harmonization of drug registration จึงกำหนดบทบาทหน้าที่ของ Drug Administration of Vietnam เช่น กำกับดูแลการปฏิบัติตามหนังสือเวียนฉบับนี้ ปรับปรุงรายชื่อผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยาที่ได้รับการขึ้นทะเบียนแล้วในเว็บไซต์ให้เป็นปัจจุบัน

(6) **Circular No. 15/2019/TT-BYT on Regulation on Bidding for Drugs at Public Health Establishments** ออกโดยกระทรวงสาธารณสุขเมื่อวันที่ 11 กรกฎาคม 2562 และมีผลบังคับใช้เมื่อวันที่ 1 ตุลาคม 2562 หนังสือเวียนฉบับนี้กำหนดหลักเกณฑ์เกี่ยวกับการจัดซื้อและการประกวดราคาผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยาสำหรับใช้ในโรงพยาบาลรัฐหรือหน่วยงานสาธารณสุขของรัฐ

Circular No. 15/2019/TT-BYT ประกอบไปด้วย 51 มาตรา แบ่งออกเป็น 5 หมวด โดยสามารถสรุปบทบัญญัติที่สำคัญได้ดังนี้

<u>หมวด 1</u> บทบัญญัติทั่วไป (มาตรา 1-6)

มาตรา 1 หนังสือเวียนฉบับนี้กำหนดรายละเอียดเกี่ยวกับการจัดซื้อและประกวดราคาผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยาสำหรับใช้ในโรงพยาบาลรัฐหรือหน่วยงานสาธารณสุขของรัฐ

มาตรา 2 หนังสือเวียนฉบับนี้ใช้บังคับกับ 1) องค์กร หน่วยงาน และบุคคลทั่วไปที่เข้าร่วมหรือเกี่ยวข้องกับกระบวนการประกวดราคา 2) หน่วยงานสาธารณสุขภายใต้กฎหมายว่าด้วยรัฐวิสาหกิจ และ 3) สถานประกอบการทางการแพทย์ของเอกชนที่ให้บริการวินิจฉัยและรักษาโรคภายใต้สิทธิประกันสุขภาพ

มาตรา 3 กำหนดคำนิยามศัพท์ที่ใช้ในหนังสือเวียนฉบับนี้

<u>หมวด 2</u> หลักเกณฑ์เกี่ยวกับการยื่นซองประกวดราคาและการจัดกลุ่มผลิตภัณฑ์ยา (มาตรา 7-12)

มาตรา 7 การจัดกลุ่มยาสามัญ ตามข้อกำหนดทางเทคนิค

มาตรา 9 การจัดกลุ่มยาสมุนไพรและยาแผนโบราณ (ไม่รวมยาสมุนไพรแผนโบราณ) ตามข้อกำหนดทางเทคนิค

มาตรา 10 การจัดกลุ่มยาสมุนไพรแผนโบราณ ตามข้อกำหนดทางเทคนิค

มาตรา 11 การจัดกลุ่มวัตถุดิบเกี่ยวกับยา ตามข้อกำหนดทางเทคนิค

มาตรา 12 กำหนดหลักเกณฑ์การยื่นซองประกวดราคาของผลิตภัณฑ์ยาแต่ละกลุ่ม

<u>หมวด 3</u> หลักเกณฑ์การจัดซื้อยาที่หน่วยงานสาธารณสุขหรือสถานประกอบการทางการแพทย์ (มาตรา 13-37)

<u>หมวด 4</u> หลักเกณฑ์การจัดซื้อยาแบบ concentrated (มาตรา 38-41)

<u>หมวด 5</u> หลักเกณฑ์กำกับดูแลข้อโต้แย้งเกี่ยวกับราคา (มาตรา 42-46)

<u>หมวด 6</u> การบังคับใช้ (มาตรา 47-51)

มาตรา 50 กรณีของสถานประกอบการทางการแพทย์เอกชนนั้น สถานประกอบการสามารถเข้าร่วมการจัดซื้อยาของภาครัฐในพื้นที่ที่สำนักงานใหญ่ของสถานประกอบการดังกล่าวตั้งอยู่ได้ แต่หากสถานประกอบการไม่เข้าร่วมการจัดซื้อยาของภาครัฐ สถานประกอบการสามารถจัดซื้อยาได้เองโดยต้องปฏิบัติตามกฎหมายว่าด้วยการประกวดราคา และหนังสือเวียนฉบับนี้ด้วย ทั้งนี้ ในกรณีที่สถานประกอบการไม่สามารถจัดซื้อยาตามที่กำหนดข้างต้น ให้สำนักงานประกันสังคม (social insurance agency) จ่ายเงินค่ายาไม่เกินราคาที่หน่วยงานภาครัฐประมูลได้

2.4 การแบ่งประเภทผลิตภัณฑ์ยาของประเทศเวียดนาม

ตามกฎหมายว่าด้วยเภสัชกรรมของประเทศเวียดนาม มีการแบ่งผลิตภัณฑ์ยาตามการควบคุมกำกับเพื่อคุ้มครองผู้บริโภคให้ได้รับความปลอดภัยจากการใช้ยา ดังนี้

(1) ยาแผนปัจจุบัน (pharmaceutical drug/modern drug) หมายถึง ยาที่ใช้ในการประกอบโรคศิลปะแผนปัจจุบัน

(2) ยาสมุนไพร (medicinal material drug) หมายถึง ยาที่มีส่วนผสมจากพืช สัตว์ หรือแร่ที่มุ่งหมายให้เกิดผลต่อสุขภาพโดยมีการรับรองด้วยหลักฐานทางวิทยาศาสตร์

(3) ยาแผนโบราณ (traditional drug) หมายถึง ยาที่มีส่วนผสมจากพืช สัตว์ หรือแร่ ที่ผ่านกรรมวิธีโดยตำรับยาแผนโบราณ หรือผ่านกรรมวิธีตามประสบการณ์ชาวบ้าน (folk experience)

(4) ยาชีวภาพ (bio-drug) หมายถึง ยาที่ผลิตโดยอาศัยเทคโนโลยีทางชีวภาพ

(5) วัคซีน (vaccine) หมายถึง ยาที่มีส่วนผสมของ antigen ซึ่งกระตุ้นให้เกิดปฏิกิริยาตอบสนองทางภูมิคุ้มกันของมนุษย์

(6) ยาใหม่ (new drug) หมายถึง ยาที่มีส่วนผสมซึ่งใช้ครั้งแรกในประเทศเวียดนาม

(7) ยาสามัญ (generic drug) หมายถึง ยาที่ผลิตขึ้นโดยให้มีคุณสมบัติด้านเภสัชวิทยาเหมือนกับยาต้นแบบ

(8) ยามียี่ห้อ (brand name drug) หมายถึง ยาที่ขึ้นทะเบียนในประเทศเวียดนามโดยมีข้อมูลรับรองด้านคุณภาพ ความปลอดภัย และความมีประสิทธิภาพ

(9) ยาเสพติด (habit-forming drug) หมายถึง ยาเสพติดตามรายชื่อที่กระทรวงสาธารณสุขกำหนด

(10) ยาเสพติดออกฤทธิ์ต่อจิตประสาท (psychotropic drug) หมายถึง ยาเสพติดที่มีผลออกฤทธิ์ต่อจิตประสาทตามรายชื่อที่กระทรวงสาธารณสุขกำหนด

(11) ยา Pre-substance (pre-substance drug) หมายถึง ยา Pre-substance ตามรายชื่อที่กระทรวงสาธารณสุขกำหนด

(12) ยาที่มีส่วนผสมของสารเสพติด (combination drug containing a habit-forming pharmaceutical ingredient) หมายถึง ยาที่ประกอบไปด้วยสารออกฤทธิ์หลายประเภทรวมทั้งสารเสพติด

(13) ยาที่มีส่วนผสมของสารออกฤทธิ์ต่อจิตประสาท (combination drug containing a psychotropic pharmaceutical ingredient) หมายถึง ยาที่ประกอบไปด้วยสารออกฤทธิ์หลายประเภทรวมทั้งสารเสพติดออกฤทธิ์ต่อจิตประสาท

(14) ยาที่มีส่วนผสมของ Pre-substance (combination drug containing a pre-substance) หมายถึง ยาที่ประกอบไปด้วยสารออกฤทธิ์หลายประเภทรวมทั้ง Pre-substance

(15) ยากัมมันตรังสี (radioactive drug) หมายถึง ยาที่มีส่วนประกอบของกัมมันตรังสีซึ่งมุ่งใช้เพื่อวินิจฉัยหรือรักษาโรคในมนุษย์ หรือเพื่อการศึกษาวิจัย

(16) ยาควบคุมพิเศษ (drug under special control) หมายถึง ยาที่กำหนดให้เป็นยาควบคุมพิเศษ เช่น ยาเสพติด (Habit-forming drug) ยาเสพติดออกฤทธิ์ต่อจิตประสาท (Psychotropic drug) ยา Pre-substance (Pre-substance drug) ยากัมมันตรังสี (Radioactive drug) รวมถึงยาอันตราย (Toxic drug) ที่กระทรวงสาธารณสุขกำหนด

(17) ยาที่ไม่ต้องใช้ใบสั่งแพทย์ (non-prescription drug) หมายถึง ยาที่สามารถจำหน่ายหรือใช้ได้โดยไม่ต้องใช้ใบสั่งแพทย์ ทั้งนี้ ตามรายชื่อที่กระทรวงสาธารณสุขกำหนด

(18) ยาที่ต้องใช้ใบสั่งแพทย์ (prescription drug) หมายถึง ยาที่สามารถจำหน่ายหรือใช้ได้เมื่อมีใบสั่งแพทย์ เนื่องจากยาดังกล่าวอาจเป็นอันตรายต่อชีวิตของผู้ใช้ได้หากไม่ปฏิบัติตามใบสั่งแพทย์

(19) ยาหลัก (essential drug) หมายถึง ยาที่ประชาชนส่วนใหญ่ต้องการ ทั้งนี้ ตามรายชื่อที่กระทรวงสาธารณสุขกำหนด

(20) ยาหายาก (rare drug) หมายถึง ยาที่มุ่งหมายสำหรับใช้ในการป้องกัน วินิจฉัย และรักษาโรคที่รักษายาก หรือยาที่หายากตามรายชื่อที่กระทรวงสาธารณสุขกำหนด

(21) ยาต่ำกว่ามาตรฐาน (substandard drug) หมายถึง ยาที่มีคุณภาพต่ำกว่ามาตรฐานที่กำหนดโดยหน่วยงานรัฐที่เกี่ยวข้อง

(22) ยาปลอม (counterfeit drug) หมายถึง ยาที่ผลิตโดยไม่มีส่วนประกอบของเภสัชเคมีภัณฑ์หรือสมุนไพร หรือมีส่วนประกอบไม่ตรงตามฉลาก หรือมีการปลอมแปลงชื่อผู้ผลิต/ประเทศผู้ผลิต

2.5 การขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

โดยหลักแล้ว ยาและวัตถุดิบเกี่ยวกับยาที่ไม่เคยขึ้นทะเบียนในประเทศเวียดนาม หรือเคยขึ้นทะเบียนในประเทศเวียดนามมาก่อนแต่มีการเปลี่ยนแปลงส่วนผสม วัตถุดิบ รูปแบบการจัดเตรียม หรือผู้ผลิต จะต้องได้รับการขึ้นทะเบียนก่อนการวางจำหน่ายในประเทศเวียดนามตามที่กำหนดในกฎหมายว่าด้วยเภสัชกรรมของประเทศเวียดนาม ประกอบ Circular No. 32/2018/TT-BYT on Marketing Authorization of Drugs and Medicinal Ingredients โดยหน่วยงานรัฐที่มีหน้าที่รับผิดชอบเกี่ยวกับการขึ้นทะเบียนผลิตภัณฑ์ยา คือ กระทรวงสาธารณสุข โดยคำแนะนำของ Advisory Board ทั้งนี้ การขึ้นทะเบียนผลิตภัณฑ์จะมีอายุ 5 ปี นับแต่วันขึ้นทะเบียนหรือวันต่ออายุทะเบียน เว้นแต่กรณีดังต่อไปนี้จะมีอายุ 3 ปี ได้แก่ กรณียาใหม่หรือวัคซีนที่ขึ้นทะเบียนในประเทศเวียดนามเป็นครั้งแรก ยาที่มีสารออกฤทธิ์เช่นเดียวกับยาใหม่ที่มีอายุทะเบียน 3 ปี ยาที่ไม่ได้มีการยื่นรายงานความปลอดภัยและความมีประสิทธิภาพประกอบการขึ้นทะเบียน และยาที่ต้องเฝ้าระวังความปลอดภัยและความมีประสิทธิภาพตามที่ Advisory Board แนะนำ

อย่างไรก็ดี มียาบางประเภทที่ได้รับการยกเว้นไม่ต้องขึ้นทะเบียนผลิตภัณฑ์ก่อนการวางจำหน่ายในประเทศเวียดนาม ได้แก่

(1) ยาที่ต้องใช้ใบสั่งแพทย์ซึ่งจัดเตรียมที่ร้านขายยาและขายเฉพาะที่ร้านขายยานั้น และยาที่ผลิตหรือจัดเตรียมที่สถานที่รักษาหรือวินิจฉัยโรค (medical examination and treatment establishment)

(2) ยาแผนโบราณตามที่กำหนด ได้แก่ ยาแผนโบราณที่ผลิต จัดเตรียม และใช้ ที่สถานที่รักษาหรือวินิจฉัยโรค และยาแผนโบราณที่ผลิตหรือจัดเตรียมโดยโรงพยาบาลระดับจังหวัดหรือสูงกว่าและจำหน่ายให้สถานที่รักษาหรือวินิจฉัยโรค

(3) ยานำเข้าตามที่กำหนด เช่น ยาที่มีความจำเป็นต้องนำเข้าเพื่อวัตถุประสงค์ทางด้านความปลอดภัยของประเทศ/ควบคุมหรือป้องกันโรคระบาด/ภัยธรรมชาติ/หรือเหตุพิเศษอื่น ยาหายาก ยาที่มีชื่อทางการค้า/สารออกฤทธิ์/วิธีการจัดเตรียมเช่นเดียวกับยามียี่ห้อที่ได้ขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามแล้วแต่มีราคาถูกกว่ายามียี่ห้อที่ได้วางจำหน่ายในประเทศเวียดนาม ยาที่ใช้เพื่อสนับสนุนนโยบายสาธารณสุขของรัฐ ยาที่ได้รับบริจาค ยาที่ใช้สำหรับการศึกษาทางคลินิก (clinical trial) หรือการศึกษาชีวสมมูล (bioequivalence trial) ยาที่ไม่ได้มีวัตถุประสงค์เพื่อการค้า

ทั้งนี้ แม้ผลิตภัณฑ์ยาข้างต้นจะได้รับการยกเว้นไม่ต้องขึ้นทะเบียนผลิตภัณฑ์ แต่การนำเข้าผลิตภัณฑ์ยาดังกล่าวต้องได้รับใบอนุญาตนำเข้าตามเงื่อนไขและกระบวนการที่กำหนดใน Decree No. 54/2017/ND-CP on Guidelines for Implementation of the Law on Pharmacy ด้วย

2.5.1 ผู้ประกอบการที่สามารถยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยา

สำหรับยาที่ต้องมีการขึ้นทะเบียนผลิตภัณฑ์ก่อนการวางจำหน่ายในประเทศเวียดนามนั้น กฎหมายว่าด้วยเภสัชกรรมกำหนดให้ผู้ประกอบการดังต่อไปนี้ที่สามารถยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยา รวมไปถึงต่ออายุทะเบียน และแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ยาได้

(1) ผู้ประกอบการผลิต ผู้ประกอบการขายส่ง ผู้ประกอบการนำเข้าหรือส่งออก ยาหรือวัตถุดิบเกี่ยวกับยา โดยผู้ประกอบการดังกล่าวต้องมีใบอนุญาตประกอบธุรกิจยา (Certificate of eligibility for pharmaceutical business) ในประเทศเวียดนาม

ทั้งนี้ วิธีการขอใบอนุญาตประกอบธุรกิจยาจะเป็นไปตามที่กำหนดในกฎหมายว่าด้วยเภสัชกรรม โดยผู้ประกอบการจะต้องยื่นคำขอพร้อมเอกสารประกอบ ได้แก่ เอกสารรับรองทางเทคนิค หนังสือจดทะเบียนบริษัท ใบประกอบวิชาชีพเภสัชกรรม (Pharmacy practice certificate) โดยยื่นต่อ 1) กระทรวงสาธารณสุข สำหรับใบอนุญาตประกอบธุรกิจยาประเภทโรงงานผลิตยา บริษัทนำเข้า/ส่งออกยาหรือวัตถุดิบเกี่ยวกับยา บริษัทจัดเก็บรักษายาหรือวัตถุดิบเกี่ยวกับยา บริษัทให้บริการทดสอบยาหรือวัตถุดิบเกี่ยวกับยา บริษัทให้บริการศึกษาทางคลินิก และบริษัทให้บริการศึกษาชีวสมมูล หรือ 2) หน่วยงานสาธารณสุขระดับจังหวัด สำหรับใบอนุญาตประกอบธุรกิจยาประเภทบริษัทขายส่งยาหรือวัตถุดิบเกี่ยวกับยา และบริษัทขายปลีกยาหรือวัตถุดิบเกี่ยวกับยา

(2) สำนักงานตัวแทนในประเทศเวียดนาม กรณีผู้ประกอบการต่างประเทศ

2.5.2 รายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยา

ในการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยา ต่ออายุทะเบียน หรือแก้ไขเนื้อหาในทะเบียน จะต้องมีเอกสารแสดงคุณภาพของผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาและเอกสารอื่น ๆ ประกอบด้วย โดยเอกสารดังกล่าวสามารถใช้ภาษาอังกฤษหรือภาษาเวียดนามก็ได้ เว้นแต่เอกสารกำกับยาแบบ Package insert ต้องจัดทำเป็นภาษาเวียดนามเท่านั้น นอกจากนี้ เอกสารที่ออกโดยหน่วยงานรัฐต่างประเทศจะต้องได้รับการรับรองเอกสาร (consular legalization) ด้วย

ทั้งนี้ รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอจะแตกต่างกันตามประเภทของผลิตภัณฑ์ยา แบ่งออกเป็น 4 กรณี ได้แก่ 1) ยาแผนปัจจุบัน วัคซีน และยาชีวภาพ 2) ยาสมุนไพร 3) วัตถุดิบเกี่ยวกับยา 4) ยาแผนโบราณ สรุปตามตารางได้ดังนี้

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์	
ยาแผนปัจจุบัน วัคซีน และยาชีวภาพ	**เอกสารทั่วไป** 1. คำขอขึ้นทะเบียนผลิตภัณฑ์ 2. หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ 3. ตัวอย่างฉลากที่จะใช้วางจำหน่ายในประเทศเวียดนาม - หากฉลากเป็นภาษาอื่นที่ไม่ใช่ภาษาอังกฤษ ต้องมีการแปลเป็นภาษาเวียดนามประกอบด้วย และฉลากต้องเป็นไปตามข้อกำหนดในหลักเกณฑ์ด้านฉลากที่ออกโดยกระทรวงสาธารณสุข *(รายละเอียดเพิ่มเติมตามหมายเหตุ)* 4. สรุปคุณสมบัติของผลิตภัณฑ์ 5. หนังสือรับรองผู้ผลิตสารออกฤทธิ์ สารเพิ่มปริมาณ แคปซูล และส่วนผสมสมุนไพร 6. หนังสือรับรองผลวิเคราะห์ Good Laboratory Practice (GLP) หรือ Good Manufacturing Practice (GMP) ของผู้ผลิต - ได้รับการยกเว้น หากผู้ผลิตดังกล่าวอยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ 7. แผนการบริหารจัดการความเสี่ยง 8. เอกสารรับรองแหล่งที่มาของวัตถุดิบ 9. เอกสารแสดงคุณภาพของผลิตภัณฑ์ - ต้องเป็นไปตามที่กำหนดใน Part II ของ ASEAN Common Technical Dossier (ACTD) หรือ Module 3 ของ ICH-CTD และที่กำหนดเพิ่มเติมสำหรับวัคซีน ซีรัมที่มีแอนติบอดี้ สารสกัดจากเลือดและพลาสมา ยาหายาก ยาที่ประกอบด้วยวัตถุดิบที่ได้รับการขึ้นทะเบียนในประเทศเวียดนามแล้ว ยาที่อยู่ภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี การบรรจุยาในภาชนะบรรจุ	**<u>การต่ออายุทะเบียนผลิตภัณฑ์</u>** **เอกสารทั่วไป** 1. คำขอต่ออายุทะเบียนผลิตภัณฑ์ 2. หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ 3. แผนการบริหารจัดการความเสี่ยง 4. รายงานความปลอดภัยและความมีประสิทธิภาพ (safety and efficacy report) 5. รายงานการจำหน่ายผลิตภัณฑ์ (marketing report) 6. เอกสารรับรองแหล่งที่มาของวัตถุดิบ 7. สำเนาหนังสือรับรองการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม 8. ในกรณีเอกสารที่ได้ยื่นไว้ตอนขึ้นทะเบียนผลิตภัณฑ์มีการเปลี่ยนแปลง ให้ผู้ประกอบการยื่นเอกสารฉบับใหม่ด้วย **เอกสารเพิ่มเติมสำหรับผู้ประกอบการเวียดนาม** 1. ใบอนุญาตประกอบธุรกิจยา	**<u>หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP)</u>** ในกรณียาต่างประเทศ ผู้ประกอบการต้องยื่น CPP โดยมีรายละเอียดข้อมูลตามแบบฟอร์มที่กระทรวงสาธารณสุขของประเทศเวียดนามกำหนด (Form 7/TT) และตามที่ Circular No. 32/2018/TT-BYT 32/2018 กำหนดดังนี้ **กรณี Form 7/TT:** 1. ชื่อ รูปแบบของยา และคุณลักษณะเฉพาะของผลิตภัณฑ์ (name, dosage, specification of product) ซึ่งรวมถึงคุณลักษณะเฉพาะของสารออกฤทธิ์ (specification of active ingredient) คุณลักษณะเฉพาะของวัตถุดิบเกี่ยวกับยา (specification of medicinal material) และชื่อและที่อยู่ของผู้ผลิตสารออกฤทธิ์และวัตถุดิบเกี่ยวกับยาด้วย 2. ข้อมูลเกี่ยวกับหนังสืออนุญาตผลิตภัณฑ์ (product license) 3. ข้อมูลเกี่ยวกับการตรวจสอบสถานที่ผลิต

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	ภายนอกที่ไม่ได้สัมผัสกับยา (secondary packaging) การขึ้นทะเบียนผลิตภัณฑ์แบบง่าย *(รายละเอียดเพิ่มเติมตามหมายเหตุ)* 10. ข้อมูลไม่ใช่การศึกษาทางคลินิก (non-clinical document) - ต้องเป็นไปตามที่กำหนดใน Part III ของ ACTD หรือ Module 4 ของ ICH-CTD 11. ข้อมูลการศึกษาทางคลินิก (clinical document) - ต้องเป็นไปตามที่กำหนดใน Part IV ของ ACTD หรือ Module 5 ของ ICH-CTD หรือมาตรฐานของหน่วยงานอื่นที่ประเทศเวียดนามยอมรับ ได้แก่ European Medicines Agency (EMA) หรือหน่วยงานรัฐที่รับผิดชอบด้านผลิตภัณฑ์ยาในประเทศสหรัฐอเมริกา ประเทศญี่ปุ่น ประเทศฝรั่งเศส ประเทศเยอรมนี ประเทศสวีเดน ประเทศอังกฤษ ประเทศสวิตเซอร์แลนด์ ประเทศออสเตรเลีย ประเทศแคนาดา ประเทศเบลเยี่ยม ประเทศออสเตรีย ประเทศไอร์แลนด์ ประเทศเดนมาร์ก และประเทศเนเธอร์แลนด์ - <u>กรณียาใหม่ วัคซีน หรือยาชีวภาพ อาจได้รับการยกเว้นจากกระทรวงสาธารณสุขให้ไม่ต้องมีผลการศึกษาทางคลินิกได้</u> ในกรณีต่อไปนี้ 1) หากมีความจำเป็นอย่างเร่งด่วนที่ต้องใช้ยาดังกล่าวเพื่อวัตถุประสงค์ทางด้านความปลอดภัยของประเทศ/ควบคุมหรือป้องกันโรคระบาด/ภัยธรรมชาติ และไม่สามารถหายาอื่นทดแทนได้ 2) เป็นยาที่ได้รับการขึ้นทะเบียนในกลุ่มประเทศที่กำหนดข้างต้นอย่างน้อย 2 ประเทศ หรือได้รับการขึ้นทะเบียนโดย US FDA หรือ EMA 3) เป็นยาที่ใช้สำหรับรักษาโรคร้ายแรง หรือ 4) เป็นวัคซีน/ยาชีวภาพที่ผลิตในประเทศเวียดนาม ผ่านการถ่ายทอดเทคโนโลยีจากประเทศอื่นซึ่งมีกรรมวิธีการผลิตบางส่วนหรือทั้งหมดมีผลการศึกษาทางคลินิก	- ได้รับการยกเว้น หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ** 1. ใบอนุญาตจัดตั้งสำนักงานตัวแทนในประเทศเวียดนาม 2. ใบอนุญาตการผลิต การขายส่ง การนำเข้า การส่งออก ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาอย่างใดอย่างหนึ่ง ที่ออกโดยหน่วยงานรัฐต่างประเทศ - ได้รับการยกเว้นการยื่นเอกสารทั้ง 2 รายการ หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับยาต่างประเทศ** 1. หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP)	**กรณี Circular No. 32/2018/TT-BYT 32/2018:** 1. ตำรับยา (Formulation of the drug) ซึ่งประกอบด้วยชื่อ ส่วนประกอบ ความเข้มข้นและความรุนแรงของสารออกฤทธิ์ (active ingredient) วัตถุดิบเกี่ยวกับยา (medicinal material) และสารเพิ่มปริมาณ (excipient) แต่ละชนิด รวมถึงสูตรของแคปซูล 2. คุณลักษณะเฉพาะของผลิตภัณฑ์ (specification of finished product) ของตัวยาสำคัญ (drug substance) และของวัตถุดิบเกี่ยวกับยา (medicinal material) รวมถึงชื่อและที่อยู่ของผู้ผลิต 3. ในกรณีที่ผลิตภัณฑ์ยามีกระบวนการผลิตจากโรงงานหลายแห่งประกอบกัน ให้ระบุชื่อที่อยู่ และหน้าที่ของแต่ละโรงงานที่เกี่ยวข้องใน CPP ด้วย 4. ในกรณีที่ CPP ไม่ได้ระบุข้อมูลเกี่ยวกับมาตรฐาน GMP ของผู้ผลิต ให้ผู้ยื่นคำขอยื่น GMP certificate ของผู้ผลิตแต่ละรายด้วย

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	เอกสารเพิ่มเติมสำหรับผู้ประกอบการเวียดนาม 1. ใบอนุญาตประกอบธุรกิจยา - ได้รับการยกเว้น หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ** 1. ใบอนุญาตจัดตั้งสำนักงานตัวแทนในประเทศเวียดนาม 2. ใบอนุญาตการผลิต การขายส่ง การนำเข้า การส่งออก ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาอย่างใดอย่างหนึ่ง ที่ออกโดยหน่วยงานรัฐต่างประเทศ - ได้รับการยกเว้นการยื่นเอกสารทั้ง 2 รายการ หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับยาต่างประเทศ** 1. หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) 2. ตัวอย่างฉลาก และเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศแหล่งกำเนิด หรือประเทศที่ออก CPP 3. การประเมินการปฏิบัติตามมาตรฐาน GMP กรณีผู้ผลิตต่างประเทศ ซึ่งได้มีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามเป็นครั้งแรก	2. การประเมินการปฏิบัติตามมาตรฐาน GMP กรณีผู้ผลิตต่างประเทศ ซึ่งได้มีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามเป็นครั้งแรก **<u>การแก้ไขเนื้อหาทะเบียนผลิตภัณฑ์</u>** 1. คำขอแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ 2. ข้อมูลที่มีการเปลี่ยนแปลงไป เช่น มีการเปลี่ยนแปลงสถานที่ผลิต (manufacturing location) ทั้งนี้ การแก้ไขเนื้อหาทะเบียนผลิตภัณฑ์ที่ไม่ต้องยื่นคำขอ เช่น การแก้ไขฉลากหรือเอกสารกำกับยาแบบ Package insert ตามที่กระทรวงสาธารณสุขร้องขอ การแก้ไขข้อมูลผู้นำเข้าบนฉลากหรือเอกสารกำกับยาแบบ Package insert การแก้ไขคำผิด และการแก้ไขลำดับการระบุข้อมูลในเอกสารกำกับยาแบบ Package insert	5. เอกสารแนบต่าง ๆ ของ CPP (หากมี) ต้องได้รับการรับรองโดยหน่วยงานรัฐที่ออก CPP ด้วย **<u>ฉลากผลิตภัณฑ์</u>** Circular No. 01/2018/TT-BYT on Labelling and Package Inserts of Drugs and Medicinal Ingredients กำหนดรายละเอียดข้อมูลที่ต้องมีบนฉลากผลิตภัณฑ์ และ Package Insertดังนี้ **1. ฉลากของบรรจุภัณฑ์ทุติยภูมิ (secondary package label) ของผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา** **1.1 กรณียา** - ชื่อผลิตภัณฑ์ - รูปแบบยา (dosage form) - ส่วนประกอบของยา น้ำหนักหรือความเข้มข้นของสารออกฤทธิ์หรือวัตถุดิบสมุนไพร - เนื้อหาบนบรรจุภัณฑ์ (package content) - ข้อบ่งใช้ วิธีการใช้

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	เอกสารเพิ่มเติมสำหรับยามียี่ห้อ 1. เอกสารที่รับรองว่ายาดังกล่าวได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศใดประเทศหนึ่งดังต่อไปนี้ ประเทศสหรัฐอเมริกา ประเทศญี่ปุ่น ประเทศฝรั่งเศส ประเทศเยอรมนี ประเทศสวีเดน ประเทศอังกฤษ ประเทศสวิตเซอร์แลนด์ ประเทศออสเตรเลีย ประเทศแคนาดา ประเทศเบลเยี่ยม ประเทศออสเตรีย ประเทศไอร์แลนด์ ประเทศเดนมาร์ก และประเทศเนเธอร์แลนด์ หรือได้รับการขึ้นทะเบียนผลิตภัณฑ์โดยหน่วยงานที่ถือเป็น Stringent Regulatory Authority (SRA) ตาม WHO เช่น หน่วยงานที่เป็นสมาชิกของ ICH ก่อนวันที่ 23 ตุลาคม 2558		- เลขทะเบียนผลิตภัณฑ์ หรือเลขใบอนุญาตนำเข้าผลิตภัณฑ์ (หากมี) - Batch number วันที่ผลิต วันหมดอายุ มาตรฐานคุณภาพ และวิธีการเก็บรักษา - ข้อควรระวัง ข้อแนะนำ - ชื่อและที่อยู่ผู้ผลิต - ชื่อและที่อยู่ผู้นำเข้า (กรณียานำเข้า) - แหล่งกำเนิดผลิตภัณฑ์
	กรณียาสามัญ (generic drug) 1. คำขอขึ้นทะเบียนผลิตภัณฑ์ 2. หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ 3. ตัวอย่างฉลากที่จะใช้วางจำหน่ายในประเทศเวียดนาม - หากฉลากเป็นภาษาอื่นที่ไม่ใช่ภาษาอังกฤษ ต้องมีการแปลเป็นภาษาเวียดนามประกอบด้วย และฉลากต้องเป็นไปตามข้อกำหนดในหลักเกณฑ์ด้านฉลากที่ออกโดยกระทรวงสาธารณสุข *(รายละเอียดเพิ่มเติมตามหมายเหตุ)* 4. สรุปคุณสมบัติของผลิตภัณฑ์ 5. หนังสือรับรองผู้ผลิตสารออกฤทธิ์ สารเพิ่มปริมาณ แคปซูล และส่วนผสมสมุนไพร 6. หนังสือรับรองผลวิเคราะห์ Good Laboratory Practice (GLP) หรือ Good Manufacturing Practice (GMP) ของผู้ผลิต - ได้รับการยกเว้น หากผู้ผลิตดังกล่าวอยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์		**1.2 กรณีวัตถุดิบเกี่ยวกับยา (รวมถึงวัตถุดิบสมุนไพร วัตถุดิบของยาแผนโบราณ ผลิตภัณฑ์กึ่งสำเร็จรูป (semi-finished drug และ semi-finished herbal drug)** - ชื่อวัตถุดิบเกี่ยวกับยา - น้ำหนักหรือปริมาณวัตถุดิบ - มาตรฐานคุณภาพของวัตถุดิบ - เลขทะเบียนผลิตภัณฑ์ หรือเลขใบอนุญาตนำเข้าผลิตภัณฑ์ (หากมี) - Batch number วันที่ผลิต วันหมดอายุ มาตรฐานคุณภาพ และวิธีการเก็บรักษา - ชื่อและที่อยู่ผู้ผลิต - ชื่อและที่อยู่ผู้นำเข้า (กรณียานำเข้า)

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	7. เอกสารรับรองแหล่งที่มาของวัตถุดิบ 8. เอกสารแสดงคุณภาพของผลิตภัณฑ์ - ต้องเป็นไปตามที่กำหนดใน Part II ของ ASEAN Common Technical Dossier (ACTD) หรือ Module 3 ของ ICH-CTD และที่กำหนดเพิ่มเติมสำหรับวัคซีน ซีรัมที่มีแอนติบอดี้ สารสกัดจากเลือดและพลาสมา ยาหายาก ยาที่ประกอบด้วยวัตถุดิบที่ได้รับการขึ้นทะเบียนในประเทศเวียดนามแล้ว ยาที่อยู่ภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี การบรรจุยาในภาชนะบรรจุภายนอกที่ไม่ได้สัมผัสกับยา (secondary packaging) การขึ้นทะเบียนผลิตภัณฑ์แบบง่าย *(รายละเอียดเพิ่มเติมตามหมายเหตุ)* **เอกสารเพิ่มเติมสำหรับผู้ประกอบการเวียดนาม** 1. ใบอนุญาตประกอบธุรกิจยา - ได้รับการยกเว้น หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ** 1. ใบอนุญาตจัดตั้งสำนักงานตัวแทนในประเทศเวียดนาม 2. ใบอนุญาตการผลิต การขายส่ง การนำเข้า การส่งออก ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาอย่างใดอย่างหนึ่ง ที่ออกโดยหน่วยงานรัฐต่างประเทศ - ได้รับการยกเว้นการยื่นเอกสารทั้ง 2 รายการ หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์		- แหล่งกำเนิดผลิตภัณฑ์ **1.3 กรณียาควบคุมพิเศษ** กรณียาควบคุมพิเศษ ต้องระบุบนฉลากให้ชัดเจนด้วยว่ามีสารออกฤทธิ์ หรือวัตถุดิบสมุนไพร ที่เข้าข่ายเป็นสารเสพติดหรือสารอันตรายใดบ้าง เพิ่มเติมจากข้อมูลที่จะต้องมีตามที่กำหนดข้างต้น **2. ฉลากของบรรจุภัณฑ์ที่อยู่ระหว่างบรรจุภัณฑ์ปฐมภูมิและบรรจุภัณฑ์ทุติยภูมิ (intermediate package label)** - ชื่อผลิตภัณฑ์ - Batch number - วันหมดอายุ ทั้งนี้ ไม่จำเป็นต้องมีข้อมูลดังกล่าว หากบรรจุภัณฑ์ Intermediate มีลักษณะใสจนเห็นข้อมูลที่ระบุอยู่บนบรรจุภัณฑ์ปฐมภูมิ **3. ฉลากของบรรจุภัณฑ์ปฐมภูมิ (primary package label)** **3.1 กรณียา** - ชื่อผลิตภัณฑ์

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	เอกสารเพิ่มเติมสำหรับยาต่างประเทศ 1. หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) 2. ตัวอย่างฉลาก และเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศแหล่งกำเนิด หรือประเทศที่ออก CPP 3. การประเมินการปฏิบัติตามมาตรฐาน GMP กรณีผู้ผลิตต่างประเทศ ซึ่งได้มีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามเป็นครั้งแรก		- ส่วนประกอบของยา น้ำหนักหรือความเข้มข้นของสารออกฤทธิ์หรือวัตถุดิบสมุนไพร - Batch number - วันหมดอายุ - ชื่อผู้ผลิต **3.2 กรณีวัตถุดิบเกี่ยวกับยา** - ไม่ต้องมีข้อมูลเกี่ยวกับวัตถุดิบเกี่ยวกับยาบนบรรจุภัณฑ์ปฐมภูมิ หากบนบรรจุภัณฑ์ทุติยภูมิมีข้อมูลวัตถุดิบเกี่ยวกับยาครบถ้วนตามข้างต้นแล้ว **4. เอกสารกำกับยาแบบ Package insert** - ชื่อผลิตภัณฑ์ - ข้อควรระวัง และข้อแนะนำ - ส่วนประกอบของยา - รูปแบบยา (dosage form) - ข้อบ่งใช้ - วิธีการใช้ และขนาดการใช้ - ข้อห้าม - คำเตือน - คำเตือนการใช้ยาระหว่างตั้งครรภ์หรือให้นมบุตร
	กรณียาที่ผลิตภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี (pharmaceutical technology transfer) โดยยาต้นแบบ (source drug of transfer) ได้รับการขึ้นทะเบียนผลิตภัณฑ์แล้ว 1. คำขอขึ้นทะเบียนผลิตภัณฑ์ 2. หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ 3. ตัวอย่างฉลากที่จะใช้วางจำหน่ายในประเทศเวียดนาม - หากฉลากเป็นภาษาอื่นที่ไม่ใช่ภาษาอังกฤษ ต้องมีการแปลเป็นภาษาเวียดนามประกอบด้วย และฉลากต้องเป็นไปตามข้อกำหนดในหลักเกณฑ์ด้านฉลากที่ออกโดยกระทรวงสาธารณสุข *(รายละเอียดเพิ่มเติมตามหมายเหตุ)* 4. หนังสือรับรองผลวิเคราะห์ Good Laboratory Practice (GLP) หรือ Good Manufacturing Practice (GMP) ของผู้ผลิต - ได้รับการยกเว้น หากผู้ผลิตดังกล่าวอยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ 5. แผนการบริหารจัดการความเสี่ยง 6. ข้อตกลงด้านการถ่ายทอดเทคโนโลยี		

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	7. รายงานความปลอดภัยและความมีประสิทธิภาพ (safety and efficacy report) 8. รายงานการจำหน่ายผลิตภัณฑ์ (marketing report) 9. เอกสารรับรองแหล่งที่มาของวัตถุดิบ 10. สำเนาหนังสือรับรองการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม 11. เอกสารแสดงคุณภาพของผลิตภัณฑ์ - ต้องเป็นไปตามที่กำหนดใน Part II ของ ASEAN Common Technical Dossier (ACTD) หรือ Module 3 ของ ICH-CTD และที่กำหนดเพิ่มเติมสำหรับวัคซีน ซีรัมที่มีแอนติบอดี้ สารสกัดจากเลือดและพลาสมา ยาหายาก ยาที่ประกอบด้วยวัตถุดิบที่ได้รับการขึ้นทะเบียนในประเทศเวียดนามแล้ว ยาที่อยู่ภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี การบรรจุยาในภาชนะบรรจุภายนอกที่ไม่ได้สัมผัสกับยา (secondary packaging) การขึ้นทะเบียนผลิตภัณฑ์แบบง่าย *(รายละเอียดเพิ่มเติมตามหมายเหตุ)* 12. เอกสารแสดงข้อมูลกรณียาต้นแบบ (source drug) มีการเปลี่ยนแปลงไป **เอกสารเพิ่มเติมสำหรับผู้ประกอบการเวียดนาม** 1. ใบอนุญาตประกอบธุรกิจยา - ได้รับการยกเว้น หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ** 1. ใบอนุญาตจัดตั้งสำนักงานตัวแทนในประเทศเวียดนาม		- ผลกระทบของยาต่อการขับรถหรือใช้เครื่องจักร - ปฏิกิริยาที่เกิดจากการใช้ยาร่วมกับสิ่งอื่น - ผลข้างเคียง - การใช้ยาเกินขนาด - ข้อมูลเกี่ยวกับเภสัชพลศาสตร์ (Pharmacodynamics) - ข้อมูลเกี่ยวกับเภสัชจลนศาสตร์ (Pharmacokinetics) - เนื้อหาบนบรรจุภัณฑ์ (package content) - วิธีการเก็บรักษา วันหมดอายุ และมาตรฐานคุณภาพ - ชื่อและที่อยู่ผู้ผลิต ทั้งนี้ ยาทุกชนิดที่จำหน่ายในประเทศเวียดนามต้องมีเอกสารกำกับยาแบบ Package insert เป็นภาษาเวียดนามด้วย เว้นแต่เป็นยาแผนโบราณที่ผลิต จัดเตรียม และใช้เฉพาะที่สถานรักษาหรือวินิจฉัยโรค หรือยาที่ต้องใช้ใบสั่งแพทย์ซึ่งจัดเตรียมที่ร้านขายยา

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	2. ใบอนุญาตการผลิต การขายส่ง การนำเข้า การส่งออก ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาอย่างใดอย่างหนึ่ง ที่ออกโดยหน่วยงานรัฐต่างประเทศ - ได้รับการยกเว้นการยื่นเอกสารทั้ง 2 รายการ หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์		และขายเฉพาะที่ร้านขายยานั้น หรือยาที่ยังไม่ได้ขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนามแต่จำเป็นต้องนำเข้ามาเพื่อวัตถุประสงค์ในการศึกษาชีวมูล (bioequivalence study) เป็นต้น
	กรณียาที่ผลิตภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี (pharmaceutical technology transfer) โดยยาต้นแบบ (source drug of transfer) ยังไม่ได้รับการขึ้นทะเบียนผลิตภัณฑ์ 1. เอกสารเกี่ยวกับยาต้นแบบ (source drug) ตามข้างต้น (แล้วแต่กรณี) 2. ข้อตกลงด้านการถ่ายทอดเทคโนโลยี		**<u>เอกสารแสดงคุณภาพของผลิตภัณฑ์สำหรับยาแผนปัจจุบัน วัคซีน และยาชีวภาพ</u>** ต้องเป็นไปตามที่กำหนดใน Part II ของ ASEAN Common Technical Dossier (ACTD) หรือ Module 3 ของ ICH-CTD และที่กำหนดเพิ่มเติมสำหรับกรณีดังต่อไปนี้ **1. วัคซีน ซีรัมที่มีแอนติบอดี้ สารสกัดจากเลือดและพลาสมา** - หนังสือรับรองรุ่นการผลิต (batch release certificate) ซึ่งออกโดยหน่วยงานรัฐในประเทศที่ออก CPP - รายงานการทดสอบ (test report) ที่ได้รับการรับรองโดย National Institute for
	กรณีบรรจุยาในภาชนะบรรจุภายนอกที่ไม่ได้สัมผัสกับยา (secondary packaging) ในประเทศเวียดนาม 1. หากยาดังกล่าวได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนามแล้ว ให้ผู้ประกอบการแจ้งการเปลี่ยนสถานที่บรรจุยาตามแนวทางที่กระทรวงสาธารณสุขกำหนด 2. หากยาดังกล่าวยังไม่ได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม หรือทะเบียนผลิตภัณฑ์หมดอายุแล้ว ให้ผู้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ตามประเภทยาข้างต้น พร้อมเอกสารดังต่อไปนี้ - ใบรับรอง GMP สำหรับสถานที่บรรจุยาในประเทศเวียดนาม - เอกสารแสดงคุณภาพผลิตภัณฑ์ - ต้องเป็นไปตามที่กำหนดใน Part II ของ ASEAN Common Technical Dossier (ACTD) หรือ Module 3 ของ ICH-CTD และที่กำหนดเพิ่มเติมสำหรับวัคซีน ซีรัมที่มีแอนติบอดี้ สารสกัดจากเลือดและพลาสมา ยาหายาก ยาที่ประกอบด้วยวัตถุดิบที่ได้รับการขึ้นทะเบียนใน		

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	ประเทศเวียดนามแล้ว ยาที่อยู่ภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี การบรรจุยาในภาชนะบรรจุภายนอกที่ไม่ได้สัมผัสกับยา (secondary packaging) การขึ้นทะเบียนผลิตภัณฑ์แบบง่าย *(รายละเอียดเพิ่มเติมตามหมายเหตุ)*		Control of Vaccines and Biologicals (NICVB) ในประเทศเวียดนาม **2. ยาหายากและยาที่ใช้เพื่อวัตถุประสงค์เป็นการเฉพาะ** - ผลการศึกษาด้านการคงสภาพของยาตามแนวทางของ ASEAN หรือ ICH กรณียาหายาก - ผลการศึกษาด้านการคงสภาพของยาตามแนวทางของ ASEAN หรือ ICH หรือความเห็นของกระทรวงสาธารณสุขตามคำแนะนำของ Advisory Board กรณียาที่ใช้เพื่อวัตถุประสงค์เป็นการเฉพาะ **3. ยาที่ประกอบด้วยวัตถุดิบที่ได้รับการขึ้นทะเบียนในประเทศเวียดนามแล้ว** - ไม่ต้องยื่นเอกสารแสดงคุณภาพของวัตถุดิบ และหนังสือรับรองผู้ผลิตสารออกฤทธิ์ สารเพิ่มปริมาณ แคปซูล และส่วนผสมสมุนไพร - แต่ต้องยื่นรายงานการทดสอบวัตถุดิบเกี่ยวกับยาที่จัดทำโดยผู้ผลิตยา และรายงาน
	การขึ้นทะเบียนผลิตภัณฑ์แบบง่าย (simplified procedure) 1. คำขอขึ้นทะเบียนผลิตภัณฑ์ 2. หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ 3. ตัวอย่างฉลากที่จะใช้วางจำหน่ายในประเทศเวียดนาม - หากฉลากเป็นภาษาอื่นที่ไม่ใช่ภาษาอังกฤษ ต้องมีการแปลเป็นภาษาเวียดนามประกอบด้วย และฉลากต้องเป็นไปตามข้อกำหนดในหลักเกณฑ์ด้านฉลากที่ออกโดยกระทรวงสาธารณสุข *(รายละเอียดเพิ่มเติมตามหมายเหตุ)* 4. หนังสือรับรองผู้ผลิตสารออกฤทธิ์ สารเพิ่มปริมาณ แคปซูล และส่วนผสมสมุนไพร 5. หนังสือรับรองผลวิเคราะห์ Good Laboratory Practice (GLP) หรือ Good Manufacturing Practice (GMP) ของผู้ผลิต - ได้รับการยกเว้น หากผู้ผลิตดังกล่าวอยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ 6. เอกสารรับรองแหล่งที่มาของวัตถุดิบ **เอกสารเพิ่มเติมสำหรับผู้ประกอบการเวียดนาม** 1. ใบอนุญาตประกอบธุรกิจยา		

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	- ได้รับการยกเว้น หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ** 1. ใบอนุญาตจัดตั้งสำนักงานตัวแทนในประเทศเวียดนาม 2. ใบอนุญาตการผลิต การขายส่ง การนำเข้า การส่งออก ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาอย่างใดอย่างหนึ่ง ที่ออกโดยหน่วยงานรัฐต่างประเทศ - ได้รับการยกเว้นการยื่นเอกสารทั้ง 2 รายการ หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับยาต่างประเทศ** 1. หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) 2. ตัวอย่างฉลาก และเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศแหล่งกำเนิด หรือประเทศที่ออก CPP		การทดสอบวัตถุดิบเกี่ยวกับยาที่จัดทำโดยผู้ผลิตวัตถุดิบเกี่ยวกับยา **4. ยาที่อยู่ภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี** - ตารางแสดงความแตกต่างระหว่างยาต้นแบบกับยาที่จะวางจำหน่ายในประเทศเวียดนาม - เอกสารเกี่ยวกับสารออกฤทธิ์ของยาที่จะวางจำหน่ายในประเทศเวียดนามซึ่งจัดเตรียมโดยผู้รับโอนเทคโนโลยี - เอกสารอื่น ๆ ซึ่งจัดเตรียมโดยผู้รับโอนเทคโนโลยี เช่น กรรมวิธีการผลิต ผลการศึกษาด้านการคงสภาพของยา **5. การบรรจุยาในภาชนะบรรจุภายนอกที่ไม่ได้สัมผัสกับยา (secondary packaging)** - ต้องเป็นไปตามที่กำหนดใน Part II ของ ACTD หรือ Module 3 ของ ICH-CTD **6. การขึ้นทะเบียนผลิตภัณฑ์แบบง่าย** - เอกสารเกี่ยวกับสารออกฤทธิ์ ซึ่งประกอบด้วยชื่อสารออกฤทธิ์ ชื่อและที่อยู่ของ

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
			ผู้ผลิตสารออกฤทธิ์ วิธีการทดสอบสารออกฤทธิ์ และรายงานการทดสอบสารออกฤทธิ์ - เอกสารเกี่ยวกับผลิตภัณฑ์ยา ซึ่งประกอบด้วยข้อมูลตาม Part I ของ ACTD วิธีการทดสอบผลิตภัณฑ์ ข้อมูลเกี่ยวกับผู้ผลิต รายงานการทดสอบ บรรจุภัณฑ์ปฐมภูมิ และผลการศึกษาด้านการคงสภาพของยา
ยาสมุนไพร	**เอกสารทั่วไป** 1. คำขอขึ้นทะเบียนผลิตภัณฑ์ 2. หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ 3. ตัวอย่างฉลากที่จะใช้วางจำหน่ายในประเทศเวียดนาม - หากฉลากเป็นภาษาอื่นที่ไม่ใช่ภาษาอังกฤษ ต้องมีการแปลเป็นภาษาเวียดนามประกอบด้วย และฉลากต้องเป็นไปตามข้อกำหนดในหลักเกณฑ์ด้านฉลากที่ออกโดยกระทรวงสาธารณสุข *(รายละเอียดเพิ่มเติมตามหมายเหตุ)* 4. หนังสือรับรองผู้ผลิตสารออกฤทธิ์ สารเพิ่มปริมาณ แคปซูล และส่วนผสมสมุนไพร 5. หนังสือรับรองผลวิเคราะห์ Good Laboratory Practice (GLP) หรือ Good Manufacturing Practice (GMP) ของผู้ผลิต - ได้รับการยกเว้น หากผู้ผลิตดังกล่าวอยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ 6. เอกสารรับรองแหล่งที่มาของวัตถุดิบ	**<u>การต่ออายุทะเบียนผลิตภัณฑ์</u>** **เอกสารทั่วไป** 1. คำขอต่ออายุทะเบียนผลิตภัณฑ์ 2. หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ 3. รายงานความปลอดภัยและความมีประสิทธิภาพ (safety and efficacy report) 4. รายงานการจำหน่ายผลิตภัณฑ์ (marketing report) 5. เอกสารรับรองแหล่งที่มาของวัตถุดิบ 7. สำเนาหนังสือรับรองการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม	รายละเอียดเกี่ยวกับฉลากและเอกสารกำกับยาแบบ Package insert ตามข้างต้น

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	7. เอกสารแสดงคุณภาพของผลิตภัณฑ์ - เอกสารแสดงคุณภาพของส่วนผสม (Ingredient) ซึ่งครอบคลุมถึงวิธีการทดสอบ (Test method) - เอกสารแสดงคุณภาพของผลิตภัณฑ์ยา ซึ่งครอบคลุมถึงกรรมวิธีการผลิต กระบวนการควบคุมการผลิต บรรจุภัณฑ์ และวิธีการทดสอบ 8. เอกสารรับรองความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์ 8.1 ต้องเป็นไปตามที่กำหนดในภาคผนวก 5 ของ Circular No. 32/2018/TT-BYT ตาม ACTD หรือ ICH-CTD 8.2 ผลการศึกษาทางคลินิกในกรณียาใหม่ - การศึกษาต้องสอดคล้องกับแนวทางที่กระทรวงสาธารณสุขกำหนด หรือหน่วยงานอื่นที่ได้รับการรับรองจากประเทศเวียดนาม รวมถึง WHO's Research Guidelines for evaluating the safety and efficacy of herbal medicines หรือหน่วยงานที่ถือเป็น Stringent Regulatory Authority (SRA) ตาม WHO - <u>ข้อมูลที่นำมาจากแหล่งข้อมูลดังต่อไปนี้ให้สามารถใช้แทนผลการศึกษาทางคลินิกได้</u> - ข้อมูลจาก Phamacopeias ของประเทศเวียดนามหรือประเทศอื่น - การประเมินความปลอดภัยและความมีประสิทธิภาพของยาที่เผยแพร่ในวารสาร Science Citation Index (SCI) หรือสิ่งพิมพ์อื่น - การประเมินความปลอดภัยและความมีประสิทธิภาพของยาในงานวิจัยระดับประเทศ ระดับกระทรวง หรือระดับจังหวัด - <u>กรณีดังต่อไปนี้ได้รับการยกเว้นไม่ต้องมีผลการศึกษาทางคลินิกสำหรับยาสมุนไพร</u>	**เอกสารเพิ่มเติมสำหรับผู้ประกอบการเวียดนาม** 1. ใบอนุญาตประกอบธุรกิจยา - ได้รับการยกเว้น หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ** 1. ใบอนุญาตจัดตั้งสำนักงานตัวแทนในประเทศเวียดนาม 2. ใบอนุญาตการผลิต การขายส่ง การนำเข้า การส่งออก ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาอย่างใดอย่างหนึ่ง ที่ออกโดยหน่วยงานรัฐต่างประเทศ - ได้รับการยกเว้นการยื่นเอกสารทั้ง 2 รายการ หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับยาต่างประเทศ**	

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	- ยาดังกล่าวมีส่วนประกอบ ปริมาณของส่วนผสมสมุนไพร วิธีการใช้ เช่นเดียวกับยาสมุนไพรที่ได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนามแล้ว (แม้ทะเบียนจะหมดอายุแล้ว) - ยาดังกล่าวมีส่วนประกอบ ปริมาณของส่วนผสมสมุนไพร วิธีการใช้ เช่นเดียวกับยาสมุนไพรใหม่ ที่ได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม โดยมีอายุทะเบียน 5 ปี เนื่องจากมีผลการศึกษาทางคลินิกครบถ้วน - <u>กระทรวงสาธารณสุข โดยคำแนะนำของ Advisory Board พิจารณายกเว้นการศึกษาทางคลินิกบางระยะ (Stages of clinical trial)</u> สำหรับกรณี 1) มีความจำเป็นอย่างเร่งด่วนที่ต้องใช้ยาดังกล่าวเพื่อวัตถุประสงค์ทางด้านความปลอดภัยของประเทศ/ควบคุมหรือป้องกันโรคระบาด/ภัยธรรมชาติ และไม่สามารถหายาอื่นทดแทนได้ 2) เป็นยาที่ได้รับการขึ้นทะเบียนในกลุ่มประเทศที่กำหนดข้างต้น (เช่น ประเทศสหรัฐอเมริกา ประเทศญี่ปุ่น ประเทศฝรั่งเศส ประเทศเยอรมนี ประเทศสวีเดน ประเทศอังกฤษ ประเทศสวิตเซอร์แลนด์) อย่างน้อย 2 ประเทศ หรือได้รับการขึ้นทะเบียนโดย US FDA หรือ EMA 3) ยาดังกล่าวไม่ได้มีวัตถุประสงค์เพื่อรักษาโรคที่กำหนดโดยกระทรวงสาธารณสุข 4) วัตถุดิบสมุนไพรที่เคยใช้ในประเทศเวียดนามแต่มีสูตรผสมใหม่ (new combination of herbal ingredients) **เอกสารเพิ่มเติมสำหรับผู้ประกอบการเวียดนาม** 1. ใบอนุญาตประกอบธุรกิจยา - ได้รับการยกเว้น หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ**	1. หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) 2. การประเมินการปฏิบัติตามมาตรฐาน GMP กรณีผู้ผลิตต่างประเทศ ซึ่งได้มีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามเป็นครั้งแรก **<u>การแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์</u>** 1. คำขอแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ 2. ข้อมูลที่มีการเปลี่ยนแปลงไป เช่น มีการเปลี่ยนแปลงสถานที่ผลิต (manufacturing location)	

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	1. ใบอนุญาตจัดตั้งสำนักงานตัวแทนในประเทศเวียดนาม 2. ใบอนุญาตการผลิต การขายส่ง การนำเข้า การส่งออก ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาอย่างใดอย่างหนึ่ง ที่ออกโดยหน่วยงานรัฐต่างประเทศ - ได้รับการยกเว้นการยื่นเอกสารทั้ง 2 รายการ หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับยาต่างประเทศ** 1. หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) 2. ตัวอย่างฉลาก และเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศแหล่งกำเนิด หรือประเทศที่ออก CPP 3. การประเมินการปฏิบัติตามมาตรฐาน GMP กรณีผู้ผลิตต่างประเทศ ซึ่งได้มีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามเป็นครั้งแรก		
วัตถุดิบเกี่ยวกับยา	**เอกสารทั่วไป** 1. คำขอขึ้นทะเบียนผลิตภัณฑ์ 2. หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ 3. ตัวอย่างฉลากที่จะใช้วางจำหน่ายในประเทศเวียดนาม - หากฉลากเป็นภาษาอื่นที่ไม่ใช่ภาษาอังกฤษ ต้องมีการแปลเป็นภาษาเวียดนามประกอบด้วย และฉลากต้องเป็นไปตามข้อกำหนดในหลักเกณฑ์ด้านฉลากที่ออกโดยกระทรวงสาธารณสุข *(รายละเอียดเพิ่มเติมตามหมายเหตุ)* 4. หนังสือรับรองผู้ผลิตสารออกฤทธิ์ สารเพิ่มปริมาณ แคปซูล และส่วนผสมสมุนไพร	**<u>การต่ออายุทะเบียนผลิตภัณฑ์</u>** **เอกสารทั่วไป** 1. คำขอต่ออายุทะเบียนผลิตภัณฑ์ 2. หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ 3. หนังสือรับรองผู้ผลิตสารออกฤทธิ์ สารเพิ่มปริมาณ แคปซูล และส่วนผสมสมุนไพร	รายละเอียดเกี่ยวกับฉลากและเอกสารกำกับยาแบบ Package insert ตามข้างต้น

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	5. หนังสือรับรองผลวิเคราะห์ Good Laboratory Practice (GLP) หรือ Good Manufacturing Practice (GMP) ของผู้ผลิต - ได้รับการยกเว้น หากผู้ผลิตดังกล่าวอยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ 6. เอกสารรับรองแหล่งที่มาของวัตถุดิบ 7. เอกสารแสดงคุณภาพวัตถุดิบเกี่ยวกับยา **เอกสารเพิ่มเติมสำหรับผู้ประกอบการเวียดนาม** 1. ใบอนุญาตประกอบธุรกิจยา - ได้รับการยกเว้น หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ** 1. ใบอนุญาตจัดตั้งสำนักงานตัวแทนในประเทศเวียดนาม 2. ใบอนุญาตการผลิต การขายส่ง การนำเข้า การส่งออก ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาอย่างใดอย่างหนึ่ง ที่ออกโดยหน่วยงานรัฐต่างประเทศ - ได้รับการยกเว้นการยื่นเอกสารทั้ง 2 รายการ หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับวัตถุดิบเกี่ยวกับยาต่างประเทศ**	4. รายงานการจำหน่ายผลิตภัณฑ์ (marketing report) 5. เอกสารรับรองแหล่งที่มาของวัตถุดิบ 6. สำเนาหนังสือรับรองการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม **เอกสารเพิ่มเติมสำหรับผู้ประกอบการเวียดนาม** 1. ใบอนุญาตประกอบธุรกิจยา - ได้รับการยกเว้น หากผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ** 1. ใบอนุญาตจัดตั้งสำนักงานตัวแทนในประเทศเวียดนาม 2. ใบอนุญาตการผลิต การขายส่ง การนำเข้า การส่งออก ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาอย่างใดอย่างหนึ่ง ที่ออกโดยหน่วยงานรัฐต่างประเทศ	

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
	1. ตัวอย่างฉลาก และเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศแหล่งกำเนิด หรือประเทศที่ออก CPP 2. การประเมินการปฏิบัติตามมาตรฐาน GMP กรณีผู้ผลิตต่างประเทศ ซึ่งได้มีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามเป็นครั้งแรก 3. หนังสือรับรองว่าวัตถุดิบเกี่ยวกับยาได้รับอนุญาตให้ผลิตหรือจำหน่ายในประเทศแหล่งกำเนิด (Country of origin)	- ได้รับการยกเว้นการยื่นเอกสารทั้ง 2 รายการ หาก ผู้ยื่นคำขออยู่ในรายชื่อที่กระทรวงสาธารณสุขของประเทศเวียดนามประกาศบนเว็บไซต์ **เอกสารเพิ่มเติมสำหรับวัตถุดิบเกี่ยวกับยาต่างประเทศ** 1. ตัวอย่างฉลาก และเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศแหล่งกำเนิด หรือประเทศที่ออก CPP 2. การประเมินการปฏิบัติตามมาตรฐาน GMP กรณีผู้ผลิตต่างประเทศ ซึ่งได้มีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามเป็นครั้งแรก 3. หนังสือรับรองว่าวัตถุดิบเกี่ยวกับยาได้รับอนุญาตให้ผลิตหรือจำหน่ายในประเทศแหล่งกำหนด (country of origin) **<u>การแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์</u>** 1. คำขอแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์	

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	**การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์**	
		2. ข้อมูลที่มีการเปลี่ยนแปลงไป เช่น มีการเปลี่ยนแปลงสถานที่ผลิต (manufacturing location)	
ยาแผนโบราณ	**เอกสารทั่วไป** 1. คำขอขึ้นทะเบียนผลิตภัณฑ์ 2. หนังสือรับรองของสำนักงานตัวแทน (กรณีผู้ประกอบการต่างชาติ) หรือใบอนุญาตประกอบธุรกิจยา (กรณีผู้ประกอบการเวียดนาม) 3. หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) (กรณียานำเข้า) 4. ตัวอย่างฉลาก และเอกสารอื่นที่แสดงข้อมูลเกี่ยวกับผลิตภัณฑ์ยา 5. เอกสารรับรองความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์ยา 6. ตัวอย่างฉลากผลิตภัณฑ์ยาที่จำหน่ายในประเทศแหล่งกำเนิดหรือประเทศอ้างอิง (กรณียานำเข้า)	**<u>การต่ออายุทะเบียนผลิตภัณฑ์</u>** 1. คำขอต่ออายุทะเบียนผลิตภัณฑ์ 2. หนังสือรับรองของสำนักงานตัวแทน (กรณีผู้ประกอบการต่างชาติ) หรือใบอนุญาตประกอบธุรกิจยา (กรณีผู้ประกอบการเวียดนาม) 3. หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) (กรณียานำเข้า) 4. รายงานการจำหน่ายผลิตภัณฑ์ (marketing report) 5. รายงานความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์ 6. สำเนาหนังสือรับรองการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม **<u>การแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์</u>** 1. คำขอแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์	รายละเอียดเกี่ยวกับฉลากและเอกสารกำกับยาแบบ Package insert ตามข้างต้น

ประเภท	รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอ		หมายเหตุ
	การขึ้นทะเบียนผลิตภัณฑ์	การต่ออายุ/แก้ไขทะเบียนผลิตภัณฑ์	
		2. ข้อมูลที่มีการเปลี่ยนแปลงไป เช่น มีการเปลี่ยนแปลงสถานที่ผลิต (manufacturing location)	

2.5.3 การศึกษาทางคลินิกหรือการศึกษาชีวมูล

(1) การศึกษาทางคลินิก (clinical trial)

การศึกษาทางคลินิกเป็นการศึกษาความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์ยาก่อนที่จะนำผลิตภัณฑ์ยาดังกล่าวออกมาใช้รักษาผู้ป่วยหรือจำหน่ายในท้องตลาด โดยการศึกษาทางคลินิกจะแบ่งออกเป็น 4 ระยะ ได้แก่

ระยะที่ 1 ศึกษาความปลอดภัย: เป็นการศึกษาความปลอดภัยของยาเมื่อใช้กับมนุษย์หลังจากที่ได้ทดสอบยาดังกล่าวในห้องปฏิบัติการหรือค้นคว้าวิจัยในสัตว์ทดลองแล้ว

ระยะที่ 2 ศึกษาประสิทธิภาพและภาวะแทรกซ้อน: ศึกษาประสิทธิภาพและภาวะแทรกซ้อนของยา เพื่อหาขนาดยาที่เหมาะสมต่อการรักษาโรคนั้น ๆ

ระยะที่ 3 ศึกษาประสิทธิภาพและอาการไม่พึงประสงค์: การทดสอบในอาสาสมัครที่จำนวนมากขึ้น เพื่อให้ทราบถึงประโยชน์ในการรักษาที่แท้จริงของยา ความคงสภาพของยา รวมไปถึงอาการไม่พึงประสงค์ที่อาจเกิดขึ้นได้ในระยะยาว

ระยะที่ 4 ติดตามหลังจากวางจำหน่าย: ศึกษาผลการรักษาและอาการไม่พึงประสงค์อย่างต่อเนื่อง โดยจะมีการติดตามผลที่ได้จากการใช้ยาในท้องตลาดว่ามีอันตรายจากการใช้ยาในระยะยาวหรือไม่

ทั้งนี้ การศึกษาทางคลินิกระยะที่ 1-3 จะเป็นการศึกษาผลิตภัณฑ์ยาก่อนการขึ้นทะเบียนผลิตภัณฑ์ และการศึกษาทางคลินิกระยะที่ 4 จะเป็นการศึกษาผลิตภัณฑ์ยาภายหลังการขึ้นทะเบียนผลิตภัณฑ์

ผลิตภัณฑ์ยาที่ต้องผ่านการศึกษาทางคลินิกก่อนการขึ้นทะเบียนผลิตภัณฑ์ ได้แก่ 1) ยาใหม่ 2) ยาที่มีส่วนผสมของสมุนไพรที่มีส่วนผสมแบบใหม่ และ 3) วัคซีนที่ขึ้นทะเบียนในประเทศเวียดนามเป็นครั้งแรก สำหรับกระบวนการในการศึกษาทางคลินิกนั้น ผู้ประกอบการต้องยื่นคำขอสำหรับการศึกษาทางคลินิก พร้อมเอกสารประกอบดังต่อไปนี้ 1) เอกสารแสดงข้อมูลของผลิตภัณฑ์ที่จะเข้ารับการทดสอบ 2) เอกสารทางกฎหมายที่เกี่ยวกับผลิตภัณฑ์ที่จะเข้ารับการทดสอบ 3) เค้าโครงการศึกษาและคำอธิบาย 4) ประวัติของผู้ทำการศึกษาหรือนักวิจัย 5) เอกสารแสดงความยินยอมของอาสาสมัครกลุ่มตัวอย่างในการเข้าร่วมทดสอบ 6) เอกสารเกี่ยวกับมาตรฐานด้านจริยธรรมและวิทยาศาสตร์ในการทดสอบ 7) ฉลากของผลิตภัณฑ์ ทั้งนี้ การศึกษาทางคลินิกจะเริ่มได้ก็ต่อเมื่อเอกสารดังกล่าวผ่านการพิจารณาของ National Council of Ethics in Biomedical Research และได้รับการอนุมัติเป็นลายลักษณ์อักษรจากกระทรวงสาธารณสุขแล้ว

อย่างไรก็ดี ผลิตภัณฑ์ยาบางประเภทได้รับการยกเว้นไม่ต้องการผ่านการศึกษาทางคลินิกบางระยะหรือทุกระยะ สรุปได้ดังนี้

(1.1) ผลิตภัณฑ์ยาที่ได้รับการยกเว้นไม่ต้องผ่านการศึกษาทางคลินิกบางระยะ

ผลิตภัณฑ์ยาบางประเภทได้รับการยกเว้นไม่ต้องผ่านการศึกษาทางคลินิกบางระยะ ได้แก่ 1) ยาใหม่ที่ได้ขึ้นทะเบียนผลิตภัณฑ์ในประเทศใดประเทศหนึ่งในโลก แต่มีข้อมูลทางคลินิกเกี่ยวกับความปลอดภัยและความมีประสิทธิภาพของยาดังกล่าวไม่เพียงพอ 2) วัคซีนที่ได้ขึ้นทะเบียนผลิตภัณฑ์ในประเทศใดประเทศหนึ่งในโลก แต่มีข้อมูลทางคลินิกเกี่ยวกับความปลอดภัยและความมีประสิทธิภาพของวัคซีนดังกล่าวไม่เพียงพอ 3) ยาแผนปัจจุบัน วัคซีน ยาชีวภาพ หรือยาสมุนไพร ในกรณีที่มีความจำเป็นอย่างเร่งด่วนที่ต้องใช้ยาดังกล่าวเพื่อวัตถุประสงค์ทางด้านความปลอดภัยของประเทศ ควบคุมหรือป้องกันโรคระบาด/ภัยธรรมชาติ และไม่สามารถหายาอื่นทดแทนได้ 4) ยาแผนปัจจุบัน วัคซีน ยาชีวภาพ หรือยาสมุนไพร ที่ได้รับการขึ้นทะเบียนในกลุ่มประเทศที่กำหนดโดยกระทรวงสาธารณสุข (เช่น ประเทศสหรัฐอเมริกา ประเทศญี่ปุ่น ประเทศฝรั่งเศส ประเทศเยอรมนี ประเทศสวีเดน ประเทศอังกฤษ ประเทศสวิตเซอร์แลนด์) อย่างน้อย 2 ประเทศ หรือได้รับการขึ้นทะเบียนโดย US FDA หรือ EMA 5) ยาแผนปัจจุบัน วัคซีน ยาชีวภาพ ดังกล่าวเป็นยาที่ใช้สำหรับรักษาโรคร้ายแรง 6) เป็นวัคซีน/ยาชีวภาพที่ผลิตในประเทศเวียดนาม ผ่านการถ่ายทอดเทคโนโลยีจากประเทศอื่นซึ่งมีกรรมวิธีการผลิตบางส่วนหรือทั้งหมดมีผลการศึกษาทางคลินิก 7) ยาสมุนไพรที่ไม่ได้มีวัตถุประสงค์เพื่อรักษาโรคที่กำหนดโดยกระทรวงสาธารณสุข 8) วัตถุดิบสมุนไพรที่เคยใช้ในประเทศเวียดนามแต่มีสูตรผสมใหม่ (new combination of herbal ingredients) หรือ 9) ยาที่มีส่วนผสมของสมุนไพร ที่ไม่เข้าข้อยกเว้นตามข้อ (1.2) ด้านล่าง

(1.2) ผลิตภัณฑ์ยาที่ได้รับการยกเว้นไม่ต้องผ่านการศึกษาทางคลินิก

ผลิตภัณฑ์ยาดังต่อไปนี้ได้รับการยกเว้นไม่ต้องผ่านการศึกษาทางคลินิก ได้แก่ 1) ยาสามัญ (generic drug) 2) ยาใหม่ที่ได้ขึ้นทะเบียนผลิตภัณฑ์ในประเทศใดประเทศหนึ่งในโลก และมีข้อมูลทางคลินิกเกี่ยวกับความปลอดภัยและความมีประสิทธิภาพของยาดังกล่าวเพียงพอ (ยกเว้นวัคซีน) 2) ยาที่มีส่วนผสมของสมุนไพรที่ได้ขึ้นทะเบียนผลิตภัณฑ์ก่อนวันที่ 1 มกราคม 2560 ซึ่งเป็นวันที่กฎหมายว่าด้วยเภสัชกรรมฉบับใหม่มีผลบังคับใช้ 3) ยาที่มีส่วนผสมของสมุนไพร ที่มีส่วนประกอบ ปริมาณสมุนไพร วิธีการใช้ เช่นเดียวกับยาสมุนไพรที่ได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนามแล้ว (แม้ทะเบียนจะหมดอายุแล้ว) หรือ 4) ยาที่มีส่วนผสมของสมุนไพร ที่มีส่วนประกอบ ปริมาณสมุนไพร วิธีการใช้ เช่นเดียวกับยาสมุนไพรใหม่ ที่ได้รับการขึ้นทะเบียนในประเทศเวียดนาม โดยมีอายุทะเบียน 5 ปี เนื่องจากมีผลการศึกษาทางคลินิกเพียงพอ

(2) การศึกษาชีวสมมูล (bioequivalence study)

การศึกษาชีวสมมูลเป็นวิธีการหนึ่งในการศึกษาประสิทธิของยาสามัญ (generic drug) เทียบกับยาต้นแบบ ซึ่งการศึกษาจะแบ่งออกเป็น 2 ระยะดังนี้

ระยะการศึกษาทางคลินิก (clinical research stage): การทดสอบชีวประสิทธิผล (bioavailability) ของยาสามัญกับยาต้นแบบ ที่ได้ผ่านการประเมินความปลอดภัยและความมีประสิทธิภาพแล้ว

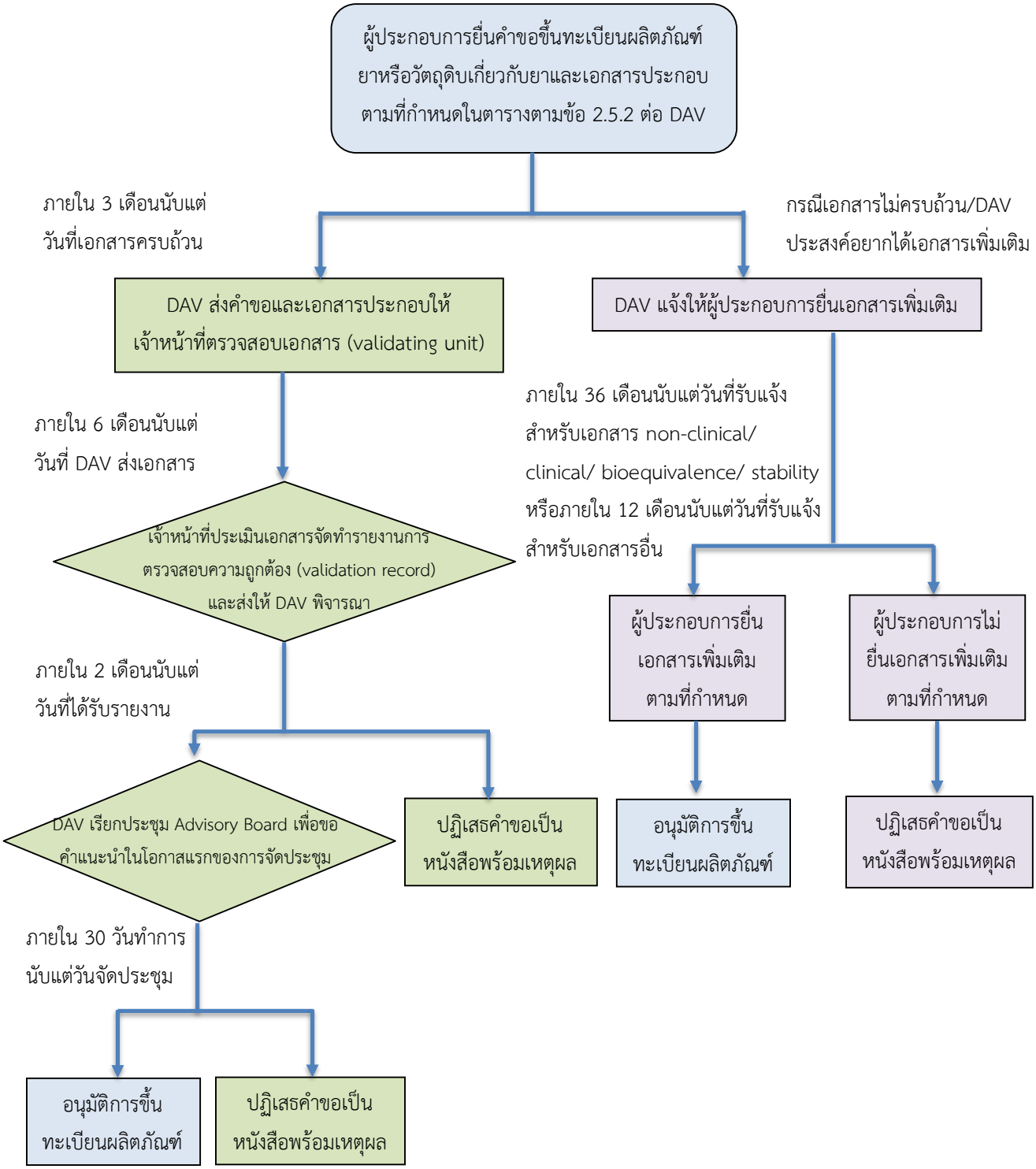
ระยะการศึกษาใน biofluid ของมนุษย์ (human biofluid analysis stage): การวิเคราะห์ผลของยาสามัญกับยาต้นแบบใน bio-specimen ของอาสาสมัคร เพื่อเปรียบเทียบชีวประสิทธิผลและเพื่อพิสูจน์ชีวสมมูลของยาทั้งสองชนิด

สำหรับกระบวนการในการศึกษาชีวสมมูลนั้น ผู้ประกอบการต้องยื่นคำขอการศึกษาชีวสมมูล พร้อมเอกสารประกอบดังต่อไปนี้ 1) เอกสารแสดงข้อมูลของผลิตภัณฑ์ที่จะเข้ารับการทดสอบ 2) เค้าโครงการศึกษาและคำอธิบาย 3) ประวัติของผู้ทำการศึกษาหรือนักวิจัย 4) เอกสารแสดงความยินยอมของอาสาสมัครกลุ่มตัวอย่างในการเข้าร่วมทดสอบ และ 5) ฉลากของผลิตภัณฑ์ ทั้งนี้ การศึกษาทางชีวสมมูลจะเริ่มได้ก็ต่อเมื่อเอกสารดังกล่าวผ่านการพิจารณาของ National Council of Ethics in Biomedical Research และได้รับการอนุมัติเป็นลายลักษณ์อักษรจากผู้ที่ประกอบอาชีพด้านการศึกษาชีวสมมูล

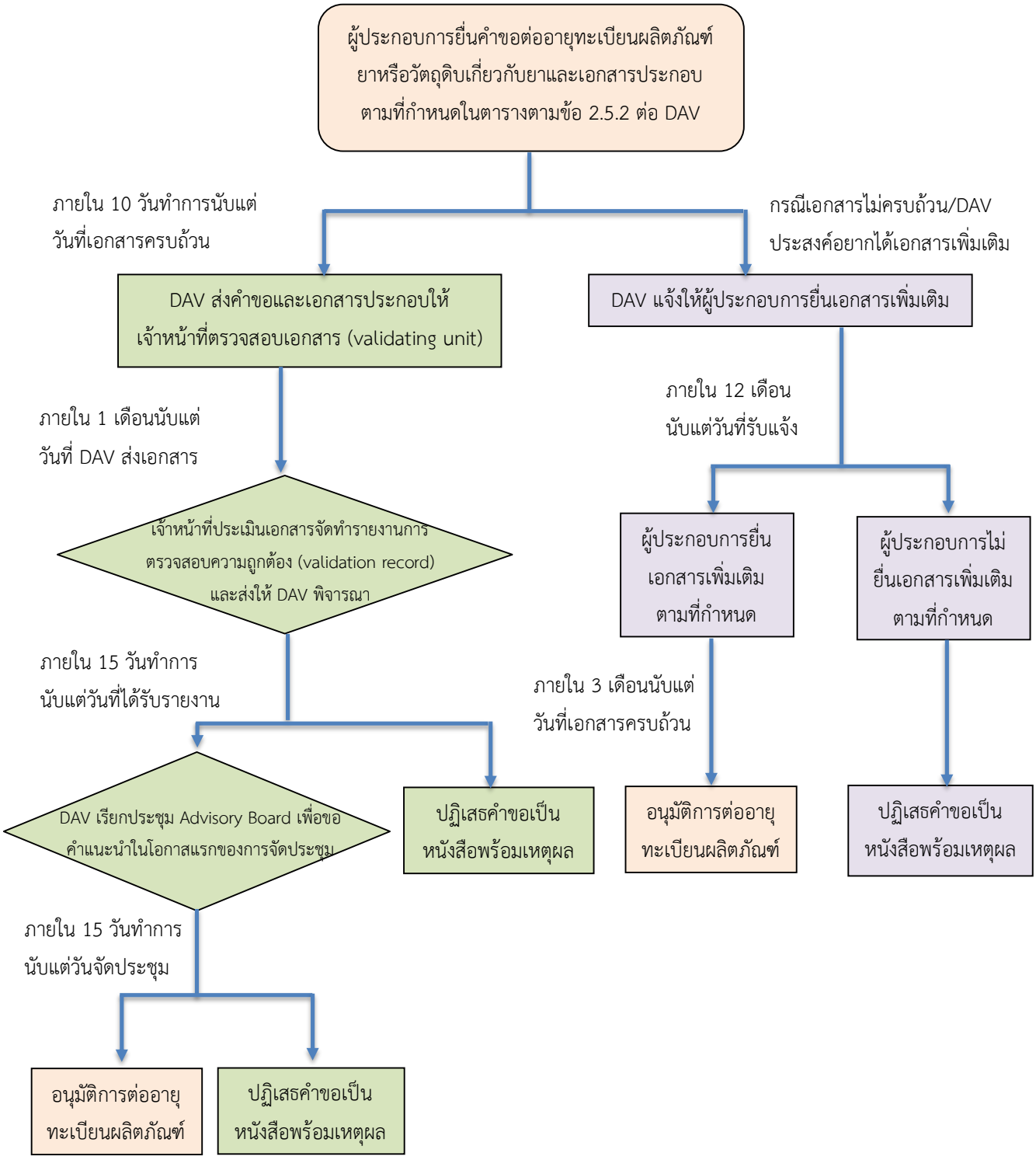
2.6 ขั้นตอนการปฏิบัติงานของกระทรวงสาธารณสุขที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา

Drug Administration of Vietnam (DAV) สังกัดกระทรวงสาธารณสุข เป็นหน่วยงานที่มีหน้าที่รับผิดชอบเกี่ยวกับการขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา โดยขั้นตอนและระยะเวลาการปฏิบัติงานของ DAV จะขึ้นอยู่กับประเภทคำขอ (ขึ้นทะเบียน ต่ออายุทะเบียน หรือแก้ไขเนื้อหาในทะเบียน) สรุปตามแผนภาพได้ดังนี้

2.6.1 ขั้นตอนการขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา

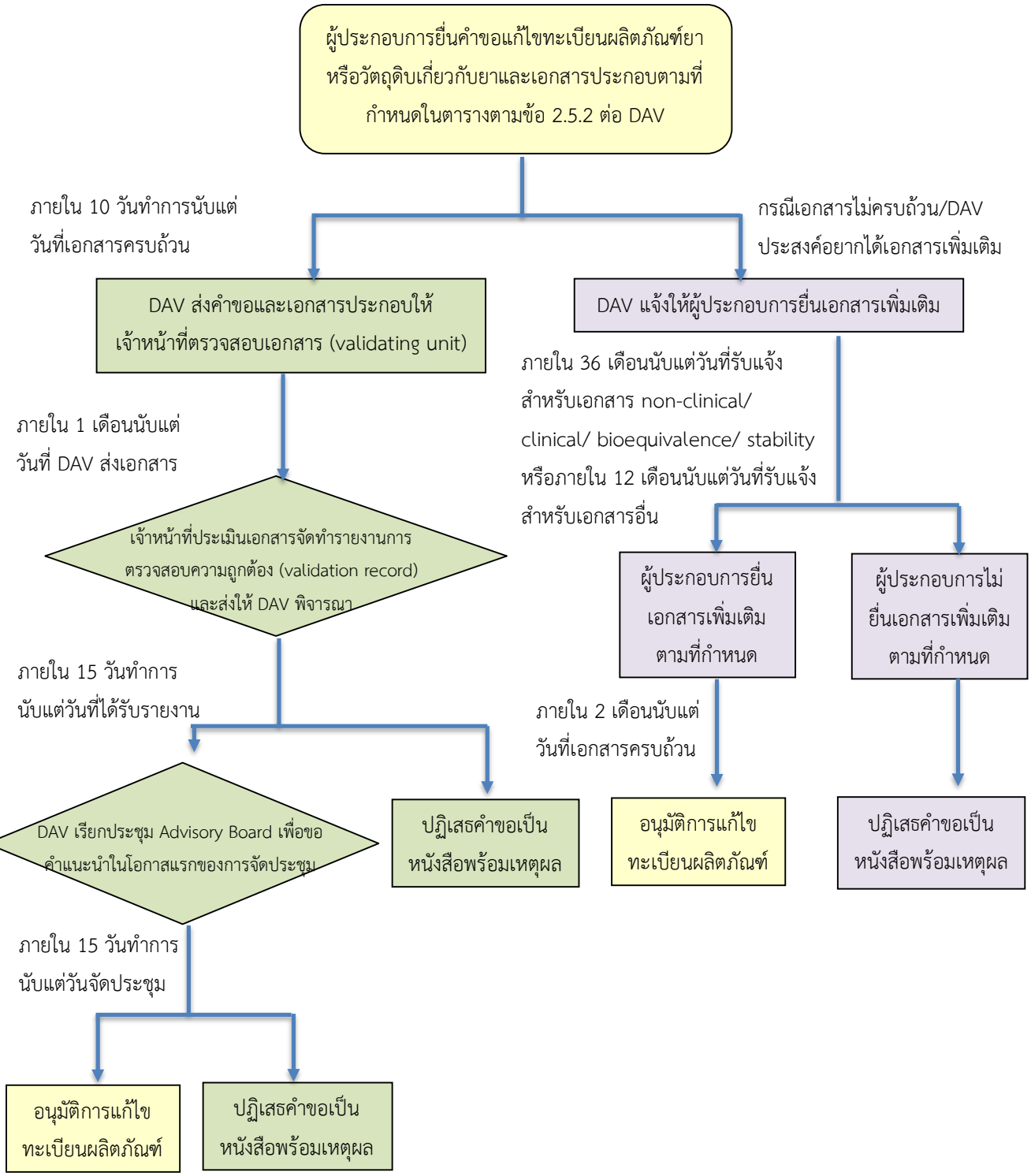


2.6.2 ขั้นตอนการต่ออายุทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา

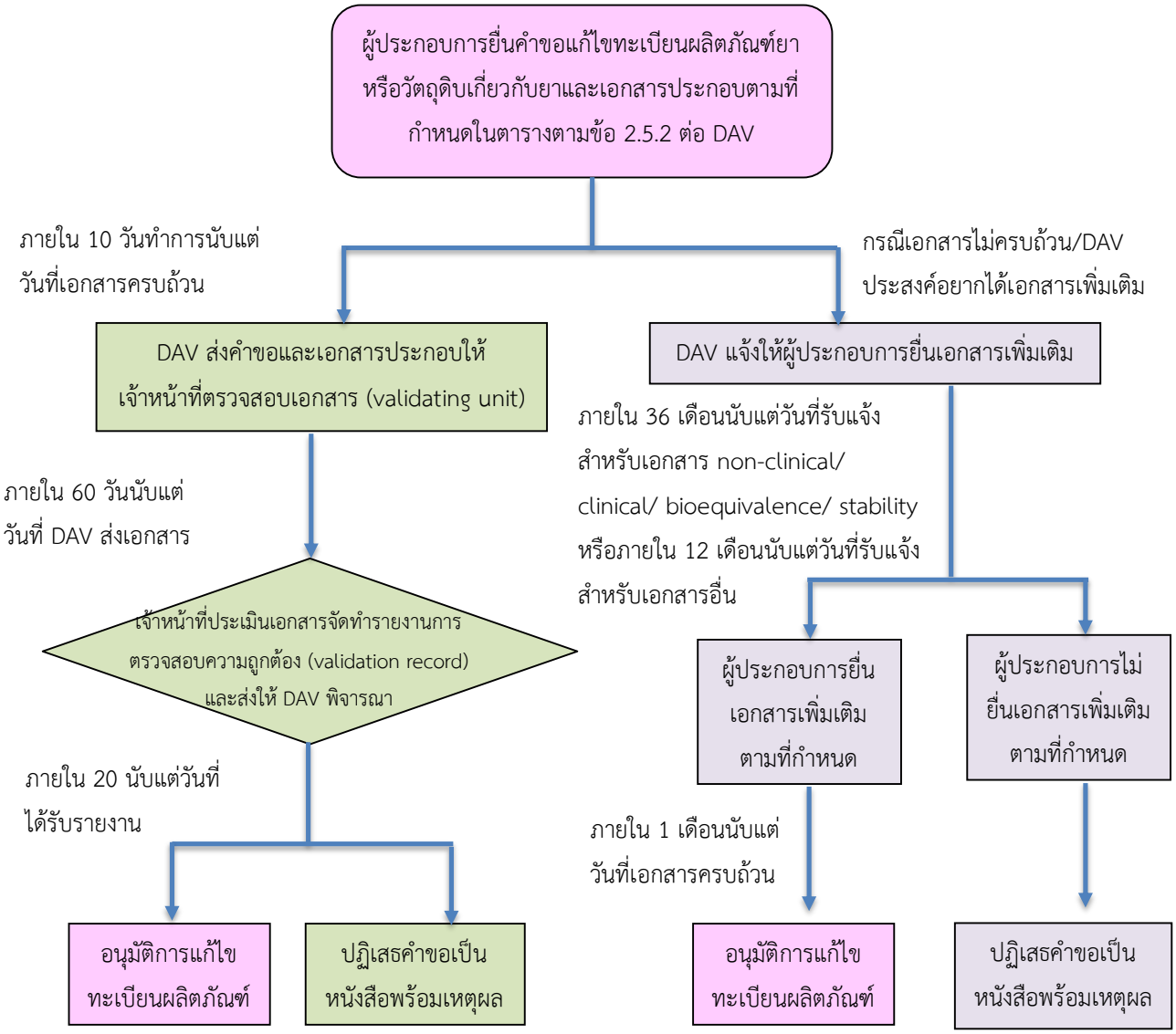


2.6.3 ขั้นตอนการแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา

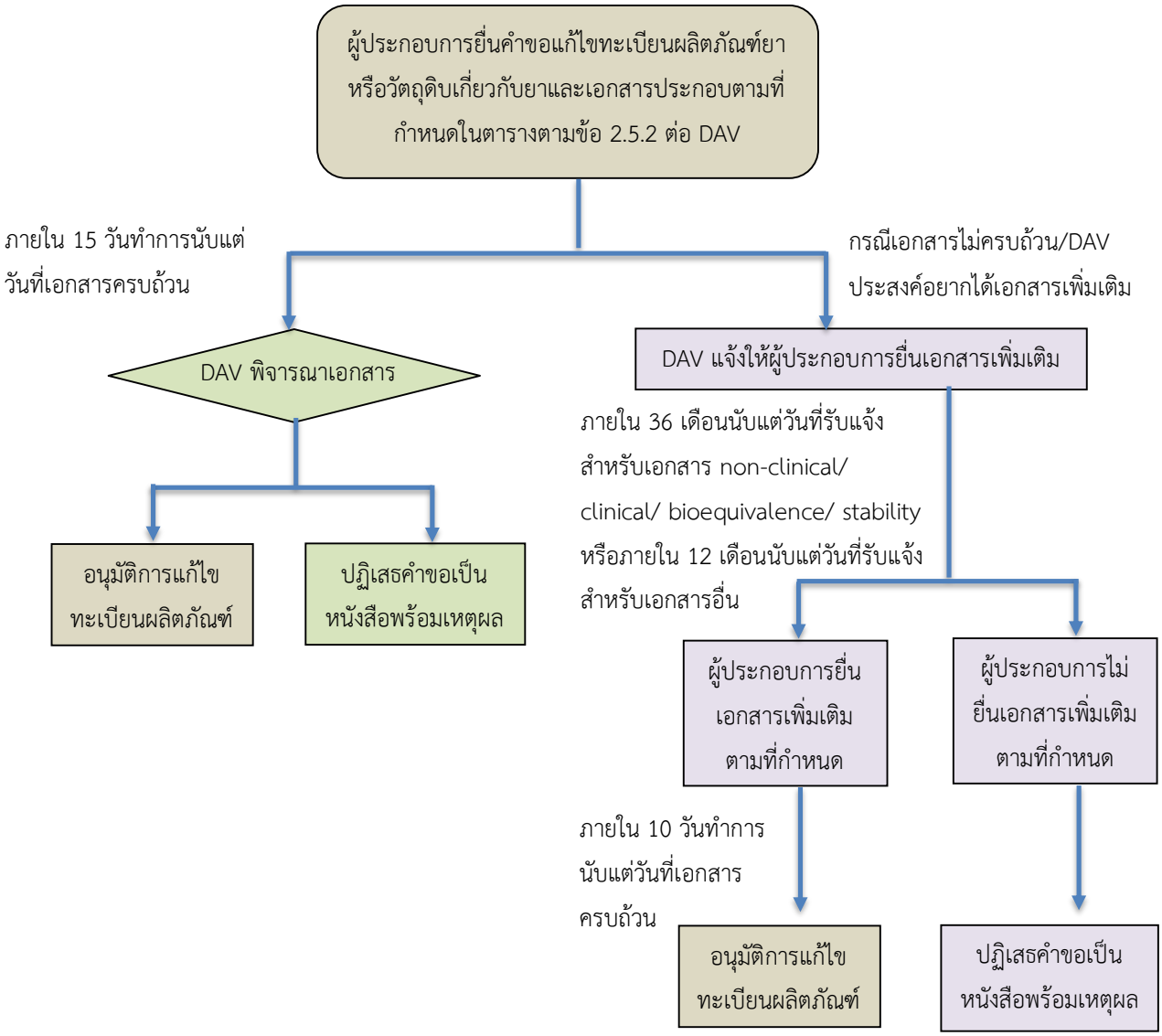
(1) กรณีแก้ไขเนื้อหาที่เป็นสาระสำคัญ (major revision) เช่น ข้อบ่งใช้ ขนาด (dose) กลุ่มผู้ใช้ (intended user)



(2) กรณีแก้ไขในส่วนที่ไม่ใช่สาระสำคัญตาม (1) และไม่ใช่การแก้ไขเล็กน้อยตาม (3)



(3) กรณีแก้ไขเล็กน้อย (minor revision)



2.7 การขอใบอนุญาตนำเข้าผลิตภัณฑ์ยาที่ได้รับยกเว้นไม่ต้องขึ้นทะเบียนผลิตภัณฑ์

แม้ยาบางประเภทจะได้รับการยกเว้นไม่ต้องขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม แต่ยาดังกล่าวต้องได้รับใบอนุญาตนำเข้าก่อนนำเข้ามาในประเทศเวียดนาม ตามหลักเกณฑ์และวิธีการที่กำหนดใน Decree No. 54/2017/ND-CP on Guidelines for Implementation of the Law on Pharmacy ซึ่งถูกแก้ไขเพิ่มเติมโดย Decree No. 155/2018/ND-CP on Amendments to Some Articles Related to Business Conditions under State Management of the Ministry of Health สรุปรายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอใบอนุญาตนำเข้าตามประเภทยา และขั้นตอนการปฏิบัติงานของกระทรวงสาธารณสุขได้ดังนี้

2.7.1 รายการเอกสารที่ใช้ประกอบการยื่นคำขอใบอนุญาตนำเข้า

(1) ยาที่มีสารออกฤทธิ์ (active ingredients) เป็นส่วนประกอบ ซึ่งไม่ได้มีการขึ้นทะเบียนผลิตภัณฑ์ยา และผลิตภัณฑ์ยาที่มีสมุนไพรเป็นส่วนประกอบซึ่งใช้ในประเทศเวียดนามเป็นครั้งแรก โดยยาดังกล่าวได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศผู้ผลิต หรือประเทศที่เป็นสมาชิกของ ICH หรือประเทศออสเตรเลีย และยาดังกล่าวมีความจำเป็นที่ต้องใช้เพื่อควบคุมพิษ (poison control) โดยเร่งด่วน หรือใช้สำหรับการวินิจฉัยหรือรักษาโรคติดต่อ HIV/AIDs ไวรัสตับอักเสบ วัณโรค มาลาเรีย และโรคอื่นที่ประกาศโดยกระทรวงสาธารณสุข

(1.1) คำสั่งซื้อ (purchase order)

(1.2) หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP)

(1.3) เอกสารแสดงการปฏิบัติตามมาตรฐานด้านคุณภาพ และวิธีการทดสอบโดยผู้ผลิต

(1.4) ตัวอย่างฉลากและเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศผู้ผลิตหรือประเทศผู้ส่งออก เว้นแต่มีตัวอย่างแสดงใน CPP แล้ว

(1.5) ตัวอย่างฉลากที่ประสงค์จะใช้กับผลิตภัณฑ์ที่วางจำหน่ายในประเทศเวียดนามและเอกสารกำกับยาแบบ Package insert ฉบับภาษาเวียดนาม

(1.6) ข้อมูลการศึกษาทางคลินิกเกี่ยวกับความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์

(1.7) รายงานการจำหน่ายผลิตภัณฑ์ ในกรณีที่ผลิตภัณฑ์ดังกล่าวมีส่วนผสมของสารเสพติด

(1.8) หนังสือรับรองการปฏิบัติตามมาตรฐาน GMP ของผู้ผลิตทุกกรรมวิธี ในกรณีที่มีผู้ผลิตหลายราย

(1.9) ใบอนุญาตให้ดำเนินการเกี่ยวกับรังสี (radiological work) ในกรณีที่ผลิตภัณฑ์ดังกล่าวเป็นสารเภสัชรังสี (radiopharmaceutical)

(2) ยาที่มีสารออกฤทธิ์เป็นส่วนประกอบซึ่งได้มีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามแล้ว และผลิตภัณฑ์ยาที่มีสมุนไพรเป็นส่วนประกอบซึ่งเคยใช้ในประเทศเวียดนามแล้ว โดยยาดังกล่าวอยู่ในรายชื่อยาที่มีปริมาณไม่เพียงพอหรือขาดแคลนในประเทศเวียดนามตามที่กระทรวงสาธารณสุขกำหนด และเป็นยาที่ได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศผู้ผลิต หรือประเทศสมาชิก ICH หรือประเทศออสเตรเลีย

(2.1) คำสั่งซื้อ (purchase order)

(2.2) หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP)

(2.3) เอกสารแสดงการปฏิบัติตามมาตรฐานด้านคุณภาพที่กระทรวงสาธารณสุขกำหนด

(2.4) ตัวอย่างฉลากและเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศผู้ผลิตหรือประเทศผู้ส่งออก เว้นแต่มีตัวอย่างแสดงใน CPP แล้ว

(2.5) ตัวอย่างฉลากที่ประสงค์จะใช้กับผลิตภัณฑ์ที่วางจำหน่ายในประเทศเวียดนามและเอกสารกำกับยาแบบ Package insert ฉบับภาษาเวียดนาม

(2.6) ข้อมูลการศึกษาทางคลินิกเกี่ยวกับความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์

(2.7) กรณียาแผนโบราณที่มีสมุนไพรซึ่งเคยใช้ในประเทศเวียดนามเป็นส่วนประกอบจะต้องมีข้อมูลการศึกษาทางคลินิกเกี่ยวกับความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์ประกอบด้วย

(2.8) รายงานการจำหน่ายผลิตภัณฑ์ ในกรณีที่ผลิตภัณฑ์ดังกล่าวมีส่วนผสมของสารเสพติด

(2.9) หนังสือรับรองการปฏิบัติตามมาตรฐาน GMP ของผู้ผลิตทุกกรรมวิธี ในกรณีที่มีผู้ผลิตหลายราย

(3) ผลิตภัณฑ์ยาที่ต้องนำเข้ากรณีเร่งด่วนเพื่อประโยชน์ทางด้านความปลอดภัยของประเทศหรือควบคุมโรคระบาดหรือบรรเทาภัยพิบัติ โดยยาดังกล่าวได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศใดประเทศหนึ่ง และการนำเข้าเป็นไปตามที่กระทรวงกลาโหม (Ministry of National Defense) หรือกระทรวงความมั่นคงสาธารณะ (Ministry of Public Security) ร้องขอ เนื่องจากมีความจำเป็น หรือกระทรวงสาธารณสุขได้อนุมัติว่ายาดังกล่าวเหมาะสมสำหรับการควบคุมโรคระบาดหรือบรรเทาภัยพิบัติ

(3.1) คำสั่งซื้อ (purchase order)

(3.2) หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP)

(3.3) หนังสือจากกระทรวงตามข้างต้น

(4) ผลิตภัณฑ์ยาเพื่อรักษาโรคเป็นการเฉพาะ (special treatment) โดยยาดังกล่าวใช้เพื่อวัตถุประสงค์ในการควบคุมพิษ หรือยากลุ่ม Anti-rejection ซึ่งใช้สำหรับผู้ป่วยเฉพาะกลุ่ม

(4.1) คำสั่งซื้อ (purchase order)

(4.2) ข้อมูลการศึกษาทางคลินิกเกี่ยวกับความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์

(4.3) หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP)

(4.4) เอกสารแสดงการปฏิบัติตามมาตรฐานด้านคุณภาพ และวิธีการทดสอบโดยผู้ผลิต

(4.5) ตัวอย่างฉลากและเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศที่ออก CPP

(4.6) ตัวอย่างฉลากที่ประสงค์จะใช้กับผลิตภัณฑ์ที่วางจำหน่ายในประเทศเวียดนามและเอกสารกำกับยาแบบ Package insert ฉบับภาษาเวียดนาม

(4.7) รายงานการจำหน่ายผลิตภัณฑ์ ในกรณีที่ผลิตภัณฑ์ดังกล่าวมีส่วนผสมของสารเสพติด

(4.8) หนังสือรับรองการปฏิบัติตามมาตรฐาน GMP ของผู้ผลิตทุกกรรมวิธี ในกรณีที่มีผู้ผลิตหลายราย

(4.9) ใบอนุญาตให้ดำเนินการเกี่ยวกับรังสี (radiological work) ในกรณีที่ผลิตภัณฑ์ดังกล่าวเป็นสารเภสัชรังสี (radiopharmaceutical)

(5) ยาหายาก (rare drug) โดยยาดังกล่าวอยู่ในรายชื่อยาหายากที่กำหนดโดยกระทรวงสาธารณสุข และได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศใดประเทศหนึ่ง

(5.1) คำสั่งซื้อ (purchase order)

(5.2) หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP)

(5.3) เอกสารแสดงการปฏิบัติตามมาตรฐานด้านคุณภาพ และวิธีการทดสอบโดยผู้ผลิต

(5.4) ตัวอย่างฉลากและเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศผู้ผลิตหรือประเทศผู้ส่งออก เว้นแต่มีตัวอย่างแสดงใน CPP แล้ว

(5.5) ตัวอย่างฉลากที่ประสงค์จะใช้กับผลิตภัณฑ์ที่วางจำหน่ายในประเทศเวียดนามและเอกสารกำกับยาแบบ Package insert ฉบับภาษาเวียดนาม

(5.6) รายงานการจำหน่ายผลิตภัณฑ์ ในกรณีที่ผลิตภัณฑ์ดังกล่าวมีส่วนผสมของสารเสพติด

(5.7) หนังสือรับรองการปฏิบัติตามมาตรฐาน GMP ของผู้ผลิตทุกกรรมวิธี ในกรณีที่มีผู้ผลิตหลายราย

(6) ยาที่มีชื่อทางการค้า สารออกฤทธิ์ ปริมาณ เช่นเดียวกับยามียี่ห้อที่เคยได้ขึ้นทะเบียนในประเทศเวียดนามแล้ว โดยยาดังกล่าวมีชื่อทางการค้า สารออกฤทธิ์ ปริมาณ และผู้ผลิตเดียวกับยามียี่ห้อที่ได้ขึ้นทะเบียนในประเทศเวียดนามแล้ว แต่ยาดังกล่าวมีราคาถูกกว่ายาที่จำหน่ายในประเทศเวียดนาม และยาดังกล่าวได้รับการขึ้นทะเบียนผลิตภัณฑ์และส่งออกมาจำหน่ายยังประเทศเวียดนามโดยประเทศผู้ผลิตหรือประเทศที่เป็นสมาชิกของ ICH หรือประเทศออสเตรเลีย และไม่ใช่สารเภสัชรังสี วัคซีน หรือยาชีวภาพ

(6.1) คำสั่งซื้อ (purchase order)

(6.2) เอกสารรับรองว่ายาดังกล่าวได้รับการขึ้นทะเบียนในประเทศผู้ผลิตหรือประเทศที่เป็นสมาชิกของ ICH หรือประเทศออสเตรเลีย

(6.3) ตัวอย่างฉลากและเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศผู้ผลิต

(6.4) ตัวอย่างฉลากบรรจุภัณฑ์ทุติยภูมิ และเอกสารกำกับยาแบบ Package insert ฉบับภาษาเวียดนาม

(7) ยาที่เกี่ยวข้องกับโครงการสุขภาพของภาครัฐ โดยยาดังกล่าวใช้เพื่อวัตถุประสงค์ตามโครงการสุขภาพของรัฐ และยาดังกล่าวได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศผู้ผลิต หรือประเทศสมาชิกของ ICH หรือประเทศออสเตรเลียแล้ว

(7.1) คำสั่งซื้อ (purchase order)

(7.2) หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP)

(7.3) หนังสือแสดงคุณภาพของผลิตภัณฑ์ตาม ACTD และผลการศึกษาชีวสมมูล ในกรณีที่กระทรวงสาธารณสุขร้องขอ

(7.4) ข้อมูลการศึกษาทางคลินิกเกี่ยวกับความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์ ในกรณีที่กระทรวงสาธารณสุขร้องขอ

(7.5) ตัวอย่างฉลากและเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศผู้ผลิตหรือประเทศผู้ส่งออก เว้นแต่มีตัวอย่างแสดงใน CPP แล้ว

(7.6) ตัวอย่างฉลากที่ประสงค์จะใช้กับผลิตภัณฑ์ที่วางจำหน่ายในประเทศเวียดนามและเอกสารกำกับยาแบบ Package insert ฉบับภาษาเวียดนาม

(7.7) หนังสือรับรองจากหน่วยงานรัฐที่เกี่ยวข้องว่ายาดังกล่าวใช้ในโครงการสุขภาพของรัฐ

(7.8) หนังสือรับรองการปฏิบัติตามมาตรฐาน GMP ของผู้ผลิตทุกกรรมวิธี ในกรณีที่มีผู้ผลิตหลายราย

(8) ยาที่ได้รับการช่วยเหลือจากประเทศอื่น (emergency aid หรือ humanitarian aid) โดยยาดังกล่าวได้รับการขึ้นทะเบียนผลิตภัณฑ์ในประเทศผู้ผลิตหรือประเทศสมาชิก ICH หรือประเทศออสเตรเลีย และยาดังกล่าวนำเข้าตามที่ได้รับการช่วยเหลือจากประเทศอื่น

(8.1) คำสั่งนำเข้า (import order)

(8.2) หนังสือรับรองจากผู้รับความช่วยเหลือเกี่ยวกับปริมาณผลิตภัณฑ์ยาแต่ละชนิดที่ได้รับความช่วยเหลือและแสดงเจตจำนงว่าจะใช้ยาดังกล่าวตามวัตถุประสงค์ที่ได้แจ้งไว้

(8.3) หนังสือรับรองจากหน่วยงานรัฐที่เกี่ยวข้องว่ายาต่างประเทศที่ได้รับการช่วยเหลือใช้เพื่อสนับสนุนโครงการสุขภาพของรัฐ

(8.4) หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP)

(8.5) หนังสือแสดงคุณภาพของผลิตภัณฑ์ตาม ACTD และผลการศึกษาชีวสมมูล ในกรณีที่กระทรวงสาธารณสุขร้องขอ

(8.6) ข้อมูลการศึกษาทางคลินิกเกี่ยวกับความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์ ในกรณีที่กระทรวงสาธารณสุขร้องขอ

(8.7) ตัวอย่างฉลากและเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศผู้ผลิตหรือประเทศผู้ส่งออก เว้นแต่มีตัวอย่างแสดงใน CPP แล้ว

(8.8) ตัวอย่างฉลากที่ประสงค์จะใช้กับผลิตภัณฑ์ที่วางจำหน่ายในประเทศเวียดนามและเอกสารกำกับยาแบบ Package insert ฉบับภาษาเวียดนาม

(8.9) หนังสือรับรองการปฏิบัติตามมาตรฐาน GMP ของผู้ผลิตทุกกรรมวิธี ในกรณีที่มีผู้ผลิตหลายราย

(9) ยาที่นำเข้าเพื่อวัตถุประสงค์ในการศึกษาทางคลินิก โดยยาดังกล่าวใช้เพื่อวัตถุประสงค์ในการศึกษาทางคลินิกตามเค้าโครงการศึกษาที่ได้รับอนุมัติจากกระทรวงสาธารณสุข หรือยาดังกล่าวใช้เพื่อวัตถุประสงค์ในการศึกษาชีวสมมูล (bioequivalence) หรือชีวประสิทธิ (bioavailability) ผลตามกฎหมายว่าด้วยเภสัชกรรม และเป็นการใช้ยาเฉพาะในห้องปฏิบัติการเท่านั้น

(9.1) คำสั่งซื้อ (purchase order)

(9.2) หนังสือรับรองจากหน่วยงานรัฐที่เกี่ยวข้องว่ายาดังกล่าวใช้เพื่อวัตถุประสงค์ในการศึกษาทางคลินิก ศึกษาชีวสมมูลหรือชีวประสิทธิผล

(9.3) หนังสือจากผู้นำเข้าแสดงวัตถุประสงค์และปริมาณผลิตภัณฑ์ที่นำเข้าเพื่อใช้ในวัตถุประสงค์ตามที่ระบุ

(10) ยาที่นำเข้าเพื่อการจัดแสดงนิทรรศการ

(10.1) ในกรณียาที่มีส่วนประกอบของสารเสพติด ใช้เฉพาะคำสั่งซื้อ (purchase order)

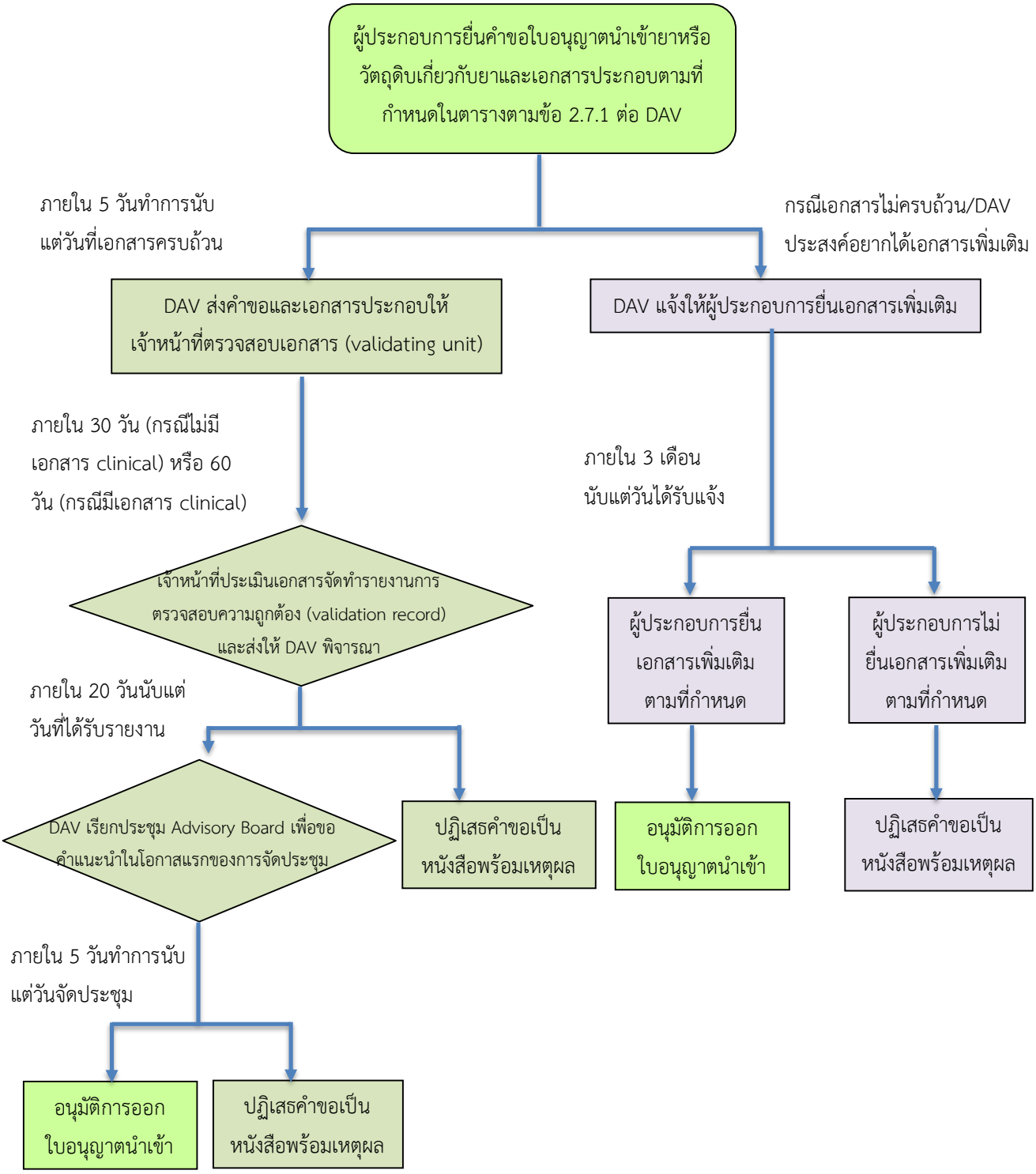
(10.2) ในกรณียาประเภทอื่น ต้องเป็นไปตามที่กำหนดในกฎหมายว่าด้วยการนำเข้าชั่วคราวหรือของส่งกลับ (Law on Temporary Import and Re-Export of Goods)

(11) ยาที่นำเข้าโดยไม่ได้มีวัตถุประสงค์เพื่อการค้า โดยยาดังกล่าวเป็นของส่วนตัวของผู้ที่เดินทางเข้ามาในประเทศ และไม่ใช่ยาเสพติด (narcotic drug) โดยขนส่งมาทางเรือ

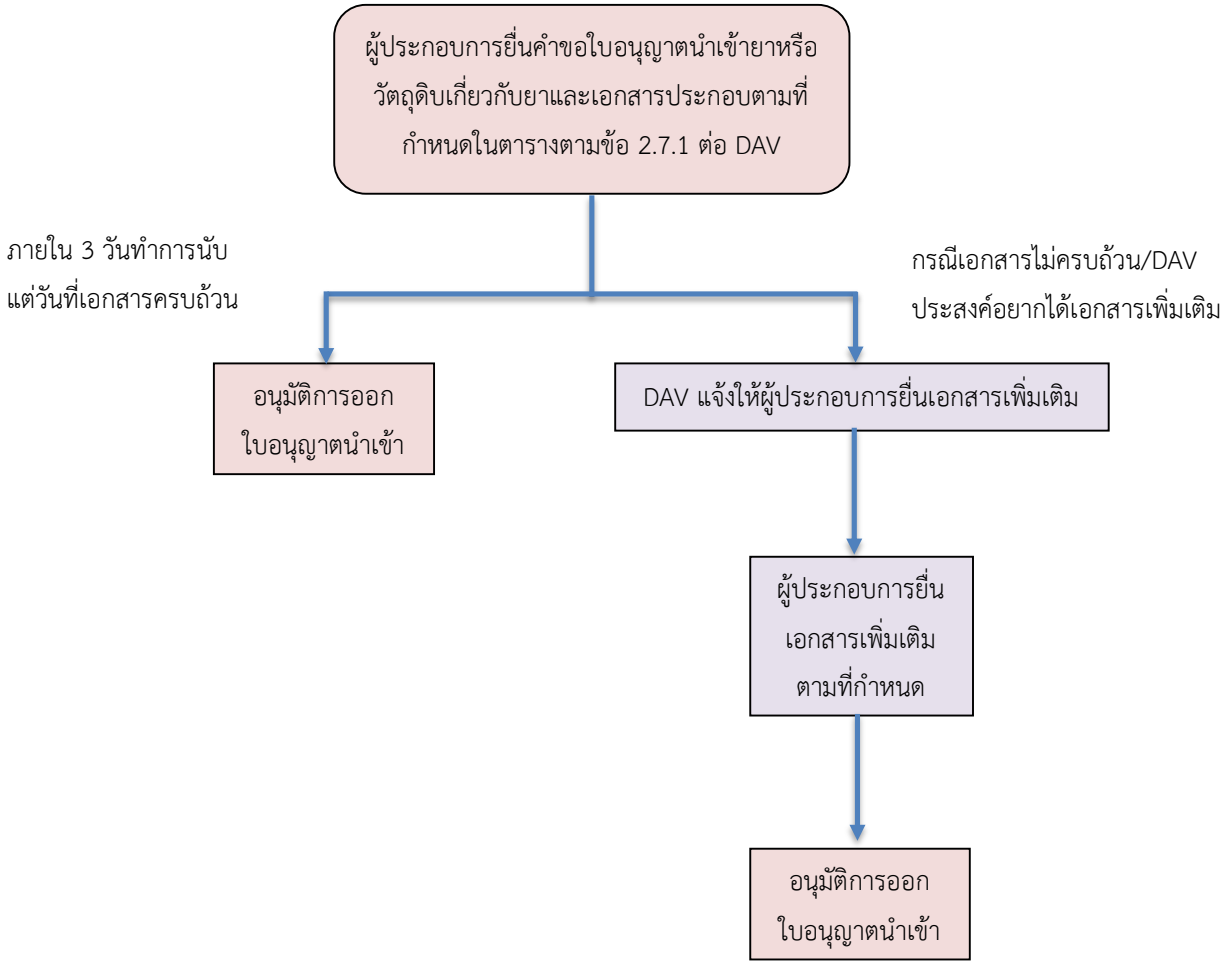
(11.1) ใบสั่งยาของแพทย์หรือประวัติการรักษาพยาบาล

2.7.2 ขั้นตอนการปฏิบัติงานของกระทรวงสาธารณสุขที่เกี่ยวข้องกับการออกใบอนุญาตนำเข้า

(1) กรณีไม่ใช่ยาที่ต้องนำเข้ากรณีเร่งด่วนเพื่อประโยชน์ทางด้านความปลอดภัยของประเทศหรือควบคุมโรคระบาดหรือบรรเทาภัยพิบัติ



(2) กรณียาที่ต้องนำเข้ากรณีเร่งด่วนเพื่อประโยชน์ทางด้านความปลอดภัยของประเทศหรือควบคุมโรคระบาดหรือบรรเทาภัยพิบัติ



2.8 ช่องทางการจำหน่ายผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยา

กฎหมายของประเทศเวียดนามไม่อนุญาติให้ผู้ประกอบการต่างชาติจัดจำหน่ายผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยาในประเทศเวียดนามโดยตรง ดังนั้น ผู้ประกอบการต่างชาติจึงมักจะร่วมมือกับผู้แทนจำหน่ายเวียดนามเพื่อจำหน่ายผลิตภัณฑ์ในตลาดเวียดนาม โดยการจำหน่ายผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาสามารถดำเนินการได้ผ่าน 2 ช่องทาง คือ Treatment channel ได้แก่ โรงพยาบาล หน่วยงานสาธารณสุข และสถานประกอบการทางการแพทย์ หรือ Commercial channel หรือ Over the Counter ได้แก่ ดำเนินการผ่านร้านขายยา คลินิก หรือตลาดขายส่ง ทั้งนี้ ช่องทาง Treatment channel เป็นช่องทางการจัดจำหน่ายหลักเนื่องจากเป็นช่องทางที่มียอดจำหน่ายสูงที่สุด

การจำหน่ายผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาให้กับโรงพยาบาลรัฐ หน่วยงานสาธารณสุขของรัฐหรือสถานประกอบการทางการแพทย์เอกชนที่ให้บริการวินิจฉัยและรักษาโรคภายใต้สิทธิประกันสุขภาพจะต้องผ่านกระบวนการประกวดราคาตามหลักเกณฑ์ที่กำหนดใน Circular No. 15/2019/TT-BYT on Regulation on Bidding for Drugs at Public Health Establishments ซึ่งออกโดยกระทรวงสาธารณสุข สรุปได้ดังนี้

2.8.1 การประกวดราคาของยาสามัญ (generic drug)

ซองประกวดราคา (bidding package) ของยาสามัญสามารถประกอบไปด้วยยาสามัญหนึ่งชนิดหรือมากกว่าหนึ่งชนิด โดยการยื่นซองประกวดราคาจะแบ่งออกเป็น 5 กลุ่มตามข้อกำหนดทางเทคนิค สรุปได้ดังนี้

(1) **กลุ่มที่ 1**: ยาสามัญที่เข้าคุณสมบัติอย่างน้อย 1 ใน 3 ข้อ ดังต่อไปนี้

(1.1) กรรมวิธีการผลิตทั้งหมดเป็นไปตามมาตรฐาน EU-GMP หรือมาตรฐานอื่นที่เทียบเคียงได้กับมาตรฐาน EU-GMP และมาตรฐานของประเทศในกลุ่ม SRA

(1.2) ยาที่อยู่ในรายชื่อยามียี่ห้อหรือยาชีวภาพของกระทรวงสาธารณสุข

(1.3) กรรมวิธีการผลิตทั้งหมดอยู่ในประเทศเวียดนาม และเข้าเงื่อนไข ได้แก่ 1) กระบวนการผลิตเป็นไปตามมาตรฐาน EU-GMP หรือมาตรฐานอื่นที่เทียบเคียงได้กับมาตรฐาน EU-GMP และได้รับการประเมินการปฏิบัติตามมาตรฐานโดยกระทรวงสาธารณสุขของประเทศเวียดนาม 2) ได้รับการขึ้นทะเบียนผลิตภัณฑ์โดยหน่วยงานที่รับผิดชอบด้านการบริหารจัดการยาของประเทศในกลุ่ม SRA และ 3) ยาที่จำหน่ายในประเทศเวียดนามและยาที่ขึ้นทะเบียนในประเทศกลุ่ม SRA ต้องมีสูตร (formula) กรรมวิธีการผลิต มาตรฐานคุณภาพ และวิธีการทดสอบ แบบเดียวกัน รวมทั้งสารออกฤทธิ์และสารเพิ่มปริมาณต้องมีมาตรฐานคุณภาพ และสถานที่ผลิตเดียวกัน

(2) **กลุ่มที่ 2**: ยาสามัญที่เข้าคุณสมบัติอย่างน้อย 1 ใน 2 ข้อ ดังต่อไปนี้

(2.1) กรรมวิธีการผลิตทั้งหมดเป็นไปตามมาตรฐาน EU-GMP หรือมาตรฐานอื่นที่เทียบเคียงได้กับมาตรฐาน EU-GMP และได้รับการประเมินการปฏิบัติตามมาตรฐานโดยกระทรวงสาธารณสุขของประเทศเวียดนาม

(2.2) กรรมวิธีการผลิตทั้งหมดอยู่ในประเทศที่เป็นสมาชิกของ Pharmaceutical Inspection Co-operation Scheme (PIC/S)[1] และ International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)[2] และได้รับการประเมินโดยหน่วยงานที่รับผิดชอบด้านการบริหารจัดการยาของประเทศดังกล่าวและกระทรวงสาธารณสุขของประเทศเวียดนามว่ากระบวนการผลิตเป็นไปตามมาตรฐาน PIC/S-GMP

(3) **กลุ่มที่ 3**: ยาที่มีกรรมวิธีการผลิตที่ผ่านการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน GMP และมีผลการศึกษาชีวสมมูลที่ได้รับการเผยแพร่โดยกระทรวงสาธารณสุขของประเทศเวียดนาม

(4) **กลุ่มที่ 4**: ยาที่มีกรรมวิธีการผลิตทั้งหมดอยู่ในประเทศเวียดนามและได้รับการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน WHO-GMP

(5) **กลุ่มที่ 5**: ยาที่มีกรรมวิธีการผลิตที่ผ่านการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน WHO-GMP

2.8.2 การประกวดราคาของยาสมุนไพรและยาแผนโบราณ (ไม่รวมยาสมุนไพรแผนโบราณ)

ซองประกวดราคา (bidding package) ของยาสมุนไพรและยาแผนโบราณสามารถประกอบไปด้วยยาสมุนไพรหรือยาแผนโบราณหนึ่งชนิดหรือมากกว่าหนึ่งชนิด โดยการยื่นซองประกวดราคาจะแบ่งออกเป็น 3 กลุ่มตามข้อกำหนดทางเทคนิค สรุปได้ดังนี้

(1) **กลุ่มที่ 1**: ยาที่เข้าคุณสมบัติ 2 ข้อดังต่อไปนี้

(1.1) ผลิตมาจากสมุนไพรที่ปลูกหรือเก็บเกี่ยวและได้รับการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน Good Agricultural Practice (GACP)

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[1] ตัวอย่างสมาชิกของ PIC/S เช่น National Institute of Drugs ของประเทศอาร์เจนตินา Therapeutic Goods Administration ของประเทศออสเตรเลีย Health Canada ของประเทศแคนาดา Taiwan Food and Drug Administration ของไต้หวัน Danish Medicines Agency ของประเทศเดนมาร์ก French National Agency for Medicines and Health Products Safety ของประเทศฝรั่งเศส Federal Ministry of Health ของประเทศเยอรมนี National Agency for Drug and Food Control ของประเทศอินโดนีเซีย Ministry of Health, Labour and Welfare ของประเทศญี่ปุ่น Health and Youth Care Inspectorate ของประเทศเนเธอร์แลนด์ Swissmedic ของประเทศสวิตเซอร์แลนด์ และ Health Sciences Authority ของประเทศสิงคโปร์

2 ตัวอย่างสมาชิกของ ICH เช่น European Commission ยุโรป Food and Drug Administration ของประเทศสหรัฐอเมริกา Ministry of Health, Labour and Welfare ของประเทศญี่ปุ่น Health Canada ของประเทศแคนาดา Swissmedic ของประเทศสวิตเซอร์แลนด์ Health Sciences Authority ของประเทศสิงคโปร์ Taiwan Food and Drug Administration ของไต้หวัน

(1.2) กรรมวิธีการผลิตทั้งหมดอยู่ในประเทศเวียดนาม และได้รับการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน GMP

(2) **กลุ่มที่ 2**: ยาที่มีกรรมวิธีการผลิตทั้งหมดอยู่ในประเทศเวียดนาม และได้รับการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน GMP

(3) **กลุ่มที่ 3**: ยาอื่นที่ไม่เข้าคุณสมบัติของกลุ่มที่ 1 และ 2 ตามข้างต้น

2.8.3 การประกวดราคาของยาสมุนไพรแผนโบราณ

ซองประกวดราคา (bidding package) ของยาสมุนไพรแผนโบราณสามารถประกอบไปด้วยยาสมุนไพรแผนโบราณหนึ่งชนิดหรือมากกว่าหนึ่งชนิด โดยการยื่นซองประกวดราคาจะแบ่งออกเป็น 3 กลุ่มตามข้อกำหนดทางเทคนิค สรุปได้ดังนี้

(1) **กลุ่มที่ 1**: ยาที่เข้าคุณสมบัติ 2 ข้อดังต่อไปนี้

(1.1) ผลิตมาจากสมุนไพรที่ปลูกหรือเก็บเกี่ยวและได้รับการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน Good Agricultural Practice (GACP)

(1.2) กรรมวิธีการผลิตทั้งหมดอยู่ในประเทศเวียดนาม และได้รับการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน GMP

(2) **กลุ่มที่ 2**: ยาที่มีกรรมวิธีการผลิตทั้งหมดอยู่ในประเทศเวียดนาม และได้รับการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน GMP

(3) **กลุ่มที่ 3**: ยาอื่นที่ไม่เข้าคุณสมบัติของกลุ่มที่ 1 และ 2 ตามข้างต้น

2.8.4 การประกวดราคาของวัตถุดิบเกี่ยวกับยา

ซองประกวดราคา (bidding package) ของวัตถุดิบเกี่ยวกับยาสามารถประกอบไปด้วยวัตถุดิบเกี่ยวกับยาหนึ่งชนิดหรือมากกว่าหนึ่งชนิด โดยการยื่นซองประกวดราคาจะแบ่งออกเป็น 3 กลุ่มตามข้อกำหนดทางเทคนิค สรุปได้ดังนี้

(1) **กลุ่มที่ 1**: วัตถุดิบเกี่ยวกับยาที่ได้จากเกษตรธรรมชาติ (natural farming) หรือการเก็บเกี่ยวหรือการใช้ประโยชน์จากเภสัชเคมีภัณฑ์และได้รับการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน Good Agricultural Practice (GACP)

(2) **กลุ่มที่ 2**: ผลิตภัณฑ์จากเภสัชเคมีภัณฑ์กึ่งสำเร็จรูปที่ผลิตในประเทศเวียดนามและได้รับการประเมินโดยกระทรวงสาธารณสุขของประเทศเวียดนามว่าเป็นไปตามมาตรฐาน GMP

(3) **กลุ่มที่ 3**: วัตถุดิบเกี่ยวกับยาอื่นที่ไม่เข้าคุณสมบัติของกลุ่มที่ 1 และ 2 ตามข้างต้น

2.8.5 หลักเกณฑ์เกี่ยวกับการประกวดราคาผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยาแต่ละกลุ่ม

(1) หลักการในการยื่นซองประกวดราคา

ผู้ประกอบการที่มีผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยาที่มีคุณสมบัติเข้าตามเงื่อนไขของกลุ่มใดกลุ่มหนึ่ง สามารถยื่นซองประกวดราคาในกลุ่มนั้นได้ และสำหรับในกรณีที่ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยามีคุณสมบัติเข้าตามเงื่อนไขของหลายกลุ่ม ผู้ประกอบการสามารถยื่นซองประกวดราคาในกลุ่มใดกลุ่มหนึ่งหรือหลายกลุ่มก็ได้ แต่ราคาที่เสนอต้องเป็นราคาเดียวกันในทุกกลุ่มที่ประกวดราคา

(2) เงื่อนไขในการยื่นซองประกวดราคากรณียาสามัญ

(2.1) ยาที่มีคุณสมบัติเข้ากลุ่ม 1 สามารถเข้าประกวดราคาในกลุ่ม 1 กลุ่ม 2 และกลุ่ม 5 ได้

(2.2) ยาที่มีคุณสมบัติเข้ากลุ่ม 2 สามารถเข้าประกวดราคาในกลุ่ม 2 และกลุ่ม 5 ได้

(2.3) ยาที่มีคุณสมบัติเข้ากลุ่ม 3 สามารถเข้าประกวดราคาในกลุ่ม 3 และกลุ่ม 5 ได้

(2.4) ยาที่มีคุณสมบัติเข้ากลุ่ม 4 สามารถเข้าประกวดราคาในกลุ่ม 4 และกลุ่ม 5 ได้

(2.5) ยาที่ไม่มีคุณสมบัติเข้ากลุ่ม 1-4 สามารถเข้าประกวดราคาในกลุ่ม 5 ได้เท่านั้น

(3) เงื่อนไขในการยื่นซองประกวดราคากรณียาสมุนไพรและยาแผนโบราณ

(3.1) ยาที่มีคุณสมบัติเข้ากลุ่ม 1 สามารถเข้าประกวดราคาในกลุ่ม 1 กลุ่ม 2 และกลุ่ม 3 ได้

(3.2) ยาที่มีคุณสมบัติเข้ากลุ่ม 2 สามารถเข้าประกวดราคาในกลุ่ม 2 และกลุ่ม 3 ได้

(3.3) ยาที่ไม่มีคุณสมบัติเข้ากลุ่ม 1-2 สามารถเข้าประกวดราคาในกลุ่ม 3 ได้เท่านั้น

(4) เงื่อนไขในการยื่นซองประกวดราคากรณียาสมุนไพรแผนโบราณ

(4.1) ยาที่มีคุณสมบัติเข้ากลุ่ม 1 สามารถเข้าประกวดราคาในกลุ่ม 1 กลุ่ม 2 และกลุ่ม 3 ได้

(4.2) ยาที่มีคุณสมบัติเข้ากลุ่ม 2 สามารถเข้าประกวดราคาในกลุ่ม 2 และกลุ่ม 3 ได้

(4.3) ยาที่ไม่มีคุณสมบัติเข้ากลุ่ม 1-2 สามารถเข้าประกวดราคาในกลุ่ม 3 ได้เท่านั้น

(5) เงื่อนไขในการยื่นซองประกวดราคากรณีวัตถุดิบเกี่ยวกับยา

(5.1) ยาที่มีคุณสมบัติเข้ากลุ่ม 1 สามารถเข้าประกวดราคาในกลุ่ม 1 และกลุ่ม 3 ได้

(5.2) ยาที่มีคุณสมบัติเข้ากลุ่ม 2 สามารถเข้าประกวดราคาในกลุ่ม 2 ได้

(5.3) ยาที่ไม่มีคุณสมบัติเข้ากลุ่ม 1-2 สามารถเข้าประกวดราคาในกลุ่ม 3 ได้เท่านั้น

บทที่ 3
บทวิเคราะห์กฎระเบียบ/ข้อกฎหมายที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

ปัจจุบันตลาดยาในประเทศเวียดนามเติบโตเฉลี่ยกว่าร้อยละ 10 ต่อปี โดยในปี 2560 มีมูลค่าสูงถึง 4.6 พันล้านดอลลาร์ สรอ. และในปี 2564 คาดว่าจะเติบโตสูงถึง 6.6 พันล้านดอลลาร์ สรอ. (ข้อมูลจากศูนย์ข้อมูลธุรกิจไทยในนครโฮจิมินห์) นอกจากนี้ ประเทศเวียดนามพึ่งพิงยานำเข้าในอัตราส่วนที่สูง เนื่องจากอุตสาหกรรมยาของประเทศเวียดนามไม่สามารถสนองความต้องการของผู้บริโภคได้เท่าที่ควร ซึ่งจากข้อมูลสถิติของกรมศุลกากรของประเทศเวียดนาม ในปี 2558 ประเทศเวียดนามมีการนำเข้าผลิตภัณฑ์เภสัชกรรมประมาณ 2.3 พันล้านดอลลาร์ สรอ. คิดเป็นร้อยละ 56 ของผลิตภัณฑ์เภสัชกรรมทั้งหมดในประเทศเวียดนาม โดยมีการนำเข้าผลิตภัณฑ์เภสัชกรรมจากประเทศฝรั่งเศสมากที่สุดที่ 275 ล้านดอลลาร์ สรอ. รองลงมาเป็นประเทศอินเดีย ประเทศเยอรมนี และประเทศเกาหลีใต้ (ข้อมูลจากสำนักงานส่งเสริมการค้าระหว่างประเทศ ณ กรุงฮานอย)

อย่างไรก็ดี แม้ตลาดยาในประเทศเวียดนามจะเป็นที่น่าสนใจของผู้ลงทุนรวมถึงผู้ประกอบการไทย ประกอบกับผลิตภัณฑ์ยาของประเทศไทยเป็นผลิตภัณฑ์ที่มีศักยภาพในการแข่งขันในกลุ่มประเทศ CLMV เนื่องจากได้รับความเชื่อมั่นในด้านคุณภาพ แต่การเปลี่ยนแปลงด้านกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยาในประเทศเวียดนามโดยการออกกฎหมายว่าด้วยเภสัชกรรม (Law on Pharmacy No. 105/2016/QH13) และกฎระเบียบลำดับรองที่ออกภายใต้กฎหมายดังกล่าว ส่งผลกระทบต่อความสามารถในการแข่งขันของผู้ประกอบการไทย เนื่องจากมีหลักเกณฑ์และกระบวนการที่ยุ่งยากซับซ้อนและเป็นอุปสรรคในการขึ้นทะเบียนและวางจำหน่ายผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยามากยิ่งขึ้น โดยสามารถสรุปได้ดังนี้

3.1 อุปสรรคจากเนื้อหาของกฎระเบียบ

(1) อุปสรรคที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

(1.1) ผู้ที่สามารถยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา

ในการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยานั้น กฎหมายว่าด้วยเภสัชกรรมของประเทศเวียดนามกำหนดไว้ชัดเจนว่าต้องเป็นผู้ประกอบการที่ได้รับใบอนุญาตประกอบธุรกิจยา (Certificate of eligibility for pharmaceutical business) หรือสำนักงานตัวแทนใน

ประเทศเวียดนาม อย่างไรก็ดี การที่ผู้ประกอบการไทยจะไปทำธุรกิจยาที่ประเทศเวียดนาม เช่น ตั้งโรงงานผลิตในประเทศเวียดนาม นั้น อาจไม่ประสบความสำเร็จเท่าที่ควรเนื่องจากไม่สามารถทำตลาดแข่งขันกับผู้ผลิตรายใหญ่ในประเทศเวียดนามได้ รวมถึงมีข้อจำกัดด้านภาษาในการทำธุรกิจ นอกจากนี้ การตั้งสำนักงานตัวแทนในประเทศเวียดนามนั้น มีข้อจำกัดในการทำธุรกิจเนื่องจากสำนักงานตัวแทนมีอำนาจหน้าที่จำกัด โดยสามารถให้บริการด้านข้อมูล การส่งเสริมการขายและการทำตลาด และดำเนินการด้านเอกสารต่าง ๆ เท่านั้น แต่สำนักงานตัวแทนไม่สามารถทำการค้าขายกับผู้บริโภคหรือหน่วยงานรัฐได้โดยตรงเนื่องจากไม่มีใบอนุญาตประกอบธุรกิจยา ประกอบกับสำนักงานตัวแทนอาจไม่มีความรู้ความเชี่ยวชาญหรือความเข้าใจเกี่ยวกับกฎระเบียบในประเทศเวียดนาม ดังนั้น ผู้ประกอบการไทยจำเป็นต้องตัวแทนจำหน่ายในประเทศเวียดนาม หรือหาพันธมิตรทางธุรกิจในประเทศเวียดนาม ซึ่งเป็นอุปสรรคกับผู้ผลิตยาไทยขนาดกลางหรือขนาดเล็กที่ยังไม่มีชื่อเสียง ในการหาตัวแทนจำหน่ายหรือพันธมิตรทางธุรกิจในประเทศเวียดนาม

(1.2) รายการเอกสารที่ต้องใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยา

การยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาประเภทต่าง ๆ มีรายการเอกสารที่ต้องใช้จำนวนมาก โดยหากเป็นเอกสารที่ออกโดยหน่วยงานรัฐต่างประเทศต้องมีการรับรองเอกสาร (consular legalization) อีกทั้งการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาแผนปัจจุบัน วัคซีน และยาชีวภาพ ต้องมีหนังสือรับรองการปฏิบัติตามมาตรฐาน GMP เอกสารแสดงคุณภาพของผลิตภัณฑ์ตาม ACTD หรือ ICH-CTD และผลการศึกษาทางคลินิกตามมาตรฐาน ACTD หรือ ICH-CTD ประกอบ ซึ่งผู้ประกอบการไทยจะต้องปรับตัวให้เทียบเท่ามาตรฐานดังกล่าวด้วย

นอกจากนี้ ในกรณีที่เป็นยาต่างประเทศ ผู้ประกอบการต้องยื่นหนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) ประกอบการขึ้นทะเบียนผลิตภัณฑ์และต่ออายุทะเบียนผลิตภัณฑ์ ซึ่งรายละเอียดที่ต้องระบุใน CPP ตามกฎระเบียบของประเทศเวียดนามมีมากกว่ารายละเอียดใน CPP ที่ออกโดย อย. ของประเทศไทย เช่น CPP ตามกฎระเบียบของประเทศเวียดนามต้องระบุถึงคุณลักษณะเฉพาะของผลิตภัณฑ์ (specification of finished product) และคุณลักษณะเฉพาะของสารออกฤทธิ์ (specification of active ingredient) ซึ่งรวมถึง source of active pharmaceutical product ด้วย ดังนั้น อาจเกิดอุปสรรคต่อการขึ้นทะเบียนหรือต่ออายุทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามได้ หากกระทรวงสาธารณสุขของประเทศเวียดนาม ไม่ยอมรับ CPP ที่ออกโดย อย. ของประเทศไทย เนื่องจากมีรายละเอียดไม่ครบถ้วนตามที่กฎระเบียบของประเทศเวียดนามกำหนด

(2) อุปสรรคที่เกี่ยวข้องกับช่องทางการจำหน่ายผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยา: การประกวดราคาในการจัดซื้อยาของภาครัฐ

การจำหน่ายผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยาผ่านโรงพยาบาลหรือหน่วยงานสาธารณสุขเป็นช่องทางที่มียอดจำหน่ายสูงสุด แต่การจำหน่ายยาให้กับโรงพยาบาลหรือหน่วยงานสาธารณสุขของรัฐหรือแม้แต่สถานประกอบการทางการแพทย์ของเอกชนที่ให้บริการวินิจฉัยและรักษาโรคภายใต้สิทธิประกันสุขภาพ ต้องผ่านการประกวดราคาก่อน ซึ่งกฎระเบียบที่เกี่ยวข้องกับการประกวดราคาในการจัดซื้อยาของภาครัฐหรือที่ใช้งบประมาณจากภาครัฐมีการแบ่งกลุ่มของยา โดยในส่วนของยาสามัญจะแบ่งออกเป็น 5 กลุ่ม โดยกลุ่มที่ 1 จะเป็นกลุ่มยาที่มีมาตรฐานตาม EU-GMP กลุ่มที่ 2 จะเป็นกลุ่มยาที่มีมาตรฐานตาม EU-GMP หรือยาที่ผลิตในประเทศที่เป็นสมาชิก PIC/S และสมาชิก ICH ซึ่งได้รับการประเมินว่ายามีมาตรฐานตาม PIC/S-GMP กลุ่มที่ 3 จะเป็นกลุ่มยาที่มีการผลิตสอดคล้องกับมาตรฐาน GMP และมีผลการศึกษาชีวสมมูลเผยแพร่โดยกระทรวงสาธารณสุขของประเทศเวียดนาม กลุ่มที่ 4 จะเป็นกลุ่มยาที่ผลิตในประเทศเวียดนามและมีมาตรฐาน WHO-GMP และกลุ่มที่ 5 จะเป็นยาที่มีมาตรฐาน WHO-GMP

นอกจากนี้ กฎระเบียบของประเทศเวียดนามมีการกำหนดว่ายาที่เข้าคุณสมบัติของแต่ละกลุ่ม สามารถประกวดราคาแข่งกับกลุ่มใดได้บ้าง โดยยากลุ่มที่ 1 สามารถประกวดราคาแข่งกับกลุ่มที่ 1 กลุ่มที่ 2 และกลุ่มที่ 5 และยากลุ่มที่ 2 สามารถประกวดราคาแข่งกับกลุ่มที่ 2 และกลุ่มที่ 5 ได้ ในขณะที่ ยากลุ่มที่ 5 สามารถประกวดราคาแข่งกับกลุ่มที่ 5 ได้เท่านั้น จึงเห็นได้ว่ายาที่มีมาตรฐาน EU-GMP จะมีข้อได้เปรียบมากกว่ายากลุ่มอื่น เนื่องจากสามารถเข้าร่วมประกวดราคาได้หลายกลุ่ม จึงมีโอกาสได้รับเลือกและได้ราคาสูงกว่ายาที่ได้รับมาตรฐานอื่น ในขณะที่ยาของประเทศไทยจะมีอุปสรรคในการแข่งขัน เนื่องจากแม้ยาของประเทศไทยจะได้รับการรับรองว่ามีมาตรฐานตาม PIC/S-GMP ก็ตาม แต่ประเทศไทยเป็นเพียงสมาชิกของ PIC/S และเป็น ICH observer โดยไม่ได้เป็นสมาชิก ICH ทำให้ยาของประเทศไทยไม่สามารถประกวดราคาแข่งขันในกลุ่มที่ 2 ได้ จึงต้องเข้าร่วมการประกวดราคาในกลุ่มที่ 3 (หากมีผลการศึกษาชีวสมมูล) หรือกลุ่มที่ 5 แทน

จากการกำหนดหลักเกณฑ์การประกวดราคาดังกล่าว เห็นได้ชัดว่าประเทศเวียดนามมีข้อกำหนดที่มุ่งคุ้มครองผู้ผลิตในประเทศเวียดนามอยู่ เนื่องจากไม่มียาในกลุ่มใดที่สามารถประกวดราคาแข่งกับยาในกลุ่มที่ 4 ซึ่งเป็นยาที่ผลิตในประเทศเวียดนามได้ นอกจากยาในกลุ่มที่ 4 เอง ประกอบกับประเทศเวียดนามได้กำหนดนโยบายไว้ในกฎหมายว่าด้วยเภสัชกรรมว่า กรณีการจัดซื้อยาโดยใช้งบประมาณของรัฐ หรือกองทุนประกันสุขภาพ จะให้ความสำคัญกับการจัดซื้อยาที่ผลิตในประเทศเวียดนามก่อน พร้อมทั้งให้หลีกเลี่ยงการจัดซื้อหรือคัดเลือกยาที่นำเข้าจากการประกวดราคา หากยาดังกล่าวสามารถผลิตได้ในประเทศเวียดนามและคุณภาพ/ราคาที่ยอมรับได้

3.2 อุปสรรคด้านขั้นตอนกระบวนการขึ้นทะเบียนผลิตภัณฑ์

(1) ความไม่แน่นอนของการบังคับใช้กฎระเบียบ

ประเทศเวียดนามได้ออกกฎหมายว่าด้วยเภสัชกรรมฉบับใหม่ในปี 2559 ซึ่งมีผลบังคับใช้ในปี 2560 ทำให้หน่วยงานที่เกี่ยวข้องโดยเฉพาะกระทรวงสาธารณสุขต้องมีการปรับปรุงกฎระเบียบและหลักเกณฑ์ที่เกี่ยวข้องเพื่อรองรับกฎหมายว่าด้วยเภสัชกรรมดังกล่าว ส่งผลให้มีการปรับปรุงกฎระเบียบและหลักเกณฑ์ที่เกี่ยวกับการกำกับดูแลผลิตภัณฑ์ยาบ่อยครั้ง จึงอาจทำให้เกิดความไม่แน่นอนของการบังคับใช้กฎระเบียบ

(2) ข้อมูลเกี่ยวกับกฎระเบียบยังไม่ได้รับการตีพิมพ์หรือเผยแพร่อย่างเพียงพอ

ข้อมูลเกี่ยวกับกฎระเบียบไม่ได้รับการตีพิมพ์หรือเผยแพร่อย่างเพียงพอ รวมถึงไม่มีการรวบรวมข้อมูลเกี่ยวกับกฎระเบียบเรื่องต่าง ๆ ไว้เป็นหมวดหมู่ ส่งผลให้ผู้ประกอบการต้องใช้ระยะเวลานานในการศึกษาและรวบรวมข้อมูลกฎระเบียบ

(3) กฎระเบียบมักไม่จัดทำเป็นภาษาอังกฤษ

ผู้ประกอบการมีข้อจำกัดในด้านภาษา เนื่องจากกฎระเบียบบางฉบับจัดทำขึ้นในภาษาเวียดนามเท่านั้น จึงอาจทำให้ผู้ประกอบการไม่สามารถศึกษาหรือทำความเข้าใจกฎระเบียบของประเทศเวียดนามได้อย่างครบถ้วนสมบูรณ์

(4) เอกสารยากแก่การกรอก

ในการยื่นคำขอดำเนินการในเรื่องต่าง ๆ เพื่อวางจำหน่ายผลิตภัณฑ์ยาในประเทศเวียดนาม ต้องเป็นไปตามแบบฟอร์มที่กระทรวงสาธารณสุขของประเทศเวียดนามกำหนด ซึ่งแบบฟอร์มส่วนใหญ่จัดทำเป็นภาษาเวียดนาม จึงอาจทำให้ผู้ประกอบการประสบอุปสรรคในการดำเนินการเรื่องเอกสาร

(5) การปฏิบัติงานของเจ้าหน้าที่ที่เกี่ยวข้องไม่แน่นอน

จากการสืบค้นข้อมูลพบว่า ในทางปฏิบัตินั้น การปฏิบัติงานของเจ้าหน้าที่ที่เกี่ยวข้องมีความไม่แน่นอน เช่น เจ้าหน้าที่แต่ละคนใช้ดุลพินิจในการพิจารณาคำขอและเรียกเอกสารที่แตกต่างกันไม่เป็นไปตามระบุไว้ในกฎระเบียบที่เกี่ยวข้อง

(6) ความล่าช้าในการดำเนินการของเจ้าหน้าที่ที่เกี่ยวข้อง

จากการสืบค้นข้อมูลพบว่า ในทางปฏิบัติ เจ้าหน้าที่ของกระทรวงสาธารณสุขของประเทศเวียดนาม มีการดำเนินการที่ล่าช้ากว่าระยะเวลาที่กำหนดไว้ตามกฎระเบียบที่เกี่ยวข้อง

บทที่ 4

การจัดลำดับกฎระเบียบที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

ตามขอบเขตการดำเนินงาน ผลของโครงการการศึกษากฎระเบียบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ที่ได้รับการรับรองจาก อย. ประจำปีงบประมาณ พ.ศ. 2563 ครอบคลุมถึงการจัดลำดับกฎระเบียบที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม และระบุข้อเสนอแนะในการแก้ไขปัญหา จึงนำไปสู่การดำเนินการสัมภาษณ์หน่วยงานภาครัฐ พร้อมการจัดประชุมหารือร่วมกับผู้ประกอบการภาคเอกชน และการสำรวจข้อมูลผ่านแบบสอบถามจากผู้ประกอบการภาคเอกชน โดยมีรายชื่อผู้ให้ข้อมูลตามที่ได้หารือกับ อย. ประกอบด้วย

(1) กรณีสัมภาษณ์หน่วยงานภาครัฐ ได้แก่ ผู้บริหารของกองยา สำนักงานคณะกรรมการอาหารและยา

(2) กรณีจัดประชุมหารือเพื่อรับฟังความคิดเห็นและข้อเสนอแนะของผู้ประกอบการภาคเอกชนเกี่ยวกับกฎระเบียบที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ได้แก่

(2.1) บริษัท ที.โอ. เคมีคอลส์ (1979) จำกัด

(2.2) บริษัท สยามเภสัช จำกัด

(2.3) บริษัท อาร์เอ็กซ์ แมนูแฟคเจอริ่ง จำกัด

(2.4) บริษัท ไบโอฟาร์ม เคมิคัลส์ จำกัด

(2.5) บริษัท ไบโอแลป จำกัด

(2.6) บริษัท โปลิฟาร์ม จำกัด

(2.7) หจก. แอลบีเอส แลบบอเรตอรี่ จำกัด

(2.8) บริษัท แอดวานซ์ฟาร์มาซูติคอล แมนูเฟคเจอริ่ง จำกัด

(3) กรณีสำรวจข้อมูลผ่านแบบสอบถามจากผู้ประกอบการภาคเอกชน ได้แก่

(3.1) บริษัท อาร์เอ็กซ์ แมนูแฟคเจอริ่ง จำกัด

(3.2) บริษัท สยามเภสัช จำกัด

(3.3) บริษัท ไบโอแลป จำกัด

(3.4) บริษัท โปลิฟาร์ม จำกัด

(3.5) หจก. แอลบีเอส แลบบอเรตอรี่ จำกัด

(3.6) บริษัท พาราไดม์ ฟาร์มา จำกัด

(3.7) บริษัท เมก้า ไลฟ์ไซแอ็นซ์ จำกัด (มหาชน)

(3.8) บริษัท OLIC (Thailand) จำกัด

(3.9) บริษัท ชุมชนเภสัชกรรม จำกัด (มหาชน)

การคัดเลือกผู้ประกอบการภาคเอกชน พิจารณาจาก ผู้ประกอบการที่มีการส่งออกผลิตภัณฑ์ยาไปยังประเทศเวียดนาม หรือมีแผนขยายตลาดไปยังประเทศเวียดนาม และเพื่อให้ได้ข้อมูลที่ครบถ้วนและรอบด้าน จึงคัดเลือกผู้ประกอบการที่มีขนาดแตกต่างกัน และมีการผลิตหรือจัดจำหน่ายผลิตภัณฑ์ยาในหลายประเภท โดยผู้ประกอบการในกลุ่มตัวอย่างดำเนินการผลิตหรือจัดจำหน่ายผลิตภัณฑ์ยาครอบคลุมผลิตภัณฑ์ยาในประเภทต่าง ๆ ได้แก่ ยาแผนปัจจุบันบรรจุเสร็จที่ไม่ใช่ยาอันตรายหรือยาควบคุมพิเศษ ยาสามัญประจำบ้านแผนปัจจุบัน ยาแผนปัจจุบันที่เป็นยาอันตราย ยาแผนปัจจุบันที่เป็นยาควบคุมพิเศษ ยาใช้เฉพาะ ยาสมุนไพรแผนโบราณ ยาแผนโบราณที่เป็นยาอันตราย ยาใหม่ เภสัชเคมีภัณฑ์กึ่งสำเร็จรูป

อย่างไรก็ดี พบว่า การสำรวจข้อมูลผ่านแบบสอบถามจากผู้ประกอบการมีข้อจำกัดบางประการ เนื่องจากตัวแทนของผู้ประกอบการบางราย มิได้มีหน้าที่ ความรับผิดชอบ หรือข้อมูลครอบคลุมทุกประเด็นตามแบบสอบถาม จึงส่งผลให้ผู้ประกอบการบางราย มิได้ตอบคำถามในแบบสอบถามครบถ้วนทุกประเด็น อาทิ มีผู้ประกอบการจำนวน 6 รายที่ไม่สามารถให้ข้อมูลเกี่ยวกับกำลังการผลิต และมีผู้ประกอบการจำนวน 3 รายที่ไม่สามารถให้ข้อมูลเกี่ยวกับจำนวนคนงาน

อนึ่ง รายงานในบทนี้จำแนกการรายงานผลการศึกษาสอดคล้องกับรูปแบบการสัมภาษณ์ และการจัดประชุมหารือและการสำรวจข้อมูลผ่านแบบสอบถาม อันประกอบด้วย

(1) กรณีสัมภาษณ์หน่วยงานภาครัฐ ประกอบด้วย

คำถามที่ 1 ภาพรวมการกำกับดูแลและส่งเสริมผลิตภัณฑ์ยาของประเทศไทยในปัจจุบัน

คำถามที่ 2 อุปสรรคในการส่งเสริมผู้ประกอบการของ อย. ในการสนับสนุนการส่งออกผลิตภัณฑ์ยาไปยังประเทศเวียดนามในด้านต่าง ๆ ได้แก่ ด้านเนื้อหาของกฎระเบียบของประเทศเวียดนามที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม และด้านขั้นตอนการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

คำถามที่ 3 ความคิดเห็นต่อการดำเนินการในการสนับสนุนการส่งออกของ อย. ในด้านต่าง ๆ ได้แก่ ด้านนโยบายเพื่อสนับสนุนการส่งออก และด้านระบบเพื่อสนับสนุนการส่งออก

คำถามที่ 4 ข้อเสนอแนะเพื่อนำไปใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาของภูมิภาคอาเซียนในประเด็นปัญหาอุปสรรคของประเทศเวียดนาม

(2) กรณีจัดประชุมหารือร่วมกับผู้ประกอบการภาคเอกชน และการสำรวจข้อมูลผ่านแบบสอบถาม ประกอบด้วย

ส่วนที่ 1 ข้อมูลเกี่ยวกับสถานประกอบการ

ส่วนที่ 2 กฎระเบียบที่เป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

ส่วนที่ 3 ข้อมูลด้านความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุน

ส่วนที่ 4 ประเด็นปัญหา อุปสรรค และข้อเสนอแนะ

จากการสัมภาษณ์หน่วยงานภาครัฐ รวมถึงการจัดประชุมหารือและการสำรวจข้อมูลผ่านแบบสอบถามจากผู้ประกอบการภาคเอกชนสามารถสรุปประเด็นต่าง ๆ ได้ ดังนี้

4.1 ข้อมูลจากหน่วยงานภาครัฐ

4.1.1 ภาพรวมการกำกับดูแลและส่งเสริมผลิตภัณฑ์ยาของประเทศไทยในปัจจุบัน

กองยา อย. เป็นหน่วยงานหลักในการกำกับดูแลด้านผลิตภัณฑ์ยาของประเทศไทย ซึ่งการดำเนินการของกองยาจะสอดคล้องกับวิสัยทัศน์ของ อย. คือ “เป็นองค์กรหลักด้านการคุ้มครองผู้บริโภค และส่งเสริมผู้ประกอบการด้านผลิตภัณฑ์สุขภาพเพื่อประชาชนสุขภาพดี” ดังนั้น ยุทธศาสตร์หลักของ อย. จะมุ่งเน้นที่การคุ้มครองผู้บริโภค และยุทธศาสตร์รอง คือการส่งเสริมผู้ประกอบการ ผ่านการพัฒนากลไกและกฎระเบียบที่เป็นมาตรฐานสากล รวมถึงการพัฒนางานบริการที่มีประสิทธิภาพโดยอาศัยเทคโนโลยีต่าง ๆ ในการให้บริการ เช่น อย. อยู่ในระหว่างดำเนินการตามแผน digital transformation เพื่อลดการใช้กระดาษในการทำธุรกรรมต่าง ๆ ซึ่งจะช่วยให้การติดต่อประสานงานกับ อย. เป็นไปได้อย่างรวดเร็วขึ้น และเป็นการลดค่าใช้จ่ายของผู้ประกอบการในการทำธุรกรรม

อย่างไรก็ดี อุปสรรคที่สำคัญต่อการส่งเสริมผลิตภัณฑ์ยาของประเทศไทยให้สามารถแข่งขันได้ในปัจจุบัน คือ ศักยภาพของผู้ประกอบการไทยในการพัฒนายานวัตกรรม โดยผู้ประกอบการไทยส่วนใหญ่มุ่งเน้นพัฒนายาสามัญ มากกว่ายานวัตกรรม จึงทำให้ผลิตภัณฑ์ยาไทยมีมูลค่าต่ำเมื่อเทียบกับผลิตภัณฑ์ยาจากต่างประเทศที่ใช้นวัตกรรมมากกว่า ดังนั้น กองยาจึงมุ่งส่งเสริมผู้ประกอบการไทยให้หันมาผลิตสินค้าที่เป็นนวัตกรรมมากยิ่งขึ้น เพื่อสร้างมูลค่าเพิ่มให้กับผลิตภัณฑ์ และเป็นการยกระดับอุตสาหกรรมยาของประเทศไทย

4.1.2 อุปสรรคในการส่งเสริมผู้ประกอบการของ อย. ในการสนับสนุนการส่งออกผลิตภัณฑ์ยาไปยังประเทศเวียดนาม ในด้านต่าง ๆ ได้แก่ ด้านเนื้อหาของกฎระเบียบของประเทศเวียดนามที่เกี่ยวข้อง

กับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม และด้านขั้นตอนการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

จากข้อมูลการศึกษากฎระเบียบของประเทศเวียดนามที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาที่ผู้วิจัยได้จัดทำขึ้น ผู้บริหารของ กองยา อย. มีความเห็นว่า ข้อกำหนดเกี่ยวกับหนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) ของประเทศเวียดนามที่กำหนดให้ CPP มีรายละเอียดมากกว่าข้อกำหนดของ WHO หรือข้อกำหนดเกี่ยวกับเงื่อนไขการประกวดราคาในการจัดซื้อยาของภาครัฐ เป็นอุปสรรคทางการค้า (non-technical barrier) รูปแบบหนึ่ง ซึ่งภาครัฐได้มีการหารือร่วมกับผู้ประกอบการเพื่อหาวิธีการลดอุปสรรคทางการค้าดังกล่าวอยู่เป็นระยะ เพื่อนำประเด็นไปเจรจาต่อในเวทีระดับอาเซียน โดยในการประชุมระดับอาเซียนที่ผ่านมา ได้มีการหยิบยกประเด็นเรื่องข้อกำหนดเกี่ยวกับ CPP ของประเทศเวียดนามขึ้นหารือเช่นกัน ซึ่งทาง อย. ของประเทศเวียดนามชี้แจงว่า CPP ในรูปแบบของ WHO สามารถใช้ประกอบการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนามได้ แต่ในทางปฏิบัติ ผู้ประกอบการไทยกลับพบว่า CPP ในรูปแบบของ WHO ยังคงถูกปฏิเสธโดยเจ้าหน้าที่ที่เกี่ยวข้องของประเทศเวียดนาม ซึ่งเป็นเรื่องที่ภาครัฐต้องเจรจาหารือร่วมกันเพื่อหาแนวทางแก้ไขให้ได้ผลลัพธ์ที่ชัดเจนต่อไป

สำหรับประเด็นเรื่องการจัดซื้อยาของภาครัฐนั้น สามารถแยกประเด็นพิจารณาได้ดังนี้

(1) กรณีประเทศเวียดนามกำหนดให้ยาที่ได้รับมาตรฐาน EU-GMP อยู่ในกลุ่ม 1 และยาที่ผลิตในประเทศสมาชิก PIC/S และสมาชิก ICH ที่ได้รับมาตรฐาน PIC/S-GMP อยู่ในกลุ่ม 2 นั้น เห็นว่าข้อกำหนดดังกล่าวใช้กับทุกประเทศที่ประสงค์จะเข้าร่วมประกวดราคาในการจัดซื้อยาของภาครัฐ มิได้กีดกันเฉพาะผลิตภัณฑ์ยาของประเทศไทย ซึ่งเหตุผลของการกำหนดข้อกำหนดในลักษณะดังกล่าวน่าจะสืบเนื่องจากที่ประเทศเวียดนามให้ความสำคัญกับยานวัตกรรม มากกว่ายาสามัญทั่วไป เนื่องจากผู้ประกอบการของประเทศเวียดนามเองยังคงมีข้อจำกัดในการผลิตยานวัตกรรมดังกล่าว

ทั้งนี้ การที่ประเทศไทยเป็นเพียง ICH observer โดยไม่ได้เป็นสมาชิก ICH เนื่องจากการเข้าเป็นสมาชิก ICH ส่งผลให้ผู้ประกอบการไทยต้องถือปฏิบัติตามมาตรฐานของ ICH อย่างเต็มรูปแบบ ดังนั้น ในการเข้าเป็นสมาชิก ICH จึงต้องพิจารณาถึงความพร้อมของผู้ประกอบการไทยเป็นสำคัญ

(2) นอกจากนี้ การที่ประเทศเวียดนามกำหนดให้ยาที่ผลิตได้ในประเทศเวียดนามอยู่ในกลุ่ม 4 ซึ่งผลิตภัณฑ์ยาจากกลุ่มอื่นไม่สามารถเข้าร่วมประกวดราคาแข่งขันได้นั้น เป็นประเด็นที่สามารถพบได้ในหลายประเทศว่ามีการกำหนดเงื่อนไขการจัดซื้อยาของภาครัฐที่สนับสนุนยาที่ผลิตในประเทศของตน

ดังนั้น ผู้บริหารจึงเห็นว่าอุปสรรคที่สำคัญในการขึ้นทะเบียนผลิตภัณฑ์หรือวางจำหน่ายผลิตภัณฑ์ยาในประเทศเวียดนาม ส่วนใหญ่เกิดขึ้นจากศักยภาพของผู้ประกอบการไทยที่มีจำกัดมากกว่ากฎระเบียบของประเทศเวียดนาม ดังนั้น หากผู้ประกอบการไทยประสงค์จะทำตลาดในประเทศเวียดนาม

ควรมุ่งเน้นพัฒนาศักยภาพให้รองรับการผลิตยานวัตกรรม รวมถึงการหาคู่ค้าหรือพันธมิตรทางธุรกิจที่จะช่วยส่งเสริมการทำตลาดในประเทศเวียดนามด้วย

4.1.3 ความคิดเห็นต่อการดำเนินการในการสนับสนุนการส่งออกของ อย. ในด้านต่าง ๆ ได้แก่ ด้านนโยบายเพื่อสนับสนุนการส่งออก และด้านระบบเพื่อสนับสนุนการส่งออก

ปัจจุบัน อย. ได้มีการดำเนินการเพื่อสนับสนุนการส่งออกผลิตภัณฑ์ยาในหลายด้าน เช่น การพัฒนาระบบการให้คำแนะนำแก่ผู้ประกอบการในการผลิตยานวัตกรรม การกำหนดแผนพัฒนาและรายการยาตามบัญชียามุ่งเป้าที่จะดำเนินการเร่งรัดการขึ้นทะเบียนตำรับยา การพัฒนาระบบหรือกลไกที่ช่วยลดต้นทุนในการทำธุรกรรมของผู้ประกอบการ รวมถึงการกำหนดแนวทางหรือวิธีการพัฒนาศักยภาพของผู้ประกอบการไทยเพื่อเพิ่มขีดความสามารถในการแข่งขันในต่างประเทศและลดอุปสรรคทางการค้าต่าง ๆ

อย่างไรก็ดี เพื่อให้การสนับสนุนการส่งออกและการลดอุปสรรคทางการค้าประสบผลสำเร็จมากยิ่งขึ้น เห็นควรให้หน่วยงานภาครัฐที่มีหน้าที่รับผิดชอบด้านการค้า และการเจรจาระหว่างประเทศโดยตรง เข้ามามีส่วนร่วมในการแก้ไขอุปสรรคต่าง ๆ ที่เกิดขึ้นจากกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาของประเทศเวียดนามด้วย

4.1.4 ข้อเสนอแนะเพื่อนำไปใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาของภูมิภาคอาเซียนในประเด็นปัญหาอุปสรรคของประเทศเวียดนาม

โดยปกติการประชุมอาเซียนที่เกี่ยวกับผลิตภัณฑ์ยาจะจัดขึ้นปีละ 2 ครั้ง โดยครั้งที่ 1 จะเป็นการประชุมระหว่างหน่วยงานภาครัฐที่รับผิดชอบด้านการกำกับดูแลผลิตภัณฑ์ยาของแต่ละประเทศสมาชิกอาเซียนกับตัวแทนผู้ประกอบการ เพื่อเป็นการเปิดโอกาสให้ผู้ประกอบการเข้ามามีส่วนร่วมในการเสนอประเด็นปัญหาที่ผู้ประกอบการประสบจากการค้าและการส่งออกไปยังประเทศสมาชิก และเสนอแนะแนวทางในการแก้ไขปัญหาผ่านการประชุม และครั้งที่ 2 จะเป็นการประชุมระหว่างหน่วยงานภาครัฐเท่านั้น เพื่อหยิบยกประเด็นปัญหาที่ผู้ประกอบการประสบเกี่ยวกับการค้าและการส่งออก หรือประเด็นอื่น ๆ ที่สำคัญ เช่น ความร่วมมือในด้านเศรษฐกิจ หรือการจัดทำมาตรฐานกลางของประเทศสมาชิกอาเซียน มาเจรจาเพื่อหาแนวทางออกในเชิงนโยบายร่วมกันระหว่างประเทศสมาชิกอาเซียน ทั้งนี้ อย. ได้มีการจัดตั้งทีมเจรจาขึ้นเพื่อเป็นตัวแทนในการเจรจาในเวทีของภูมิภาคอาเซียน พร้อมทั้ง ได้มีการพัฒนาความรู้และทักษะการเจรจาของทีมเจรจาอย่างต่อเนื่องเพื่อให้การเจรจาในเวทีของภูมิภาคอาเซียนเป็นไปอย่างมีประสิทธิภาพและเกิดประสิทธิผลต่ออุตสาหกรรมยาของประเทศไทยมากที่สุด

นอกจากนี้ ผู้บริหารมีข้อเสนอแนะเพื่อนำไปใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาของภูมิภาคอาเซียนในประเด็นปัญหาอุปสรรคของประเทศเวียดนามว่า ควรมีการจัดตั้งคณะทำงานเพื่อส่งเสริมการส่งออกผลิตภัณฑ์ยาโดยเฉพาะ เพื่อให้สามารถแก้ไขปัญหาที่เกี่ยวข้องกับการส่งออกได้อย่างตรงจุด รวดเร็ว และสัมฤทธิ์ผล โดยคณะทำงานควรมีตัวแทนของหน่วยงานต่าง ๆ ที่เกี่ยวข้องกับการกำกับ

ดูแลผลิตภัณฑ์ยา และการค้าและการส่งออก เช่น อย. กระทรวงพาณิชย์ กระทรวงการต่างประเทศ และกระทรวงอุตสาหกรรม เพื่อให้มีข้อมูลที่ครบถ้วนและรอบด้าน เนื่องจากในปัจจุบัน การทำงานระหว่างหน่วยงานดังกล่าวจะอยู่ในรูปแบบของการประสานงานระหว่างหน่วยงานเท่านั้น

4.2 ข้อมูลจากผู้ประกอบการ

4.2.1 ข้อมูลเกี่ยวกับสถานประกอบการ

ในส่วนของข้อมูลเกี่ยวกับสถานประกอบการ สามารถสรุปจากแบบสอบถามได้ดังนี้

(1) เงินลงทุน/ทุนจดทะเบียน

สถานประกอบการมีเงินลงทุน/ทุนจดทะเบียนตั้งแต่ 50-436 ล้านบาท โดยสถานประกอบการในกลุ่มตัวอย่างที่มีเงินลงทุน/ทุนจดทะเบียนต่ำกว่า 100 ล้านบาทมี 2 แห่ง และมีสถานประกอบการ 3 แห่งที่ไม่ได้ระบุเงินลงทุน/ทุนจดทะเบียน

(2) จำนวนปีที่มีการดำเนินธุรกิจนับจากเริ่มก่อตั้ง

สถานประกอบการที่มีการดำเนินธุรกิจมามากกว่า 30 ปี มี 6 แห่ง และสถานประกอบการที่มีการดำเนินธุรกิจน้อยกว่า 30 ปี มี 1 แห่ง และมีสถานประกอบการ 2 แห่งที่ไม่ได้ระบุจำนวนปีที่มีการดำเนินธุรกิจนับจากเริ่มก่อตั้ง

(3) ประเภทของสถานประกอบการ

สถานประกอบการในกลุ่มตัวอย่างทุกแห่งเป็นผู้ส่งออก โดยกลุ่มสถานประกอบการดังกล่าว มีสถานประกอบการที่เป็นทั้งผู้ผลิต ผู้นำเข้า ผู้ส่งออก ผู้จัดจำหน่ายส่ง จำนวน 3 แห่ง

(4) ร้อยละของลักษณะ/รูปแบบการผลิต

สถานประกอบการในกลุ่มตัวอย่าง 2 แห่ง ผลิตยาโดยมีตราสินค้าเป็นของตนเอง ร้อยละ 100 สถานประกอบการในกลุ่มตัวอย่าง 1 แห่ง ผลิตยาตามที่ลูกค้ากำหนด ร้อยละ 100 และสถานประกอบการในกลุ่มตัวอย่างอีก 2 แห่ง มีการผลิตยาทั้งแบบที่มีตราสินค้าเป็นของตนเองและการผลิตยาตามที่ลูกค้ากำหนด โดยมีสัดส่วนการผลิตยาแบบที่มีตราสินค้าเป็นของตนเองในสัดส่วนที่มากกว่า ทั้งนี้ มีสถานประกอบการในกลุ่มตัวอย่าง 2 แห่งที่ไม่ได้ระบุร้อยละของลักษณะ/รูปแบบการผลิต

(5) กำลังการผลิต

จากแบบสอบถาม พบว่า มีสถานประกอบการเพียง 3 แห่งที่ระบุกำลังการผลิต โดยผู้ประกอบการทั้งสามแห่งมีกำลังการผลิตมากกว่า 150 แรงม้า

(6) จำนวนคนงาน

สถานประกอบการในกลุ่มตัวอย่างมีจำนวนคนงานมากกว่า 500 คนจำนวน 3 แห่ง และมีสถานประกอบการในกลุ่มตัวอย่างที่มีจำนวนคนงานน้อยกว่า 500 คนจำนวน 3 แห่งเช่นกัน ส่วนสถานประกอบอีก 3 แห่งไม่ได้ระบุจำนวนคนงาน

(7) ประเภทผลิตภัณฑ์ยาที่สถานประกอบการดำเนินการผลิต หรือจัดจำหน่าย

สถานประกอบการแต่ละแห่งมีการดำเนินการผลิต หรือจัดจำหน่ายผลิตภัณฑ์ยาแตกต่างกัน โดยผลิตภัณฑ์ยาที่สถานประกอบการในกลุ่มตัวอย่างผลิต หรือจัดจำหน่าย ครอบคลุมถึงผลิตภัณฑ์ยาแผนปัจจุบันบรรจุเสร็จที่ไม่ใช่ยาอันตรายหรือยาควบคุมพิเศษ ยาสามัญประจำบ้านแผนปัจจุบัน ยาแผนปัจจุบันที่เป็นยาอันตราย ยาแผนปัจจุบันที่เป็นยาควบคุมพิเศษ ยาใช้เฉพาะ ยาสมุนไพรแผนโบราณ ยาแผนโบราณที่เป็นยาอันตราย ยาใหม่ และเภสัชเคมีภัณฑ์กึ่งสำเร็จรูป

(8) ประมาณการรายได้รวมของกิจการ

สถานประกอบการในกลุ่มตัวอย่างมีประมาณการรายได้รวมตั้งแต่ 11-3,500 ล้านบาทต่อปี โดยสถานประกอบการที่มีประมาณการรายได้รวมมากกว่า 1,000 ล้านบาทต่อปี มี 2 แห่ง

(9) การส่งออกผลิตภัณฑ์ยา

สถานประกอบการในกลุ่มตัวอย่างทุกแห่งมีการส่งออกผลิตภัณฑ์ยาไปต่างประเทศ เช่น ประเทศพม่า ประเทศฟิลิปปินส์ ประเทศลาว ประเทศเวียดนาม โดยสถานประกอบการที่มีการส่งออกผลิตภัณฑ์ยาไปยังประเทศเวียดนาม มี 7 แห่ง ประมาณการมูลค่าการส่งออกอยู่ที่ 0.5-133 ล้านบาทต่อปี โดยตัวอย่างผลิตภัณฑ์ยาที่มีการส่งออกไปประเทศเวียดนาม เช่น ยารักษาสิว ยาเม็ดคุมกำเนิด ยาลดความดันโลหิต ยานวดบรรเทาปวด ยาแก้ท้องอืด ยาคลายกล้ามเนื้อ และยาฆ่าเชื้อ

(10) แผนการขยายตลาดไปยังต่างประเทศ

สถานประกอบการในกลุ่มตัวอย่างทุกแห่งมีแผนที่จะขยายตลาดไปยังต่างประเทศ โดยเฉพาะกลุ่มประเทศสมาชิกอาเซียน ทั้งนี้ ผู้ประกอบการที่ในปัจจุบันมีการส่งออกผลิตภัณฑ์ยาไปยังประเทศเวียดนามอยู่แล้ว ได้มีแผนที่จะขยายตลาดในประเทศเวียดนามโดยการเพิ่มปริมาณการส่งออก รวมถึงการส่งออกผลิตภัณฑ์ยาประเภทอื่นหรือรูปแบบอื่น เช่น ยาแก้ท้องอืดซึ่งมีรสชาติหลากหลายมากขึ้น และยาฆ่าเชื้อที่มีระดับความรุนแรงหลายระดับ นอกจากนี้ ผู้ประกอบการ 2 แห่งที่ในปัจจุบันไม่ได้มีการส่งออกผลิตภัณฑ์ยาไปประเทศเวียดนาม มีแผนที่จะขยายตลาดไปยังประเทศเวียดนามเช่นกัน

(11) การตั้งโรงงานการผลิตในต่างประเทศ

สถานประกอบการในกลุ่มตัวอย่าง มีเพียง 1 แห่งที่มีการตั้งโรงงานการผลิตในต่างประเทศ คือประเทศเวียดนาม

(12) การลงทุนด้านการวิจัยและพัฒนา

สถานประกอบการในกลุ่มตัวอย่างจำนวน 7 แห่งมีการลงทุนด้านการวิจัยและพัฒนาหรือมีฝ่ายวิจัยและพัฒนา

4.2.2 กฎระเบียบที่เป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

(1) ขั้นตอนและเอกสารสำหรับประกอบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

จากการศึกษาข้อมูล ขั้นตอนและเอกสารสำหรับประกอบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ตามกฎระเบียบที่เกี่ยวข้อง แบ่งออกเป็น 3 ด้านหลัก กล่าวคือ

(1.1) การขึ้นทะเบียนผลิตภัณฑ์ ซึ่งแบ่งออกเป็น

- ข้อกำหนดเกี่ยวกับผู้ที่สามารถยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา
- ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยากรณียาแผนปัจจุบัน วัคซีน และยาชีวภาพ หรือยาสามัญ (generic drug)
- ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมกรณียาที่ผลิตภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี (pharmaceutical technology transfer) โดยยาต้นแบบ (source drug of transfer)
- ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์กรณียาสมุนไพร
- ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์กรณีวัตถุดิบเกี่ยวกับยา
- ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์กรณียาแผนโบราณ
- ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ
- ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมสำหรับยาต่างประเทศ

(1.2) การต่ออายุทะเบียนผลิตภัณฑ์ ซึ่งประกอบด้วยข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการต่ออายุทะเบียนผลิตภัณฑ์

(1.3) การแก้ไขทะเบียนผลิตภัณฑ์ ซึ่งประกอบด้วยข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการแก้ไขทะเบียนผลิตภัณฑ์

จากการสำรวจข้อมูลจากผู้ประกอบการเอกชน พบว่ารายการเอกสารที่ผู้ประกอบการต้องยื่นเพื่อประกอบคำขอดำเนินการต่าง ๆ โดยรวมสอดคล้องกับรายงานการศึกษานี้ แต่บางกรณีพบว่าเจ้าหน้าที่ที่ปฏิบัติงานของประเทศเวียดนามมีการเรียกเอกสารเกินกว่าข้อกำหนดในกฎระเบียบ เช่น มีการเรียกเอกสารการขึ้นทะเบียนผลิตภัณฑ์ยา (market authorization) ในประเทศอื่นอย่างน้อย 3 ประเทศ เพื่อแสดงว่าผลิตภัณฑ์ยาที่จะขึ้นทะเบียนในประเทศเวียดนามนั้นได้มีการวางจำหน่ายที่ประเทศใดแล้วบ้าง และเอกสารการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศอื่นดังกล่าวต้องเป็นต้นฉบับที่มีการรับรองโดยสถานทูต ไม่สามารถใช้สำเนาเอกสารได้

(2) การจัดลำดับกฎระเบียบที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

การจัดลำดับกฎระเบียบที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยา แบ่งออกเป็นอุปสรรคจากเนื้อหาของกฎระเบียบของประเทศเวียดนาม และอุปสรรคด้านขั้นตอนการขึ้นทะเบียนผลิตภัณฑ์ ดังนี้

(2.1) อุปสรรคจากเนื้อหาของกฎระเบียบของประเทศเวียดนาม

(2.1.1) อุปสรรคที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

ในการจัดลำดับข้อกฎหมายของประเทศเวียดนามที่เป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม แบบสอบถามในส่วนนี้จะระบุให้ผู้ประกอบการระบุความรุนแรงของอุปสรรคที่เกิดจากเนื้อหาของกฎระเบียบของประเทศเวียดนาม โดยแบ่งข้อกำหนดออกเป็นหมวดหมู่ตามข้อ 4.2.2(1) ข้างต้น และผู้วิจัยใช้วิธีการให้น้ำหนักคะแนน แบ่งเป็น 6 ระดับ คือ

ระดับคะแนน	หมายถึง
1	ผู้ประกอบการเห็นว่าไม่เป็นอุปสรรค
2	ผู้ประกอบการเห็นว่าเป็นอุปสรรคในระดับน้อยที่สุด
3	ผู้ประกอบการเห็นว่าเป็นอุปสรรคในระดับน้อย
4	ผู้ประกอบการเห็นว่าเป็นอุปสรรคในระดับปานกลาง
5	ผู้ประกอบการเห็นว่าเป็นอุปสรรคในระดับมาก
6	ผู้ประกอบการเห็นว่าเป็นอุปสรรคในระดับมากที่สุด

ผู้วิจัยใช้สูตรการคำนวณระดับการให้คะแนนค่าเฉลี่ย เพื่อนำมาวิเคราะห์อุปสรรคจากเนื้อหาของกฎระเบียบของประเทศเวียดนามในมุมมองของผู้ประกอบการและ จัดลำดับกฎระเบียบของประเทศเวียดนามที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ซึ่งจากผลการสำรวจข้อมูล สรุปได้ดังนี้

1) ในภาพรวม ผู้ประกอบการในกลุ่มตัวอย่างพบอุปสรรคใน**ระดับต่ำกว่าน้อย-น้อยที่สุด** จากข้อกำหนดดังต่อไปนี้

- ข้อกำหนดเกี่ยวกับผู้ที่สามารถยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา (2.9 คะแนน)

- ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ (2.8 คะแนน)

- ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์กรณียาแผนโบราณ (2.5 คะแนน)

ผู้ประกอบการในกลุ่มตัวอย่างพบอุปสรรคในระดับ**ต่ำกว่าปานกลาง-น้อย** จากข้อกำหนดดังต่อไปนี้

- ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมสำหรับยาต่างประเทศ (3.9 คะแนน) ทั้งนี้ เมื่อพิจารณาในรายละเอียดของข้อกำหนดย่อยที่เกี่ยวกับเอกสารเพิ่มเติมสำหรับยาต่างประเทศ พบว่า หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) เป็นอุปสรรคในระดับต่ำกว่ามาก-ปานกลาง (4.7 คะแนน) ซึ่งเป็นระดับที่สูงที่สุดเมื่อเทียบกับข้อกำหนดย่อยของข้อกำหนดในเรื่องอื่น ๆ ทั้งหมด

- ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมกรณียาที่ผลิตภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี (pharmaceutical technology transfer) โดยยาต้นแบบ (source drug of transfer) (3.8 คะแนน)

- ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการต่ออายุทะเบียนผลิตภัณฑ์ (3.7 คะแนน)

- ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการแก้ไขทะเบียนผลิตภัณฑ์ (3.6 คะแนน)

- ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยากรณียาแผนปัจจุบัน วัคซีน และยาชีวภาพ หรือยาสามัญ (generic drug) (3.5 คะแนน) ทั้งนี้ แม้ว่าโดยภาพรวมข้อกำหนดเกี่ยวกับรายการเอกสารนี้ จะถือเป็นอุปสรรคในระดับต่ำ

กว่าปานกลาง-น้อย แต่เมื่อพิจารณาในรายละเอียดของข้อกำหนดย่อยที่เกี่ยวกับรายการเอกสารที่ใช้ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยากรณียาแผนปัจจุบัน วัคซีน และยาชีวภาพ หรือยาสามัญ (generic drug) พบว่า ผลการศึกษาทางคลินิก (clinical document) และเอกสารรับรองแหล่งที่มาของวัตถุดิบ (certificate of patent of paper proving the origin of raw material) เป็นอุปสรรคในระดับต่ำกว่ามาก-ปานกลาง (4.5 คะแนน และ 4.2 คะแนน ตามลำดับ) ซึ่งเป็นระดับที่สูงเป็นอันดับ 2 และ 3 เมื่อเทียบกับข้อกำหนดย่อยของข้อกำหนดในเรื่องอื่น ๆ ทั้งหมด

- ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์กรณียาสมุนไพร (3.1 คะแนน)

- ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์กรณีวัตถุดิบเกี่ยวกับยา (3.1 คะแนน)

2) จากข้อมูลข้างต้นสามารถจัดลำดับกฎระเบียบของประเทศเวียดนามที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามได้ดังนี้

อุปสรรคลำดับที่ 1 ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมสำหรับยาต่างประเทศ (3.9 คะแนน)

อุปสรรคลำดับที่ 2 ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมกรณียาที่ผลิตภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี (pharmaceutical technology transfer) โดยยาต้นแบบ (source drug of transfer) (3.8 คะแนน)

อุปสรรคลำดับที่ 3 ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการต่ออายุทะเบียนผลิตภัณฑ์ (3.7 คะแนน)

ทั้งนี้ ในบรรดาข้อกำหนดย่อยของทุกข้อกำหนด ประเด็นที่เป็นอุปสรรคต่อผู้ประกอบการเอกชนมากที่สุด คือ หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) ซึ่งอยู่ในส่วนของข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมสำหรับยาต่างประเทศ โดยผู้ประกอบการในกลุ่มตัวอย่างให้ข้อมูลเพิ่มเติมว่า การที่ประเทศเวียดนามกำหนด CPP ที่มีรายละเอียดแตกต่างจาก CPP ตามข้อกำหนดของ WHO หรือของประเทศไทย ทำให้ประเทศเวียดนามไม่ยอมรับ CPP ที่ผู้ประกอบการไทยยื่นเพื่อประกอบการคำขอขึ้นทะเบียนผลิตภัณฑ์ยาหรือคำขอต่ออายุทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม หรือการดำเนินการในเรื่องอื่น ๆ ที่จำเป็นต้องยื่น CPP ประกอบ

3) นอกจากนี้ ผู้ประกอบการในกลุ่มตัวอย่างมีความเห็นเพิ่มเติมว่า หากเป็นเอกสารที่ออกโดยหน่วยงานรัฐต่างประเทศ เช่น GMP certificate และ CPP ต้องมีการรับรองต้นฉบับเอกสาร (consular legalization) โดยสถานทูตเวียดนามในประเทศไทยทุกครั้งที่ผู้ประกอบการประสงค์จะ

ยื่นเอกสารดังกล่าวให้แก่กระทรวงสาธารณสุขของประเทศเวียดนามเพื่อประกอบการพิจารณาคำขอ ซึ่งทำให้เกิดค่าใช้จ่ายจำนวนมาก และทำให้กระบวนการขึ้นทะเบียนผลิตภัณฑ์ล่าช้าเนื่องจากการรับรองเอกสารใช้เวลานาน

(2.1.2) อุปสรรคที่เกี่ยวข้องกับช่องทางการจำหน่ายผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยา: การประกวดราคาในการจัดซื้อยาของภาครัฐ

นอกเหนือจากกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามข้างต้นแล้ว ผู้ประกอบการในกลุ่มตัวอย่างเห็นว่า อุปสรรคที่สำคัญอีกประการหนึ่งที่เกิดจากเนื้อหากฎระเบียบของประเทศเวียดนาม คือ กฎระเบียบที่เกี่ยวข้องกับการประกวดราคาในการจัดซื้อยาของภาครัฐหรือที่ใช้งบประมาณจากภาครัฐ ซึ่งจะกระทบต่อความสามารถในการแข่งขันของผลิตภัณฑ์ยาของประเทศไทยในการวางจำหน่ายหรือทำตลาดผลิตภัณฑ์ยาในประเทศเวียดนาม เนื่องจากกฎระเบียบของประเทศเวียดนามที่เพิ่งออกบังคับใช้เมื่อปลายปี 2562 มีการแบ่งกลุ่มผลิตภัณฑ์ยาที่มีเงื่อนไขแตกต่างจากกฎระเบียบฉบับเดิม โดยกำหนดว่าในการประกวดราคายาสามัญ ให้แบ่งกลุ่มยาสามัญออกเป็น 5 กลุ่ม โดยกลุ่มที่ 1 จะเป็นกลุ่มยาที่มีมาตรฐานตาม EU-GMP กลุ่มที่ 2 จะเป็นกลุ่มยาที่มีมาตรฐานตาม EU-GMP หรือยาที่ผลิตในประเทศที่เป็นสมาชิก PIC/S และสมาชิก ICH ซึ่งได้รับการประเมินว่ายามีมาตรฐานตาม PIC/S-GMP กลุ่มที่ 3 จะเป็นกลุ่มยาที่มีการผลิตสอดคล้องกับมาตรฐาน GMP และมีผลการศึกษาชีวสมมูลเผยแพร่โดยกระทรวงสาธารณสุขของประเทศเวียดนาม กลุ่มที่ 4 จะเป็นกลุ่มยาที่ผลิตในประเทศเวียดนามและมีมาตรฐาน WHO-GMP และกลุ่มที่ 5 จะเป็นยาที่มีมาตรฐาน WHO-GMP พร้อมทั้ง กำหนดว่ายาที่เข้าคุณสมบัติของแต่ละกลุ่ม สามารถประกวดราคาแข่งกับกลุ่มใดได้บ้าง

การกำหนดแบ่งกลุ่มใหม่ในลักษณะดังกล่าว ทำให้จากเดิมที่ผลิตภัณฑ์ยาของประเทศไทยสามารถเข้าร่วมประกวดราคาในกลุ่มที่ 2 ได้ เนื่องจากเป็นผลิตภัณฑ์ยาที่เป็นไปตามมาตรฐาน PIC/S-GMP จะตกลงมาอยู่ที่กลุ่มที่ 5 ซึ่งมีราคาต่ำมาก เนื่องจากประเทศไทยไม่ได้เป็นสมาชิก ICH

(2.2) อุปสรรคด้านขั้นตอนการขึ้นทะเบียนผลิตภัณฑ์

อุปสรรคด้านขั้นตอนการขึ้นทะเบียนผลิตภัณฑ์แบ่งออกเป็น 6 ประการ ได้แก่ 1) ความไม่แน่นอนของการบังคับใช้กฎระเบียบ 2) ข้อมูลเกี่ยวกับกฎระเบียบที่ยังไม่ได้รับการตีพิมพ์หรือเผยแพร่อย่างเพียงพอ 3) กฎระเบียบมักไม่จัดทำเป็นภาษาอังกฤษ 4) เอกสารยากแก่การกรอก 5) การปฏิบัติงานของเจ้าหน้าที่ที่เกี่ยวข้องไม่แน่นอน และ 6) ความล่าช้าในการดำเนินการของเจ้าหน้าที่ที่เกี่ยวข้อง

ผู้วิจัยนำมาจัดลำดับอุปสรรคด้านขั้นตอนการขึ้นทะเบียนผลิตภัณฑ์ โดยใช้วิธีการให้น้ำหนักคะแนนแบ่งเป็น 6 ระดับ คือ

ระดับคะแนน	หมายถึง
1	ผู้ประกอบการเห็นว่าไม่เป็นอุปสรรค
2	ผู้ประกอบการเห็นว่าเป็นอุปสรรคในระดับน้อยที่สุด
3	ผู้ประกอบการเห็นว่าเป็นอุปสรรคในระดับน้อย
4	ผู้ประกอบการเห็นว่าเป็นอุปสรรคในระดับปานกลาง
5	ผู้ประกอบการเห็นว่าเป็นอุปสรรคในระดับมาก
6	ผู้ประกอบการเห็นว่าเป็นอุปสรรคในระดับมากที่สุด

ผู้วิจัยใช้สูตรการคำนวณระดับการให้คะแนนค่าเฉลี่ย เพื่อนำมาประกอบการจัดลำดับกฎระเบียบของประเทศเวียดนามที่อาจเป็นอุปสรรค ซึ่งจากผลการสำรวจข้อมูล สามารถจัดลำดับได้ดังนี้

อุปสรรคลำดับที่ 1 ความไม่แน่นอนของการบังคับใช้กฎระเบียบ (5 คะแนน)

อุปสรรคลำดับที่ 2 กฎระเบียบมักไม่จัดทำเป็นภาษาอังกฤษ (4.8 คะแนน) และความล่าช้าในการดำเนินการของเจ้าหน้าที่ที่เกี่ยวข้อง (4.8 คะแนน)

อุปสรรคลำดับที่ 3 ข้อมูลเกี่ยวกับกฎระเบียบที่ยังไม่ได้รับการตีพิมพ์หรือเผยแพร่อย่างเพียงพอ (4.3 คะแนน)

ทั้งนี้ ผู้ประกอบการให้ความเห็นเพิ่มเติมว่า ในขั้นตอนการตรวจเอกสารเจ้าหน้าที่แต่ละคนมีการตีความข้อกำหนดที่แตกต่างกัน ส่งผลให้เกิดปัญหาในทางปฏิบัติเนื่องจากการพิจารณาคำขอต่าง ๆ และเอกสารที่ต้องใช้ยื่นประกอบการพิจารณาจะขึ้นอยู่กับดุลพินิจของเจ้าหน้าที่แต่ละคน และในการพิจารณาอนุมัติคำขอในเรื่องต่าง ๆ เจ้าหน้าที่ที่เกี่ยวข้องจะใช้เวลาดำเนินนานกว่าระยะเวลาที่กำหนดตามกฎระเบียบ โดยในบางกรณีเจ้าหน้าที่ใช้เวลาพิจารณาถึง 2-3 ปีก่อนที่จะอนุมัติคำขอ

นอกจากนี้ ในการติดต่อประสานงานกับเจ้าหน้าที่ของประเทศเวียดนามมักพบอุปสรรคด้านภาษาเนื่องจากเจ้าหน้าที่ไม่สามารถสื่อสารภาษาอังกฤษได้ ดังนั้น ผู้ประกอบการไทยจึงจำเป็นที่จะต้องหาตัวแทนจำหน่ายที่สามารถสื่อสารภาษาอังกฤษได้ เพื่อช่วยดำเนินการด้านเอกสาร

4.2.3 ข้อมูลด้านความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุน

ในการศึกษาข้อมูลด้านความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุน ผู้วิจัยได้ระบุประเด็นความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุนในแบบสอบถาม 8 ประการ ได้แก่ 1) การให้ความช่วยเหลือด้านการถ่ายทอดเทคโนโลยี เช่น การจัดอบรม 2) การจัดทำคู่มือเกณฑ์ความตกลงอาเซียนที่เข้าใจง่าย และสามารถนำไปปฏิบัติได้จริง 3) การจัดทำสรุปข้อกฎหมายของกลุ่มประเทศสมาชิกอาเซียนที่เกี่ยวกับผลิตภัณฑ์ยา 4) การจัดศึกษาดูงานด้านผลิตภัณฑ์ยาของกลุ่มประเทศสมาชิกอาเซียน 5) การสนับสนุนด้าน

การวิจัยพัฒนาผลิตภัณฑ์ ทั้งในรูปตัวเงิน และไม่เป็นตัวเงิน 6) การกำหนดมาตรการด้านแรงจูงใจ อาทิ มาตรการลดหย่อนภาษี 7) การจัดหาแหล่งเงินทุนในอัตราดอกเบี้ยต่ำ และ 8) ส่งเสริมภาพลักษณ์ และความน่าเชื่อถือในคุณภาพ และมาตรฐานของผลิตภัณฑ์ส่งออกของประเทศไทย

แบบสอบถามในส่วนนี้จะกำหนดให้ผู้ประกอบการจัดลำดับประเด็นความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุน และผู้วิจัยใช้วิธีการให้น้ำหนักคะแนน แบ่งเป็น 9 ระดับ คือ

ระดับคะแนน	หมายถึง
1	ผู้ประกอบการต้องการ แต่ไม่ได้จัดลำดับ
2	ผู้ประกอบการจัดลำดับเป็นความต้องการลำดับที่ 8
3	ผู้ประกอบการจัดลำดับเป็นความต้องการลำดับที่ 7
4	ผู้ประกอบการจัดลำดับเป็นความต้องการลำดับที่ 6
5	ผู้ประกอบการจัดลำดับเป็นความต้องการลำดับที่ 5
6	ผู้ประกอบการจัดลำดับเป็นความต้องการลำดับที่ 4
7	ผู้ประกอบการจัดลำดับเป็นความต้องการลำดับที่ 3
8	ผู้ประกอบการจัดลำดับเป็นความต้องการลำดับที่ 2
9	ผู้ประกอบการจัดลำดับเป็นความต้องการลำดับที่ 1

ผู้วิจัยใช้สูตรการคำนวณระดับการให้คะแนนค่าเฉลี่ย เพื่อนำมาประกอบการจัดลำดับความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุน ซึ่งจากผลการสำรวจข้อมูล สามารถจัดลำดับได้ดังนี้

ความต้องการลำดับที่ 1 การจัดทำสรุปข้อกฎหมายของกลุ่มประเทศสมาชิกอาเซียนที่เกี่ยวกับผลิตภัณฑ์ยา (6.8 คะแนน)

ความต้องการลำดับที่ 2 การกำหนดมาตรการด้านแรงจูงใจ อาทิ มาตรการลดหย่อนภาษี (6.2 คะแนน)

ความต้องการลำดับที่ 3 ส่งเสริมภาพลักษณ์ และความน่าเชื่อถือในคุณภาพ และมาตรฐานของผลิตภัณฑ์ส่งออกของประเทศไทย (5.9 คะแนน)

ความต้องการลำดับที่ 4 การจัดทำคู่มือเกณฑ์ความตกลงอาเซียนที่เข้าใจง่าย และสามารถนำไปปฏิบัติได้จริง (5.8 คะแนน)

ความต้องการลำดับที่ 5 การให้ความช่วยเหลือด้านการถ่ายทอดเทคโนโลยี เช่น การจัดอบรม (5.4 คะแนน)

ความต้องการลำดับที่ 6 การจัดศึกษาดูงานด้านผลิตภัณฑ์ยาของกลุ่มประเทศสมาชิกอาเซียน (5 คะแนน)

ความต้องการลำดับที่ 7 การสนับสนุนด้านการวิจัยพัฒนาผลิตภัณฑ์ ทั้งในรูปตัวเงิน และไม่เป็นตัวเงิน (4.5 คะแนน)

ความต้องการลำดับที่ 8 การจัดหาแหล่งเงินทุนในอัตราดอกเบี้ยต่ำ (4.3 คะแนน)

นอกจากนี้ ผู้ประกอบการในกลุ่มตัวอย่างมีความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุนให้สถานประกอบการมีความสามารถในการส่งออกสินค้าในประเด็นเพิ่มเติมใน 3 ประเด็น ได้แก่

1) การให้ อย. หรือหน่วยงานรัฐอื่นที่เกี่ยวข้อง เจรจาหรือชี้แจงกับทางกระทรวงสาธารณสุขของประเทศเวียดนามเพื่อให้ยอมรับ CPP ตามข้อกำหนดของ WHO หรือของประเทศไทย เนื่องจากภายในระยะเวลาอันใกล้นี้ จะมีผลิตภัณฑ์ยาที่ต้องต่ออายุทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามหลายรายการ และในการยื่นคำขอต่ออายุทะเบียนผลิตภัณฑ์ยานั้น จำเป็นต้องยื่น CPP ประกอบคำขอด้วย ดังนั้น ในกรณีที่กระทรวงสาธารณสุขของประเทศเวียดนามไม่ยอมรับ CPP ตามข้อกำหนดของ WHO หรือของประเทศไทย ย่อมส่งผลกระทบเชิงลบต่อการค้าของผู้ประกอบการไทยเป็นอย่างมาก

2) การให้หน่วยงานภาครัฐของประเทศไทยเจรจากับหน่วยงานภาครัฐของประเทศเวียดนามเพื่อให้มีการยอมรับผลิตภัณฑ์ยาของประเทศไทยที่เป็นไปตามมาตรฐาน PIC/S-GMP ให้สามารถเข้าร่วมประกวดราคาผลิตภัณฑ์ยาในกลุ่มที่ 2 เทียบเท่าผลิตภัณฑ์ยาที่เป็นไปตามมาตรฐาน EU-GMP หรือยาที่ผลิตในประเทศสมาชิก PIC/S และประเทศสมาชิก ICH ที่เป็นไปตามมาตรฐาน PIC/S-GMP ได้

3) การให้หน่วยงานภาครัฐของประเทศไทยเจรจากับหน่วยงานภาครัฐของประเทศเวียดนามเพื่อยกเว้นการรับรองเอกสารต้นฉบับที่ต้องใช้ดำเนินการต่าง ๆ ที่เกี่ยวข้องกับการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยา เพื่อลดค่าใช้จ่ายของผู้ประกอบการและลดขั้นตอน/ระยะเวลาในการดำเนินการที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยา ตัวอย่างเช่น ในกรณี GMP certificate นั้น หน่วยงานภาครัฐของประเทศไทยอาจทำข้อตกลงหรือสร้างช่องทางให้หน่วยงานภาครัฐของประเทศเวียดนามสามารถตรวจสอบสถานะของผู้ผลิตผ่านทางเว็บไซต์ได้ โดยการใช้ official user/password แทนการใช้เอกสารต้นฉบับหรือการรับรองเอกสารต้นฉบับ

4.2.4 ประเด็นปัญหา อุปสรรค และข้อเสนอแนะ

ในภาพรวมผู้ประกอบการในกลุ่มตัวอย่างเห็นว่าอุปสรรคในการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามเกิดขึ้นจากทั้งเนื้อหาของกฎระเบียบของประเทศเวียดนามเอง และขั้นตอนในการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม โดยอุปสรรคสำคัญที่ผู้ประกอบการในกลุ่มตัวอย่างประสงค์จะให้

อย. เร่งแก้ไขปัญหามากที่สุดคือ เรื่อง CPP ที่ประเทศเวียดนามมีการกำหนดรายละเอียดใน CPP แตกต่างจาก CPP ตามข้อกำหนดของ WHO หรือของประเทศไทย

บทที่ 5

สรุป และข้อเสนอแนะ

5.1 สรุป

รายงานการศึกษากฎระเบียบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามฉบับนี้ เป็นส่วนหนึ่งของแผนการดำเนินงานที่จัดทำโดยกองแผนงานและวิชาการ อย. เพื่อส่งเสริมผู้ประกอบการแบบมุ่งเป้าเพื่อสนับสนุนผลิตภัณฑ์ยาของประเทศไทยให้สามารถแข่งขันได้ในตลาดต่างประเทศ ซึ่งแผนการดำเนินงานดังกล่าวสอดคล้องกับยุทธศาสตร์ที่ 3 ของ อย. ที่มุ่งพัฒนางานบริการสู่ความเป็นเลิศและให้ผู้ประกอบการมีความสามารถในการแข่งขัน กลยุทธ์ที่ 2 พัฒนาศักยภาพและเตรียมความพร้อมผู้ประกอบการรองรับกฎระเบียบใหม่และส่งเสริมการส่งออก โดยรายงานฉบับนี้มีวัตถุประสงค์หลัก คือ การศึกษากฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม การจัดลำดับข้อกฎหมายที่เป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยา และระบุข้อเสนอแนะในการแก้ไขปัญหา

จากการศึกษาข้อมูลกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม พบว่า กฎหมายหลักที่กำกับดูแลผลิตภัณฑ์ยาในประเทศเวียดนาม คือกฎหมายว่าด้วยเภสัชกรรม (Law on Pharmacy No. 105/2016/QH13) ซึ่งมีผลบังคับใช้ตั้งแต่วันที่ 1 มกราคม 2560 โดยในการกำหนดรายละเอียดเพิ่มเติมเกี่ยวกับผลิตภัณฑ์ยาในประเทศเวียดนามนั้น รัฐบาลและกระทรวงสาธารณสุขได้ออกกฎหมายลำดับรองในรูปแบบกฤษฎา (Decree) และในรูปหนังสือเวียน (Circular) อีกหลายฉบับ โดยอาศัยอำนาจตามกฎหมายว่าด้วยเภสัชกรรมดังกล่าว

ภายใต้กฎระเบียบของประเทศเวียดนาม ยาและวัตถุดิบเกี่ยวกับยาที่ไม่เคยขึ้นทะเบียนในประเทศเวียดนาม หรือเคยขึ้นทะเบียนในประเทศเวียดนามมาก่อนแต่มีการเปลี่ยนแปลงส่วนผสม วัตถุดิบ รูปแบบการจัดเตรียม หรือผู้ผลิต จะต้องได้รับการขึ้นทะเบียนจากกระทรวงสาธารณสุขก่อนการวาง จำหน่ายในประเทศเวียดนาม ซึ่งเมื่อพิจารณาข้อกำหนดเกี่ยวกับการขึ้นทะเบียนผลิตภัณฑ์ยาที่แบ่งตามประเภทของยาออกเป็น 1) ข้อกำหนดเกี่ยวกับผู้ที่สามารถยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา 2) ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยากรณียาแผนปัจจุบัน วัคซีน และยาชีวภาพ หรือยาสามัญ (generic drug) 3) ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมกรณียาที่ผลิตภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี (pharmaceutical technology transfer) โดยยาต้นแบบ (source drug of transfer) 4) ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์กรณียาสมุนไพร 5) ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์กรณีวัตถุดิบเกี่ยวกับยา 6) ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์กรณียาแผนโบราณ 7) เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ และ 8) เอกสาร

เพิ่มเติมสำหรับยาต่างประเทศ รวมถึงข้อกำหนดเกี่ยวกับการต่ออายุทะเบียนผลิตภัณฑ์ยา และข้อกำหนดเกี่ยวกับการแก้ไขทะเบียนผลิตภัณฑ์ยา เห็นได้ว่า การออกกฎระเบียบของประเทศเวียดนามก่อให้เกิดอุปสรรคที่สำคัญต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามของผู้ประกอบการไทยเนื่องจากมีหลักเกณฑ์และกระบวนการที่ยุ่งยากซับซ้อนในการขึ้นทะเบียนและวางจำหน่ายผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยามากยิ่งขึ้น เช่น กรณีการขึ้นทะเบียนหรือต่ออายุทะเบียนผลิตภัณฑ์ยาต่างประเทศ ผู้ประกอบการจะต้องยื่นหนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) ซึ่งมีรายละเอียดตามที่กระทรวงสาธารณสุขของประเทศเวียดนามกำหนด ซึ่งจะแตกต่างจากรายละเอียดของ CPP ตามข้อกำหนดของ WHO หรือของประเทศไทย

ทั้งนี้ จากการสำรวจข้อมูลจากผู้บริหารของ อย. และผู้ประกอบการเอกชน สามารถจัดลำดับกฎระเบียบที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามได้ ดังนี้

1) **อุปสรรคด้านเนื้อหาของกฎระเบียบ** โดย**อุปสรรคลำดับที่ 1** คือ ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมสำหรับยาต่างประเทศ **อุปสรรคลำดับที่ 2** คือ ข้อกำหนดเกี่ยวกับเอกสารเพิ่มเติมกรณียาที่ผลิตภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี (pharmaceutical technology transfer) โดยยาต้นแบบ (source drug of transfer) และ**อุปสรรคลำดับที่ 3** คือ ข้อกำหนดเกี่ยวกับรายการเอกสารที่ใช้ประกอบการต่ออายุทะเบียนผลิตภัณฑ์

นอกจากนี้ ผู้ประกอบการเอกชนมีความเห็นเพิ่มเติมว่า อุปสรรคที่สำคัญอีกประการหนึ่งที่เกิดจากเนื้อหากฎระเบียบของประเทศเวียดนาม นอกเหนือจากกฎระเบียบที่เกี่ยวข้องกับขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามข้างต้น คือ กฎระเบียบที่เกี่ยวข้องกับการประกวดราคาในการจัดซื้อยาของภาครัฐหรือที่ใช้งบประมาณจากภาครัฐ ซึ่งมีการแบ่งกลุ่มผลิตภัณฑ์ยาโดยให้ความสำคัญกับยาที่เป็นไปตามมาตรฐาน EU-GMP หรือยาที่ผลิตโดยสมาชิก PIC/S และสมาชิก ICH หรือยาที่ผลิตในประเทศเวียดนามมากกว่ายาที่ผลิตตามมาตรฐานอื่นหรือผลิตโดยประเทศอื่น

2) **อุปสรรคด้านขั้นตอนการขึ้นทะเบียนผลิตภัณฑ์** โดย**อุปสรรคลำดับที่ 1** คือ ความไม่แน่นอนของการบังคับใช้กฎระเบียบ **อุปสรรคลำดับที่ 2** คือ กฎระเบียบมักไม่จัดทำเป็นภาษาอังกฤษ และความล่าช้าในการดำเนินการของเจ้าหน้าที่ที่เกี่ยวข้อง และ**อุปสรรคลำดับที่ 3** คือ ข้อมูลเกี่ยวกับกฎระเบียบที่ยังไม่ได้รับการตีพิมพ์หรือเผยแพร่อย่างเพียงพอ

ในส่วนของความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุนนั้น ผู้ประกอบการประสงค์จะได้รับความช่วยเหลือหรือสนับสนุนจากภาครัฐ ดังนี้ **ความต้องการลำดับที่ 1** คือ การจัดทำสรุปข้อกฎหมายของกลุ่มประเทศสมาชิกอาเซียนที่เกี่ยวกับผลิตภัณฑ์ยา **ความต้องการลำดับที่ 2** คือ การกำหนดมาตรการด้านแรงจูงใจ อาทิ มาตรการลดหย่อนภาษี **ความต้องการลำดับที่ 3** คือ การส่งเสริมภาพลักษณ์ และความน่าเชื่อถือในคุณภาพ และมาตรฐานของผลิตภัณฑ์ส่งออกของประเทศไทย **ความต้องการลำดับที่ 4** คือ การจัดทำคู่มือเกณฑ์ความตกลงอาเซียนที่เข้าใจง่าย และสามารถนำไปปฏิบัติได้จริง **ความต้องการลำดับที่ 5**

คือ การให้ความช่วยเหลือด้านการถ่ายทอดเทคโนโลยี เช่น การจัดอบรม **ความต้องการลำดับที่ 6** คือ การจัดศึกษาดูงานด้านผลิตภัณฑ์ยาของกลุ่มประเทศสมาชิกอาเซียน **ความต้องการลำดับที่ 7** คือ การสนับสนุนด้านการวิจัยพัฒนาผลิตภัณฑ์ ทั้งในรูปตัวเงิน และไม่เป็นตัวเงิน และ**ความต้องการลำดับที่ 8** คือ การจัดหาแหล่งเงินทุนในอัตราดอกเบี้ยต่ำ

5.2 ข้อเสนอแนะเพื่อนำไปใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาของภูมิภาคอาเซียน

จากการศึกษาข้อมูลกฎระเบียบของประเทศเวียดนาม รวมถึงผลการวิเคราะห์กฎระเบียบที่อาจเป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม พร้อมทั้งผลการศึกษาที่ได้จากการสำรวจข้อมูลจากผู้บริหาร อย. และผู้ประกอบการภาคเอกชน นำไปสู่ข้อเสนอแนะเพื่อใช้ประกอบการวางแผนแก้ไขปัญหาในเวทีการเจรจาของภูมิภาคอาเซียนได้ดังนี้

(1) ความร่วมมือระหว่างหน่วยงานภาครัฐ

หน่วยงานภาครัฐที่เกี่ยวข้องกับการส่งออกผลิตภัณฑ์ยาไปยังต่างประเทศมีหลายหน่วยงาน และแต่ละหน่วยงานมีบทบาทหน้าที่ภายใต้ภารกิจตามกฎหมายและพันธกิจที่แตกต่างกัน โดยจากการสืบค้นข้อมูลพบว่า อย. มีบทบาทหน้าที่หลักในการคุ้มครองผู้บริโภค และบทบาทหน้าที่รองในการส่งเสริมผู้ประกอบการด้านผลิตภัณฑ์สุขภาพ ส่วนกรมเจรจาสังกัดกระทรวงการต่างประเทศ มีบทบาทหน้าที่หลักในการเจรจาขยายโอกาสทางเศรษฐกิจและการค้าอย่างเป็นรูปธรรม และกรมส่งเสริมการค้าระหว่างประเทศสังกัดกระทรวงพาณิชย์ มีบทบาทหน้าที่หลักในการส่งเสริมการส่งออก ขยายตลาดสินค้าและธุรกิจบริการของไทย พัฒนาและสร้างมูลค่าเพิ่มของสินค้าและธุรกิจบริการส่งออก และเพิ่มศักยภาพการแข่งขันของผู้ประกอบการไทยในตลาดโลก เพื่อเพิ่มมูลค่าและปริมาณการส่งออกของประเทศไทย

ดังนั้น ในการส่งเสริมการส่งออกผลิตภัณฑ์ยาของประเทศไทยไปยังต่างประเทศนั้น ต้องอาศัยความร่วมมือระหว่างหน่วยงานภาครัฐ เช่น อย. ควรร่วมมือกับกระทรวงการต่างประเทศ และกระทรวงพาณิชย์ ให้มีการแลกเปลี่ยนข้อมูลระหว่างกันเพื่อสนับสนุนการส่งออกและวางแผนการเจรจาด้านการส่งออกผลิตภัณฑ์ยาไปยังต่างประเทศโดยเฉพาะกลุ่มประเทศสมาชิกอาเซียน หรืออาจพิจารณาตั้งคณะทำงานกลุ่มย่อยขึ้นเพื่อพิจารณาประเด็นอุปสรรคทางการค้าที่สำคัญ

นอกจากนี้ อย. ควรมีการเจรจากับหน่วยงานภาครัฐของประเทศเวียดนามเพื่อลดอุปสรรคที่เกิดขึ้นจากกฎระเบียบต่าง ๆ เช่น การเจรจาเพื่อให้กระทรวงสาธารณสุขของประเทศเวียดนามยอมรับ CPP ที่มีรายละเอียดตามข้อกำหนดของ WHO หรือของประเทศไทยด้วย รวมถึงควรมีการเจรจาเพื่อกำหนดมาตรการจูงใจหรือสิทธิพิเศษทางการค้าต่าง ๆ เพื่อจูงใจให้ผู้ประกอบการไทยส่งออกสินค้าไปยังประเทศเวียดนามมากยิ่งขึ้น เช่น การลดอัตราการจัดเก็บภาษีมูลค่าสำหรับผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยาซึ่งปัจจุบันประเทศเวียดนามมีการจัดเก็บในอัตราร้อยละ 5 และการลดอัตราการจัดเก็บภาษีเงินได้นิติบุคคลที่ปัจจุบันประเทศเวียดนามมีการจัดเก็บในอัตราร้อยละ 20

อย่างไรก็ดี สำหรับประเด็นการจัดซื้อยาของภาครัฐนั้น การเจรจาให้ประเทศเวียดนามปรับแก้กฎระเบียบคงเป็นไปได้ยาก ดังนั้น อย. และหน่วยงานภาครัฐที่เกี่ยวข้องจึงควรมุ่งเน้นที่การพัฒนาศักยภาพของผู้ประกอบการไทยเพื่อให้สามารถคิดค้นหรือผลิตยานวัตกรรมใหม่ ๆ หรือยกระดับอุตสาหกรรมยาในประเทศไทย ซึ่งจะช่วยทำให้ผลิตภัณฑ์ยาของประเทศไทยมีมูลค่าสูงขึ้นและสามารถแข่งขันในประเทศเวียดนามได้ดียิ่งขึ้น นอกจากนี้ การพัฒนาศักยภาพของผู้ประกอบการไทยยังเป็นการเตรียมความพร้อมรองรับการเข้าเป็นสมาชิก ICH ด้วย เนื่องจากในปัจจุบัน ประเทศไทยเป็นสมาชิก PIC/S แล้ว แต่ยังเป็นเพียง ICH observer เนื่องจากทาง อย. เห็นว่าผู้ประกอบการของประเทศไทยไม่มีความพร้อมที่จะปฏิบัติตามข้อกำหนดหรือมาตรฐานต่าง ๆ ที่ต้องถือปฏิบัติเมื่อประเทศไทยเข้าเป็นสมาชิก ICH แล้ว จึงยังไม่เห็นควรให้ประเทศไทยเข้าเป็นสมาชิก ICH

(2) การจัดทำคู่มือการขึ้นทะเบียนผลิตภัณฑ์

จากการสำรวจข้อมูลจากผู้ประกอบการเอกชน พบว่าอุปสรรคในการขึ้นทะเบียนผลิตภัณฑ์ยา 3 ลำดับแรก คือ ความไม่แน่นอนของการบังคับใช้กฎระเบียบ กฎระเบียบมักไม่จัดทำเป็นภาษาอังกฤษ และความล่าช้าในการดำเนินการของเจ้าหน้าที่ที่เกี่ยวข้อง และข้อมูลเกี่ยวกับกฎระเบียบที่ยังไม่ได้รับการตีพิมพ์หรือเผยแพร่อย่างเพียงพอ ดังนั้น อย. จึงควรมีการเจรจาหรือขอความร่วมมือให้ประเทศสมาชิกอาเซียนแต่ละประเทศมีการจัดทำคู่มือการขึ้นทะเบียนผลิตภัณฑ์ยา ซึ่งระบุถึงขั้นตอนและเอกสารที่ต้องใช้ประกอบ รวมถึงข้อกำหนดในกฎระเบียบที่ชัดเจนและเข้าใจง่ายเป็นภาษาอังกฤษ เพื่อเผยแพร่แก่ผู้ประกอบการในกลุ่มประเทศสมาชิกผ่านทางเว็บไซต์ เพื่อเป็นการส่งเสริมความรู้ และความเข้าใจในการดำเนินธุรกิจภายใต้กฎระเบียบ รวมถึงควรมีการแลกเปลี่ยนข้อมูลด้านการออกหรือปรับปรุงกฎระเบียบที่เกี่ยวข้องกับผลิตภัณฑ์ยาอยู่เป็นระยะ เพื่อช่วยลดอุปสรรคด้านระยะเวลาในการศึกษากฎระเบียบต่าง ๆ และลดข้อจำกัดทางด้านภาษาของผู้ประกอบการและเจ้าหน้าที่ของหน่วยงานภาครัฐเอง

นอกจากนี้ อย. อาจพิจารณาจัดทำระบบสารสนเทศและฐานข้อมูลที่จำเป็นและเข้าถึงได้ง่ายสำหรับผู้ประกอบการ เพื่อให้สามารถศึกษาข้อมูลเบื้องต้นที่เกี่ยวกับการขึ้นทะเบียนผลิตภัณฑ์ยาในต่างประเทศได้

(3) การสนับสนุนด้านวิจัยและพัฒนา

ควรมีการสนับสนุนให้มีความร่วมมือด้านการวิจัยและพัฒนาเทคโนโลยี และแลกเปลี่ยนความรู้ด้านเทคโนโลยีใหม่ ๆ ระหว่างกลุ่มประเทศสมาชิก โดยเฉพาะที่เกี่ยวข้องกับการผลิตยานวัตกรรม เพื่อส่งเสริมศักยภาพของผู้ประกอบการ

(4) การพัฒนาศักยภาพทีมเจรจาด้านต่างประเทศของ อย.

ในเวทีการเจรจาระดับอาเซียน ผู้ที่มีบทบาทหน้าที่สำคัญที่สุดคือ ทีมเจรจาด้านต่างประเทศของ อย. ดังนั้น ควรมีการพัฒนาศักยภาพรวมถึงความรู้ที่เกี่ยวข้องกับผลิตภัณฑ์ยาอย่างต่อเนื่อง เพื่อช่วยส่งเสริมให้ อย. สามารถบรรลุวัตถุประสงค์ในการพัฒนาผลิตภัณฑ์ได้อย่างมีประสิทธิผล และประสิทธิภาพ

5.3 แนวทางส่งเสริมผลิตภัณฑ์ยาภายใต้การกำกับดูแลของ อย. ให้สามารถแข่งขันได้ในระดับสากล

การส่งเสริมผลิตภัณฑ์ยาภายใต้การกำกับดูแลของ อย. สามารถดำเนินการได้ ดังนี้

(1) การพัฒนาศักยภาพของผู้ประกอบการไทย

การพัฒนาศักยภาพของผู้ประกอบการไทยจะช่วยส่งเสริมให้ผู้ประกอบการสามารถส่งออกสินค้าไปยังต่างประเทศได้มากขึ้น และยังช่วยลดอุปสรรคที่อาจเกิดจากกฎระเบียบในต่างประเทศ โดยการพัฒนาศักยภาพของผู้ประกอบการสามารถทำได้หลายประการ โดยประการที่ 1 คือ การเปิดเวทีจับคู่เจรจาทางธุรกิจโดยเฉพาะสำหรับผู้ประกอบการ SMEs เนื่องจากผู้ประกอบการ SMEs อาจจะยังไม่เป็นที่รู้จักหรือได้รับการยอมรับในต่างประเทศมากพอกับผู้ประกอบการรายใหญ่ที่จะมีผู้ประกอบการเวียดนามเป็นฝ่ายยื่นข้อเสนอทางการค้าหรือขอเป็นคู่ค้า

ประการที่ 2 คือ การสนับสนุนด้านการวิจัยและพัฒนาเพื่อสร้างองค์ความรู้และเทคโนโลยีในการผลิต และการกำหนดมาตรการจูงใจต่าง ๆ เพื่อให้ผู้ประกอบการไทยพัฒนาผลิตภัณฑ์ใหม่ ๆ รวมถึงยานวัตกรรมที่ตอบโจทย์ตลาดได้มากขึ้น โดยในช่วงเริ่มต้นทำวิจัยหรือพัฒนาเทคโนโลยีและนวัตกรรมควรมุ่งเน้นที่มาตรการด้านเงินทุนเพื่อสนับสนุนการวิจัยและคิดค้นนวัตกรรมใหม่ ๆ เช่น อย. อาจหารือกับสถาบันการเงินเพื่อสนับสนุนโครงการยานวัตกรรมโดยการให้สินเชื่อดอกเบี้ยต่ำ หรือการสนับสนุนเงินทุนให้เปล่า ประกอบกับ อย. ควรมีการถ่ายทอดความรู้ผ่านการจัดอบรมและการจัดกิจกรรมเพิ่มพูนความรู้ให้แก่ผู้ประกอบการ ทั้งนี้ เมื่อผู้ประกอบการเข้าสู่ระยะการผลิตสินค้าเชิงพาณิชย์แล้ว อย. อาจหารือกับกระทรวงการคลังเพื่อพิจารณากำหนดสิทธิประโยชน์ทางภาษีต่าง ๆ ให้แก่ผู้ผลิตยานวัตกรรม

ประการที่ 3 คือ การจัดทำ e-learning หรือการเผยแพร่ความรู้เกี่ยวกับขั้นตอนและเอกสารที่ต้องใช้ประกอบการยื่นคำขอต่าง ๆ หน่วยงานที่เกี่ยวข้อง ปัญหาอุปสรรค รวมถึงกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม ให้เหมาะสมกับประเภทของผู้ประกอบการ เนื่องจากผู้ประกอบการแต่ละรายอาจมีประสบการณ์หรือความรู้ความเข้าใจด้านขั้นตอนหรือกฎระเบียบในระดับที่แตกต่าง รวมถึงการจ้างผู้เชี่ยวชาญทั้งจากในและต่างประเทศมาให้ความรู้หรือแนะนำผู้ประกอบการไทยเพื่อช่วยยกระดับอุตสาหกรรมยาของประเทศไทยให้สามารถแข่งขันในต่างประเทศได้ดียิ่งขึ้น

ประการที่ 4 คือ การจัดศึกษาดูงานด้านผลิตภัณฑ์ยาของกลุ่มประเทศสมาชิกอาเซียน เพื่อเป็นการสร้างองค์ความรู้ให้แก่ผู้ประกอบการนอกเหนือจากความรู้ด้านเทคโนโลยี อีกทั้งยังเป็นการเปิดโอกาสให้ผู้ประกอบการไทยได้แลกเปลี่ยนความคิดเห็น หรือประเด็นปัญหาในการดำเนินธุรกิจกับผู้ประกอบการต่างประเทศ รวมถึงจะได้เข้าใจตลาดหรือผู้บริโภคของกลุ่มประเทศสมาชิกอาเซียนได้อย่างถ่องแท้ เพื่อที่จะได้นำข้อมูล และประสบการณ์ดังกล่าว มาปรับปรุงหรือพัฒนาการดำเนินธุรกิจของตนเอง

ประการที่ 5 คือ การส่งเสริมภาพลักษณ์ ความน่าเชื่อถือในคุณภาพและมาตรฐานของผลิตภัณฑ์ส่งออกของประเทศไทยให้เป็นที่ยอมรับในระดับสากล ซึ่งควรเริ่มจากการสร้างความน่าเชื่อถือในคุณภาพและมาตรฐานของผลิตภัณฑ์ยาในระดับภายในประเทศก่อน เช่น การประชาสัมพันธ์ผ่านบุคคลากรทางการแพทย์

และประชาชนในรูปแบบต่าง ๆ โดยเฉพาะผ่านทางอินเตอร์เน็ต หรือสื่อโซเชียล จากนั้นจึงค่อยขยายการรับรู้ถึงคุณภาพและมาตรฐานของผลิตภัณฑ์ไปยังระดับสากล นอกจากนี้ อย. อาจพิจารณานำมาตรฐานการผลิตที่สูงขึ้นมาใช้กับกระบวนการผลิตยาในประเทศ รวมถึงการเฝ้าระวังการปฏิบัติตามมาตรฐานสากลของผู้ประกอบการอย่างเคร่งครัด ซึ่งจะต้องดำเนินการควบคู่ไปกับการพัฒนาศักยภาพของผู้ประกอบการตามข้างต้นด้วย

(2) การพัฒนาศักยภาพของเจ้าหน้าที่ที่เกี่ยวข้อง

ผู้บริหารของ อย. และหน่วยงานภาครัฐอื่นที่เกี่ยวข้องกับผลิตภัณฑ์ยาหรือที่เกี่ยวข้องกับการส่งออก ควรผลักดันให้มีการพัฒนาศักยภาพของเจ้าหน้าที่ให้มีความรู้ความเข้าใจเกี่ยวกับกฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในต่างประเทศ โดยอาจจัดให้มีการฝึกอบรมหรือจัดทำคู่มือให้แก่เจ้าหน้าที่ดังกล่าว รวมถึงควรจัดให้มีการแลกเปลี่ยนความคิดเห็นหรือข้อมูลระหว่างหน่วยงานภาครัฐกับผู้ประกอบการภาคเอกชนเป็นระยะ เพิ่มเติมจากการมุ่งพัฒนาศักยภาพของผู้ประกอบการด้วย

(3) การให้ความช่วยเหลือผู้ประกอบการไทยในต่างประเทศ

อย. และหน่วยงานภาครัฐที่เกี่ยวข้องควรมีการให้ความช่วยเหลือและส่งเสริมทั้งผู้ประกอบการไทยที่ดำเนินธุรกิจอยู่ในประเทศไทยและผู้ประกอบการไทยที่ดำเนินธุรกิจอยู่ในต่างประเทศ โดยอาจขอความร่วมมือจากสถานทูตไทยหรือหน่วยงานภาครัฐไทยในต่างประเทศในการให้ความช่วยเหลือด้านข้อมูลหรือด้านกฎระเบียบต่าง ๆ รวมถึงมีมาตรการส่งเสริมผู้ประกอบการไทยในต่างประเทศโดยอาจเทียบเคียงได้กับกรณีการให้ความช่วยเหลือและส่งเสริมผู้ประกอบการของ Japan International Cooperation Agency (JICA) ของประเทศญี่ปุ่น

บรรณานุกรม

เอกสารภาษาต่างประเทศ

Plan for People's Health Protection, Care, and Promotion 2016-2020

Law on Pharmacy No. 105/2016/QH13

Decree No. 54/2017/ND-CP on Guidelines for Implementation of the Law on Pharmacy

Decree No. 155/ 2018/ ND- CP on Amendments to Some Articles Related to Business Conditions under State Management of the Ministry of Health

Circular No. 01/ 2018/ TT- BYT on Labelling and Package Inserts of Drugs and Medicinal Ingredients

Circular No. 11/2018/TT-BYT on Drug/Drug Ingredient Quality

Circular No. 29/2018/TT-BYT on Provisions on Clinical Trials of Drugs

Circular No. 32/2018/TT-BYT on Marketing Authorization of Drugs and Medicinal Ingredients

Circular No. 15/ 2019/ TT- BYT on Regulation on Bidding for Drugs at Public Health Establishments

เอกสารภาษาไทย

ศูนย์ข้อมูลธุรกิจไทยในนครโฮจิมินห์. (2562). **เวียดนามกับกฎหมายเภสัชกรรมฉบับใหม่: โอกาสทางธุรกิจที่ไม่ควรมองข้าม.**

สำนักงานส่งเสริมการค้าระหว่างประเทศ ณ กรุงฮานอย. (2558). ตลาดยาในเวียดนามปี 2558.

กรมส่งเสริมการค้าระหว่างประเทศ. กระทรวงพาณิชย์. (2561). คู่มือโอกาสและทิศทางการค้าการลงทุนในประเทศเวียดนาม.

ภาคผนวก

THE NATIONAL ASSEMBLY	**THE SOCIALIST REPUBLIC OF VIETNAM**
No. 105/2016/QH13	**Independence - Freedom - Happiness**

LAW
On Pharmacy

Pursuant to the Constitution of the Socialist Republic of Vietnam;

The National Assembly promulgates the Law on Pharmacy.

Chapter I
GENERAL PROVISIONS

Article 1. Scope of regulation and subjects of application

1. This Law prescribes state policies on pharmacy and development of pharmaceutical industry; pharmacy practice; pharmaceutical business; registration, circulation and recall of drugs and drug materials; medicinal materials and traditional drugs; medical prescription and use of drugs; drug information, pharmacovigilance and drug advertisement; clininal pharmacy; management of drugs at medical examination and treatment establishments; clinical trial and bioequivalence trial of drugs; management of the quality of drugs and drug materials and management of drug prices.

2. This Law applies to domestic agencies, organizations and individuals and foreign organizations and individuals involved in pharmacy activities in Vietnam.

Article 2. Interpretation of terms

In this Law, the terms below are construed as follows:

1. *Pharmaceuticals* include drugs and drug materials.

2. *Drug* means a preparation containing a pharmaceutical ingredient or medicinal materials for the purpose of prevention, diagnosis, cure, treatment or mitigation of human diseases or modification of physiological functions of the human body. Drugs include pharmacochemical drugs, drugs made from medicinal materials, traditional drugs, vaccines and biological products.

3. *Drug materials* means components forming a drug, including pharmaceutical ingredients, medicinal materials, adjuvants and capsules used in the course of drug manufacture.

4. *Pharmaceutical ingredient* (also called active ingredient) means a substance or mixture of substances used to manufacture a drug and having pharmacological effects or direct effects in the prevention, diagnosis, cure, treatment or mitigation of disease or in the modification of physiological functions of the human body.

5. *Medicinal materials* means drug materials which are derived from plant, animal or mineral origin and satisfy drug manufacture standards.

6. *Pharmacochemical drug* means a drug containing a pharmaceutical ingredient of identified composition, formula and purity and satisfying drug manufacture standards. Pharmacochemical drugs also include injection drugs which are extracted from medicinal materials and drugs combining pharmaceutical ingredients with medicinal materials which have been proven to be safe and effective.

7. *Drug from medicinal materials* means a drug composed of medicinal materials and having its effects supported by scientific evidence, except traditional drugs mentioned in Clause 8 of this Article.

8. *Traditional drug* (including also traditional medicament) means a drug composed of medicinal materials which are processed, prepared or blended according to traditional medicine theories and methods or according to folk experiences into a product with a traditional or modern form.

9. *Traditional medicament* means medicinal materials prepared according to traditional medicine theories and methods and used to manufacture a traditional drug or to prevent and treat disease.

10. *Biological product* (also called bio-drug) means a drug manufactured by a bio-technology or bio-process from a polymeric substance or mixture of polymeric substances of biological origin, including also human blood and plasma derivatives.

Biological products do not include antibiotics, low-molecular-weight substances of biological origin which can be isolated as pure substances, and *in vitro* diagnostic biological products.

11. *Reference biological product* (also called reference bio-drug) means a biological product permitted for circulation in Vietnam on the basis of sufficient data on its quality, safety and efficacy.

12. *Similar biological product* (also called similar bio-drug) means a biological product whose quality, safety and efficacy are similar to those of a reference bio-drug.

13. *Vaccine* means a drug containing antigens which induce an immune response in the human body, and used to treat and cure disease.

14. *New drug* means a drug containing a new pharmaceutical ingredient or medicinal materials used for the first time as a drug in Vietnam; or a drug with a new combination of a pharmaceutical ingredient already in circulation or of medicinal materials previously used as drugs in Vietnam.

15. *Generic drug* means a drug having the same pharmaceutical ingredient, content and formulation with those of a brand name specific and usually used as a substitute for the brand name specific.

16. *Brand name specific* means a drug first licensed for circulation on the basis of sufficient data on its quality, safety and efficacy.

17. *Habit-forming drug* means a drug containing pharmaceutical ingredients with neural stimulation or inhibition effects which can easily cause addiction to users, and included in the list of habit-forming drugs promulgated by the Minister of Health.

18. *Psychotropic drug* means a drug containing pharmaceutical ingredients with neural stimulation or inhibition effects or causing hallucination, having the potential to induce a state of addiction when used consistently, and included in the list of psychotropic drugs issued by the Minister of Health.

19. *Pre-substance drug* means a drug containing a pre-substance included in the list of pre-substances used as drugs issued by the Minister of Health.

20. *Combination drug containing a habit-forming pharmaceutical ingredient* means a drug containing many active ingredients including a habit-forming active ingredient with a concentration or content prescribed by the Minister of Health.

21. *Combination drug containing a psychotropic pharmaceutical ingredient* means a drug containing many active ingredients including a psychotropic active ingredient with a concentration or content prescribed by the Minister of Health.

22. *Combination drug containing a pre-substance* means a drug containing many pharmaceutical ingredients including a pre-substance with a concentration or content prescribed by the Minister of Health.

23. *Radioactive drug* means a drug containing a radioactive nuclear component used to diagnose and cure diseases in humans or to conduct biomedical research, including radioisotopes or radioisotopes combined with a tracer.

24. *Radioisotope* means an isotope of a chemical element whose atom has an unstable nucleus that emits ionizing radiation in the process of decay to become stable following the emission.

25. *Tracer* (also called label) means a substance or compound used for preparation and combination with a radioisotope to form a radioactive drug.

26. *Drugs and drug materials under special control* (below referred to as drugs under special control for short) include:

a/ Drugs defined in Clauses 17, 18, 19, 20, 21, 22, 23 and 24 of this Article;

b/ Drug materials that are psychotropic pharmaceutical ingredients, habit-forming substances, pre-substances used as drugs or radioactive substances for drug manufacture defined in Clauses 17, 18, 19, 20, 21, 22, 23 and 24 of this Article;

c/ Toxic drugs and toxic drug materials on the list promulgated by the Minister of Health;

d/ Drugs and pharmaceutical materials on the list of substances banned from use in a number of specific sectors and fields as prescribed by the Government.

27. *Non-prescription drug* mean a drug that can be dispensed, retailed and used without a prescription and is included in the list of non-prescription drugs promulgated by the Minister of Health.

28. *Prescription drug* means a drug that can be dispensed, retailed and used only with a prescription. Such a drug may be dangerous to the user's life or health if it is used not in accordance with the prescription.

29. *Essential drug* means a drug that satisfies the healthcare demand of a vast majority of people and is included in the list of essential drugs issued by the Minister of Health.

30. *Rare drug* means a drug used to prevent, diagnose and cure a rare disease, or a drug which is not always available as prescribed by the Minister of Health.

31. *Shelf life of a drug* means the period predetermined for a drug after which the drug must not be used.

Shelf life of a drug shall be expressed either as a period of time computed from the date of manufacture to the date of expiry or as a specific expiry date (day, month and year). In case the expiry date is indicated only in month and year, the shelf life will last until the last day of the month of expiry.

32. *Substandard drug* means a drug that fails to satisify the quality standards registered with a competent state agency.

33. *Counterfeit drug* means a drug manufactured in one of the following cases:

a/ It does not have any pharmaceutical ingredients or medicinal materials;

b/ It has pharmaceutical ingredients other than those shown on its label or failing to satisfy the standards registered for circulation or stated in its import permit;

c/ It has pharmaceutical ingredients or medicinal materials with a concentration or content or an amount inconsistent with that registered for circulation or stated in its import permit, except drugs that fail to satisfy quality standards as prescribed in Clause 32 of this Article in the course of preservation, circulation or distribution;

d/ It is manufactured, displayed or labeled in a way counterfeiting a genuine manufacturer, a country of manufacture or a country of origin.

34. *Counterfeit medicinal materials* means medicinal materials in one of the following cases:

a/ They are not derived from the species, parts or origin intentionally shown by the trading establishment on their labels or in accompanying documents;

b/ They are intentionally mixed with or replaced by ingredients other than medicinal materials shown on their labels or mixed with or replaced by medicinal ingredients intentionally extracted from active ingredients;

c/ They are manufactured, displayed or labeled in a way to counterfeit a manufacturer, a country of manufacture or a country of origin.

35. *Adverse reactions of a drug* means undesirable harmful effects of a drug which may occur with a normal dose.

36. *Pharmacy practice* means the use by a person of his/her professional qualifications to do drug business and conduct clinical pharmacy activities.

37. *Good practices* means a set of principles and standards on the manufacture, preservation, testing or circulation of drugs, prescription of drugs, clinical trial of drugs, and culture, cultivation and harvest of medicinal materials, and other sets of principles and standards promulgated or announced by the Minister of Health for application based on the instructions of the World Health Organization or other international organizations which are joined or accredited by Vietnam.

38. *Bioavailability* means a measurement of the rate and extent to which a pharmaceutical ingredient or active substance from a drug is absorbed into a living body and appears at the site of activity inside the body.

39. *Bioequivalence* means the similarity of bioavailability between two drugs when compared under the same testing condition.

40. *Clinical pharmacy* means the pharmaceutical scientific research and pharmacy pratice to provide advice on the rational, safe and effective use of a drug in order to optimize its use.

41. *Pharmacovigilance* means the detection, assessment and prevention of adverse effects related to the use of a drug.

42. *Primary package of a drug* means the package containing a drug, being in direct contact with the drug, and shaping the drug or tightly wrapping around the shape of the drug.

43. *Drug business* means the carrying out of one, a number or all of the stages of the investment process, from manufacture to sale of drugs or provision of services related to drugs and drug materials in the market for profit-making purposes.

Article 3. National reserves of drugs and drug materials

1. The State shall set up national reserves of drugs and drug materials for use in the following cases:

a/ Prevention and control of diseases and epidemics, and overcoming of consequences of natural disasters or catastrophes;

b/ Maintenance of national defense and security;

c/ Prevention, diagnosis and cure of rare diseases;

d/ Unavailability of drugs.

2. The setting up, organization, management and use of the national reserves of drugs and drug materials must comply with the law on national reserves.

Article 4. State management agencies in charge of pharmacy

1. The Government shall perform the unified state management of pharmacy.

2. The Ministry of Health is answerable to the Government for performing the state management of pharmacy.

3. Ministries and ministerial-level agencies shall, within the ambit of their tasks and powers, perform the state management of pharmacy and coordinate with the Ministry of Health in performing the state management of pharmacy as assigned by the Government.

4. People's Committees at all levels shall, within the ambit of their tasks and powers, perform the state management of pharmacy in their respective localities.

Article 5. Pharmacy association

1. A pharmacy association is a socio-professional organization engaged in pharmacy.

2. Organizations and individuals engaged in pharmacy may join and found a pharmacy association.

3. The organization and operation of a pharmacy association must comply with this Law and the law on associations.

4. A pharmacy association has the following responsibilities and powers:

a/ To issue the code of professional ethics in pharmacy practice based on the principles of pharmacy practice ethics promulgated by the Minister of Health;

b/ To participate in the drafting and organization and supervision of implementation of legal documents on pharmacy;

c/ To participate in supervising the pharmacy practice and observation of pharmacy practice ethics and in making social criticisms concerning pharmacy-related activities;

d/ To participate in pharmacy training and pharmacy knowledge updating;

dd/ To participate in the advisory council for grant of pharmacy practice certificates.

Article 6. Prohibited acts

1. Conducting pharmaceutical business without a certificate of eligibility for pharmaceutical business or during the period of being suspended from doing the business or being deprived of the right to use such certificate.

2. Conducting pharmaceutical business outside the registered pharmaceutical business place.

3. Trading in drugs or drug materials specified in Clause 26, Article 2 of this Law and other drugs or drug materials for purposes or supplying them to subjects other than those permitted by a competent state management agency.

4. Conducting pharmaceutical business outside the professional scope stated in the certificate of eligibility for pharmaceutical business.

5. Trading in any of the following:

a/ Counterfeit drugs or drug materials;

b/ Drugs or drug materials that fail to satisfy quality standards; drugs or drug materials which are being recalled under notices of competent state agencies; drugs or drug materials which are unclear origin or have expired;

c/ Drugs or drug materials on the list of drugs and drug materials banned from import or manufacture;

d/ Drugs for clinical trial;

dd/ Drugs or drug materials used as samples for registration, testing, scientific research or display at exhibitions or fairs;

e/ Drugs or drug materials not yet permitted for circulation;

g/ Drugs under national target programs, donated drugs and other drugs not permitted for sale;

h/ Retailing a prescription drug without prescriptions; retailing a vaccine;

i/ Selling a drug at a price higher than its declared or posted price.

6. Forging or modifying dossiers, papers, documents or certificates of competent agencies or organizations and of other organizations and individuals in pharmacy activities.

7. Changing or modifying the shelf life of a drug, except the case of change of the shelf life of a drug prescribed in Clause 3, Article 61 of this Law.

8. Practicing pharmacy without a pharmacy practice certificate or during the period of being deprived of the right to use a pharmacy practice certificate, for persons in the working positions prescribed in Article 11 of this Law.

9. Renting, borrowing, leasing, lending or letting another person use a pharmacy practice certificate or a certificate of eligibility for pharmaceutical business for practicing pharmacy or conducting pharmaceutical business.

10. Advertising in the following cases:

a/ Advertising a drug without a state management agency's certification of the advertising content or not in accordance with the certified content;

b/ Using a certificate not yet recognized by the Ministry of Health, using material benefits or taking advantage of the name and status of an organization or individual or of a symbol, image, position, reputation, correspondence or letter of thank for advertising a drug;

c/ Using clinical or preclinical research, testing or bioequivalence trial results not yet recognized by the Ministry of Health for advertising a drug.

11. Organizing drug sales promotions in contravention of law.

12. Taking advantage of drug prescription to seek personal benefits.

13. Manufacturing, preparing or selling traditional drugs combined with pharmaceutical ingredients without permission of a competent state management agency.

14. Dispensing or selling to users expired drugs, drugs which have been preserved not in accordance with instructions on their labels, drugs which are being recalled under notices of a competent state agency, or drugs of unclear origin.

15. Providing information, advertising, marketing, making prescriptions for, providing consultations on, labeling or providing use instructions for non-drug products, except medical equipment for the purpose of prevention, cure, diagnosis, treatment or mitigation of disease or modification of physiological functions of the human body.

16. Exporting medicinal materials on the list of precious, rare or endemic medicinal material species and varieties under control without permission of a competent state management agency.

Chapter II

STATE POLICIES ON PHARMACY AND DEVELOPMENT OF PHARMACEUTICAL INDUSTRY

Article 7. State policies on pharmacy

1. To ensure sufficient and prompt supply of quality drugs at reasonable prices to meet the people's disease prevention and treatment needs, suit the structure of diseases and meet requirements of national defense and security, epidemic prevention and control and overcoming of consequences of natural disasters and catastrophes, and of rare drugs.

2. To ensure the rational, safe and effective use of drugs; to prioritize the development of clinical pharmacy and pharmacovigilance.

3. To provide incentives for investment in the manufacture of drugs and drug materials, essential drugs, drugs for prevention and control of social diseases, vaccines, biological products, drugs from medicinal materials, traditional drugs and rare drugs; to provide incentives for scientific research in manufacturing technology and bio-technology to manufacture new drugs.

4. For drugs to be purchased with state budget funds, health insurance fund, revenues from medical examination and treatment services and other lawful revenues of public medical establishments, the following provisions shall be complied with:

a/ To refrain from offering bids of imported drugs on the list of imported drugs issued by the Minister of Health based on technical criteria when domestically manufactured drugs satisfy the treatment, price and supply requirements.

To prioritize the purchase of generic drugs and similar biological products that are first manufactured and granted certificates of registration for circulation in Vietnam; drugs from medicinal materials, traditional drugs made from domestic medicinal materials; drugs using pharmaceutical ingredients, adjuvants, capsules or primary packages manufactured by domestic establishments satisfying good manufacturing practices; raw medicinal materials; drugs from medicinal materials and traditional drugs manufactured under national, ministerial or provincial scientific and technological tasks;

b/ To refrain from offering bids of imported medicinal materials on the list issued by the Minister of Health when domestically cultured, cultivated or harvested medicinal materials satisfy the treatment, price and supply requirements.

The Government shall prescribe reasonable prices mentioned at this Point;

c/ To prioritize the purchase of drugs on the list of national products.

5. To facilitate the submission of applications for registration for circulation of generic drugs whose relevant patents will expire soon and of first similar biological products; to priotitize the registration for circulation and grant of import permits for rare drugs and vaccines which have been assessed for prequalification by the World Health Organization.

6. To combine investment from the state budget and other mobilized resources in the development of the manufacture of vaccines, biological products, drugs from medicinal materials, traditional drugs or drugs whose relevant patents will expire soon; culture, cultivation or production of medicinal materials; discovery, conservation and application of science and technology to the research and development of gene sources of precious, rare and endemic medicinal materials.

7. To support and facilitate the discovery, clinical trial and registration for intellectual property rights protection, registration for circulation and inheritance of traditional drugs and drugs from medicinal materials under national, ministerial or provincial scientific and technological projects already tested and accepted; search for exploitation and use of new medicinal materials; export of cultured and cultivated medicinal materials; acclimatization of medicinal materials; rational exploitation of natural medicinal materials; research, survey and investigation into appropriate medicinal material species for culture and cultivation in localities; development of medicinal material culture and cultivation zones; modernization of the production of medicinal materials, drugs from medicinal materials and traditional drugs.

8. To keep secret information in the preparation and processing of and clinical trial data on traditional drugs; to provide reasonable incentives for those who donate precious traditional medicaments to the State; to facilitate the grant of traditional medicine or pharmacy practice certificates to persons whose folk remedies have been recognized by the Ministry of Health.

9. To encourage technology transfer in drug manufacture; to develop the networks of drug circulation and distribution, drugstores and drug preservation and supply toward professionalism, modernity and effectiveness, ensuring timely and sufficient supply of quality drugs to meet the people's needs; to encourage drugstores and pharmacies to open around the clock.

To provide investment incentives and support for the development of drug suppliers and mobile drug retailers for ethnic minority people and inhabitants in mountainous areas, on islands, and in areas with extremely difficult socio-economic conditions.

10. To mobilize medical establishments in the people's armed forces to participate in the supply of drugs and culture and cultivation of medicinal materials in order to meet the disease prevention and treatment needs of people in ethnic minority areas and mountainous areas, on islands, and in areas with extremely difficult socio-economic conditions.

11. To raise the quality of human resources in the pharmacy sector; to give priority in pharmacy practice to persons who have obtained pharmacy practice certificates after passing examinations prescribed by the Government.

Article 8. Prioritized fields in the development of pharmaceutical industry

1. Research and production of drug materials from medicinal material sources available in Vietnam to serve the preparation and production of drug from medicinal material drugs and traditional drugs.

2. Manufacture of drugs upon the expiration of patents and relevant protection titles, vaccines, biological products, medicinal materials, drugs from medicinal materials, traditional drugs and rare drugs.

3. Development of medicinal material sources and medicinal material culture and cultivation zones; conservation of gene sources and development of precious, rare and endemic medicinal material species and varieties.

4. Investment incentives and supports for the prioritized fields in the development of pharmaceutical industry shall be provided in accordance with the investment law.

Article 9. Pharmaceutical industry development master plans

1. Pharmaceutical industry development master plans include those on manufacture, distribution, preservation and testing of drugs and drug materials, development of medicinal material sources and medicinal material culture and cultivation zones.

2. A pharmaceutical industry development master plan must satisfy the following requirements:

a/ Being compliant with this Law and other relevant laws;

b/ Being conformable with the national socio-economic development strategy in each period; contributing to environmental protection and sustainable development;

c/ Focusing on concentration, modernization and specialization;

d/ Containing scientific forecasts, meeting practical requirements and being in line with the development and international integration trend.

3. A master plan on development of production of medicinal materials, drugs from medicinal materials and traditional drugs or development of medicinal material sources and medicinal material culture and cultivation zones must satisfy the requirements prescribed in Clause 2 of this Article and the following requirements:

a/ Ensuring reasonable exploitation and use of natural resources; suitability to local soil, climate, ecological and other natural and social conditions;

b/ Setting orientations for the production and preparation of medicinal materials on an industrial scale, development of medicinal materials culture and cultivation zones, conservation of gene sources and development of precious, rare and endemic medicinal material species and varieties on the basis of increased investment in advanced techniques and technologies combined with traditional experiences.

4. The elaboration, approval and management of pharmaceutical industry development master plans must comply with law.

Article 10. Responsibility for pharmaceutical industry development

1. The Ministry of Health shall:

a/ Assume the prime responsibility for, and coordinate with related ministries, ministerial-level agencies and government-attached agencies in,

promulgating according to their competence, or submitting to competent authorities for promulgation and organizing the implementation of, legal documents, strategies, policies, master plans and plans on pharmaceutical industry development;

b/ Assume the prime responsibility for, and coordinate with the Ministry of Education and Training in, elaborating plans on training and use of human resources for the research and manufacture of generic drugs, vaccines, biological products, drugs from medicinal materials, traditional drugs and rare drugs;

c/ Assume the prime responsibility for, and coordinate with the Ministry of Natural Resources and Environment, Ministry of Agriculture and Rural Development and related agencies in, planning the development of medicinal material culture and cultivation zones and implementing measures to conserve and reasonably and sustainably exploit and use medicinal material sources;

d/ Assume the prime responsibility for, and coordinate with the Ministry of Agriculture and Rural Development and related ministries, ministerial-level agencies and government-attached agencies in, issuing the lists of precious, rare and endemic medicinal material species and varieties under control.

2. The Ministry of Industry and Trade shall assume the prime responsibility for, and coordinate with related ministries, ministerial-level agencies and government-attached agencies in, promulgating according to their competence or submitting to competent authorities for promulgation and organizing the implementation of, legal documents, master plans and plans on pharmaco-chemical industry development.

3. The Ministry of Agriculture and Rural Development shall:

a/ Assume the prime responsibility for, and coordinate with the Ministry of Health and Ministry of Science and Technology in, conducting scientific research into selection and creation of varieties and breeds, culture, cultivation and harvest of medicinal materials; researching and widely applying techniques of culture and cultivation of, and prevention and control of harmful pests on, medicinal plants and animals;

b/ Assume the prime responsibility for, and coordinate with related ministries, ministerial-level agencies and government-attached agencies in, submitting to the Government for promulgation special policies on varieties, breeds, capital and technology for the development of medicinal material culture, cultivation and exploitation.

4. The Ministry of Natural Resources and Environment shall assume the prime responsibility for, and coordinate with related ministries, ministerial-level agencies and government-attached agencies in, submitting to the Government for promulgation policies on access to gene sources of medicinal materials and sharing of benefits from the use of these gene sources.

5. The Ministry of Planning and Investment shall:

a/ Allocate and balance investment resources for pharmaceutical industry development, and mobilize foreign capital sources prioritized for pharmaceutical industry development;

b/ Assume the prime responsibility for, and coordinate with the Ministry of Finance and related ministries, ministerial-level agencies and government-attached agencies in, elaborating and submitting to competent authorities for promulation specific regulations and policies on investment incentives and support for the pharmacy sector as prescribed in Article 8 of this Law.

6. The Ministry of Finance shall:

a/ Assume the prime responsibility for, and coordinate with related ministries, ministerial-level agencies and government-attached agencies in, developing a financial mechanism and mobilize and ensure resources for the implementation of pharmaceutical industry development master plans and plans before submitting them to competent authorities for approval;

b/ Assume the prime responsibility for, and coordinate with the Ministry of Industry and Trade, the Ministry of National Defense, the Ministry of Health and provincial-level People's Committees in localities with border gates in, managing and controlling the import of drugs and drug materials not yet permitted for circulation, import of medicinal materials not yet permitted by competent state agencies, export of medicinal materials on the list of precious, rare and endemic medicinal material species and varieties under control.

7. The Ministry of Science and Technology shall:

a/ Propose competent authorities to allocate or allocate according to its competence annual state budget funds for scientific and technological activities for research and application of research results in the manufacture of drugs, especially those on the list of national products;

b/ Assume the prime responsibility for, and coordinate with the Ministry of Agriculture and Rural Development and the Ministry of Health in, organizing research and conservation of gene sources and development of precious, rare and endemic medicinal materials;

c/ Assume the prime responsibility for, and coordinate with the Ministry of Health in, developing mechanism and policies on intellectual property protection of traditional drugs.

8. Provincial-level People's Committees shall:

a/ Elaborate and approve master plans and plans on development of pharmaceutical industry and development of local medicinal materials (covering also the exploitation and conservation of natural medicinal material sources) in conformity with the national master plans and plans on development of pharmaceutical industry, socio-economic development objectives and local advantages;

b/ Allocate land areas for building pharmaceutical factories and industrial zones; prioritize the allocation of land for projects on development of medicinal material sources and medicinal material culture and cultivation zones in accordance with the land law.

Chapter III

PHARMACY PRACTICE

Section 1

PHARMACY PRACTICE CERTIFICATE

Article 11. Working positions requiring a pharmacy practice certificate

1. Person responsible for professional pharmacy activities at a pharmaceutical business establishment.

2. Person in charge of quality assurance at a drug or drug material manufacturing establishment.

3. Person in charge of clinical pharmacy at a medical examination and treatment establishment.

Article 12. Grant, re-grant or modification of a pharmacy practice certificate

1. A pharmacy practice certificate shall be granted in the form of consideration and approval for applicants or examination for persons who wish to have a certificate the following cases:

a/ A person who applies for a pharmacy practice certificate for the first time;

b/ A person who has had his/her pharmacy practice certificate revoked under Article 28 of this Law.

A person who has his/her pharmacy practice certificate revoked under Clause 4, 6, 10 or 11, Article 28 of this Law, may only be re-granted such certificate after 12 months since the date of revocation.

2. A pharmacy practice certificate may be re-granted if it is lost or damaged.

3. The content of a pharmacy practice certificate may be modified when there is a change in the scope of practice of the certificate holder, the form of grant of the certificate or information of the certificate holder.

Article 13. Conditions for a person to be granted a pharmacy practice certificate

1. Possessing a professional degree or certificate (below collectively referred to as professional degree) granted or recognized in Vietnam and relevant to the working position and employing pharmaceutical business establishment, including:

a/ University degree in pharmacy (below referred to as pharmacist degree);

b/ University degree in general medicine;

c/ University degree in traditional medicine or traditional pharmacy;

d/ University degree in biology;

dd/ University degree in chemistry;

e/ College degree in pharmacy;

g/ Professional secondary school degree in pharmacy;

h/ College or professional secondary school degree in medicine;

i/ Professional secondary school degree in traditional medicine or traditional pharmacy;

k/ Professional primary school degree or certificate in pharmacy;

l/ Traditional physician's certificate, traditional pharmacist's certificate or certificate of folk remedy or another degree or certificate of traditional medicine or pharmacy granted before the effective date of this Law.

The application of the condition of possessing a degree or certificate prescribed at Point 1 of this Clause shall be prescribed by the Minister of Health to suit the socio-economic development conditions and medical examination and treatment needs of people in each locality in each period.

2. Having a certain period of practice at a pharmaceutical business establishment or a pharmacy section of a medical examination and treatment establishment, a professional pharmacy training school, a pharmacy research institution, a drug and drug material testing establishment, a pharmacy management agency, or a representative office of a foreign trader engaged in pharmacy in Vietnam (below collectively referred to as pharmacy establishment); or at a medical examination and treatment establishment suitable to the professional qualification of the practitioner. Such period of practice is prescribed as follows:

a/ For a person whose pharmacy practice certificate was revoked under Clause 9, Article 28 of this Law, he/she does not need such period of practice but shall participate in a professional pharmacy knowledge updating course;

b/ For a person who has a postgraduate specialized qualification relevant to his/her practice, his/her period of practice may be shortened as prescribed by the Government;

c/ For a person who possesses a professional degree specified at Point 1, Clause 1, Article 13 of this Law, his/her period of practice shall be prescribed by the Minister of Health.

3. Having a written certification that the applicant is physically fit for pharmacy practice, granted by a competent medical establishment.

4. Not falling into one of the following cases:

a/ Being examined for penal liability or serving a court's judgment or decision; being banned from practicing or performing a job related to pharmacy activities under a court's judgment or decision;

b/ Having a limited civil act capacity.

5. A person who wishes to take an examination for obtaining a pharmacy practice certificate must fully satisfy the conditions prescribed in this Article.

Article 14. Conditions for a foreigner or an overseas Vietnamese to be granted a pharmacy practice certificate

1. Fully satisfying the conditions prescribed in Article 13 of this Law.

2. Satisfying the language requirement in pharmacy practice as prescribed by the Minister of Health.

Article 15. Conditions on persons responsible for professional pharmacy activities and persons in charge of quality assurance at establishments manufacturing drugs or drug materials

1. Conditions on a person responsible for professional pharmacy activities at an establishment manufacturing drugs or drug materials being pharmaceutical ingredients, adjuvants or capsules include:

a/ A person responsible for professional pharmacy activities at a drug manufacturing establishment must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 5 years at an appropriate pharmacy establishment, except the case specified at Point c of this Clause;

b/ A person responsible for professional pharmacy activities at an establishment manufacturing drug materials being pharmaceutical ingredients, adjuvants and capsules must possess a professional degree specified at Point a or dd, Clause 1, Article 13 of this Law and have practiced for 3 years at an appropriate pharmacy establishment;

c/ A person responsible for professional pharmacy activities at an establishment manufacturing vaccines, biological products and vaccine and biological product materials must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 5 years at an appropriate pharmacy establishment.

2. Conditions on persons in charge of quality assurance at establishments manufacturing drugs and drug materials being pharmaceutical ingredients, adjuvants or capsules are as follows:

a/ A person in charge of quality assurance at a drug manufacturing establishment must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 5 years at a drug manufacturing or testing establishment, except the cases specifies at Points b and c of this Clause;

b/ A person in charge of quality assurance at a vaccine or biological product manufacturing establishment must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 5 years at an establishment manufacturing or testing vaccines or medical biological products;

c/ A person in charge of quality assurance at an establishment manufacturing drug materials being pharmaceutical ingredients, adjuvants or capsules must possess a professional degree specified at Point a or dd, Clause 1, Article 13 of this Law and have practiced for 3 years at an establishment manufacturing drugs and drug materials or testing drugs.

3. Conditions on persons responsible for professional pharmacy activities and persons in charge of quality assurance at medicinal material producing establishments are as follows:

a/ A person responsible for professional pharmacy activities or a person in charge of quality assurance at a medicinal material producing establishment must possess a professional degree specified at Point a or c, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the case specified at Point b of this Clause;

b/ A person responsible for professional pharmacy activities or a person in charge of quality assurance at a business household or a cooperative producing medicinal materials must possess a professional degree specified at Point a, c, e, g, i or l, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the case specified at Point c, Clause 2, Article 13 of this Law;

c/ A person responsible for professional pharmacy activities may concurrently take charge of quality assurance at a medicinal material producing establishment.

Article 16. Conditions on persons responsible for professional pharmacy activities at establishments wholesaling drugs or drug materials

1. A person responsible for professional pharmacy activities at an establishment wholesaling drugs or drug materials must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the cases specified in Clauses 2 and 3 of this Article.

2. A person responsible for professional pharmacy activities at an establishment wholesaling vaccines or biological products must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment.

3. A person responsible for professional pharmacy activities at an establishment wholesaling medicinal materials, medicinal material drugs or traditional drugs must possess a professional degree specified at Point a, c, i or l,

Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the case specified at Point c, Clause 2, Article 13 of this Law.

Article 17. Conditions on persons responsible for professional pharmacy activities at establishments exporting or importing drugs or drug materials

1. A person responsible for professional pharmacy activities of an establishment exporting or importing drugs or drug materials must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the cases specified in Clauses 2 and 3 of this Article.

2. A person responsible for professional pharmacy activities at an establishment exporting or importing vaccines or biological products must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment.

3. A person responsible for professional pharmacy activities at an establishment exporting or importing medicinal materials, medicinal material drugs or traditional drugs must possess a professional degree specified at Point a or c, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment.

Article 18. Conditions on persons responsible for professional pharmacy activities at drug retailing establishments

1. A person responsible for professional pharmacy activities at a drugstore must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment. He/she may concurrently take charge of clinical pharmacy activities at the drugstore.

2. A person responsible for professional pharmacy activities at a drug dispensary must possess a professional degree specified at Point a, e or g, Clause 1, Article 13 of this Law and have practiced for 18 months at an appropriate pharmacy establishment.

3. A person responsible for professional pharmacy activities at a commune health station's medicine cabinet must possess a professional degree specified at Point a, e, g or k, Clause 1, Article 13 of this Law and have practiced for 1 year at an appropriate pharmacy establishment or at a medical examination and treatment establishment. In case the commune health station is located in an ethnic minority or mountainous area, on an island or in an area with extremely difficult socio-economic conditions where there is no person possessing a professional degree specified at Point a, e, g or k, Clause 1, Article 13 of this Law, the person responsible for professional pharmacy activities at such station's medicine cabinet must possess a professional degree specified at Point b or h,

Clause 1, Article 13 of this Law and have practiced for 1 year at a medical examination and treatment establishment.

4. A person responsible for professional pharmacy activities at an establishment retailing medicinal materials, drugs from medicinal materials or traditional drugs must possess a professional degree specified at Point a, c, e, g, i or l, Clause 1, Article 13 of this Law and have practiced for 1 year at a pharmacy establishment or a medical examination and treatment establishment applying traditional medicine, except the case specified at Point c, Clause 2, Article 13 of this Law.

Article 19. Conditions on persons responsible for professional pharmacy activities at establishments providing the service of testing drugs or drug materials

1. A person responsible for professional pharmacy activities at an establishment providing the service of testing drugs or drug materials must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 3 years at an appropriate pharmacy establishment, except the cases specified in Clause 2 of this Article.

2. A person responsible for professional pharmacy activities at an establishment providing the service of testing vaccines or biological products must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 3 years at an appropriate pharmacy establishment.

Article 20. Conditions on persons responsible for professional pharmacy activities at establishments providing the service of clinical trial or bioequivalence trial of drugs

1. A person responsible for professional pharmacy activities at an establishment providing the service of clinical trial or bioequivalence trial of drugs must possess a professional degree specified at Point a or b, Clause 1, Article 13 of this Law and have practiced for 3 years at an appropriate pharmacy establishment, a hospital or a medical institute having patient beds, except the case specified in Clause 2 of this Article.

2. A person responsible for professional pharmacy activities at an establishment providing the service of clinical trial or bioequivalence trial of drugs must possess a professional degree specified at Point a, b or c, Clause 1, Article 13 of this Law and have practiced for 3 years at an appropriate pharmacy establishment, a hospital or a medical institute having patient beds.

Article 21. Conditions on persons responsible for professional pharmacy activities at medical examination and treatment establishments

1. A person responsible for professional pharmacy activities at a medical examination and treatment establishment must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 2

years at an appropriate pharmacy establishment, a hospital or a medical institute having patient beds, except the case specified in Clause 2 of this Article.

2. A person responsible for professional pharmacy activities at a medical examination and treatment establishment must possess a professional degree specified at Point c, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, a hospital or a medical institute having patient beds and traditional medical activities.

Article 22. Conditions on persons responsible for professional pharmacy activities at establishments providing the service of preserving drugs or drug materials

1. A person responsible for professional pharmacy activities at an establishment providing the service of preserving drugs or drug materials must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the case specified in Clause 2 of this Article.

2. A person responsible for professional pharmacy activities at an establishment providing the service of preserving vaccines or biological products must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment.

Article 23. Competence to grant, re-grant, modify or revoke pharmacy practice certificates

1. Directors of provincial-level Health Departments may grant pharmacy practice certificates on the basis of consideration and approval, and may re-grant, modify or revoke such certificates.

Directors of provincial-level Health Departments shall establish an advisory council with the participation of representatives from a pharmacy association to advise them on the grant, re-grant or revocation of the certificates.

2. The Ministry of Health may grant pharmacy practice certificates on the basis of examination.

Article 24. A dossier of application for a pharmacy practice certificate

1. An application for a pharmacy practice certificate stuck with a portrait photo of the applicant taken within 6 months by the date of application.

2. Certified copies of professional degrees.

3. A written certification that the applicant is physically fit for pharmacy practice, issued by a competent medical establishment.

4. A written certification of the period of practice of the applicant issued by the head of the establishment where the applicant practiced.

5. A written certification of completion of a pharmacy training or professional knowledge updating course, for a person whose pharmacy practice certificate was revoked under Clause 9, Article 28 of this Law.

6. A certified copy of the citizen identity card, people's identify card or passport of the applicant.

7. A judicial record card of the applicant. For a foreigner or an overseas Vietnamese, there must be a judicial record or document certifying that the applicant neither commits a crime nor faces a penal liability examination nor a ban from practice or performance of a job related to pharmacy activities under a court's judgment or decision issued by a competent foreign agency.

8. For re-grant of a pharmacy practice certificate which was revoked under Clause 3, Article 28 of this Law, the applicant shall only submit an application specified in Clause 1 of this Article.

Article 25. A dossier of application for re-grant of a pharmacy practice certificate

1. An application for re-grant of a pharmacy practice certificate stuck with a portrait photo of the applicant taken within 6 months by the date of application.

2. A copy of the granted pharmacy practice certificate. If the certificate is lost, the applicant's commitment is required.

Article 26. A dossier of application for modification of a pharmacy practice certificate

1. An application for modification of a pharmacy practice certificate stuck with a portrait photo of the applicant taken within 6 months by the date of application.

2. Copies of papers proving to-be-modified contents.

3. Copy of the granted pharmacy practice certificate.

Article 27. Procedures for grant, re-grant or modification of a pharmacy practice certificate

1. An applicant for a pharmacy practice certificate shall submit a dossier to certificate-granting agency.

Within 20 days after receiving a complete dossier of application for a pharmacy practice certificate or within 10 days after receiving a dossier of application for re-grant or modification of a pharmacy practice certificate, the head of the agency granting pharmacy practice certificates shall grant, re-grant or modify such certificate. In case of refusal to do so, it shall reply in writing, clearly stating the reason.

2. The time limit for grant of a pharmacy practice certificate under Clause 8, Article 24 of this Law is 5 working days after the receipt of an application.

Article 28. Cases of revocation of a pharmacy practice certificate

1. The certificate has been granted *ultra vires*.

2. The certificate holder requests revocation of its certificate.

3. The certificate contains errors due to the fault of the granting agency.

4. The dossier of application for the certificate contains a forged paper.

5. The certificate holder possesses more than one pharmacy practice certificate.

6. The certificate holder leases, lends, rents or borrows the certificate or lets another person use it.

7. The certificate holder no longer satisfies one of the conditions for grant of a pharmacy practice certificate prescribed in Article 13, or in Clause 2, Article 14, of this Law.

8. The certificate holder has stopped practicing pharmacy for 12 consecutive months.

9. The pharmacy practitioner possesses no written certification of completion of a pharmacy training or professional knowledge updating course issued within 3 years after obtaining a pharmacy practice certificate or obtaining the last certificate of completion of a pharmacy training or professional knowledge updating course.

10. The certificate holder violates the professional code of ethics in pharmacy practice, causing serious harms to other people's life or health.

11. The certificate holder has been deprived more than once of the pharmacy practice certificate for committing the same administrative violation.

Article 29. Management of pharmacy practice certificates

1. A person may be granted only one pharmacy practice certificate. A pharmacy practice certificate must indicate the scope of practice for which the holder satisfies the prescribed conditions and within which he/she may practice. A pharmacy practice certificate does not have a validity duration and is valid nationwide.

A pharmacy practice certificate shall be invalidated when its holder is dead or missing under a court's decision or judgment or does not obtain a certificate of completion of a pharmacy training or professional knowledge updating course within 3 years after being granted a pharmacy practice certificate or after obtaining the last certificate of completion of a pharmacy training or professional knowledge updating course.

2. The recognition of pharmacy practice certificates among countries must comply with international agreements to which Vietnam is a party or treaties to which the Socialist Republic of Vietnam is a contracting party.

3. A pharmacy practice certificate must have the following principal details:

a/ Personal information of the pharmacy practitioner;

b/ Professional degrees;

c/ Form of practice;

d/ Scope of professional activities;

dd/ Mode of grant of the certificate: through consideration and approval or examination; examination time in case the certificate is granted through an examination;

e/ Date of grant, granting agency and date of validity.

4. The Government shall prescribe in detail dossiers and procedures for grant, re-grant, modification or revocation of a pharmacy practice certificate and its form; training institutions, pharmacy training and professional knowledge updating programs, contents and durations; standardization of professional degrees and titles; form of the certificate of completion of a pharmacy training or professional knowledge updating course; form of the written certification of the period of practice and appropriate establishments for professional practice; the practice period applied to persons with postgraduate specialized qualifications; and grant of pharmacy practice certificates based on examinations.

Section 2

RIGHTS AND OBLIGATIONS OF A PHARMACY PRACTITIONER

Article 30. Rights of a pharmacy practitioner

1. To be trained in and updated with professional knowledge, and to exchange professional information and information about the law on pharmacy.

2. To be granted a pharmacy practice certificate when fully satisfying the conditions prescribed by this Law.

3. When absent, a person responsible for professional pharmacy activities at a pharmaceutical business establishment may authorize another person possessing an appropriate pharmacy practice certificate to take responsibility for such activities under regulations.

4. A person responsible for professional pharmacy activities at a drugstore may replace a drug in a prescription with another drug that has the same active ingredients, route of administration and dosage if agreed by the buyer, and shall take responsibility for the replacement.

5. To refuse to carry out professional activities in contravention of law or the code of professional ethics.

Article 31. Obligations of a pharmacy practitioner

1. To observe the code of professional ethics in pharmacy practice.

2. A person responsible for professional activities at a drug retailing establishment must be present throughout the course of its operation, except when authorizing another person during his/her absence under Clause 3, Article 30 of this Law.

3. To be responsible for professional activities of only one drug business establishment and at only one place of drug business.

4. To practice pharmacy within the scope indicated in his/her pharmacy practice certificate and according to professional technical regulations.

5. To comply with decisions of competent state agencies when a dangerous epidemic, natural disaster or catastrophe occurs.

6. To complete a pharmacy professional training or knowledge updating course within 3 years after obtaining a pharmacy practice certificate or obtaining the last certificate of completion of such a course.

7. To notify a competent agency or person of violations of law or the code of professional ethics committee by other pharmacy practitioners and take responsibility for such information.

Chapter IV

PHARMACEUTICAL BUSINESS

Section 1

PHARMACEUTICAL BUSINESS ESTABLISHMENTS AND CONDITIONS

Article 32. Pharmaceutical business activities and establishments

1. Pharmaceutical business activities include:

a/ Trading in drugs or drug materials;

b/ Providing the service of preserving drugs or drug materials;

c/ Providing the service of testing drugs or drug materials;

d/ Providing the service of clinical trial of drugs;

dd/ Providing the service of bioequivalence trial of drugs.

2. Pharmaceutical business establishments include:

a/ Establishments manufacturing drugs or drug materials;

b/ Establishments importing or exporting drugs or drug materials;

c/ Establishments providing the service of preserving drugs or drug materials;

d/ Establishments wholesaling drugs or drug materials;

dd/ Establishments retailing drugs, including drugstores, drug dispensaries, medicine cabinets of commune health stations, establishments retailing medicinal materials, drugs from medicinal materials or traditional drugs;

e/ Establishments providing the service of testing drugs or drug materials;

g/ Establishments providing the service of clinical trial of drugs;

h/ Establishments providing the service of bioequivalence trial of drugs.

Article 33. Conditions for grant of a certificate of eligibility for pharmaceutical business

1. Conditions of physical and technical foundations and personnel are as follows:

a/ An establishment manufacturing drugs or drug materials must have a place, workshop, laboratory and storehouse for preservation of drugs or drug materials, auxiliary system, tools, equipment and machinery for manufacture, testing and preservation of drugs, quality management system, professional and technical documents and employees satisfying the requirements of good practices of manufacturing drugs or drug materials;

b/ An establishment importing or exporting drugs or drug materials or providing the service of storage of drugs or drug materials must have a place and storehouse for drug storage, preserving tools and equipment, vehicles, quality management system, professional and technical documents and employees satisfying the requirements of good practices of storage of drugs or drug materials;

c/ An establishments wholesaling drugs or drug materials must have a place and storehouse for drug preservation, preserving tools and equipment, vehicles, quality management system, professional and technical documents and employees satisfying the requirements of good practices of distribution of drugs or drug materials;

d/ An establishment retailing drugs must have a place and area for drug storage, preserving tools and equipment, professional and technical documents and employees satisfying the requirements of good practices of drug retailing; an establishment retailing medicinal materials, drugs from medicinal materials or traditional drugs must comply with Point b, Clause 2, Article 69 of this Law;

dd/ An establishment providing the service of testing drugs or drug materials must have a place, laboratory for chemical, microbiological or biological testing, auxiliary system, testing tools and equipment, chemicals, reagents, quality management system, professional and technical documents and employees satisfying the requirements of good laboratory practices for drug quality inspection;

e/ An establishment providing the service of clinical trial of drugs must have a place, clinical trial laboratory, laboratory and equipment for bio-chemical testing, quality management system, professional and technical documents and employees satisfying the requirements of good practices of clinical trial of drugs;

g/ An establishments providing the service of bioequivalence trial of drugs must have a place, laboratory for analysis of biofluids, experiment tools and equipment for analysis of biofluids, area for accomodation and monitoring of drug users to serve the assessment of bioequivalence, quality management system, professional and technical documents and employees satisfying the requirements of good laboratory practices for the stage of biofluid analysis and of good practices of clinical trial of drugs for the stage of clinical research.

An establishment providing the service of bioequivalence trial of drugs and satisfying only the requirements of good laboratory practices for biofluid analysis shall contract or cooperate with an establishment conducting clinical trial of drugs and satisfying the requirements of good practices of clinical trial of drugs to perform clinical research in the bioequivalence trial of drugs.

2. Persons responsible for professional pharmacy activities and those holding the working positions specified in Article 11 of this Law must possess a pharmacy practice certificate relevant to the pharmaceutical business establishments specified in Clause 2, Article 32 of this Law.

3. The satisfaction of the conditions of physical and technical foundations and personnel prescribed in Clause 1 of this Article shall be assessed once every three years or on an extraordinary basis under regulations of the Minister of Health or a treaty to which the Socialist Republic of Vietnam is a contracting party.

Article 34. Business conditions for drugs under special control and drugs on the list of drugs restricted from retail

1. An establishment trading in drugs under special control shall obtain a written approval from the state management agency in charge of pharmacy. Such approval shall be granted based on the following conditions:

a/ The conditions prescribed in Article 33 of this Law as appropriate to each type of business establishment;

b/ Having security measures to present loss of drugs or drug materials under special control;

c/ If trading in radioactive drugs, satisfying the conditions prescribed by the Law on Atomic Energy and other relevant laws.

2. An establishment retailing drugs on the list of drugs restricted from retail issued by the Minister of Health must fully satisfy the conditions prescribed at Point d, Clause 1, Article 33 of this Law and obtain a written approval from the provincial-level Health Department. Such approval shall be granted based on the structure of diseases and drug supply capacity of the province or centrally run city under the guidance of the Minister of Health.

3. The Government shall prescribe the order and procedures for permitting the trading of drugs under special control and drugs on the list of drugs restricted

from retail; and security measures to prevent loss of drugs or drug materials under special control.

Article 35. Establishments engaged in pharmacy activities not required to have a certificate of eligibility for pharmaceutical business

1. Establishments engaged in pharmacy activities not required to have a certificate of eligibility for pharmaceutical business include:

a/ Establishments engaged in pharmacy activities for non-commercial purposes;

b/ Business establishments that have a drug shelf;

c/ Establishments culturing, cultivating and harvesting medicinal materials;

d/ Medical establishments of the people's armed forces engaged in the supply of drugs in ethnic minority areas, mountainous areas, on islands and in areas with extremely difficult socio-economic conditions.

2. The operation conditions of the establishments specified in Clause 1 of this Article are as follows:

a/ An establishment specified at Point a, Clause 1 of this Article must satisfy the business conditions prescribed in Clause 1, Article 33 of this Law;

b/ An establishment specified at Point a, Clause 1 of this Article must have business registration, the conditions for drug preservation consistent with the preservation conditions indicated on the drug labels, and a person responsible for professional activities who possesses a professional pharmacy degree of primary or higher level, and may only sell drugs on the list of drugs permitted for sale on drug shelves issued by the Minister of Health;

c/ An establishment culturing, cultivating and harvesting medicinal materials must observe the good practices of culturing, cultivating and harvesting medicinal materials;

d/ An establishment specified at Point d, Clause 1 of this Article must have the conditions for drug preservation consistent with the preservation conditions indicated on the drug labels and a person responsible for professional activities who possesses a professional pharmacy degree of primary or higher level.

3. The Minister of Health shall detail this Article.

Section 2

CERTIFICATE OF ELIGIBILITY FOR PHARMACEUTICAL BUSINESS

Article 36. Grant, re-grant or modification of a certificate of eligibility for pharmaceutical business

1. A certificate of eligibility for pharmaceutical business shall be granted to:

a/ An establishment that applies for a certificate for the first time;

b/ An establishment that already has a certificate but then changes its type or scope of pharmaceutical business, leading to a change in the business conditions; or an establishment that changes its pharmaceutical business location;

c/ An establishment whose certificate of eligibility for pharmacy business was revoked under Article 40 of this Law.

2. A certificate of eligibility for pharmaceutical business shall be re-granted in the following cases:

a/ It is lost or damaged;

b/ It contains incorrect information due to the granting agency.

3. A certificate of eligibility for pharmaceutical business shall be modified when there is a change in the name, business address, person managing professional activities or business scope of the pharmaceutical business establishment, which does not result in a change in the pharmaceutical business conditions.

Article 37. Competence to grant, re-grant, modify and revoke certificates of eligibility for pharmaceutical business

1. The Minister of Health may grant, re-grant, modify and revoke certificates of eligibility for pharmaceutical business of business establishments specified at Points a, b, c, e, g and h, Clause 2, Article 32 of this Law.

2. Directors of provincial-level Health Departments may grant, re-grant, modify and revoke certificates of eligibility for pharmaceutical business of business establishments specified at Points d and dd, Clause 2, Article 32 of this Law.

Article 38. Dossier of application for grant or re-grant or of request for modification of a certificate of eligibility for pharmaceutical business

1. A dossier of application for a certificate of eligibility for pharmaceutical business in the cases specified at Points a and c, Clause 1, Article 36 of this Law must comprise:

a/ An application for a certificate of eligibility for pharmaceutical business;

b/ Relevant technical documents of the pharmaceutical business establishment specified in Clause 2, Article 32 of this Law;

c/ A certified copy of the enterprise registration certificate or a valid document proving the founding of the establishment;

d/ A certified copy of the pharmacy practice certificate.

2. A dossier of application for a certificate of eligibility for pharmaceutical business in the cases specified at Point b, Clause 1, Article 36 of this Law must comprise:

a/ An application for a certificate of eligibility for pharmaceutical business;

b/ Relevant technical documents of the changed business conditions;

c/ A certified copy of the enterprise registration certificate or a valid document proving the founding of the establishment;

d/ A certified copy of the pharmacy practice certificate.

3. A dossier of application for re-grant of a certificate of eligibility for pharmaceutical business must comprise:

a/ An application for re-grant of a certificate of eligibility for pharmaceutical business;

b/ The certificate of eligibility for pharmaceutical business which contains incorrect information due to the granting agency, for the case specified at Point b, Clause 2, Article 36 of this Law.

4. A dossier of request for modification of a certificate of eligibility for pharmaceutical business must comprise:

a/ A written request for modification of a certificate of eligibility for pharmaceutical business;

b/ A certified copy of the pharmacy practice certificate, in case of change of the working position that requires a pharmacy practice certificate;

c/ A certified copy of the enterprise registration certificate or a valid document proving the change of the name or address of the establishment, if any.

5. The Government shall detail this Article.

Article 39. Procedures for grant, re-grant or modification of a certificate of eligibility for pharmaceutical business

1. A dossier of application for grant or re-grant or of request for modification of a certificate of eligibility for pharmaceutical business shall be submitted to a competent agency specified in Article 37 of this Law.

2. Within 30 days after receiving a complete dossier of application for grant or 20 days after receiving a complete dossier of application for re-grant or of request for modification of a certificate of eligibility for pharmaceutical business, the Minister of Health or the director of a provincial-level Health Department shall examine the dossier and grant a certificate of eligibility for pharmaceutical business according to his/her competence. In case of refusal to grant, re-grant or modify a certificate of eligibility for pharmaceutical business, he/she shall reply in writing, clearly stating the reason.

In case of applying for re-grant of a certificate of eligibility for pharmaceutical business due to the fault of the granting agency, the applicant shall submit a dossier as prescribed in Clause 3, Article 38 of this Law. The time

limit for re-grant of a certificate of eligibility for pharmaceutical business is 7 days after the receipt of a complete dossier of application.

Article 40. Cases in which a certificate of eligibility for pharmaceutical business is revoked

1. The pharmaceutical business establishment terminates its pharmaceutical business.

2. The pharmaceutical business establishment no longer satisfies one of the conditions for grant of a certificate of eligibility for pharmaceutical business as prescribed in Articles 33 and 34 of this Law.

3. The certificate has been granted ultra vires or contains an unlawful content.

4. The pharmaceutical business establishment has ceased its business operation for 12 consecutive months without notifying to the state management agency in charge of pharmacy.

Article 41. Management of certificates of eligibility for pharmaceutical business

1. A certificate of eligibility for pharmaceutical business does not has a validity duration.

2. The Government shall detail the following:

a/ Dossiers and procedures for grant, re-grant, modification and revocation of a certificate of eligibility for pharmaceutical business;

b/ Geographical areas and scope of business operation of retailing establishments being drug dispensaries or medicine cabinets of commune health stations;

c/ A roadmap for realization of good practices for each type of pharmaceutical business establishment.

Section 3

RIGHTS AND RESPONSIBILITIES OF A PHARMACEUTICAL BUSINESS ESTABLISHMENT

Article 42. Rights and responsibilities of a pharmaceutical business establishment

1. A pharmaceutical business establishment has the following rights:

a/ To conduct one, several or all of pharmaceutical business activities if fully satisfying the conditions prescribed by this Law for each type of business establishment;

b/ To enjoy preferential policies when conducting pharmaceutical business activities in accordance with law;

c/ To disseminate information about or advertise drugs in accordance with law;

d/ To implement the program on free supply of drugs to medical examination and treatment establishments for treatment of patients under regulations of the Minister of Health;

dd/ To organize mobile drug retailers in ethnic minority areas, mountainous areas, on islands, and in areas with extremely difficult socio-economic conditions under regulations of the Government.

2. A pharmaceutical business establishment has the following responsibilities:

a/ To obtain a certificate of eligibility for pharmaceutical business and to conduct business suitable to its type and within the scope and at the location indicated in the certificate;

b/ To maintain the pharmaceutical business conditions throughout the course of operation in accordance with this Law;

c/ To recall drugs or drug materials in accordance with Article 62 of this Law;

d/ To pay compensations for damage caused due to its fault to organizations and individuals in accordance with law;

dd/ To comply with decisions of competent state agencies to ensure supply of drugs or drug materials when a dangerous disease, natural disaster or catastrophe occurs;

e/ To report to the Health Ministry or provincial-level Health Department and perform the obligations prescribed by law when the establishment suspends its operation for at least 6 months or terminates its operation;

g/ To report and update the list of persons who have a pharmacy practice certificate and are practicing at the establishment to competent agencies as prescribed by the Minister of Health;

h/ To publicly display the pharmacy practice certificate and certificate of eligibility for pharmaceutical business at the establishment;

i/ To make annual reports and reports at the request of competent management agencies in charge of pharmacy;

k/ To comply with regulations of the Ministry of Health on purchase and sale of drugs on the list of drugs restricted from retail;

l/ To display wholesale and retail prices in Vietnam dong at its transaction places or places of drug sale where customers and competent state agencies can easily notice, and to comply with other regulations on drug price management;

m/ To keep documents relating to each lot of drugs or drug materials for at least 1 year from the expiry date of such drugs or drug materials;

n/ To preserve drugs or drug materials under the conditions indicated on their labels;

o/ To clearly write down the drug's name, content and expiry date for the user in case of retailing a drug without secondary package; and also the drug's dose, number of times and route of administration in case of retailing a drug without a prescription;

p/ To sell prescription drugs at its drug retailers only when there is a prescription.

3. When trading in drugs under special control, in addition to the responsibilities prescribed in Clause 2 of this Article, a pharmaceutical business establishment has the following responsibilities:

a/ To make periodical reports, import or export reports or reports at the request of competent management agencies;

b/ To make dossiers and keep documents relating to each type of drug or drug material under regulations of the Health Ministry.

Article 43. Rights and responsibilities of an establishment manufacturing drugs or drug materials

1. An establishment manufacturing drugs or drug materials has the following rights:

a/ The rights prescribed in Clause 1, Article 42 of this Law;

b/ To research, manufacture on a trial basis or manufacture drugs or drug materials; to franchise and receive the franchised drug manufacturing right; to process, and undertake the processing of, drugs or drug materials;

c/ To register for circulation drugs or drug materials; to transfer the ownership of certificates of registration for circulation of drugs or drug materials; to request revocation of certificates of registration for circulation of drugs or drug materials which they manufacture; to request recall of drugs or drug materials in accordance with this Law;

d/ To import or purchase drug materials to serve drug manufacture; to import drugs or drug materials to serve research or testing or to be used as samples for drug circulation registration;

dd/ To sell drug materials imported to serve its drug manufacture to other drug manufacturing establishments;

e/ To wholesale drugs or drug materials to establishments whosaling or retailing drugs and to medical examination and treatment establishments;

g/ To export drugs or drug materials specified in Clauses 4 and 5, Article 60 of this Law.

2. An establishment manufacturing drugs or drug materials has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, c, d, dd, e, g, h, i, k, l, m and n, Clause 2, Article 42 of this Law;

b/ To manufacture drugs or drug materials according to the registered or announced manufacturing process and quality standards;

c/ To take responsibility for the origin and quality of its drugs or drug materials and to ex-workshop only drugs or drug materials satisfying the registered quality standards;

d/ To monitor the quality, safety and effects of its drugs or drug materials in circulation and recall its drugs or drug materials in accordance with this Law;

dd/ To take responsibility for imported, purchased, sold and used quantities of drugs or drug materials and report thereon under regulations of the Minister of Health.

Article 44. Rights and responsibilities of an establishment importing or exporting drugs or drug materials

1. An establishment importing or exporting drugs or drug materials has the following rights:

a/ The rights prescribed at Points a, b, c and d, Clause 1, Article 42 of this Law;

b/ To import drugs or drug materials specified in Article 60 of this Law;

c/ To register for circulation drugs or drug materials; to transfer the ownership of certificates of registration for circulation of drugs or drug materials; to request revocation of certificates of registration for circulation of drugs or drug materials; to request recall of drugs or drug materials in accordance with this Law;

d/ To sell imported drugs or drug materials to establishments wholesaling, retailing or manufacturing drugs and to medical examination and treatment establishments. In case it cannot exercise the right to distribute drugs in Vietnam, the establishment may sell imported drugs or drug materials under regulations of the Minister of Health;

dd/ To export drugs or drug materials specified in Clauses 4 and 5, Article 60 of this Law.

2. An establishment importing or exporting drugs or drug materials has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, c, d, dd, e, g, h, i, k, l, m and n, Clause 2, Article 42 of this Law;

b/ To take responsibility for the quantities and quality of drugs or drug materials which it imports or exports and report thereon under regulations of the Minister of Health.

Article 45. Rights and responsibilities of an establishment providing the service of preserving drugs or drug materials

1. An establishment providing the service of preserving drugs or drug materials has the following rights:

a/ The rights prescribed at Points a, b and c, Clause 1, Article 42 of this Law;

b/ To preserve drugs or drug materials for organizations and individuals;

c/ To export drugs or drug materials specified in Clauses 4 and 5, Article 60 of this Law.

2. An establishment providing the service of preserving drugs or drug materials has the responsibilities prescribed at Points a, b, c, d, dd, e, g, h, i, m and n, Clause 2, Article 42 of this Law.

Article 46. Rights and responsibilities of an establishment wholesaling drugs or drug materials

1. An establishment wholesaling drugs or drug materials has the following rights:

a/ The rights prescribed in Clause 1, Article 42 of this Law;

b/ To whosale drugs or drug materials;

c/ To purchase drugs or drug materials;

d/ To register for circulation of drugs or drug materials; to transfer the ownership of certificates of registration for circulation of drugs or drug materials; to request revocation of certificates of registration for circulation of drugs or drug materials; to request recall of drugs or drug materials in accordance with this Law;

dd/ To export drugs or drug materials specified in Clauses 4 and 5, Article 60 of this Law.

2. An establishment wholesaling drugs or drug materials has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, c, d, dd, e, g, h, i, k, l, m and n, Clause 2, Article 42 of this Law;

b/ To ensure that the delivery, receipt and preservation of drugs or drug materials are conducted by professionally qualified persons.

Article 47. Rights and responsibilities of a drugstore

1. A drugstore has the following rights:

a/ The rights prescribed at Points a, b, c and dd, Clause 1, Article 42 of this Law;

b/ To purchase drug materials for preparation of prescription drugs and sell such drugs at the store. A person managing professional pharmacy activities at the drugstore shall directly manage the preparation of drugs at the drugstore;

c/ To purchase drugs for retail, except vaccines. The purchase and sale of drugs under special control and drugs on the list of drugs restricted from retail must comply with Article 34 of this Law;

d/ To participate in dispensing drugs covered by insurance or under health programs or projects when satisfying the requirements and conditions set by the insurers or such programs or projects;

dd/ A person with a pharmacist degree may replace a drug indicated in a prescription with another drug with the same active ingredient, route of administration and dosage if agreed by the buyer, and shall take responsibility for the replacement.

2. A drugstore has the following responsibilities:

a/ The responsibilities prescribed in Clause 2, Article 42 and Clause 2, Article 81 of this Law;

b/ To ensure the conditions for drug preparation prescribed by the Minister of Health;

c/ To refrain from selling drug materials, except medicinal materials.

Article 48. Rights and responsibilities of a dispensary

1. A dispensary has the following rights:

a/ The rights prescribed at Points a, b, c and dd, Clause 1, Article 42 of this Law;

b/ To purchase and retail drugs on the list of essential drugs and list of non-prescription drugs, excluding vaccines. The purchase and sale of drugs on the list of drugs under special control and the list of drugs restricted from retail must comply with Article 34 of this Law. Dispensaries located in ethnic minority areas, mountainous areas, on islands and in areas with extremely difficult socio-economic conditions may also sell some other drugs as prescribed by the Minister of Health.

c/ To participate in dispensing drugs covered by insurance or under health programs or projects when satisfying the requirements and conditions set by the insurers or such programs or projects.

2. A dispensary has the following responsibilities:

a/ The responsibilities prescribed in Clause 2, Article 42 of this Law;

b/ To refrain from selling drug materials, except medicinal materials.

Article 49. Rights and responsibilities of a commune health station's medicine cabinet

1. A commune health station's medicine cabinet has the following rights:

a/ The rights prescribed at Points a, b, c and dd, Clause 1, Article 42 of this Law;

b/ To purchase and retail drugs on the list of essential drugs suitable to its assigned professional and technical duties. The purchase and sale of drugs on the list of drugs under special control and the list of drugs restricted from retail must comply with Article 34 of this Law;

c/ To participate in dispensing drugs covered by insurance or under health programs or projects when satisfying the requirements and conditions set by the insurers or such programs or projects.

2. A commune health station's medicine cabinet has the following responsibilities:

a/ The responsibilities prescribed in Clause 2, Article 42 of this Law;

b/ To refrain from selling drug materials, except medicinal materials.

Article 50. Rights and responsibilities of an establishment retailing medicinal materials, drugs from medicinal material or traditional drugs

1. An establishment retailing medicinal materials, drugs from medicinal materials or traditional drugs has the following rights:

a/ The rights prescribed at Points a, b, c and dd, Clause 1, Article 42 of this Law;

b/ To retail medicinal materials, drugs from medicinal materials or traditional drugs;

c/ To purchase medicinal materials, drugs from medicinal materials or traditional drugs for retail;

d/ To participate in dispensing drugs covered by insurance or under health programs or projects when satisfying the requirements and conditions set by the insurers or such programs or projects.

2. An establishment retailing medicinal materials, drugs from medicinal materials or traditional drugs has the following responsibilities:

a/ The responsibilities prescribed in Clause 2, Article 42 of this Law;

b/ To refrain from selling pharmaco-chemical drugs, vaccines, biological products and drug materials being pharmaceutical ingredients, adjuvants and capsule shells.

Article 51. Rights and responsibilities of an establishment providing the service of testing drugs or drug materials

1. An establishment providing the service of testing drugs or drug materials has the following rights:

a/ The rights prescribed at Points a and b, Clause 1, Article 42 of this Law;

b/ To test drugs or drug materials under regulations;

c/ To certify testing results for tested samples of drugs or drug materials;

d/ To import or purchase chemicals, standard substances, samples of drugs or drug materials to serve the testing of drugs or drug materials.

2. An establishment providing the service of testing drugs or drug materials has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, d, dd, e, g, h, i, m and n, Clause 2, Article 42 of this Law;

b/ To ensure the truthfulness and objectivity of the testing of drugs or drug materials;

c/ To take responsibility for testing results for tested samples of drugs or drug materials.

Article 52. Rights and responsibilities of an establishment providing the service of clinical trial of drugs

1. An establishment providing the service of clinical trial of drugs has the following rights:

a/ The rights prescribed at Points a and b, Clause 1, Article 42 of this Law;

b/ To conduct clinical trial of drugs under regulations;

c/ To import or purchase chemicals, standard substances, sample drugs to serve clinical trial of drugs;

d/ To use results of clinical trial of drugs as agreed with agencies, organizations or individuals having the drugs put for clinical trial.

2. An establishment providing the service of clinical trial of drugs has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, d, dd, e, g, h, i, m and n, Clause 2, Article 42 of this Law;

b/ To take responsibility for results of clinical trial of drugs;

c/ To take responsibility for the safety for persons participating in the clinical trial of drugs and pay compensations to these persons in case a risk occurs due to its fault in accordance with law;

d/ To ensure the truthfulness and objectivity of the clinical trial of drugs;

dd/ To be financially and organizationally independent from agencies, organizations or individuals having the drugs put for clinical trial.

Article 53. Rights and responsibilities of an establishment providing the service of bioequivalence trial of drugs

1. An establishment providing the service of bioequivalence trial of drugs has the following rights:

a/ The rights prescribed at Points a and b, Clause 1, Article 42 of this Law;

b/ To conduct clinical research and biofluid analysis in the bioequivalence trial of drugs.

In case it only conducts the biofluid analysis, the establishment may contract or cooperate with an establishment conducting clinical trial of drugs and satisfying the good practices of clinical trial of drugs to conduct the clinical research in the bioequivalence trial of drugs;

c/ To conduct bioequivalence trial of drugs under regulations;

d/ To import or purchase chemicals, standard substances and sample drugs to serve the bioequivalence trial of drugs;

dd/ To use results of bioequivalence trial of drugs as agreed with agencies, organizations or individuals having the drugs put for bioequivalence trial.

2. An establishment providing the service of bioequivalence trial of drugs has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, c, d, e, g, h, i, m and n, Clause 2, Article 42 of this Law;

b/ To take responsibility for results of bioequivalence trial of drugs with regard to the drug samples put for trial;

c/ To take responsibility for the safety for persons participating in the bioequivalence trial of drugs and pay compensations to these persons in case a risk occurs due to its fault in accordance with law;

d/ To ensure truthfulness and objectiveness of the bioequivalence trial of drugs;

dd/ To be financially and organizationally independent from agencies, organizations or individuals having the drugs put for bioequivalence trial.

Chapter V

REGISTRATION, CIRCULATION AND RECALL OF DRUGS AND DRUG MATERIALS

Section 1

REGISTRATION OF DRUGS AND DRUG MATERIALS

Article 54. Drugs and drug materials subject to registration and registration requirements

1. Drugs shall be registered before circulation in Vietnam, excluding:

a/ Prescription drugs prepared at a drugstore as prescribed at Point b, Clause 1, Article 47, and drugs manufactured and prepared at a medical examination and treatment establishment as prescribed in Article 85 of this Law;

b/ Imported drugs as prescribed in Clause 2, Article 60 of this Law;

c/ Traditional drugs as prescribed in Clauses 1 and 2, Article 70 of this Law.

2. Drug materials shall be registered before circulation in Vietnam, excluding:

a/ Drug materials which are pharmaceutical ingredients as stated in drug registration dossiers and which already have certificates of free sale in Vietnam;

b/ Imported drug materials as prescribed in Clause 3, Article 60 of this Law.

3. The following establishments may register drugs or drug materials:

a/ Establishments manufacturing, wholesaling, exporting or importing drugs or drug materials in Vietnam;

b/ Foreign establishments trading in drugs or drug materials and having representative offices in Vietnam.

4. A certificate of free sale in Vietnam may be granted for drugs and drug materials which:

a/ Meet safety and efficacy requirements;

b/ Are manufactured at an establishment that meets the conditions prescribed in this Law;

c/ Are manufactured according to the process and meet the quality standards prescribed in Articles 102 and 103 of this Law.

5. When registering imported drugs and drug materials for circulation in Vietnam, an overseas manufacturer shall be assessed in terms of its satisfaction of good manufacture practices in one of the following forms:

a/ Appraisal of documents relating to manufacture conditions;

b/ Mutual accreditation or recognition of inspection or examination results provided by the state management agency in charge of pharmacy regarding the satisfaction of the requirements of good manufacture practices;

c/ Examination at the manufacturing establishment.

6. The Government shall detail the registration for circulation of medicinal materials, adjuvants and capsules, and detail Clause 5 of this Article.

Article 55. Forms of registration of drugs and drug materials

1. Drugs and drug materials shall be registered in one of the following forms:

a/ Grant of a certificate of free sale;

b/ Extension of a certificate of free sale;

c/ Modification and supplementation of the content of a certificate of free sale.

2. A certificate of free sale shall be granted for:

a/ Drugs or drug materials which have no certificate of free sale in Vietnam;

b/ Drugs which already have certificates of free sale but then see changes in their pharmaceutical ingredients or medicinal materials; content, concentration or amount of active pharmaceutical ingredients or medicinal materials; form of preparation; route of administration; or change of their manufacturer, except change of secondary packaging establishment or manufacturing workshop or location;

c/ Drug materials which already have certificates of free sale but then see change of their manufacturer, except change of secondary packaging establishment or manufacturing workshop or location.

3. Modification and supplementation of the content of a certificate of free sale of drugs or drug materials granted in Vietnam shall be effected when there is a change in the certificate's validity duration, except the cases prescribed at Points b and c, Clause 2 of this Article.

4. Extension of a certificate of free sale of drugs or drug materials shall be effected when the certificate expires, including also the case in which drugs or drug materials see changes in their administrative documents at the time of extension registration.

Article 56. Competence, dossiers, procedures and time limits for grant, extension and modification and supplementation of the content of a certificate of free sale of drugs or drug materials

1. The Minister of Health shall grant, extend or modify and supplement the content of certificates of free sale of drugs or drug materials on the basis of dossier appraisal and advice from the advisory council for grant of certificates of free sale of drugs or drug materials.

Dossiers of application for grant, extension or modification and supplementation of the content of a certificate of free sale of drugs or drug materials shall be submitted to the Ministry of Health.

2. A dossier of application for a certificate of free sale of drugs or drug materials must comprise:

a/ Administrative documents, including an application for a certificate of free sale of drugs or drug materials; a certified copy of the representative office's establishment license which remains valid, for foreign establishments trading in drugs and drug materials, or of the certificate of eligibility for pharmaceutical business which remains valid, for Vietnamese establishments trading in drugs and drug materials; the original or a certified copy of the certificate of pharmaceutical products, for imported drugs, which remains valid; sample labels of drugs or drug materials; information on drugs and other documents on trading and circulation of drugs or drug materials;

b/ Technical documents proving that drugs or drug materials satisfy the requirements prescribed in Clause 4, Article 54 of this Law; for new drugs, reference biological products, vaccines, and drugs from medicinal materials for treatment of diseases on the list issued by the Minister of Health, clinical trial documents proving their safety and efficacy are also required; for similar biological products, documents proving the similarity in their quality, safety and efficacy against a reference biological products are also required; for drugs subject to bioequivalence trial, a report on their bioequivalence study data is also required;

c/ Sample labels of drugs or drug materials sold in the host country or a reference country, for imported drugs.

3. A dossier of request for extension of a certificate of free sale of drugs or drug materials must comprise:

a/ An application for extension of a certificate of free sale of drugs or drug materials;

b/ A certified copy of the representative office's establishment license which remains valid, for foreign establishments trading in drugs and drug materials, or of the certificate of eligibility for pharmaceutical business which remains valid, for Vietnamese establishments trading in drugs and drug materials;

c/ The original or a certified copy of the certificate of pharmaceutical products, for imported drugs, which remains valid;

d/ A report on the sale of drugs or drug materials;

dd/ A report of the safety and efficacy of drugs, for drugs whose safety and efficacy must be further monitored;

e/ A copy of the certificate of free sale of drugs or drug materials in Vietnam.

4. A dossier of request for modification and supplementation of the content of a certificate of free sale of drugs or drug materials must comprise:

a/ An application for modification and supplementation of the content of a certificate of free sale of drugs or drug materials;

b/ Technical documents, for the modified and supplemented contents;

c/ A copy of the certificate of free sale of drugs or drug materials in Vietnam which remains valid.

5. The time limit for grant, extension or modification and supplementation of the content of a certificate of free sale of drugs or drug materials is:

a/ Twelve months from the date of receipt of a complete dossier of application for a certificate, or from the date of receipt of a complete dossier for new drugs, reference biological products, similar biological products, vaccines, and drugs from medicinal materials for treatment of diseases on the list issued

by the Minister of Health, including clinical trial documents proving their safety and efficacy;

b/ Three months from the date of receipt of a complete dossier of request for extension or modification and supplementation of the content of a certificate;

c/ In case of refusal to grant or extend, or modify and supplement the content of, a certificate of free sale of drugs or drug materials or when the conditions for grant, extension or modification and supplementation of the content of such certificate are not fully satisfied, a written reply shall be issued, clearly stating the reason.

6. The validity duration of a certificate of free sale of drugs or drug materials is 5 years from the date of its grant or extension.

For drugs whose safety and efficacy must be further monitored, the validity duration of a certificate of free sale is 3 years from the date of its grant.

7. The Minister of Health shall prescribe in detail the dossier and procedures for grant, extension or modification and supplementation of the content of a certificate of free sale of drugs or drug materials.

Article 57. Rights and responsibilities of an establishment registering drugs or drug materials

1. An establishment registering drugs or drug materials has the following rights:

a/ To receive instructions on registration of drugs or drug materials, information on the progress of processing its registration dossier, and other information relating to drugs or drug materials after obtaining a certificate of free sale;

b/ To request revocation of the certificate of free sale of drugs or drug materials it has registered.

2. An establishment registering drugs or drug materials has the following responsibilities:

a/ To notify the management agency in case its drugs or drug materials which have been granted a certificate of free sale in Vietnam are recalled in any country in the world; of its suspension of manufacture or supply, or of the danger of shortage or the shortage of drugs or drug materials; or of the change of the registering establishment while the certificate remains valid;

b/ To fully preserve the registration dossiers of drugs or drug materials and provide them to competent management agencies upon request;

c/ To comply with inspection and assessment requests of competent management agencies.

Article 58. Revocation of a certificate of free sale of drugs and drug materials

1. A certificate of free sale of drugs or drug materials shall be revoked in the following cases:

a/ Drugs are recalled for a level-1 violation;

b/ Within 60 months 2 lots of drugs are recalled for a level-2 or level-3 violation or 3 or more lots of drugs are detected to violate quality regulations;

c/ For imported drugs, the certificate of pharmaceutical products, which serves as a basis for the Ministry of Health to grant a certificate of free sale of drugs or drug materials in Vietnam, is revoked by competent foreign authorities;

d/ The certificate was granted based on a forged dossier;

dd/ Drugs or drug materials are manufactured at a location not stated in the registration dossier;

e/ Pharmaceutical ingredients, medicinal materials or drugs containing pharmaceutical ingredients or medicinal materials are unsafe and ineffective for users as recommended by the World Health Organization or competent management agencies of Vietnam or countries of origin of the drugs;

g/ The establishment manufacturing or establishment registering drugs or drug materials requests revocation of the certificate.

2. The Minister of Health shall prescribe in detail the dossier and procedures for revocation of certificates of free sale of drugs or drug materials.

Section 2

CIRCULATION OF DRUGS AND DRUG MATERIALS

Article 59. Provisions on circulation of drugs and drug materials

1. Drugs and drug materials permitted for circulation in the market include:

a/ Drugs and drug materials which have a certificate of free sale;

b/ Imported drugs and drug materials prescribed in Clauses 1, 2, 3 and 4, Article 60 of this Law;

c/ Drugs prescribed at Point b, Clause 1, Article 47, Clauses 1 and 2, Article 70, and Clause 3, Article 85, of this Law;

d/ Domestically manufactured drugs and drug materials that are manufactured before their certificates of free sale expire and are allowed to be circulated until their expiry date;

dd/ Imported drugs and drug materials that are delivered at the port of departure of the exporting country before their certificates of free sale expire and are allowed to be circulated until their expiry date;

e/ Drugs and drug materials that are domestically manufactured or drugs that are imported before the date their certificates of free sale are revoked under Article 58 of this Law, unless they are recalled in accordance with Article 62 of this Law.

2. To be circulated in the market, a drug must meet the following requirements:

a/ Satisfying quality, safety and efficacy requirements;

b/ Satisfying labeling requirements prescribed in Article 61 of this Law and other relevant laws;

c/ Its packaging materials and form ensuring drug quality.

3. To be circulated in the market, a drug material must meet the following requirements:

a/ Satisfying quality, safety and efficacy requirements;

b/ Satisfying labeling requirements prescribed in Article 61 of this Law and other relevant laws;

c/ Its packaging materials and form ensuring the quality of drug materials.

Article 60. Drugs and drug materials permitted for import or export

1. Drugs and drug materials being pharmaceutical ingredients which have certificates of free sale in Vietnam; and drug materials being pharmaceutical ingredients for drug manufacture as stated in drug registration dossiers which have certificates of free sale in Vietnam may be imported without import permit, except drugs and drug materials prescribed in Clause 4 of this Article.

2. The following drugs which do not have certificates of free sale in Vietnam may be imported in a quantity not exceeding that stated in their import permits:

a/ Drugs containing pharmaceutical ingredients which do not have certificates of free sale or have certificates of free sale but being insufficient to meet treatment requirements;

b/ Drugs containing pharmaceutical ingredients which are used for the first time in Vietnam or which were previously used in Vietnam but being insufficient to meet treatment requirements;

c/ Drugs meeting urgent requirements of national defense, security, epidemic prevention and control, overcoming of consequences of natural disasters or catastrophes, or special treatment requirements;

d/ Rare drugs;

dd/ Drugs having the same trade names, active ingredients, content or concentration, or form of preparation as those of brand name specifics which have certificates of free sale in Vietnam, manufactured by the manufacturers of those brand name specifics or by authorized manufacturers, and whose prices are lower than those of brand name specifics circulated in Vietnam, at the request of by the Minister of Health;

e/ Drugs serving the State’s health programs;

g/ Drugs donated as aid or humanitarian aid;

h/ Drugs used for clinical trial, bioequivalence trial, bioavailability assessment, scientific research or display at exhibitions or fairs, or used as samples for registration or testing;

i/ Drugs in other cases for non-commercial purpose.

3. Drug materials being pharmaceutical ingredients which do not have certificates of free sale in Vietnam may be imported in a quantity not exceeding that stated in their import permits in the following cases:

a/ For use as samples for registration or testing, or for research or display at exhibitions or fairs;

b/ For manufacture of drugs for export, drugs for national defense and security, epidemic prevention and control, or overcoming of consequences of natural disasters or catastrophes.

4. Drugs under special control shall only be imported or exported under import or export permits in a quantity not exceeding that stated in the permits.

Depending on the socio-economic development, the Government shall stipulate types of drugs and drug materials subject to import control in each period.

5. Drugs and drug materials may be exported without permit of the Ministry of Health, except medicinal materials on the list of precious, rare and endemic medicinal material species and varieties subject to control issued by the Ministry of Health, drugs subject to special control, drug materials being psychotropic pharmaceutical ingredients, habit-forming pharmaceutical ingredients and presubstances used as drugs, or radioactive substances on the list issued by the Government.

6. The Ministry of Health shall disclose information relevant to drugs permitted for import under Points a, b, c and d, Clause 2 of this Article, including importer, manufacturer, quantity and name of drug, and serial number of import permit; and serial number of certificate of free sale of each active ingredient.

7. The Government shall prescribe in detail:

a/ Criteria, dossier, procedures and time limit for grant of import or export permits for drugs prescribed in Clauses 2, 3, 4 and 5 of this Article, and the list of drugs and drug materials banned from import or banned from manufacture;

b/ Import of medicinal materials, adjuvants, capsules and primary packages of drugs.

Article 61. Labels of drugs and drug materials circulated in the market

1. The label of a drug or drug material circulated in the market must have the following information:

a/ Name of drug or drug material;

b/ Form of preparation, except for drug materials;

c/ Ingredient, content, concentration or amount of pharmaceutical ingredients or medicinal materials of the drug or drug material. The label of a traditional drug on the list of state secrets and of a folk remedy may not show certain ingredients, content and amount of medicinal materials, but must contain the phrase "the drug manufacture formula is a state secret" or "the drug manufacture formula is a family secret";

d/ Packaging specifications;

dd/ Name and address of manufacturer;

e/ Name and address of importer, for imported drugs and drug materials;

g/ Serial number of certificate of free sale or of import permit, manufacture lot number, and date of manufacture;

h/ Expiry date of drug or drug material;

i/ Storage conditions and other necessary information as required.

2. The package insert constitutes an integral part of a drug label and must have all information details specified at Points a, b, c, d, dd, h and i, Clause 1 of this Article and must be in Vietnamese, except information that cannot be translated into Vietnamese or that makes no sense when being translated into Vietnamese.

3. The Minister of Health shall prescribe in detail the labeling of drugs and drug materials, and package inserts, and shall decide on the change of shelf life written on drug labels for the reasons of national defense, security, epidemic prevention and control, or overcoming of consequences of natural disasters or catastrophes.

Section 3

RECALL OF DRUGS AND DRUG MATERIALS

Article 62. Cases in which a drug or drug material shall be recalled

1. A drug shall be recalled in the following cases:

a/ It is other than those permitted for circulation as prescribed in Clause 1, Article 59 of this Law;

b/ Its certificate of free sale is revoked in the case specified at Point a, b, d, dd or e, Clause 1, Article 58 of this Law;

c/ It fails to meet the requirements prescribed in Clause 4, Article 54, or in Clause 2, Article 59, of this Law;

d/ It fails to satisfy the quality standards or is manufactured from materials that fail to satisfy the quality standards;

dd/ It fails to meet safety and efficacy requirements as concluded by a competent state agency;

e/ There is no proof that it was inspected in terms of quality in the course of manufacture and before delivery;

g/ There is a notice from foreign pharmacy management authorities to recall the drug.

2. A drug material circulated in the market shall be recalled in the following cases:

a/ It is used for improper purposes;

b/ Its certificate of free sale is revoked in the case specified at Point d, dd or e, Clause 1, Article 58 of this Law;

c/ It fails to meet the requirements prescribed in Clause 4, Article 54, or in Clause 3, Article 59, of this Law;

d/ It fails to meet the quality standards for drug manufacture; its origin is different from that already registered or indicated in the import permit;

dd/ There is no proof that it was inspected in terms of quality in the course of manufacture and before delivery;

e/ There is a notice of foreign pharmacy management authorities to recall it.

Article 63. Types of recall, levels of violation, scope and time of recall, and disposal of recalled drugs

1. Types of recall include:

a/ Voluntary recall, which is voluntarily effected by a drug registration establishment, drug manufacturer, drug importer or entrusted importer;

b/ Compulsory recall, which is effected under a decision of a competent state agency in the cases prescribed in Article 62 of this Law.

2. Levels of violation with respect to a drug include:

a/ Level-1 violation is a violation in which a drug is likely to cause serious harms to users' health or affect users' life;

b/ Level-2 violation is a violation in which there is evidence that a drug cannot ensure full treatment effect or is likely to be unsafe to users but not to the extent of causing serious harms to users' health or affecting users' life;

c/ Level-3 violation is a violation other than violations prescribed at Points a and b of this Clause which is due to other causes but does not affect treatment effect and users' safety.

3. The scope and time of recall of a drug are prescribed as follows:

a/ In case of level-1 violation, a drug shall be recalled at all pharmaceutical business establishments and medical examination and treatment establishments

and from users. The recall shall be completed within 3 days from the date of issuance of a recall decision;

b/ In case of level-2 violation, a drug shall be recalled at all pharmaceutical business establishments and medical examination and treatment establishments and from users. The recall shall be completed within 15 days from the date of issuance of a recall decision;

c/ In case of level-3 violation, a drug shall be recalled at all pharmaceutical business establishments. The recall shall be completed within 30 days from the date of issuance of a recall decision;

d/ In case of level-1 violation, if the recall of a drug falls beyond the capacity of the domestic drug manufacturer, drug importer or entrusted importer, or if past the recall time limit the manufacturer or importer still fails to recall the drug, the recall shall be coerced in accordance with law.

Competent state agencies shall directly organize the coerced recall; the domestic drug manufacturer, drug importer or entrusted importer shall pay expenses for the recall and handling of the recalled drug.

4. A recalled drug shall be disposed as follows:

a/ A drug that is recalled under Points a and b, Clause 2 of this Article shall be destroyed;

b/ A drug that is recalled under Point c, Clause 2 of this Article can been re-processed. If re-processing is impossible, it shall be re-exported or destroyed.

Article 64. Responsibility to recall a drug

1. A drug registration establishment, a domestic drug manufacturer, a drug preparation and processing establishment, a drug importer or an entrusted importer that has a drug recalled shall:

a/ Stop manufacturing or trading in the recalled drug

b/ Assume the prime responsibility for, and coordinate with related organizations and individuals in, disseminating information on the recalled drug and organize the recall and receipt of the recalled drug;

c/ Dispose of the recalled drug;

d/ Pay expenses for the recall and disposal of the recalled drug, and pay compensations in accordance with law;

dd/ Report on the recall and its result to the Ministry of Health;

e/ In case of voluntary recall, stop manufacturing or trading in and dispensing the drug and report on the recall to the Ministry of Health before the recall.

2. Drug wholesalers and retailers shall:

a/ Stop trading in or dispensing the drug;

b/ Notify and organize the recall and receipt of the drug returned by traders, suppliers and users;

c/ Return the recalled drug to the drug supplier;

d/ Pay expenses for the recall and disposal of the recalled drug, and pay compensations in accordance with law in case they are at fault.

3. Medical examination and treatment establishments and drug users shall:

a/ Stop the prescription, sale, dispensation and use of the recalled drug;

b/ Return the recalled drug to the drug supplier.

4. The Ministry of Health shall:

a/ Decide on the recall of a drug and disposal of the recalled drug nationwide, based on the level of the violation regarding the quality, safety and efficacy of the drug;

b/ Review the evaluation report and respond to the voluntary recall proposal of a drug manufacturer or trader;

c/ Inspect and supervise the organization and implementation of the recall of a drug or drug material; and handle violators in accordance with law;

d/ Publishing information on the recalled drug involved in a level-1 violation on its e-portal and via the Vietnam Television and the Voice of Vietnam right after the issuance of the recall decision.

5. The Vietnam Television and the Voice of Vietnam shall broadcast free of charge the information on the recall of a drug involved in a level-1 violation.

Article 65. Competence to issue recall decisions, procedures for recall

1. The Ministry of Health shall issue a recall decision for a drug subject to compulsory recall or for a drug subject to voluntary recall but involved in level-1 or level-2 violation. Such a decision shall be issued within 24 hours after the issuance of a conclusion that the drug shall be recalled and its violation level, or after the issuance of a conclusion that voluntary recall of a drug does not match its violation level.

2. The head of a drug registration establishment, a domestic drug-manufacturing establishment, an establishment preparing or processing a drug, or an establishment importing or entrusted to import a drug shall issue a recall decision in case of voluntary recall of a drug involved in a level-3 violation after consulting the Ministry of Health. Such decision shall be issued within 24 hours after obtaining the Ministry of Health's opinion.

3. The Minister of Health shall stipulate in detail the making of a conclusion on a drug which shall be recalled, level of violation involving the drug, procedures for the recall, and handling of the recalled drug.

4. The Government shall define the competence, order and procedures for recall of drug materials, and measures to dispose of recalled drug materials.

Chapter VI

MEDICINAL MATERIALS AND TRADITIONAL DRUGS

Section 1

MEDICINAL MATERIALS

Article 66. Culture, cultivation, harvest, exploitation and processing of medicinal materials

1. The culture, cultivation and harvest of medicinal materials must comply with the requirements of good practices in the culture, cultivation and harvest of medicinal materials.

2. The exploitation and processing of natural medicinal materials must be appropriate to each type of medicinal material, ensuring proper specifications, process, time and method of processing and method of preservation.

3. The Minister of Health shall stipulate a roadmap for application of good practices in the culture, cultivation and harvest of medicinal materials and promulgate principles and standards for exploitation of natural medicinal plants suitable to socio-economic development conditions.

Article 67. Preservation of medicinal materials

1. The preservation of medicinal materials must comply with the requirements of good practices in the preservation of drugs and drug materials.

2. Medicinal materials circulated in the market shall be contained in standard packages and labeled under regulations of the Minister of Health**.**

Article 68. Quality of medicinal materials

1. Medicinal materials must satisfy quality standards and be of clear origin. When being used for drug manufacture, processing or preparation, the residues of pesticides or preservation chemicals and the levels of heavy metals, microorganisms and toxicity of medicinal materials must not exceed the prescribed limits.

2. Manufacturers, importers, processors and suppliers of medicinal materials shall announce standards of medicinal materials in accordance with the law on standards and technical regulations in case such medicinal materials do not have certificates of free sale, and take responsibility for the origin and quality of medicinal materials; and report to relevant state management agencies on the quantity of imported medicinal materials for trading and for drug preparation, processing or manufacture.

3. The Minister of Health shall detail this Article.

Section 2

TRADITIONAL DRUGS

Article 69. Traditional drug business

1. The traditional drug business must comply with the provisions of Chapter IV of this Law.

2. An establishment manufacturing traditional drugs for circulation nationwide or an establishment retailing traditional drugs must meet the following conditions:

a/ An establishment manufacturing traditional drugs must have a location and workshop for manufacture, testing laboratory, warehouse of drugs and drug materials, auxiliary system, equipment and machinery for manufacture, testing and preservation of drugs, quality management system, technical documents, and employees satisfying the requirements of good manufacture practices for traditional drugs;

b/ An establishment retailing medicinal materials, drugs from medicinal materials and traditional drugs must comply with regulations on location, area and equipment for storage, technical documents and employees;

c/ A person responsible for professional pharmacy activities or a person in charge of drug quality at an establishment manufacturing traditional drugs must possess a professional degree as prescribed at Point a or c, Clause 1, Article 13 of this Law and have practiced for 2 years at a pharmaceutical establishment appropriate to his/her professional qualification, except the case prescribed at Point d of this Clause. A person responsible for professional pharmacy activities at an establishment manufacturing traditional drugs for circulation nationwide may concurrently be in charge of drug quality at this establishment;

d/ A person in charge of professional pharmacy activities or a person in charge of drug quality at a cooperative or business household manufacturing traditional drugs must have one of the professional degrees as prescribed at Points a, c, e, g, i and l, Clause 1, Article 13 of this Law and have practiced for 2 years at a pharmaceutical establishment appropriate to his/her professional qualification, except the case specified at Point c, Clause 2, Article 13 of this Law. A person in charge of professional pharmacy activities at a cooperative or business household manufacturing traditional drugs may concurrently in charge of drug quality at this cooperative or business household;

dd/ A person responsible for professional pharmacy activities at an establishment retailing traditional drugs must meet the conditions prescribed in Clause 4, Article 18 of this Law.

3. The Government shall prescribe in detail the traditional drug business and management of imported traditional drugs.

Article 70. Supply, processing, preparation and use of traditional drugs in medical examination and treatment establishments

1. A medical examination and treatment establishment applying traditional medicine may process, prepare and dispense traditional drugs according to

medicaments or prescriptions for use or retail under prescriptions at such establishment.

2. Traditional drugs processed or prepared by a provincial- or higher-level hospital applying traditional medicine may be sold to medical examination and treatment establishments applying traditional medicine located in the same province or centrally run city for treating patients at these establishments.

3. The head of a medical examination and treatment establishment processing and preparing traditional drugs shall take responsibility for the quality, safety and efficacy of these drugs.

4. The Minister of Health shall prescribe conditions for processing, preparation and management of traditional drugs mentioned in this Article.

Article 71. Registration, circulation and recall of traditional drugs

1. A traditional drug circulated in the market shall be registered, circulated or recalled under Chapter V of this Law, except the provisions of Clause 2 of this Article.

2. The time limit for the grant, extension or modification and supplementation of the content of a certificate of free sale of a traditional drug is:

a/ Six months from the date of receipt of a complete dossier, in case of grant of a certificate of free sale;

b/ Twelve months from the date of receipt of a complete dossier, in case of grant of a certificate of free sale of a traditional drug subject to clinical trial;

c/ One month from the date of receipt of a complete dossier, in case of extension or modification and supplementation of the content of a certificate of free sale;

d/ In case of refusal to grant, extend or modify and supplement the content of a certificate of free sale of a traditional drug, or when the conditions prescribed in this Law for grant of a certificate are not fully satisfied, a written reply shall be issued, clearly stating the reason.

3. A traditional drug dispensed according to medicaments or prescriptions and processed or prepared at a medical examination and treatment establishment prescribed in Clause 1 or 2, Article 70 of this Law are not subject to registration for circulation. The head of the medical examination and treatment establishment shall recall the drug under regulations when detecting that it fails to meet quality, safety and efficacy requirements.

Article 72. Clinical trial of traditional drugs before registration for circulation

1. A traditional drug may be exempted from clinical trial or from certain stages of clinical trial or must undergo all stages of clinical trial.

2. The following traditional drugs shall be exempted from clinical trial:

a/ Traditional drugs recognized by the Ministry of Health;

b/ Traditional drugs whose certificates of free sale are granted before the effective date of this Law, except those which are proposed by the advisory council for grant of certificates of free sale of drugs and drug materials to undergo a clinical trial.

3. The Minister of Health shall prescribe specific criteria for identifying traditional drugs which may be exempted from certain stages of clinical trial and which must undergo all stages of clinical trial.

Article 73. Quality of traditional drugs

1. Traditional drugs which are dispensed according to medicaments or prescriptions and which are processed or prepared by medical examination and treatment establishments prescribed in Clauses 1 and 2, Article 70 of this Law must meet quality requirements set by the Ministry of Health.

2. Traditional drugs for circulation nationwide must meet quality requirements prescribed in Articles 102 and 103 of this Law.

3. The Minister of Health shall stipulate the recognition of traditional medicaments, rare and precious traditional medicaments, and medicaments and prescriptions used for dispensation; guide methods of processing, preparing or combining traditional drugs according to traditional medicine theories and methods; and provide guidance on traditional drugs prepared in modern forms.

Chapter VII

PRESCRIPTIONS AND USE OF DRUGS

Article 74. Prescriptions

1. A prescription shall be used as a basis for sale, preparation, dispensation and use of drugs.

2. The Minister of Health shall prescribe in detail prescriptions and prescription of drugs.

Article 75. Use of drugs

1. The use of drugs in medical examination and treatment establishments must comply with the law on medical examination and treatment.

2. The use of drugs outside medical examination and treatment establishments is prescribed as follows:

a/ A user may choose a drug retailing establishment to buy drugs, and shall strictly follow the use instructions written in prescriptions and package inserts and the use instructions of the retailer;

b/ A prescriber shall provide use instructions for the drugs prescribed and take responsibility for the prescription he/she has made;

c/ A drug retailer shall provide instructions on how to use drugs for the user.

3. The Minister of Health shall stipulate the formation of an inter-disciplinary council for identifying causes and entities responsible for drugs that seriously affect users' health or life.

Chapter VIII

DRUG INFORMATION, PHARMACOVIGILANCE AND DRUG ADVERTISING

Article 76. Contents of, and responsibility to provide, drug information

1. Drug information aims to provide instructions on how to use drugs in a rational, safe and effective manner for medicine practitioners and drug users.

2. Drug information must be updated, clear, adequate, accurate, based on evidence, easy-to-understand, and suitable to information recipients.

3. Drug information shall be developed based on the following documents, except the information mentioned at Point c, Clause 5, and Point a, Clause 6, of this Article:

a/ The Pharmacopoeia of Vietnam;

b/ Package inserts approved by the Ministry of Health;

c/ Professional documents and instructions related to drugs issued or recognized by the Ministry of Health.

4. The Pharmacopoeia of Vietnam is an official guide to rational, safe and effective use of drugs. The Minister of Health shall issue and update the Pharmacopoeia of Vietnam.

5. Drug information includes:

a/ Information for medicine practitioners, including drug name, ingredients, concentration, content, forms of preparation, indications, contraindications, dosage, route of administration, use on special users, warnings and safety, and other necessary information;

b/ Information for drug users, including drug name, uses, indications, contraindications, dosage, route of administration, and precautions in the course of use;

c/ Information for state management agencies in charge of pharmacy, including updated information on drug quality, safety and efficacy.

6. The responsibility to provide drug information is prescribed as follows:

a/ Pharmaceutical business establishments, representative offices of foreign traders engaged in pharmaceutical business in Vietnam, and drug registration establishments shall update information on their drugs currently circulated in the market to state management agencies in charge of pharmacy;

b/ Pharmaceutical business establishments, representative offices of foreign traders engaged in pharmaceutical business in Vietnam, and drug registration establishments shall provide drug information under Clause 3 of this Article for medicine practitioners and drug users.

Employees of pharmaceutical business establishments shall introduce drugs to medicine practitioners under regulations of the Minister of Health;

c/ Medicine practitioners shall provide relevant drug information for drug users in the course of medical examination and treatment;

d/ State management agencies in charge of pharmacy shall, within the ambit of their tasks and powers, disclose information on drug quality, safety and efficacy.

7. Drug information providers shall take responsibility for the information they provide.

Article 77. Pharmacovigilance

1. Pharmacovigilance activities include:

a/ Monitoring, detecting and reporting on information relating to adverse reactions of drugs, errors related to drugs, or suspicious counterfeit drugs or substandard drugs, and information relating to drugs having no treatment effects or failing to produce desirable treatment effects;

b/ Collecting and processing information mentioned at Point a of this Clause; evaluating benefits and risks, making conclusions and managing risks related to drugs;

c/ Announcing competent agencies' conclusions on drug safety issues.

2. When detecting abnormal signs in the course of using a drug, the user shall notify them to the person who has provided medical examination and treatment or to the drug retailing establishment where he/she has bought the drug, and come to a medical examination and treatment establishment for timely treatment.

3. A medicine practitioner has the following responsibilities:

a/ To proactively monitor and detect abnormal signs or errors related to drugs or suspicious quality or effects of drugs in the course of practice;

b/ To evaluate, handle and take preventive measures when detecting any abnormal signs or errors or when receiving information from drug users as prescribed in Clause 2 of this Article;

c/ To report to competent agencies on information collected when performing the responsibilities prescribed at Points a and b of this Clause.

4. A drug retailer has the following responsibilities:

a/ To provide drug users with counseling within its professional scope on actions to be taken when detecting abnormal signs during the use of a drug;

b/ To collect, and report to competent agencies on, information on abnormal signs during the use of drugs.

5. A drug manufacture establishment, drug preparation and processing establishment, or drug registration establishment has the following responsibilities:

a/ To monitor the quality, safety and efficacy of drugs circulated in the market;

b/ To report and update information to competent agencies on the quality, safety and efficacy of drugs it has manufactured, registered, prepared or processed.

6. The Minister of Health shall prescribe the suspension of the manufacture, trading, use, sealing and storage of drugs that show unsafe signs for users.

Article 78. Organization of drug information and pharmacovigilance activities

1. Pharmaceutical business establishments and medical examination and treatment establishments shall organize drug information and pharmacovigilance activities at their establishments.

2. The Minister of Health shall organize drug information and pharmacovigilance systems.

3. The Government shall prescribe in detail the competence, dossier and procedures for receipt, appraisal and certification of drug information.

Article 79. Drug advertising

1. Drug advertising must comply with the advertising contents certified by the Ministry of Health and the law on advertising.

Within 15 days after receiving a complete dossier of request for certification of drug advertising contents, the Ministry of Health shall appraise the dossier and issue a written certification of drug advertising contents. If refusing to issue such certification or requesting modification and supplementation of drug advertising contents, the Ministry of Health shall issue a written reply, clearly stating the reason.

2. To be advertised, a drug must satisfy the following conditions:

a/ It is on the list of non-prescription drugs;

b/ It is not restricted from use or must be used under physician’s supervision as recommended by a competent state agency;

c/ Its certificate of free sale remains valid in Vietnam.

3. The Government shall prescribe in detail drug advertising contents, and the dossier and procedures for receipt, appraisal and certification of drug advertising contents.

Chapter IX

CLINICAL PHARMACY

Article 80. Contents of clinical pharmacy activities

1. Providing counseling during the compilation of the lists of drugs at medical examination and treatment establishments to ensure reasonable, safe and effective use of drugs.

2. Providing counseling on, and supervise, the prescription and use of drugs.

3. Providing drug information and use instructions for medicine practitioners, drugs users and the community.

4. Participating in developing professional processes and guidelines on drug use and supervising the observance of these processes.

5. Analyzing and evaluating the effect of drug use at medical examination and treatment establishments.

6. Participating in monitoring and supervising adverse reactions of drugs.

7. Participating in scientific researches into reasonable, safe and effective use of drugs.

Article 81. Organization of clinical pharmacy activities

1. The head of a medical examination and treatment establishment engaged in drug use activities shall organize clinical pharmacy activities in accordance with Article 80 of this Law.

2. A person responsible for professional activities at a drugstore shall carry out clinical pharmacy activities in accordance with Clauses 2, 3 and 6, Article 80 of this Law, specifically as follows:

a/ To give advice and provide information about drugs for drug buyers and users;

b/ To give advice to and talk with prescribers when detecting unreasonable prescriptions;

c/ To participate in monitoring and supervising adverse reactions of drugs.

3. The Government shall stipulate the organization of clinical pharmacy activities at medical examination and treatment establishments, including those of the people's armed forces.

Article 82. Rights and obligations of a person in charge of clinical pharmacy activities

1. A person in charge of clinical pharmacy activities at a medical examination and treatment establishment has the following rights and obligations:

a/ To have access to patients, medical records and prescriptions for advising prescribers on the use of drugs;

b/ To talk with medicine practitioners to ensure reasonable, safe and effective prescription and use of drugs;

c/ To write his/her professional opinions on clinical pharmacy in medical records and prescriptions; to give his/her opinions to the Medicine and Treatment Council or the head of the medical examination and treatment establishment in case there are divergent opinions on drug prescription and use for a patient;

d/ To participate in professional consultations and assessments of medical records and prescriptions;

dd/ To participate in developing standard treatment instructions, lists of drugs at the medical examination and treatment establishment, and technical processes related to drugs;

e/ To participate in monitoring and supervising adverse reactions of drugs;

g/ To exercise other rights and perform other obligations as prescribed by law.

2. A person in charge of clinical pharmacy activities at a drugstore has the following rights and obligations:

a/ To give advice and provide information about drugs for drug buyers and users;

b/ To give advice to and talk with prescribers when detecting unreasonable prescriptions;

c/ To participate in monitoring and supervising adverse reactions of drugs;

d/ To exercise other rights and perform other obligations in accordance with law.

Article 83. State policies on clinical pharmacy activities

1. To invest in appropriate physical foundations, equipment and human resources for clinical pharmacy activities at state-owned medical examination and treatment establishments, and prioritize the recruitment of clinical pharmacists to work at state-owned medical examination and treatment establishments.

2. To invest in appropriate physical foundations, equipment and human resources for state-owned clinical pharmacists training institutions; to provide state budget funding for clinical pharmacy students.

3. The State shall encourage organizations and individuals to participate in the training of clinical pharmacists and invest in physical foundations and equipment for clinical pharmacy activities.

Chapter X

MANAGEMENT OF DRUGS IN MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENTS

Article 84. Supply, storage, dispensation and use of drugs

1. The head of a medical examination and treatment establishment shall ensure sufficient supply of quality drugs to meet first aid and medical examination and treatment demands at his/her establishment; the head of a district- or higher-level medical examination and treatment establishment shall organize the sale of drugs at nighttime.

2. The storage of drugs at a medical examination and treatment establishment must comply with regulations on good storage practices and other relevant regulations.

3. The dispensation of drugs at a medical examination and treatment establishment must comply with physician's instructions or prescriptions. The names and contents of drugs shall be written on drug containers, together with instructions for drug users.

4. Radioactive drugs shall be used only at a medical examination and treatment establishment that has doctors specialized in nuclear medicine and is licensed by the Ministry of Science and Technology to carry out radiation activities in accordance with the law on atomic energy.

5. The Minister of Health shall stipulate the wastage rate of drugs and the payment of drug wastage costs at medical examination and treatment establishments.

Article 85. Manufacture and preparation of drugs at medical examination and treatment establishments

1. The head of a medical examination and treatment establishment that manufactures and prepares drugs for internal use shall take responsibility for the quality and management of these drugs.

2. A medical examination and treatment establishment may be licensed to manufacture and prepare drugs to meet its treatment demands when fully satisfying the conditions set by the Minister of Health.

3. In addition to the provisions of Clauses 1 and 2 of this Article, a medical examination and treatment establishment that manufactures and prepares radioactive drugs shall take security measures to avoid loss of radioactive drugs and radioactive drug materials, and shall obtain a license for radiation activities from the Ministry of Science and Technology in accordance with the law on atomic energy.

Drugs manufactured and prepared in accordance with this Clause may be supplied to other medical examination and treatment establishments under regulations of the Minister of Health.

Chapter XI

CLINICAL TRIAL, BIOEQUIVALENCE TRIAL OF DRUGS

Section 1

CLINICAL TRIAL OF DRUGS

Article 86. Stages of clinical trial

1. Stage 1 is the first stage of trial of humans to preliminarily assess the safety of a drug.

2. Stage 2 is an experimental stage to identify the optimum dose for clinical trial and to prove the safety and efficacy of a drug, including the ability of a vaccine to create immunity in the target user.

3. Stage 3 is an experimental stage conducted on a large scale to identify the stability of the formula and the overall safety and efficacy of a drug, or to assess the protective effect and safety of a vaccine on target users.

4. Stage 4 is carried out after a drug is permitted for circulation to further assess the safety and efficacy of a drug and monitor the protective effect of a vaccine after it is widely used in the community under required conditions.

Article 87. Clinical trial of drugs to be registered for circulation

1. Stages 1, 2 and 3 of clinical trial shall be conducted before a drug is registered for circulation.

2. Stage 4 of clinical trial shall be conducted after a drug is registered for circulation as required by a competent management agency in charge of pharmacy.

Article 88. Requirements on a drug put for clinical trial

1. A drug put for clinical trial must meet the following requirements:

a/ It has been researched at the pre-clinical stage;

b/ It has a stable form of preparation;

c/ It satisfies the quality standards stated in the dossier of registration for clinical trial.

2. The label of a drug put for clinical trial must have the phrase: “Drug used for clinical trial. Other uses are prohibited.”

Article 89. Drugs subject to clinical trial, drugs exempt from clinical trial or from certain stages of clinical trial before registration

1. The following drugs shall undergo all stages of clinical trial:

a/ New drugs, except the cases specified at Point a, Clause 2, and Point b, Clause 3, of this Article;

b/ Drugs from medicinal materials using a new combination of medicinal materials previously used for drug manufacture in Vietnam and for treatment of

diseases on the list issued by the Minister of Health, except the cases specified at Point b, Clause 2, and Point c, Clause 3, of this Article;

c/ Vaccines registered for the first time for circulation in Vietnam, except the case specified at Point c, Clause 2 of this Article.

2. The following drugs shall be exempted from certain stages of clinical trial:

a/ New drugs which have certificates of free sale in at least one country in the world but there are no sufficient clinical data on their safety and efficacy;

b/ Drugs from medicinal materials not mentioned at Point c, Clause 3 of this Article;

c/ Vaccines which have certificates of free sale in at least one country in the world and there are clinical data on their safety and efficacy.

3. The following drugs shall be exempted from clinical trial:

a/ Generic drugs;

b/ New drugs which have certificates of free sale in at least one country in the world and there are sufficient clinical data on their safety and efficacy, except vaccines;

c/ Drugs from medicinal materials which have certificates of free sale issued before the effective date of this Law, except drugs for treatment of diseases on the list issued by the Minister of Health.

4. The Minister of Health shall set specific requirements on clinical data to ensure safety and efficacy, and criteria for identifying drugs which are exempt from clinical trial or from certain stages of clinical trial in Vietnam and drugs which must undergo stage 4 of clinical trial.

Article 90. Conditions on a person participating in a clinical trial of a drug

1. He/she must be a volunteer meeting the professional requirements on the clinical trial of a drug; and shall sign an agreement on voluntary participation in the research with the establishment providing the clinical trial service, except a person who has a limited civil act capacity or has lost his/her civil act capacity.

2. For a person who is a minor or has a limited civil act capacity or has lost his/her civil act capacity, his/her representative's or guardian's consent is required as prescribed by law.

3. For a pregnant or breastfeeding woman, a research dossier must clearly state the reason for selecting and appropriate measures to protect such woman.

Article 91. Rights and obligations of a person participating in a clinical trial of a drug

1. A person participating in a clinical trial of a drug has the following rights:

a/ To be provided with sufficient and truthful information and possible risks before participating in the trial;

b/ To receive compensation for any damage caused by the trial from the organization or individual having the drug put for clinical trial;

c/ To have his/her personal information kept confidential;

d/ To bear no responsibility when unilaterally withdrawing from the trial;

dd/ To lodge a complaint, lawsuit or denunciation about illegal acts of the organization or individual having the drug put for clinical trial or performing the trial.

2. A person participating in a clinical trial of a drug is obliged to comply with the researcher's instructions stated in the approved dossier of the clinical trial.

Article 92. Rights and responsibilities of organizations and individuals having drugs put for clinical trial

1. An organization or individual having a drug put for clinical trial has the following rights:

a/ To select an organization that has qualified physical foundations and professional staff to conduct the trial;

b/ To own all research results.

2. An organization or individual having a drug put for clinical trial has the following responsibilities:

a/ To pay compensation in accordance with law to the person participating in the clinical trial if a risk occurs to the latter as a result of the trial;

b/ To sign a contract on the clinical trial with an establishment to conduct the trial;

c/ To take responsibility before law for the quality and safety of the drug it/he/she supplies.

Article 93. Rights and responsibilities of establishments conducting clinical trial of drugs

1. An establishment conducting a clinical trial of a drug has the following rights:

a/ To conduct a clinical trial under regulations;

b/ To import and purchase chemicals, standard substances and sample drugs for the trial;

c/ To use the trial research results as agreed with the organization or individual having the drug put for trial.

2. An establishment conducting a clinical trial of a drug has the following responsibilities:

a/ To take responsibility for the results of the clinical trial;

b/ To take responsibility for the safety of participants in the clinical trial and pay compensation in accordance with law to them if any risk occurs due to its fault;

c/ To ensure truthfulness and objectivity in the clinical trial;

d/ To be financially and organizationally independent from the organization or individual having the drug put for clinical trial.

Article 94. Principles and competence to approve a clinical trial of a drug

1. A clinical trial of a drug shall be conducted only after the dossier of the trial has been assessed in terms of scientific and ethical issues by the National Council of Ethics in Biomedical Research and the trial is approved in writing by the Minister of Health.

2. The clinical trial of a drug, scientific and ethical assessment of the dossier of the clinical trial, and approval of the clinical trial must adhere to the following principles:

a/ Respecting the right to self-determination of participants in the trial and protecting the persons who have their right to self-determination restricted;

b/ Ensuring that the research benefits outweigh risks and that the risks in the research are carefully considered and minimized according to standards;

c/ Ensuring equality in benefits and responsibilities and fair distribution of benefits and risks among participants in the trial;

d/ Strictly following the stages of clinical trial and applying good practices in clinical trial.

3. The council of ethics in biomedical research is an independent body established at the national level or at the establishment's level to protect the rights, safety and health of participants in the trial of a drug.

The Minister of Health shall stipulate the establishment, functions, tasks and powers of a council of ethics in biomedical research.

Article 95. Dossier and process for clinical trial of a drug

1. A dossier for clinical trial of a drug must comprise:

a/ A written request for clinical trial of a drug;

b/ Documents containing information on the product put for research;

c/ A legal record of the product put for research;

d/ A research outline of the clinical trial and a written explanation;

dd/ The researcher's curriculum vitae;

e/ An information sheet and the cards of voluntary participation in the research of the participants in the clinical trial;

g/ A written record of the scientific and ethical assessment of the research, made by the establishment's council of ethics in biomedical research;

h/ The label of the drug put for research.

2. The process of clinical trial of a drug is prescribed as follows:

a/ Registering for clinical trial of a drug;

b/ Approving the clinical trial;

c/ Organizing the clinical trial;

d/ Approving the results of the clinical trial.

3. The Minister of Health shall detail this Article.

Section 2

BIOEQUIVALENCE TRIAL OF DRUGS

Article 96. Stages of bioequivalence trial of a drug and drugs subject to bioequivalence trial

1. The bioequivalence trial of a drug includes the following stages:

a/ The clinical research stage, which is the stage of testing a comparative drug and the drug put for bioequivalence trial, which have been confirmed to satisfy safety and efficacy requirements, to compare their bioavailability on a volunteer;

b/ The human biofluid analysis stage, which is the stage of analyzing and identifying the concentrations of the comparative drugs and the drug put for bioequivalence trial in the volunteer's bio-specimens, after they are used in the clinical research stage, in order to compare their bioavailability and prove their bioequivalence.

2. A generic drug shall be put for bioequivalence trial when it contains a pharmaceutical ingredient and has a form of preparation on the list of pharmaceutical ingredients and forms of preparation subject to bioequivalence trial issued by the Minister of Health.

Article 97. Conditions on, and rights and obligations of persons participating in the bioequivalence trial of a drug

1. A person participating in a bioequivalence trial of a drug must satisfy the conditions specified in Article 90 of this Law.

2. A person participating in a bioequivalence trial of a drug has the rights and obligations as prescribed in Article 91 of this Law.

Article 98. Rights and responsibilities of organizations and individuals having drugs put for bioequivalence trial

1. An organization or individual having a drug put for bioequivalence trial has the following rights:

a/ To select an organization that meets the requirements on physical foundations and professional staff to conduct bioequivalence trial of drugs;

b/ To own all research results of the drug put for bioequivalence trial.

2. An organization or individual having a drug put for bioequivalence trial has the following responsibilities:

a/ To pay compensation to the person participating in the bioequivalence trial if any risk occurs during the trial in accordance with law;

b/ To sign a contract on bioequivalence trial of drugs with an establishment to conduct the trial;

c/ To take responsibility before law for the quality and safety of the drug it/he/she has supplied.

Article 99. Rights and responsibilities of establishments conducting bioequivalence trial of drugs

1. An establishment conducting a bioequivalence trial of a drug has the following rights:

a/ To conduct the clinical research and biofluid analysis stages in the bioequivalence trial of a drug.

If the establishment only conducts the biofluid analysis, it may contract or cooperate with an establishment conducting clinical trial of drugs that satisfies the requirements of good clinical trial practices to conduct the clinical research in the bioequivalence trial;

b/ To conduct the bioequivalence trial under regulations;

c/ To import and buy chemicals, standard substances and drug samples to serve the bioequivalence trial;

d/ To use the results of the bioequivalence trial as agreed with the organization or individual having the drug put for bioequivalence trial.

2. An establishment conducting a bioequivalence trial of a drug has the following responsibilities:

a/ To take responsibility for the results of the bioequivalence trial with regard to the drug samples;

b/ To take responsibility for the safety of the person participating in the bioequivalence trial and pay compensation in accordance with law to him/her if any risk occurs due to its fault;

c/ To ensure truthfulness and objectivity in the bioequivalence trial;

d/ To be financially and organizationally independent from the organization or individual having the drug put for bioequivalence trial.

Article 100. Principles of approval of a bioequivalence trial of a drug

1. A bioequivalence trial of a drug shall be conducted only after the dossier of the bioequivalence trial has been scientifically and ethically assessed by the establishment's council of ethics in biomedical research and the trial is approved in writing by the person responsible for professional activities of the establishment conducting the bioequivalence trial.

2. The approval of a bioequivalence trial of a drug must comply with the following principles:

a/ The principles specified at Points a, b and c, Clause 2, Article 94 of this Law;

b/ Strict observance of the good clinical trial practices, good laboratory practices in biofluid analysis, and of the bioequivalence trial guidelines issued by the Minister of Health.

3. The establishment's council of ethics in biomedical research shall assess scientific and ethical matters in the dossier for bioequivalence trial of a drug and approve the research outline.

Article 101. Dossier and process for bioequivalence trial of a drug

1. A dossier for bioequivalence trial of a drug must comprise:

a/ A written request for bioequivalence trial of a drug;

b/ Documents on the drug's information;

c/ A research outline for the bioequivalence trial and a written explanation;

d/ The researcher's curriculum vitae;

dd/ An information sheet and the card of voluntary participation in the research of the participant in the trial;

e/ The label of the drug.

2. The process of bioequivalence trial of a drug is prescribed as follows:

a/ Registering the bioequivalence trial;

b/ Approving the bioequivalence trial;

c/ Organizing the bioequivalence trial;

d/ Approving the bioequivalence trial results.

3. The Minister of Health shall detail this Article.

XII

REGULATIONS AND QUALITY STANDARDS, AND TESTING OF DRUGS, DRUG MATERIALS AND PRIMARY PACKAGES OF DRUGS

Article 102. Regulations and quality standards on drugs, drug materials and primary packages of drugs

1. National technical regulations on drugs, drug materials and primary packages of drugs include technical regulations on quality of drugs, drug materials and primary packages of drugs and general testing methods described in the Pharmacopoeia of Vietnam. The application of testing methods presented in the treatises on drugs, drug materials and primary packages of drugs included in the Pharmacopoeia of Vietnam is voluntary.

2. Quality standards on drugs, drug materials and primary packages of drugs include:

a/ National standards on drugs, drug materials and primary packages of drugs, which shall be developed by the Ministry of Health, and appraised and announced by the Ministry of Science and Technology in accordance with the Law on Standards and Technical Regulations;

b/ In-house standards, which shall be developed by establishments manufacturing drugs, drug materials or primary packages of drugs for application within their establishments but must not be lower than the relevant national technical regulations stated in the Pharmacopoeia of Vietnam. If the Pharmacopoeia of Vietnam has no relevant national technical regulations on drugs, drug materials or primary packages of drugs, these establishments shall develop their own standards on the basis of scientific research outcomes or foreign pharmacopoeias and have such standards approved by the Ministry of Health.

3. The Minister of Health shall issue the Pharmacopoeia of Vietnam on the basis of national standards on drugs, drug materials and primary packages of drugs and stipulate the application of foreign pharmacopoeias in Vietnam.

Article 103. Testing of drugs, drug materials and primary packages of drugs

1. Testing of drugs, drug materials and primary packages of drugs includes taking samples, considering their technical standards, and conducting relevant and necessary tests in order to identify whether they satisfy quality standards then decide whether to accept or discard them.

2. Before being used for drug manufacture, drug materials and primary packages of drugs shall be tested to ensure that they satisfy quality standards.

3. Before being delivered, drugs, drug materials and primary packages of drugs shall be tested by manufacturing establishments to ensure that they satisfy quality standards.

4. In addition to being tested under Clause 3 of this Article, the following drugs shall, before being put in circulation, be tested by a drug testing establishment designated by a competent state agency:

a/ Vaccines;

b/ Biological products which are antisera;

c/ Other drugs as prescribed by the Ministry of Health, based on the results of assessment of drug quality risks and the situation of manufactured and imported drugs.

5. The Minister of Health shall detail this Article.

Article 104. Establishments testing drugs and drug materials

1. Establishments testing drugs and drug materials include:

a/ State-owned establishments testing drugs and drug materials;

b/ Establishments providing the service of testing drugs and drug materials;

c/ Testing laboratories of pharmaceutical business establishments.

2. A state-owned establishment testing drugs and drug materials has the following responsibilities:

a/ To examination the quality of drugs, drug materials and primary packages of drugs;

b/ To examine and assess the quality and appraise quality standards of drugs, drug materials and primary packages of drugs at the request of the Ministry of Health;

c/ To advise on and propose to the Minister of Health technical measures to enhance the drug quality management as suitable to socio-economic development conditions;

d/ To ensure truthfulness and objectivity in the testing of drugs, drug materials and primary packages of drugs;

dd/ To take responsibility for the results of drug testing of samples, drug materials and primary packages of drugs.

3. An establishment providing the service of testing drugs and drug materials has the responsibilities defined in Clause 2, Article 51 of this Law.

4. A testing laboratory of a pharmaceutical business establishment must be responsible for examination and testing to determine the quality of drugs, drug materials and primary packages of drugs of the establishment.

5. The Prime Minister shall promulgate a master plan on the systems of state-owned testing establishments of the State and establishments providing the service of testing drugs and drug materials; and prescribe the organizational apparatus, physical foundations and operation of state-owned establishments testing drugs and drug materials.

Article 105. Settlement of complaints about conclusions on the quality of drugs, drug materials and primary packages of drugs

1. A pharmaceutical business establishment may lodge a complaint about conclusions on the quality of drugs, drug materials and primary packages of drugs made by a competent state management agency in charge of pharmacy.

2. When receiving a complaint about conclusions on the quality of drugs, drug materials and primary packages of drugs, the Ministry of Health shall appoint a testing establishment that has conditions similar or higher than those of the testing establishment that has made the above conclusions to re-test these drugs, drug materials and primary packages of drugs.

3. The competence and procedures for settlement of a complaint about conclusions on the quality of drugs, drug materials and primary packages of drugs must comply with the law on complaints.

Chapter XIII

MANAGEMENT OF DRUG PRICES

Article 106. Principles of state management of drug prices

1. Managing drug prices under the market mechanism and respecting the right of drug manufacturers and traders to pricing and price competition in accordance with law.

2. Ensuring publicity and transparency of prices of drugs circulated in the market.

3. Protecting lawful rights and interests of drug manufacturers and traders and consumers and interests of the State.

4. Applying measures to stabilize drug prices and other measures to manage drug prices suitable to socio-economic development conditions in each period.

Article 107. Measures to manage drug prices

1. Bidding for national reserve drugs in accordance with the Bidding Law and the law on national reserves; and bidding for drugs purchased with funds from the state budget, the health insurance fund, revenues from medical examination and treatment services, and other lawful revenues of public medical examination and treatment establishments in accordance with the Bidding Law, except the case specified in Clause 2 of this Article.

2. Bidding, placement of orders or assignment of manufacture plans for the supply of drugs for national target programs, national defense and security purposes, epidemic prevention and control, and overcoming of consequences of natural disasters and catastrophes in accordance with the law on provision of public-utility services and products.

3. Declaring drug prices before the drugs are circulated in the market and declaring changes in the initial drug prices.

4. Posting up wholesale and retail prices in Vietnam dong of drugs at transaction places or drug-selling places of pharmaceutical business establishments; printing, writing or sticking retail prices on the primary or secondary packages of drugs; publicly displaying drug prices on notice boards, on paper or in other forms.

5. Taking measures to stabilize the prices of drugs on the list of essential drugs in accordance with the Price Law when there are abnormal price fluctuations or price fluctuations affecting socio-economic stability.

6. Conducting price negotiations in bidding for drugs or medicinal materials when only one or two manufacturers participate; in bidding for brand name specifics, rare drugs, patented drugs, drugs with unpopular content, and in other special cases.

7. Setting the maximum retail surplus for drugs sold at drug retails within medical examination and treatment establishments.

8. The Government shall detail this Article.

Article 108. Responsibility for state management of drug prices

1. The Government shall perform the unified state management of drug prices.

2. The Ministry of Health shall take responsibility before the Government for performing the state management of drug prices.

3. Ministries and ministerial-level agencies shall, within the ambit of their tasks and powers, coordinate with the Ministry of Health in performing the state management of drug prices.

4. Provincial-level People's Committees shall, within the ambit of their tasks and powers, perform the state management of drug prices in localities.

Article 109. Responsibility of the Ministry of Health for state management of drug prices

To assume the prime responsibility for, and coordinate with the Ministry of Finance and other ministries, ministerial-level agencies, government-attached agencies and provincial-level People's Committees in, performing the state management of drug prices, having the following tasks:

1. To elaborate and submit to competent state agencies for promulgation, or issue according to its competence and organize the implementation of, policies and laws on drug prices;

2. To request other ministries, ministerial-level agencies, government-attached agencies and provincial-level People's Committees to regularly or extraordinarily report on the state management of drug prices;

3. To organize the dissemination of and education about the law on drug prices;

4. To assume the prime responsibility for, and coordinate with the Ministry of Finance in, taking measures to stabilize drug prices in accordance with the price law;

5. To assume the prime responsibility for, and coordinate with the Ministry of Finance in, specifying the declaration of drug prices, and setting principles of

review and announcement of drug prices declared by drug manufacturers or importers;

6. To receive and review prices of imported drugs declared or re-declared by drug importers or import authorizers, and prices of domestically manufactured drugs declared by manufacturers;

7. To guide the posting up of drug prices at drug trading establishments;

8. To publish on the Ministry's e-portal the following information:

a/ Declared wholesale and retail prices of drugs;

b/ Successful bids of drugs supplied by Vietnam Social Security and medical examination and treatment establishments;

c/ Drugs on the list of essential drugs when there are abnormal price fluctuations or price fluctuations affecting socio-economic stability.

9. To conduct examinations and inspections, and handle violations of the law on drug prices.

Article 110. Responsibility of the Ministry of Finance for state management of drug prices

1. To coordinate with the Ministry of Health in:

a/ Prescribing in detail the declaration of drug prices, and principles of review and announcement of drug prices declared by drug manufacturers and importers;

b/ Taking methods to stabilize drug prices in accordance with the price law;

c/ Conducting examinations and inspections and handling violations of the law on drug prices.

2. To set prices of drugs under orders placed or plans assigned by competent state agencies and funded by the central budget.

3. To provide the Ministry of Health with information on the actual import price (CIF price) of drugs imported into Vietnam.

Article 111. Responsibility of the Ministry of Industry and Trade for state management of drug prices

1. To provide information on prices of drugs and drug materials in regional and other countries at the proposal of the Ministry of Health to serve the state management of drug prices.

2. To coordinate with the Ministry of Health in conducting examinations and inspections and handling violations of the law on drug prices.

Article 112. Responsibility of provincial-level People's Committees for state management of drug prices

1. To perform the state management of drug prices in provinces and centrally run cities in accordance with this Law and other relevant laws.

2. To monitor, and report to the Ministry of Health and the Ministry of Finance on information about drug prices in localities when there are abnormal price fluctuations or price fluctuations affecting socio-economic stability.

3. To receive and review prices of domestically manufactured drugs re-declared by local drug manufacturers and report them to the Ministry of Health for posting on its e-portal.

4. To conduct examinations and inspections and handle violations of the law on drug prices in localities.

Article 113. Responsibility of Vietnam Social Security for managing drug prices

To announce successful bids of drugs on its e-portal and notify them to the Ministry of Health within 5 days after receiving contractor selection results from drug bidding units.

Article 114. Responsibility of drug bidding units

1. Within 10 days after announcing bidding results, drug bidding units managed by provincial-level People's Committees shall send the results to provincial-level Health Departments and social insurance agencies; other medical examination and treatment establishments organizing drug bidding shall send the results to the Ministry of Health and Vietnam Social Security.

2. Within 10 days after the bidding results for drugs are announced, for provinces and centrally run cities that organize centralized bidding for drugs, provincial-level Health Departments shall report the results to the Ministry of Health and Vietnam Social Security.

Chapter XIV

IMPLEMENTATION PROVISIONS

Article 115. Transitional provisions

1. Pharmaceutical business establishments that have been granted certificates of eligibility for pharmaceutical business in accordance with Pharmacy Law No. 34/2005/QH11 may continue manufacturing or trading in drugs until their certificates expire.

If a certificate of eligibility for pharmaceutical business does not specify the expiry date, its holder may manufacture or trade in drugs until its good practice certificate expires.

2. Dossiers of application for grant or re-grant of a pharmacy practice certificate or a certificate of eligibility for pharmaceutical business and drug registration dossiers submitted before the effective date of this Law shall be processed in accordance with Pharmacy Law No. 34/2005/QH11, unless pharmaceutical business establishments wish to apply this Law. Pharmacy practitioners whose pharmacy practice certificates are granted under Pharmacy

Law No. 34/2005/QH11 may continue practicing pharmacy until their certificates expire.

3. For a person whose pharmacy practice certificate is granted before the effective date of this Law, the time limit for him/her to update professional knowledge shall be counted from the effective date of this Law.

4. Pharmacy practice certificates that are granted before but expire after the effective date of this Law shall be re-granted in accordance with this Law.

5. Holders of certificates of eligibility for pharmaceutical business which are granted before but expire after the effective date of this Law shall apply for a new certificate in accordance with this Law.

Article 116. Effect

1. This Law takes effect on January 1, 2017.

2. The provisions on application of principles and standards on good manufacture practices at establishments producing drug materials; and provisions on certificates of eligibility for pharmaceutical business for establishments producing adjuvants and capsules, establishments producing and processing medicinal materials, and clinical pharmacy activities of medical examination and treatment establishments, drugstores and other establishments engaged in drug prescription and use, will take effect on January 1, 2021.

3. The Government shall stipulate a roadmap for implementation of Clause 2 of this Article, ensuring that by January 1, 2021, hospitals of grade 1 or higher grade shall organize clinical pharmacy activities as prescribed in Article 80 of this Law, and that all persons in the working positions mentioned in Article 11 of this Law must have a pharmacy practice certificate.

4. Pharmacy Law No. 34/2005/QH11 ceases to be effective on the effective date of this Law.

5. The Government and competent state agencies shall detail and guide the implementation of the articles and clauses in this Law as assigned.

This Law was passed on April 6, 2016, by the XIIIth National Assembly of the Socialist Republic of Vietnam at its 11th session.-

Chairwoman of the National Assembly
NGUYEN THI KIM NGAN

THE GOVERNMENT -------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
No. 54/2017/ND-CP	*Hanoi, May 08, 2017*

DECREE

GUIDELINES FOR IMPLEMENTATION OF THE LAW ON PHARMACY

Pursuant to the Law on Government organization dated June 19, 2015;

Pursuant to the Law on Pharmacy dated April 06, 2016;

At the request of the Minister of Health;

The Government promulgates a Decree to provide guidelines for implementation of the Law on Pharmacy

Chapter I

GENERAL PROVISIONS

Article 1. Scope and regulated entities

1. This Decree provides for pharmacy practice certificate; pharmacy business; export and import of drugs; registration of herbal ingredients, excipients, softgel shells; assessment of overseas drug manufacturers; power, method and procedures for recalling medicinal ingredients; handling of recalled medicinal ingredients; documents and procedures for issuance of certification of drug advertisement and drug price management.

2. This Decree applies to organizations and individuals in Vietnam and overseas whose operation involves pharmacy in Vietnam.

Article 2. Definitions

For the purpose of this Decree, the terms below are construed as follows:

1.”drug information” means collection and provisions of information about a drug, including indications, contraindications, dose, uses, adverse effects and information relevant to quality, safety and efficacy of the drug provided by a responsible facility in order to provide information for pharmacy authorities, medical practitioners and drug users.

2.”pharmaceutical conference” means a conference where a drug is introduce or drug-related issues are discussed among medical practitioners.

3. “semi-finished drug” means a product that has undergone all processing and manufacturing stages except final packaging.

4. “import price” is the customs value of imported drug on the customs value declaration at a Vietnam’s port after customs clearance is granted.

5. “prime cost” of a domestically manufactured drug equals (=) the costs of raw materials, fuel, instruments, energy plus (+) direct labour cost plus (+) depreciation of direct machinery and equipment plus (+) manufacturing overhead plus (+) financing cost plus (+) cost of sales plus (+) management cost minus (-) cost distributed to by products (if any).

6. “wholesale price” is the selling price among pharmacy business establishments or between a pharmacy business establishment and a medical facility.

7. “intended wholesale price” is the price declared by the drug importer, drug manufacturer or outsourcing entity (in case of manufacturing outsourcing) to a competent authority.

8. “retail price” of a drug is the price for selling the drug to buyers imposed by the drug retailer.

9. “retail margin” is the difference between the buying price and selling price at a drug retailer.

10. “retail margin percent” is the ratio (%) of retail margin to buying price at a drug retailer.

Chapter II

PHARMACY PRACTICE CERTIFICATE

Section 1. DOCUMENTS AND PROCEDURES FOR ISSUANCE, REISSUANCE, ADJUSTMENT AND REVOCATION OF THE PHARMACY PRACTICE CERTIFICATE

Article 3. Application for the pharmacy practice certificate

1. An application for the pharmacy practice certificate mentioned in Article 24 of the Law on Pharmacy consists of:

a) The application form No. 02 in Appendix I enclosed herewith, 02 portrait pictures (4x6 cm) of the applicant on a white background which was taken within the last 6 months;

b) Certified true copy of the applicant’s qualification. If the qualification is issued overseas, its certified true copy must be enclosed with an equivalence certification issued by a competent authority specified in Clause 2 Article 18 hereof;

c) The original copy or certified true copy of the health certificate issued by a medical facility in accordance with the Law on Medical examination and treatment;

d) The original copy or certified true copy of the certificate of internship (Form 03 in Appendix I enclosed herewith). If the internship took place in more than one facility, the internship duration will be the total duration of internship at the facilities according to the certificates of internship issued by such facilities;

dd) If the scope of practice covered by the pharmacy practice certificate applied for requires different internship durations and facilities, the application shall be enclosed with a certificate of internship of one or several facilities that meet requirements of each position.

e) The original copy or certified true copy of the confirmation of examination result specified in Clause 2 Article 28 hereof if the pharmacy practice certificate has to be obtained after passing an examination;

g) If the applicant is a foreigner or a Vietnamese citizen residing overseas applying for the pharmacy practice certificate without taking an examination, documents proving the applicant's language proficiency specified in Clause 2 Article 14 of the Law on Pharmacy.

2. Documents issued by overseas competent authorities must be consularly legalized and enclosed with notarized Vietnamese translations.

3. Only 01 set of documents specified in this Article is required.

Article 4. Application for reissuance of the pharmacy practice certificate

1. An application for reissuance the pharmacy practice certificate mentioned in Article 25 of the Law on Pharmacy consists of:

a) The application form No. 04 in Appendix I enclosed herewith, 02 portrait pictures (4x6 cm) of the applicant on a white background which was taken within the last 6 months;

b) A copy of the pharmacy practice certificate if the original one is lost.

2. Only 01 set of documents specified in this Article is required.

Article 5. Application for adjustment to the pharmacy practice certificate

1. An application for adjustment to the pharmacy practice certificate mentioned in Article 26 of the Law on Pharmacy consists of:

a) The application form No. 05 in Appendix I enclosed herewith, 02 portrait pictures (4x6 cm) of the applicant on a white background which was taken within the last 6 months;

b) If the applicant's information has to be adjusted, documents proving the adjustment which are one of the following documents: ID card, passport, family register or a confirmation issued by a competent authority as prescribed by law;

c) If the applicant's scope of practice has to be adjusted, documents proving the adjustment: relevant qualifications, certificate of internship as an appropriate pharmaceutical facility.

2. The original copy or certified true copy of the documents specified in Clause 1b and 1c of this Article.

3. The documents mentioned in Clause 1b and 1c of this Article must be consularly legalized and enclosed with notarized Vietnamese translations if issued by overseas competent authorities.

4. Only 01 set of documents specified in this Article is required.

Article 6. Procedures for issuing, reissuing and adjusting the pharmacy practice certificate

1. The applicant for issuance, reissuance or adjustment of the pharmacy practice certificate shall submit an application directly or by post to:

a) The Ministry of Health if the pharmacy practice certificate has to be obtained after passing an examination;

b) Department of Health of the province if the pharmacy practice certificate may be granted without an examination.

2. After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the receiving authority shall:

a) Issue the pharmacy practice certificate within 20 days from the day on which the application is received; if the application is rejected, provide written explanation;

b) Issue the pharmacy practice certificate within 05 days from the day on which the application is received if certificate was revoked according to Clause 3 Article 28 of the Law on Pharmacy; If the application is rejected, provide written explanation;

c) Reissue or adjust the pharmacy practice certificate within 10 days from the day on which the application is received; if the application is rejected, provide written explanation.

4. If the application is not satisfactory, the receiving authority shall request the applicant to complete the application:

a) within 10 days from the day on which the application for issuance of the pharmacy practice certificate is received; or

b) 05 working days from the day on which the application for reissuance or adjustment of the pharmacy practice certificate is received.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the receiving authority shall follow the instructions in Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant for issuance, reissuance or adjustment of the pharmacy practice certificate shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

7. Within 05 working days from the date of issuance, reissuance or adjustment of the pharmacy practice certificate, the receiving authority shall update the following information on its website:

a) Full name, date of birth of the holder of the pharmacy practice certificate;

b) Number of the pharmacy practice certificate;

c) The scope of practice.

8. The pharmacy practice certificate will be made into 02 copies. One of them will be given to the applicant, the other retained by the issuing authority.

9. When a pharmacy practice certificate is reissued or adjusted, the applicant shall return the old one.

In the cases where a pharmacy practice certificate is lost, the applicant shall submit the Form No. 04 in Appendix I enclosed herewith.

10. Specimen of the pharmacy practice certificate:

a) The specimen of the pharmacy practice certificate issued without an examination is Form No. 06 in Appendix I enclosed herewith;

b) The specimen of the pharmacy practice certificate issued after passing an examination is Form No. 07 in Appendix I enclosed herewith.

11. The Minister of Health shall specify the structure and operation of the advisory council responsible for giving counsel on issuance of the pharmacy practice certificate (hereinafter referred to as “certification advisory council”).

12. In the cases where a pharmacy practice certificate is reissued according to Clause 8 Article 24 of the Law on Pharmacy, the applicant is exempt from fees.

Article 7. Procedures for revocation of the pharmacy practice certificate

1. When a pharmacy practice certificate is revoked according to Clauses 1, 4, 5, 6, 7, 8, 9, 10, 11 Article 28 of the Law on Pharmacy:

Within 05 working days from the day on which the proposal to revoke the pharmacy practice certificate is received or from the discovery of the cases mentioned in Clauses 1, 4, 5, 6, 7, 8, 9, 10, 11 Article 28 of the Law on Pharmacy, the issuing authority shall revoke the pharmaceutical practice certificate it issued, or respond the proposing authority and provide explanation if such proposal is rejected.

2. When a pharmacy practice certificate is revoked according to Clause 2 and Clause 3 Article 28 of the Law on Pharmacy:

Within 05 working days from the day on which the pharmacy practice certificate is found erroneous or the request for revocation of the pharmacy practice certificate is received, the issuing authority shall revoke the pharmaceutical practice certificate it issued, or respond the requesting entity in writing and provide explanation if such request is rejected.

3. Responsibilities of the issuing and revoking authority:

a) Issue the decision to revoke the pharmacy practice certificate;

b) Post such decision on its website and send it to the Ministry of Health and other Departments of Health nationwide;

c) Update information about revocation of the pharmacy practice certificate on its website;

d) The Ministry of Health and Departments of Health of provinces shall post the decision on revocation of the pharmacy practice certificate on their websites within 05 working days from the day on which it is received from its issuer.

Section 2. REFRESHER COURSES IN PHARMACY

Article 8. Training content, training method, duration of the refresher course in pharmacy

The facility offering the refresher training course (hereinafter referred to as “refresher training institution”) in pharmacy shall develop a training program as follows:

1. Training contents:

a) Professional knowledge;

b) Pharmacy law and management;

c) Skills and techniques in pharmacy practice.

2. Teaching method, practicing method and assessment of learners suitable for each subject, type and level of learners.

3. Duration of the refresher course:

a) Professional knowledge: at least 06 hours for learners having a bachelor's degree; 04 hours for learners having a college degree, associate degree or other diplomas;

b) Pharmacy law and management: at least 06 hours;

c) Skills and techniques in pharmacy practice: at least 06 hours.

Article 9. Requirements to be satisfied by the refresher training institution

1. The refresher training institution shall:

a) be either: a vocational education institution licensed to provide training in medicine or pharmacy, an education institution license to provide training in health science, a research institute licensed to provide training in medicine or pharmacy, an institution licensed to provide training for health workers or a pharmacy association;

b) has a refresher training program conformable with Article 8 hereof;

c) has suitable facilities for the training program;

d) has instructors who satisfy the following requirements:

- The instructor giving professional pharmacy lectures has one of the qualifications specified in Article 17 and Article 18 hereof, has at least a degree at the same level with those of his/her learners and at least 02 years' experience in the area related to the training content;

- The instructor giving pharmacy law and management lectures has at least 02 years' experience in working for pharmacy authorities or pharmacy inspectorates or teaching pharmacy in associate training institutions or above;

- The practice instructor has at least 03 years' practical experience in the area related to the training content.

2. If the refresher training institution does not directly run the refresher course, it shall sign a contract with a pharmacy facility that meets good practice requirements suitable for the pharmacy practice covered by the course.

Article 10. Composition of the application for listing of a refresher training institution and adjustment thereto

1. An application for listing of a refresher training institution consists of:

a) Form No. 08 in Appendix I enclosed herewith;

b) The training program according to Article 8 of this Decree, which has to bears a stamp on its cover and fan stamping on its inner pages;

c) A list of facilities proving that the institution is capable of running the refresher course it registers in the form mentioned in Point a of this Clause. The list of facilities shall bear a stamp on its cover and fan stamping on its inner pages;

d) A list of professional pharmacy knowledge instructors (Form No. 09 in Appendix I) enclosed with their academic résumé and relevant qualifications;

dd) A certified true copy of the contract with the cooperating facility in the case mentioned in Clause 2 Article 9 hereof.

2. An application for adjustment to information about a listed refresher training institution except that in Clause 1d of this Article consists of:

a) Form No. 10 in Appendix I enclosed herewith;

b) Copies of documents related to the change which bears the stamp of the institution on the first page and fan stamping on the inner pages.

3. In the cases where the list mentioned in Clause 1d of this Article is changed, the institution shall submit Form No. 11 in Appendix I enclosed herewith.

4. Only 01 set of physical documents and electronic documents is required.

Article 11. Procedures for listing of a refresher training institution and adjustment thereto

1. The applicant shall submit, directly or by post, 01 application set specified in Article 10 hereof to Department of Health of the province where its headquarters are situated.

2. After receiving the application, the Department of Health shall give the applicant Form 01 in Appendix I.

3. If the application is satisfactory, the Department of Health shall:

a) Update the list of eligible refresher training institutions on its website within 30 days from the day on which the application for listing is received;

b) Update the adjustment on its website within 10 days from the day on which the application for adjustment is received;

4. If the application is not satisfactory, the Department of Health shall request the applicant to complete the application:

a) within 15 days from the day on which the application for listing is received; or

b) within 05 days from the day on which the application for adjustment is received.

5. After receiving the supplemented application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the Department of Health shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the Department of Health shall update its website in accordance with Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the Department of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

7. In the cases where a training institution is delisted according to Clause 3 Article 12 of this Decree, the Department of Health only receive the application for listing of such training institution after 12 months from the delisting date.

8. The Department of Health shall publish the following information on its website:

a) Names, addresses and phone numbers of listed training institutions

b) Scope of training.

Article 12. Cases in which a refresher training institution is delisted

1. The institution stops running refresher courses in pharmacy.

2. The institution fails to satisfy any of the requirements to be satisfied by a refresher training program specified in Article 9 hereof.

3. The application contains forged documents.

4. The institution does not run the refresher course in pharmacy for 12 consecutive months without notifying the Department of Health of the same province.

Article 13. Procedures for delisting a refresher training institution

1. Within 05 working days from the day on which the proposal to delist a refresher training institution is received from a competent authority in any of the cases mentioned in Article 12 hereof, the Department of Health shall delist the institution, or respond the proposing authority and provide explanation if such proposal is rejected.

2. Within 05 working days from the day on which the decision on delisting is issued, the Department of Health that issued such decision shall:

a) Post the decision on its website and send it to the Ministry of Health and other Departments of Health nationwide;

b) Update the list of refresher training institutions on its website.

3. Within 05 working days from the day on which the decision to delist a refresher training institution is received, the recipients mentioned in Clause 2a of this Article shall publish it on their websites.

Article 14. Responsibilities of a refresher training institution

1. Only run the refresher course after the institution is listed on the website of the Department of Health and adhere to the training program published.

2. Make assessment and issue certificates of completion of the refresher course according to Form No. 12 in Appendix I enclosed herewith.

3. Submit annual list of people that complete the refresher course to the Department of Health of the same province according to Form No. 13 in Appendix I enclosed herewith.

4. Send a written notification to the Department of Health when the institution suspends or resumes its operation.

Article 15. Responsibilities of pharmacy authorities

1. The Ministry of Health shall:

a) Inspect refresher training programs in accordance with Article 9 of this Decree;

b) Request Departments of Health to submit periodic and unscheduled reports on management of refresher training institutions.

2. The Department of Health of each province shall:

a) Inspect and cooperate with refresher training institutions in its province in organizing the provision of refresher training in pharmacy;

b) Update the list of people who have completed the refresher course at refresher training institutions in the province on its website;

c) Publish the performance of refresher training institutions in the province on its website.

Article 16. Cost of refresher training in pharmacy

A person who takes the refresher course in pharmacy shall pay for it in accordance with law.

Section 3. Determination of qualifications and positions to issue the pharmacy practice certificate

Article 17. Qualifications eligible for issuance of the pharmacy practice certificate

1. Bachelor's degree in pharmacy which is granted by a domestic educational institution and the position written in which is "Dược sĩ" ("pharmacist"), "Dược sĩ đại học" ("Bachelor of Pharmacy") or "Dược sĩ cao cấp" ("high-rank pharmacist").

2. Bachelor's degree in general medicine which is granted by a domestic educational institution and the position written in which is "Bác sĩ" ("physician") or "Bác sĩ đa khoa" ("general physician").

3. Bachelor's degree in traditional medicine or traditional pharmacy which is granted by a domestic educational institution.

4. Bachelor's degree in biology which is granted by a domestic educational institution.

5. Bachelor's degree in chemistry which is granted by a domestic educational institution.

6. College degree in pharmacy which is granted by a domestic educational institution.

7. Associate degree in pharmacy which is granted by a domestic educational institution and the position written in which is "Dược sĩ trung cấp" or "Dược sĩ trung học" ("pharmacy technician").

8. College degree or associate degree in medicine which is granted by a domestic educational institution.

9. Associate degree in traditional medicine or traditional pharmacy which is granted by a domestic educational institution.

10. Basic diploma in pharmacy which is granted by a domestic educational institution and the position written in which is "Dược tá" ("pharmacist assistant") or "Sơ cấp dược".

Article 18. Determination of scope of practice of holders of undefined qualifications and positions

1. If a qualification issued by a domestic training institution does not specify any of the positions specified in Clause 1, 2, 7, 10 Article 17 hereof, the scope of practice shall be decided by the issuer of the pharmacy practice certificate on the basis of counsel provided by the certification advisory council.

2. Scope of practice of holders of qualifications issued by overseas training institutions which have to be certified according to regulations of the Minister of Transport shall be determined in accordance with Clause 1 of this Article.

Section 4. PHARMACY INTERNSHIP

Article 19. Internship-offering establishments

1. Internship-offering establishments are establishments specified in Clause 2 Article 13 of the Law on Pharmacy, including: pharmacy business establishments, pharmacies of health facilities, pharmacy training institutions, pharmacy research institutions, laboratories testing drugs and medicinal ingredients, pharmacy authorities, representative offices of foreign drug traders (hereinafter referred to as "pharmacy establishment"); health facilities suitable for the interns' qualifications.

2. A internship-offering establishment is considered suitable is an establishment mentioned in Clause 1 of this Article and whose operation is suitable for the intern's qualifications according to Article 20 hereof.

3. The internship-offering establishment shall confirm internship durations of inters therein according to Form No. 03 in Appendix I enclosed herewith and take responsibility for such confirmation.

4. Regarding drug retailers:

a) Apart from regulations of Clause 3 of this Article, before accepting interns, the head of the establishment shall send a list of interns according to Form No. 14 in Appendix I enclosed herewith to the Department of Health of the province in which the establishment is located. The list shall specify: Name and address of the establishment, full names of interns, internship contents; commencement date of internship; instructors;

b) Within 05 working days from the day on which the list is received, the Department of Health shall publish the information mentioned in Point a of this Clause on its website.

Article 20. Internship contents

1. Pharmacists of manufacturers of drugs, active ingredients, excipients and softgel shells:

a) The chief pharmacist of a drug manufacturer, except for the cases in Point c and d of this Clause, shall complete one of the following internship contents: drug manufacture, drug testing, research and development of drug, pharmacy management at a pharmacy authority;

b) The chief pharmacist of a manufacturer of medicinal ingredients that are active ingredients, excipients and softgel shells shall complete one of the following internship contents: drug manufacture, drug testing, research and development of drug and medicinal ingredients, manufacture of chemicals, pharmacy management at a pharmacy authority;

c) The chief pharmacist of a manufacturer of vaccines, biologicals and ingredients thereof shall complete one of the following internship contents: manufacture of vaccines and biologicals, testing of vaccines and biologicals, research and development of vaccines and biologicals, pharmacy management at a pharmacy authority;

d) The chief pharmacist of a traditional drug manufacturer shall complete one of the following internship contents: manufacture and processing of traditional drugs, testing of traditional drugs, quality assurance, research and development of traditional drugs, traditional medicine or traditional pharmacy management at a pharmacy authority.

2. Persons in charge of quality assurance of manufacturers of drugs, active ingredients, excipients and softgel shells:

a) The person in charge of quality assurance of a drug manufacturer, except for the cases in Point c of this Clause, shall complete one of the following internship contents: manufacture, testing, quality assurance, research and development at a drug-manufacturing facility or drug-testing of facility;

b) The person in charge of quality assurance of a manufacturer of medicinal ingredients that are active ingredients, excipients and softgel shells shall complete one of the following internship contents: manufacture, testing, quality assurance, research and development at a facility manufacturing drugs or medicinal ingredients or a drug-testing of facility;

c) The person in charge of quality assurance of a manufacturer of vaccines and biologicals and ingredients thereof shall complete one of the following internship contents: manufacture, testing, quality assurance, research and development at a facility manufacturing or testing vaccines and biologicals.

3. Pharmacists and persons in charge of quality assurance of manufacturers of herbal ingredients

a) The pharmacist and the person in charge of quality assurance of a manufacturer of herbal ingredients shall complete one of the following internship contents: manufacture and processing of herbal ingredients, traditional drugs and herbal drugs, testing of drugs, quality assurance during the production of medicinal ingredients and traditional drugs, traditional medicine or traditional pharmacy management at a pharmacy authority;

b) The chief pharmacist and the person in charge of quality assurance of a household business or cooperative manufacturing herbal ingredients shall complete one of the following internship contents: manufacture of medicinal ingredients, drug testing, quality assurance during the production of herbal ingredients and traditional drugs, concoction of traditional drugs, traditional medicine or traditional pharmacy management at a pharmacy authority.

4. Pharmacists of wholesalers of drugs and medicinal ingredients

a) The chief pharmacist of a wholesaler of drug, except for the cases in Point c and d of this Clause, shall complete one of the following internship contents: wholesaling of drugs and medicinal ingredients; pharmacy management at a pharmacy authority; b) The pharmacist of a wholesaler of medicinal ingredients shall complete one of the following internship contents: manufacture of medicinal ingredients and chemicals, testing of drugs and medicinal ingredients, research into chemical and pharmaceutical technology; wholesaling of drugs, export and import of drugs; storage of drugs and medicinal ingredients; traditional pharmacy or traditional medicine management at a pharmacy authority; c) The chief pharmacist of a wholesaler of vaccines and biologicals shall complete one of the following internship contents: manufacture, wholesaling, storage, testing of vaccines and biologicals, research into vaccines and biologicals, pharmacy management at a pharmacy authority;

d) The chief pharmacist of a wholesaler of herbal ingredients, herbal drugs and traditional drugs shall complete one of the following internship contents: wholesaling of drugs and herbal ingredients; storage of drugs and herbal ingredients, testing of drugs and medicinal ingredients, traditional medicine; research into herbal ingredients and traditional medicine; traditional pharmacy or traditional medicine management at a pharmacy authority.

5. Pharmacists of exporters and importers of drugs and medicinal ingredients

a) The chief pharmacist of an exporter of importer of drugs and medicinal ingredients, except for the cases in Point b and c of this Clause, shall complete one of the following internship contents: wholesaling of drugs, export and import of drugs; manufacture of drugs; testing of drugs and medicinal ingredients; Good Storage Practice (GSP); pharmacy management related to sale, export, import, wholesaling of drugs and medicinal ingredients; pharmacy management at a pharmacy authority;

b) The chief pharmacist of an exporter or importer of vaccines and biologicals shall complete one of the following internship contents: manufacture, wholesaling, storage, testing of vaccines and biologicals, research into vaccines and biologicals; use of vaccines and biologicals; pharmacy management at a pharmacy authority;

c) The chief pharmacist of an exporter or importer of herbal ingredients, herbal drugs and traditional drugs shall complete one of the following internship contents: wholesaling of drugs and medicinal ingredients; storage of drugs and medicinal ingredients; manufacture of drugs and medicinal ingredients; testing of drugs, medicinal ingredients and traditional medicine; research into herbal ingredients and traditional medicine; traditional pharmacy or traditional medicine management at a pharmacy authority.

6. Pharmacists of drug retailers

a) The chief pharmacist of a drugstore or dispensary of a commune shall complete one of the following internship contents: wholesaling and retailing of drugs; export and import of drugs; clinical pharmacology; supply of drugs for health facilities; manufacture of drugs; testing of

drugs and medicinal ingredients; pharmaceutical research; drug storage; drug distribution; pharmacy management at a pharmacy authority;

b) The chief pharmacist of a retailer of herbal ingredients, herbal drugs and traditional drugs, except for the cases in Point c Clause 2 Article 13 of the Law on Pharmacy, shall complete one of the following internship contents: manufacture, research, sale, traditional medicine; traditional pharmacy or traditional medicine management at a pharmacy authority.

7. Pharmacists of providers of drug/medicinal ingredients testing services

a) The chief pharmacist of a provider of drug/medicinal ingredients testing services, except for the cases in Point b of this Clause, shall complete one of the following internship contents: testing of drugs and medicinal ingredients; research related to manufacture, testing, analysis of drugs and medicinal ingredients; pharmacy management at a pharmacy authority;

b) The chief pharmacist of a provider of vaccine and biological testing services shall complete one of the following internship contents: testing of drugs and medicinal ingredients; testing of vaccines and biologicals; research related to manufacture and testing of vaccines and biologicals; storage of vaccines and biologicals; pharmacy management at a pharmacy authority.

8. The pharmacist of a provider of clinical trial or bioequivalence study services shall complete one of the following internship contents: bioequivalence study; clinical trial; testing of drugs and medicinal ingredients; pharmacology and clinical pharmacology research; traditional pharmacy or traditional medicine management at a pharmacy authority.

9. Persons in charge of clinical pharmacology of medical facilities

a) The person in charge of clinical pharmacology of a medical facility shall complete one of the following internship contents: bioequivalence study; clinical trial; pharmacology and clinical pharmacology research; pharmacovigilance at the drug information and advert reaction monitoring center;

b) The person in charge of clinical pharmacology of a traditional medicine facility shall complete one of the following internship contents: clinical trial; pharmacology and clinical pharmacology research; pharmacovigilance at the drug information and advert reaction monitoring center.

10. Pharmacists of providers of drug/medicinal ingredients storage services

a) The chief pharmacist shall complete one of the following internship contents: Drug storage; pharmacy, traditional pharmacy or traditional medicine management at a pharmacy authority;

b) The chief pharmacist of a provider of vaccine and biological storage services shall complete one of the following internship contents: storage of vaccines and biologicals; manufacture of vaccines and biologicals, testing of vaccines and biologicals; pharmacy management at a pharmacy authority.

Article 21. Internship durations of postgraduate degree holders

1. A postgraduate degree is either:

a) a Master's degree in pharmacy, medicine, traditional medicine, chemistry or biology;

b) a doctorate degree in pharmacy, medicine, traditional medicine, chemistry or biology;

c) Specialized Level 1 (SL1) or Specialized Level 2 (SL2) degree according to regulations of the Ministry of Health.

2. Specific internship durations of postgraduate degree holders:

a) A person holding a postgraduate degree in concoction, pharmaceuticals industry or drug testing may take a shorter internship as a chief pharmacist or person in charge of quality assurance of a manufacturer of drugs or medicinal ingredients or as a pharmacist of a provider of drug/medicinal ingredients testing services. To be specific:

- 06 months for holders of SL1 degrees;

- 01 year for holders of SL2 degrees.

b) A person holding a postgraduate degree in pharmacology or clinical pharmacology may take a shorter internship as a pharmacist of a provider of bioequivalence study services, clinical trial services, of a drug retailer or as a person in charge of clinical pharmacology of a health facility. To be specific:

- 06 months for holders of SL1 degrees;

- 01 year for holders of SL2 degrees.

c) A person holding a postgraduate degree in herbal ingredients, traditional pharmacy or traditional medicine may take a shorter internship as a pharmacist of an establishment trading in herbal ingredients or traditional drugs, as the person in charge of clinical pharmacology of a traditional medicine facility. To be specific:

- 06 months for holders of SL1 degrees;

- 01 year for holders of SL2 degrees.

d) A person holding a postgraduate degree in infections, microorganisms or prophylaxis may take a shorter internship as a pharmacist of a wholesaler or provider of vaccine and biological storage services. To be specific:

- 06 months for holders of SL1 degrees;

- 01 year for holders of SL2 degrees.

dd) A person holding a postgraduate degree in pharmacy business or pharmacy management may take a shorter internship as a pharmacist of a wholesaler or retailer of modern medicines (except dispensaries of communes) or provider of drug storage services. To be specific:

- 06 months for holders of SL1 degrees;

- 01 year for holders of SL2 degrees.

e) A person holding a postgraduate degree in pharmacy business or pharmacy management may take a shorter internship as a pharmacist of a retailer of herbal drugs, traditional drugs or herbal ingredients or a dispensary of the commune. To be specific:

- 03 months for holders of SL1 degrees;

- 06 months for holders of SL2 degrees.

Section 5. EXAMINATIONS FOR THE PHARMACY PRACTICE CERTIFICATE

Article 22. Examination methods and contents

1. The examination may be held at an examination center or online.

2. Examination contents:

a) General pharmaceutical knowledge;

b) Special knowledge compulsory for the positions mentioned in Article 11 of the Law on Pharmacy.

3. The Minister of Health shall specify regulations, examination contents, question banks and grading scale.

Article 23. Requirements to be satisfied by examination centers

The organization that administers the examination for the pharmacy practice certificate (hereinafter referred to as “examination center”) shall:

1. Be an institution that provides higher education training in pharmacy or traditional pharmacy.

2. Has a plan for organizing examinations for the pharmacy practice certificate according to Form No. 15 in Appendix I enclosed herewith.

Article 24. Composition of the application for listing of an examination center

1. An application for listing of an examination center consists of:

a) Form No. 16 in Appendix I enclosed herewith;

b) The plan for organizing examinations for the pharmacy practice certificate mentioned in Clause 2 Article 23 hereof;

c) A certified true copy of the decision on establishment or operating license of the center

2. An application for adjustment of name or address of a listed examination center:

a) Form No. 17 in Appendix I enclosed herewith;

b) Certified true copies of documents proving the change in name or address of the examination center issued by competent authorities.

3. An application for adjustment of scope of examination of a listed examination center:

a) Form No. 17 in Appendix I enclosed herewith;

b) The plan for organizing examinations for the pharmacy practice certificate mentioned in Clause 2 Article 23 hereof.

4. Only 01 set of physical documents and electronic documents is required.

Article 25. Procedures for applying for listing of an examination center and adjustment thereto

1. The applicant shall submit, directly or by post, 01 application set specified in Article 24 hereof to the Ministry of Health.

2. After receiving the application, the Ministry of Health shall give the applicant Form 01 in Appendix I.

3. If the application is satisfactory, the Ministry of Health shall:

a) Update the list of examination centers within 30 days from the day on which the application is received. If the application is rejected, the Ministry of Health shall respond and provide explanation in writing; or

b) Adjust the name or address of the examination center within 10 working days from the day on which the application is received.

4. If the application is not satisfactory, the Ministry of Health shall request the applicant to complete the application:

a) within 15 days from the day on which the application for listing is received; or

b) within 05 days from the day on which the application for adjustment is received.

5. After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the Ministry of Health shall update information on its website in accordance with Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

7. In the cases where an examination center is delisted according to Clause 3 Article 26 of this Decree, the Ministry of Health shall only receive the application for listing of such examination center after 12 months from the delisting date.

8. The Ministry of Health shall publish the following information on its website:

a) Name and address of the examination center;

b) Scope of examination.

Article 26. Cases in which an examination center is delisted

1. The examination center no longer administers examinations for the pharmacy practice certificate.

2. The examination center fails to satisfy any of the requirements specified in Article 23 hereof.

3. Forged documents are used in the application for listing of the examination center.

Article 27. Procedures for delisting an examination center

1. Within 05 working days from the day on which the proposal to delist an examination center is received from a competent authority in any of the cases mentioned in Article 26 hereof, the Ministry of Health shall delist the examination center, or respond the proposing authority and provide explanation in writing if such proposal is rejected.

2. Within 05 working days from the day on which the decision on delisting is issued, the Ministry of Health shall:

a) Post the decision on its website and send it to the delisted examination center and Departments of Health nationwide;

b) Update information about the delisted examination center on its website.

3. Within 05 working days from the day on which the decision to delist an examination center is received from the Ministry of Health, Departments of Health of provinces shall publish it on their websites.

Article 28. Requirements to be satisfied by examination centers

1. An examination center may only administer the examination for the pharmacy practice certificate after it is listed by the Ministry of Health on its website and:

a) adhere to the plan published by the Ministry of Health; and

b) adhere to the regulations on examination promulgated by the Ministry of Health.

2. After 05 working days from the day on which the examination results are available, the examination center shall send notifications (Form No. 18 in Appendix I enclosed herewith) to the candidates and send a list of passing candidates to the Ministry of Health.

3. If no examination center is listed, the Ministry of Health shall appoint an organization that satisfies all requirements specified in Article 23 of this Decree to administer the examination.

Article 29. Incentives for holders of pharmacy practice certificates after passing an examination

A person who obtains the pharmacy practice certificate after passing an examination will be eligible to certain incentives when he/she applies to a public health organization. To be specific:

1. Priority during the employment process if the examination result is excellent and the undergraduate or postgraduate degree is an honours degree.

2. Exemption from internship after being hired.

3. Priority in provision of refresher training in Vietnam and overseas.

Article 30. Examination fee

The candidates shall pay the examination fees as prescribed by law.

Chapter III

PHARMACY BUSINESS

Section 1. CERTIFICATE OF ELIGIBILITY FOR PHARMACY BUSINESS

Article 31. Eligibility for traditional drug business

1. A manufacturer of traditional drugs that are sold nationwide shall meet the requirements in Clause 2a, 2c and 2d Article 69 of the Law on Pharmacy.

2. The location, storage area, storage equipment, vehicles, quality control system, documents about technologies and personnel of an importer of traditional drugs shall meet GSP requirements applied to traditional drugs. The chief pharmacist of the exporter or importer of traditional drugs shall satisfy the requirements in Clause 3 Article 17 of the Law on Pharmacy.

3. The location, storage area, storage equipment, vehicles, quality control system, specialized documents and personnel of a provider of traditional drug storage services shall meet GSP requirements applied to traditional drugs. The chief pharmacist of the exporter or importer of traditional drugs shall satisfy the requirements in Clause 1 Article 22 of the Law on Pharmacy.

4. The location, storage area, storage equipment, vehicles, quality control system, specialized documents and personnel of a wholesaler of traditional drugs shall meet Good Distribution Practice (GDP) requirements applied to traditional drugs. The chief pharmacist of the wholesaler of traditional drugs shall satisfy the requirements in Clause 3 Article 16 of the Law on Pharmacy.

5. Requirements to be satisfied by retailers of herbal ingredients, herbal drugs and traditional drugs:

a) The chief pharmacist of the retailer of herbal ingredients, herbal drugs or traditional drugs shall satisfy the requirements in Clause 4 Article 18 of the Law on Pharmacy;

b) The retailer has an isolated and fixed store which is firmly built; the store area is suitable for its scope of business, located in a high, dry, airy and safe area, at an adequate distance from sources of pollution and ensures fire safety;

c) The storage area and equipment satisfy the storage requirements written on the labels.

Herbal drugs and traditional drugs must be isolated from herbal ingredients and tradition ingredients.

Toxic herbal ingredients (if any) shall be displayed and stored in a separate area. Otherwise, it must be separated from other herbal ingredients and labeled "dược liệu độc" (“toxic ingredients”) to avoid confusion.

Prescription herbal drugs and traditional drugs (if any) shall be displayed and stored in a separate area. Otherwise, it must be separated from OTC drugs and labeled "thuốc kê đơn" (“prescription drug”) to avoid confusion.

The retailer of the herbal drugs, traditional drugs or herbal ingredients shall have suitable storage areas;

d) Instruments and packages in physical contact with herbal drugs, herbal ingredients or traditional drugs must not affect their quality;

dd) Information about purchases, sales and origins of drugs must be properly recorded;

e) The person who retails herbal ingredients, herbal drugs or traditional drugs (the shopkeeper) shall have one of the documents specified in Points a, c, e, g, i or l Clause 1 Article 13 of the Law on Pharmacy.

Regarding toxic herbal ingredients and prescription herbal drugs, the shopkeeper, who directly sells and counsel buyers, must be a pharmacist;

g) Other goods (if any) must be displayed and stored in a separate area and must not affect the herbal ingredients, herbal drugs or traditional drugs.

Article 32. Applications for issuance, reissuance and adjustment of the Certificate of eligibility for pharmacy business

An application for issuance, reissuance or adjustment of Certificate of eligibility for pharmacy business according to Article 38 of the Law on Pharmacy consists of:

1. Form No. 19, 20 or 21 in Appendix I enclosed herewith for issuance, reissuance or adjustment of the Certificate of eligibility for pharmacy business respectively;

2. Technical documents specified in Clause 1b and Clause 2b Article 38 of the Law on Pharmacy, including the Certificate of eligibility for pharmacy business or Certificate of Good Practice at the business location (if any) and the following documents:

a) If the applicant is a manufacturer of drugs or medicinal ingredients, documents about the location, factory, testing laboratory, storage area, auxiliary systems, machinery for manufacturing and storing drugs, quality control system, documents about technologies and personnel according to Good Manufacturing Practice (GMP) requirements applied to drugs and medicinal ingredients.

In the applicant applies for a Certificate of eligibility for pharmacy business that allows sale of drugs or medicinal ingredients it manufactures to retailers and health facilities, documents about technologies and personnel according to GDP requirements applied to drugs and medicinal ingredients are required;

b) If the applicant is an importer or exporter of drugs or medicinal ingredients or a provider of drug or medicinal ingredient storage services, documents about the location, storage area, storage equipment, vehicles, quality control system, documents about technologies and personnel according to GSP requirements applied to traditional drugs.

In the applicant applies for a Certificate of eligibility for pharmacy business that allows sale of drugs or medicinal ingredients imported to retailers and health facilities, documents about technologies and personnel according to GDP requirements applied to drugs and medicinal ingredients are required;

c) If the applicant is a wholesaler of drugs or medicinal ingredients, documents about the location, storage area, storage equipment, vehicles, quality control system, documents about technologies and personnel according to GDP requirements applied to drugs and medicinal ingredients;

d) If the applicant is a drug retailer, documents about the location, storage area, storage equipment, vehicles, quality control system, documents about technologies and personnel according to Good Pharmacy Practice (GPP) requirements.

If the applicant is a retailer of herbal ingredients, herbal drugs or traditional drugs, documents proving fulfillment of the requirements in Clause 5 Article 31 hereof according to regulations of the Minister of Health;

dd) If the applicant is a provider of drug or medicinal ingredient testing services, documents about the location, testing laboratory, auxiliary system, testing equipment, chemicals, reagents, quality control system, documents about technology and personnel according to Good Laboratory Practice (GLP) requirements;

e) If the applicant is a provider of clinical trial services, documents about the location, clinical trial room, testing laboratory, testing equipment, quality control system, documents about technology and personnel according to Good Clinical Practice (GCP) requirements;

g) If the applicant is a provider of bioequivalence study services, documents about the location, the laboratory for biological fluid analysis, equipment for biological fluid analysis, the area for monitoring drug users serving bioequivalence study, the quality control system, documents about technology and personnel according to GLP requirements for the biological fluid analysis and GCP requirements for the clinical study.

In the cases where the provider of bioequivalence study services sign a contract or cooperate with a clinical trial service provider that meet GCP requirements in carrying out the clinical trial, the documents according to GCP are not required.

3. The documents mentioned in Clause 2 of this Article must bear the applicant's seal on the cover and fan stamping on the inner pages. If the applicant does not have a seal, the legal representative's signature is required.

Article 33. Procedures for issuance of the Certificate of eligibility for pharmacy business

1. The applicant shall submit an application, directly or by post, to:

a) the Ministry of Health in any of the cases mentioned in Point a, b, c, e, g, h Clause 2 Article 32 of the Law on Pharmacy;

b) the Department of Health of the province where the applicant's headquarters are located in any of the cases mentioned in Point d and dd Clause 2 Article 32 of the Law on Pharmacy;

2. After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the receiving authority shall:

a) issue the Certificate of eligibility for pharmacy business within 30 days from the day on which the application is received without a site inspection at the applicant's premises if the applicant's facilities and personnel are conformable with relevant Good Practice requirements;

b) carry out a site inspection at the applicant's premises within 20 days from the day on which the application is received.

4. If the application is not satisfactory, within 10 working days the receiving authority shall request the applicant in writing to complete the application and specify necessary additional documents.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the receiving authority shall follow the instructions in Clause 3 of this Article.

6. After the site inspection is done, the receiving authority shall:

a) issue the Certificate of eligibility for pharmacy business within 10 working days from the day on which the site inspection is done and no remedial actions are requested;

b) Issue a notification of necessary remedial actions (if any) within 05 working days.

7. Within 20 days from the day on which the notification and documents proving that all necessary remedial actions are taken are received, the receiving authority shall issue the Certificate of eligibility for pharmacy business or provide explanation for rejecting the application.

8. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. If the applicant

fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

9. Within 05 working days from the date of issuance of the Certificate of eligibility for pharmacy business, the receiving authority shall update the following information on its website:

a) The name and address of the holder of the Certificate of eligibility for pharmacy business;

b) Full name of the chief pharmacist and his/her pharmacy practice certificate number;

c) Number of the Certificate of eligibility for pharmacy business.

10. In the case specified in Clause 1b Article 36 of the Law on Pharmacy, the applicant shall return the old certificate, unless it is lost.

11. The Certificate of eligibility for pharmacy business shall be made into 02 copies according to Form No. 22 in Appendix I enclosed herewith. 01 copy will be given to the applicant while the other retained by the issuing authority. 12. If the applicant has met Good Practice requirements, the authority that issues the Certificate of eligibility for pharmacy business shall issue the Certificate of Good Practice.

Article 34. Procedures for reissuing and adjusting the Certificate of eligibility for pharmacy business

1. The applicant shall submit an application for reissuance or adjustment of the Certificate of eligibility for pharmacy business, directly or by post, to:

a) the Ministry of Health in any of the cases mentioned in Point a, b, c, e, g, h Clause 2 Article 32 of the Law on Pharmacy;

b) the Department of Health of the province where the applicant's headquarters are located in any of the cases mentioned in Point d and dd Clause 2 Article 32 of the Law on Pharmacy;

2. After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the receiving authority shall:

a) reissue or adjust the Certificate of eligibility for pharmacy business within 20 days from the day on which the application is received in the case mentioned in Clause 2 and Clause 3 Article 36 of the Law on Pharmacy;

b) reissue or adjust the Certificate of eligibility for pharmacy business within 07 days from the day on which the application is received in the case mentioned in Clause 2b Article 36 of the Law on Pharmacy.

4. If the application is not satisfactory, within 05 working days the receiving authority shall request the applicant in writing to complete the application.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the receiving authority shall reissue or adjust the Certificate of eligibility for pharmacy business in accordance with Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

7. Within 05 working days from the day on which the Certificate of eligibility for pharmacy business is reissued or adjusted, the receiving authority shall update the following information on its website:

a) The name and address of the holder of the Certificate of eligibility for pharmacy business that is reissued or adjusted;

b) Full name of the chief pharmacist and his/her pharmacy practice certificate number;

c) Number of the Certificate of eligibility for pharmacy business.

8. After receiving the new Certificate of eligibility for pharmacy business, the applicant shall return the old one unless it has been lost.

9. The Certificate of eligibility for pharmacy business shall be made into 02 copies according to Form No. 22 in Appendix I enclosed herewith. 01 copy will be given to the applicant while the other retained by the issuing authority;

Article 35. Procedures for issuance of the Certificate of eligibility for pharmacy business

1. Within 05 working days from the day on which the proposal to revoke the Certificate of eligibility for pharmacy business is received or from the discovery of the cases mentioned in Article 40 of the Law on Pharmacy, the issuing authority shall revoke the Certificate of eligibility for pharmacy business it issued, or respond the proposing authority and provide explanation in writing if such proposal is rejected.

2. Within 05 working days from the day on which the decision to revoke the Certificate of eligibility for pharmacy business is issued, the issuer shall:

a) Post such decision on its website and send it to the Ministry of Health and Departments of Health nationwide;

b) Update information about revocation on its website.

3. Within 05 working days from the day on which the decision to revoke the Certificate of eligibility for pharmacy business is received, the Ministry of Health and the Departments of Health mentioned shall post it on their websites.

Article 2. SCOPE OF OPERATION OF RETAILING DISPENSARIES AND DRUG COUNTERS

Article 36. Locations of retailing dispensaries and drug counters

1. Locations of retailing dispensaries

a) Retailing dispensaries may be opened in communes and small towns;

b) If the ratio of dispensary to 2,000 people in ward that has just been converted from a commune or small town is smaller than 1, new retailing dispensaries may be opened for up to 03 years from the conversion date.

c) A retailing dispensary which is opened in an area other than those mentioned in Clause 1a of this Article and already granted a certificate of eligibility for drug business before the effective date of this Decree may operate until the expiration date of the certificate. If the certificate of eligibility for drug business does not have an expiration date, it may operate for up to 03 more years from the effective date of this Decree.

2. Locations of drug counters:

a) In medical stations of communes;

b) In medical stations of communes in ethnic areas, mountainous areas, islands, extremely disadvantaged areas.

Article 37. Scope of operation of retailing dispensaries and drug counters

1. The scope of operation of a retailing dispensary is specified in Clause 1b Article 48 of the Law on Pharmacy.

2. The scope of operation of a drug counter is specified in Clause 1b Article 49 of the Law on Pharmacy.

Section 3. MOBILE DRUGSTORES

Article 38. Requirements for operating a mobile drugstore

1. The following entities may operate a mobile drugstore:

a) Drug manufacturers;

b) Drug wholesalers;

c) Drug retailers;

d) Medical facilities of the military that supply drugs in ethnic areas, mountainous areas, islands, extremely disadvantaged areas.

2. The keeper of the mobile drugstore must be an employee of the mobile drugstore owner mentioned in Clause 1 of this Article and has one of the qualifications mentioned in Points a, b, c, e, g, h, i and k Clause 1 Article 13 of the Law on Pharmacy.

3. Drugs sold by a mobile drugstore must not expire for the next 06 months, be stored with hygienic equipment and protected from the weather.

4. Each mobile drugstore must have a signboard which specifies its owner, full name of the keeper and the operating area.

5. A mobile drugstore may only be opened after a confirmation of registration is received from the Department of Health of the province. The mobile drugstore may only operate within the registered area and sell the drugs on the list published by the Department of Health.

Article 39. List of drugs and area for mobile drugstore operation

1. A drug sold by a mobile drugstore shall satisfy the following criteria:

a) It is on the list of OTC drugs;

b) It only requires normal storage conditions;

c) It is meant to serve common purposes of local people.

2. Pursuant to Clause 1 of this Article, the Director of the Department of Health shall publish a list of drugs and areas permissible for mobile drugstores.

Article 40. Procedures for registration of a mobile drugstore

1. The applicant for registration of a mobile drugstore shall submit Form No. 23 in Appendix I enclosed herewith to the Department of Health of the province where the mobile drugstore operates.

2. After receiving the application form, the Department of Health shall give the applicant a confirmation according to Form 01 in Appendix I enclosed herewith. The confirmation shall

specify the date of receipt. 3. Within 05 days from the date of receipt written on the confirmation, the Department of Health shall publish information about the mobile drugstore on its website and inform the health authorities of districts in the province.

Section 4. MEASURES AGAINST LOSS OF DRUGS AND MEDICINAL INGREDIENTS SUBJECT TO SPECIAL CONTROL; PROCEDURES FOR GRANTING PERMISSION FOR TRADING IN DRUGS SUBJECT TO SPECIAL CONTROL AND DRUGS RESTRICTED FROM RETAILING

Article 41. List of radioactive substances permissible for health facilities and issuance of list of drugs and active ingredients banned from certain fields

1. The list of radioactive substances permissible for health facilities is promulgated in Appendix IV enclosed herewith.

2. The List of drugs and active ingredients banned from certain fields:

a) Ministries and ministerial agencies shall send the Ministry of Health their lists of banned substances in their fields or amendments thereto;

b) The Minister of Health shall take appropriate measures, considerate the risk of substance abuse and promulgate the list of banned drugs and active ingredients in certain fields.

Article 42. Eligibility for trading in drugs subject to special control

1. To be allowed to trade in drugs subject to special control, an establishment shall:

a) satisfy the requirements in Article 33 of the Law on Pharmacy applicable to its type of business;

b) comply with regulations on security measures in Articles 43, 44, 45, 46, 47 and 48 hereof.

c) comply with the Law on Atomic Energy and relevant legislative documents in addition to the conditions specified in Clause 1a and 1b of this Article if trading in radiopharmaceuticals.

2. If there is not establishment trading in drug subject to special control in a province, the Department of Health shall appoint a wholesaler in the province which satisfies the conditions in Clause 1 of this Article to trade in drugs subject to special control to ensure adequate supply of drugs.

3. The Ministry of Health and Departments of Health shall carry out an inspection every 03 years or on an ad hoc basis to ensure implementation of security measures in Section 4 Chapter III at establishments trading in drugs subject to special control in accordance with regulations of the Minister of Health or international treaties to which Vietnam is a signatory.

Article 43. Required facilities of traders of drugs subject to special control

1. A manufacturer of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall:

a) has a separate storage area that meets GSP requirements and has sturdy walls and ceiling with robust doors and locks to store the narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors.

b) have a camera system to monitor each and every stage of the manufacture and storage process;

c) have a documentary management system according to regulations of the Minister of Health;

d) have a software system for monitoring and managing the inventory of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors.

2. A manufacturer of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors shall:

a) have a separate storage area that meet GSP requirements and have sturdy walls and ceiling with robust doors and locks to store the medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors. b) have a separate area to store combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors;

c) have a camera system to monitor each and every stage of the manufacture and storage process;

d) have a documentary management system according to regulations of the Minister of Health;

dd) has a software system for monitoring and managing the inventory of medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors; inventory of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors.

3. A manufacturer of radiopharmaceuticals shall:

a) have a separate storage area that meets GSP requirements to store the radiopharmaceuticals;

b) have a license to do radiological works suitable for its scope of operation;

c) have a software system to monitor and manage the inventory of radiopharmaceuticals;

d) have a documentary management system according to regulations of the Minister of Health;

dd) have a camera system in the manufacture and storage area.

4. An exporter, importer of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors or provider of storage services for these drugs shall:

a) have a separate storage area that meet GSP requirements, is separated from the areas for storing other drugs and have sturdy walls and ceiling with robust doors and locks to store the narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors. b) have a camera system in the storage area of drugs and medicinal ingredients;

c) have a documentary management system according to regulations of the Minister of Health;

d) have a software system for monitoring and managing the inventory of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors.

5. An exporter, importer or wholesaler of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors or a provider of storage services for these drugs shall:

a) have a separate area that meet GSP requirements and have sturdy walls and ceiling with robust doors and locks to store combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors. b) have a documentary management system according to regulations of the Minister of Health;

c) have a software system for monitoring and managing the inventory of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors.

6. An exporter, importer or wholesaler of radiopharmaceuticals shall manage the inventory of radiopharmaceuticals by a software system and documentary management system according to regulations of the Minister of Health.

7. A wholesaler of narcotic drugs, psychotropic drugs or precursors shall:

a) have a separate storage area that meet GSP requirements and have sturdy walls and ceiling with robust doors and locks to store the narcotic drugs, psychotropic drugs or precursors;

b) have a camera system in the storage area;

c) have a documentary management system according to regulations of the Minister of Health;

d) have a software system to monitor and manage the inventory of narcotic drugs, psychotropic drugs or precursors.

8. A retailer of narcotic drugs, psychotropic drugs or precursors shall:

a) have a separate storage area that has sturdy walls and ceiling with robust doors and locks to store the narcotic drugs, psychotropic drugs or precursors. Otherwise, they shall be put in separate and locked cabinets or drawers;

b) have a documentary management system according to regulations of the Minister of Health.

9. A retailer of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors shall have a software system and documentary management system for monitoring and managing the inventory of these drugs according to regulations of the Minister of Health.

10. A retailer of radiopharmaceuticals shall:

a) have a separate area to store radiopharmaceuticals;

b) have a license to do radiological works suitable for its scope of operation;

c) have a documentary management system according to regulations of the Minister of Health;

d) have a software system to monitor and manage the inventory of radiopharmaceuticals;

11. A provider of clinical study services, bioequivalence study services, testing services or storage services for radiopharmaceuticals:

a) have a separate storage area that meets GSP requirements to store the radiopharmaceuticals;

b) have a license to do radiological works suitable for its scope of operation;

c) have a software system to monitor and manage the inventory of radiopharmaceuticals;

d) have a documentary management system according to regulations of the Minister of Health;

dd) A provider of radiopharmaceutical storage services shall have a camera system.

12. A provider of clinical trial services, bioequivalence study services, testing medicines subject to special control, except for those mentioned in Clause 11 of this Article, shall store the narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors, combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursor in a separate and locked area. Otherwise, they shall be put in separate and locked cabinets or drawers.

13. An trader of toxic drugs, toxic medicinal ingredients, drugs or active ingredients on the list of banned substances in certain fields shall have a software system or documentary management system to manage its inventory according to regulations of the Minister of Health.

Article 44. Personnel of traders of drugs subject to special control

1. Personnel of a manufacturer of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors:

a) The warehouse-keeper responsible for narcotic drugs, medicinal ingredients that are narcotic active ingredients shall have at least a bachelor's degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

b) The warehouse-keeper responsible for psychotropic drugs, precursors, medicinal ingredients that are psychotropic active ingredients or drug precursors shall have at least an associate degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

c) The person responsible for recording and reporting shall have at least an associate degree in pharmacy;

2. Personnel of a manufacturer of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors:

a) The warehouse-keeper responsible for medicinal ingredients that are narcotic active ingredients shall have at least a bachelor's degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

b) The warehouse-keeper responsible for medicinal ingredients that are psychotropic active ingredients or drug precursors shall have at least an associate degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

c) The person responsible for recording and reporting shall have at least an associate degree in pharmacy;

3. Personnel of a manufacturer of radiopharmaceuticals:

a) The warehouse-keeper shall have at least an associate degree in pharmacy or a bachelor's degree in radiochemistry, radiology or nuclear medicine;

b) The person responsible for recording and reporting shall have at least an associate degree in pharmacy or radiochemistry, analytic chemistry, radiology or nuclear physics;

c) The supervisor of research, manufacture, analysis, testing processes shall have at least a bachelor's degree in radiochemistry, radiology, nuclear medicine or pharmacy.

4. Personnel of an exporter or importer of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors:

a) The warehouse-keeper responsible for narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall have at least a bachelor's degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

b) The person responsible for recording and reporting shall have at least an associate degree in pharmacy.

5. The person responsible for recording and reporting of an exporter or importer of radiopharmaceuticals shall have at least an associate degree in pharmacy or radiochemistry, analytic chemistry, radiology or nuclear physics.

6. Personnel of a wholesaler of narcotic drugs, psychotropic drugs or precursors:

a) The warehouse-keeper responsible for narcotic drugs shall have at least a bachelor's degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

b) The warehouse-keeper responsible for psychotropic drugs or precursors shall have at least an associate degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

c) The person responsible for recording and reporting shall have at least an associate degree in pharmacy.

7. The person responsible for recording and reporting of a wholesaler of radiopharmaceuticals shall have at least an associate degree in pharmacy or radiochemistry, analytic chemistry, radiology or nuclear physics.

8. Personnel of a retailer of narcotic drugs, psychotropic drugs or precursors:

a) The shopkeeper shall sells narcotic drugs have at least a bachelor's degree in pharmacy;

b) The shopkeeper that sells psychotropic drugs or precursors shall have at least an associate degree in pharmacy.

9. The person responsible for retailing, recording and reporting of a retailer of radiopharmaceuticals shall have at least an associate degree in pharmacy.

10. The warehouse-keeper responsible for narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors of a drug storage service provider shall have at least a bachelor's degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

11. Personnel of a provider of clinical trial services, bioequivalence study services, testing services that involve narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that

are narcotic active ingredients, psychotropic active ingredients or drug precursors: the manager of drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients shall have at least an associate degree in pharmacy.

12. Personnel of a provider of clinical trial services, bioequivalence study services, testing services that involve radiopharmaceuticals:

a) The warehouse-keeper shall have at least an associate degree in pharmacy or a bachelor's degree in radiochemistry, radiology or nuclear medicine;

b) The person responsible for recording and reporting shall have at least an associate degree in pharmacy or radiochemistry, analytic chemistry, radiology or nuclear physics;

c) The supervisor of research, manufacture, analysis, testing processes shall have at least a bachelor's degree in radiochemistry, radiology, nuclear medicine or pharmacy.

Article 45. Delivery of drugs subject to special control

1. The deliverer and recipient of drugs or medicinal ingredients subject to special control shall have at least an associate degree in pharmacy; the deliverer and recipient of radiopharmaceuticals shall have a certificate of training in radiation safety according to regulations of the Ministry of Science and Technology in addition to the associate degree in pharmacy.

2. The deliverer of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients, drug precursors shall bring the head's assignment letter, identification paper, and the sale invoice or receipt. In case of delivery of radiopharmaceuticals, the deliverer shall bring the certificate of training in radiation safety in addition to the aforementioned documents.

3. Upon delivery of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors, a delivery note shall be made according to Form No. 01 in Appendix II enclosed herewith.

4. The transport of medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors, narcotic drugs, active ingredients and precursors must ensure security and prevent leakage. The transport of radiopharmaceuticals shall ensure radiation safety in accordance with regulations on safe transport of radioactive materials promulgated by the Minister of Science and Technology.

5. Each establishment participating in the delivery of the radiopharmaceuticals shall have the license to perform radiological works that allows transport of radiation sources as prescribed by the Ministry of Science and Technology.

Article 46. Trading in drugs subject to special control

1. Regarding medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors:

a) A manufacture may only import ingredients serving the manufacture of its drugs;

b) An importer may only sell imported ingredients to manufacturers of narcotic drugs, psychotropic drugs, precursors or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors, health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy nationwide for research and testing purposes; to drugstores for preparation of prescription drugs;

c) When a drug manufacturer wishes to sell its redundant ingredients to another manufacturer or importer eligible to trade in drugs subject to special control, it must obtain a written permission from the Ministry of Health.

2. Regarding narcotic drugs, psychotropic drugs, precursors and combined drugs that contain precursors:

a) A manufacturer may only sell drugs it manufactures to establishments that have the Certificate of eligibility for pharmacy business that allows export, import and wholesaling of drugs, health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy nationwide; and may select 01 wholesaler in a province to sell all of its products;

b) An importer may only sell drugs it imports to establishments that have the Certificate of eligibility for pharmacy business that allows export, import and wholesaling of drugs, health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy nationwide; and may select 01 wholesaler in a province to sell all of the products it imports;

c) An establishment that has the Certificate of eligibility for pharmacy business that allows export, import and wholesaling of drugs may only sell drugs to other establishments that have the Certificate of eligibility for pharmacy business that allows export, import and wholesaling of drugs, health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy nationwide, drugstores in the same province; and may select 01 wholesaler in a province to sell all of its products;

d) A wholesaler may only sell drugs to health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy and drugstores in the same province;

dd) Health facilities, rehabilitation centers and establishments providing opioid substitution treatment may purchase drugs from the establishments specified in Points a, b, c, d of this Clause through bidding.

3. Combined drugs that contain narcotic active ingredients or psychotropic active ingredients, radiopharmaceuticals, toxic drugs, toxic medicinal ingredients, drugs and active ingredients on the list of banned substances in certain fields may be traded in accordance with Chapter IV of the Law on Pharmacy.

Article 47. Reporting by traders of drugs subject to special control

1. Export and import reports:

a) Each exporter and importer of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall prepare a report on the export or import within 10 days from the date of export or import according to Form No. 02 and Form No. 03 in Appendix II enclosed herewith and send it to the Ministry of Health and the Ministry of Public Security;

b) Each exporter and importer of radiopharmaceuticals shall prepare a report on the export or import according to Form No. 04 and Form No. 05 in Appendix II enclosed herewith and send it to the Ministry of Health within 10 days from the date of export or import;

c) By the 15th of January of the succeeding year, each exporter and importer of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors or radiopharmaceuticals shall prepare the annual report on export or import of these drugs according to Forms No. 06, 07, 08 in Appendix II enclosed herewith and send it to the Ministry of Health.

2. By the 15th of July and 15th of January, each manufacturer, exporter and importer of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall prepare a biannual report and an annual report according to Form No. 09 and 10 in Appendix II enclosed herewith and send them to the Ministry of Health.

3. By the 15th of July and 15th of January, each manufacturer, exporter and importer of radiopharmaceuticals or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors shall prepare a biannual report and an annual report according to Form No. 11 and 12 in Appendix II enclosed herewith and send them to the Ministry of Health.

4. By the 15th of July and 15th of January, each wholesaler and retailer of radiopharmaceuticals, narcotic drugs, psychotropic drugs, precursors or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors shall prepare a biannual report and an annual report according to Form No. 11, 12, 13 in Appendix II enclosed herewith and send them to the Department of Health of the province where their headquarters are situated.

5. By the 15th of January, each manufacturer and exporter of drugs or active ingredients on the list of drugs and active ingredients banned from certain fields shall prepare and send a report according to Form No. 09 in Appendix II to the Ministry of Health. Each wholesaler of drugs or active ingredients on the list of drugs and active ingredients banned from certain fields shall

prepare a report according to Form No. 09 in Appendix II and send it to the Department of Health of the same province. 6. Within 48 hours from discovery of a mistake, loss of radiopharmaceuticals, narcotic drugs, psychotropic drugs, precursors or medicinal ingredients that are active ingredients, psychotropic active ingredients or drug precursors, the manufacturer, exporter, importer, drug storage service provider, clinical trial service provider, bioequivalence study service provider or drug testing service provider shall prepare a written report and send it to the Ministry of Health; the wholesaler or retailer shall submit a report to Department of Health according to Form No. 14 in Appendix II enclosed herewith.

7. By the 15th January, the Department of Health of each province shall submit a list of wholesalers of narcotic drugs, psychotropic drugs, precursors and combined drugs that contain precursors in their provinces according to Form No. 15 in Appendix II enclosed herewith to the Ministry of Health.

Article 48. Destruction of drugs subject to special control

1. The applicant for permission to destroy narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall submit an application form which specifies the name of the drug or medicinal ingredient, concentration, quantity, reason for destruction and destruction method.

2. Procedures for granting permission for destruction of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors:

a) The application shall be submitted to the Ministry of Health if the applicant is a manufacturer, exporter or importer, or to the Department of Health of the same province if the applicant is a pharmacy business establishment other than the aforementioned entities; The application may be submitted directly or by post;

b) After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the receiving authority shall issue a written permission for destruction within 30 working days from the day on which the application is received;

d) If the application is not satisfactory, the receiving authority shall request the applicant to complete the application within 30 working days from the day on which the application is received;

dd) After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith. If the supplemented application is satisfactory, the receiving authority shall issue a written permission in accordance with Point c of this Clause. If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Point d of this Clause.

3. The destruction of narcotic drugs, psychotropic drugs, precursors or medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors may only be carried out after the receiving authority issues a written permission.

4. Procedures for destruction of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors:

a) The head of the establishment shall establish a drug destruction council. The council consists of at least 03 members, one of which has to be the establishment's chief pharmacist. The council shall organize the destruction, decide the destruction method and supervise the destruction process;

b) The destruction must be witnessed by representatives of the Department of Health of the same province and be recorded using Form No. 16 in Appendix II enclosed herewith;

c) Within 10 days from the day on which the destruction is done, a report (according to Form No. 17 in Appendix II) and the destruction record shall be submitted to the receiving authority.

5. Unused radiopharmaceuticals and primary packages of radiopharmaceuticals shall be stored properly before destruction in accordance with regulations of law on atomic energy.

6. Wastes derived from radiopharmaceuticals shall be managed in accordance with regulations of law on atomic energy.

7. When destroying redundant products or wastes that contain narcotic active ingredients, psychotropic active ingredients or drug precursors, combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors, primary packages of narcotic drugs, psychotropic drugs, precursors, narcotic active ingredients, psychotropic active ingredients, drug precursors, toxic drugs, toxic medicinal ingredients, drugs and active ingredients on the list of drugs and active ingredients banned in certain fields, the owner shall gather and destroy them in accordance with Clause 4a of this Article and retain documents about the destruction.

Article 49. Composition of the application for permission to trade in drugs subject to special control

An establishment that wishes to trade in drugs subject to special control shall submit the following documents in addition to the documents specified in Article 32 hereof:

1. Documents proving that the establishment has taken measures to ensure security and prevent loss of drugs subject to special control according to Form No. 18 in Appendix II enclosed herewith (on A4 pages in Vietnamese language).

2. The original copy or certified true copy of the permission to perform radiological works issued by a competent authority if the applicant wishes to trade in radiopharmaceuticals.

3. The list of drugs and concoction thereof if the applicant is a drugstore that concocts drugs subject to special control according to prescriptions.

4. Only 01 set of documents specified in this Article is required.

Article 50. Procedures for issuance of Certificate of eligibility for pharmacy business that involve narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors or radiopharmaceuticals; manufacture of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors

1. The applicant shall submit an application, directly or by post, to:

a) the Ministry of Health if the applicant is a manufacturer, exporter, importer or provider of clinical trial services, bioequivalence study services or testing services;

b) the Department of Health of the same province if the applicant is a drug wholesaler or retailer.

2. After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the receiving authority shall request the advisory council to consider within 15 working days from the day on which the application is received.

4. If the application is not satisfactory, the receiving authority shall request the applicant in writing to complete the application and specify necessary additional documents within 20 days from the day on which the application is received.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the receiving authority shall follow the instructions in Clause 3 of this Article.

6. The receiving authority shall consider the application on the basis of counsel of the advisory council.

a) If the application is satisfactory, the receiving authority shall carry out a site inspection at the applicant’s premises within 60 working days from the day on which the application is received;

b) If the application is unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article.

7. After the site inspection is done and on the basis of counsel of the advisory council, the receiving authority shall:

a) issue the Certificate of eligibility for pharmacy business within 20 working days from the day on which the site inspection is done and no remedial actions are requested;

b) Issue a notification of necessary remedial actions (if any) within 15 working days from the day on which the site inspection is done;

c) If the applicant fails to take remedial actions at the request of the receiving authority within 06 months from the day on which the application is received, the application will be rejected.

8. Within 20 days from the day on which the notification and documents proving that all necessary remedial actions are taken are received, the receiving authority shall issue the Certificate of eligibility for pharmacy business or provide explanation for rejecting the application.

9. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, it will be rejected.

10. Within 05 working days from the date of issuance of the Certificate of eligibility for pharmacy business, the receiving authority shall update the following information on its website:

a) The name and address of the holder of the Certificate of eligibility for pharmacy business;

b) Full name of the chief pharmacist and his/her pharmacy practice certificate number;

c) Number of the Certificate of eligibility for pharmacy business;

d) The operating scope.

11. The site inspection only deals with the issues that have not met Good Practice requirements.

Article 51. Procedures for issuance of the Certificate of eligibility for pharmacy business to traders of combined drugs that contain narcotic active ingredients, or psychotropic active ingredients or precursors (except those mentioned in Article 50 hereof); traders of toxic drugs, toxic medicinal ingredients, drugs and active ingredients on the list of banned substances in certain fields

1. The applicant shall submit an application, directly or by post, to:

a) the Ministry of Health if the applicant is a manufacturer, exporter, importer or provider of clinical trial services, bioequivalence study services or testing services;

b) the Department of Health of the same province if the applicant is a drug wholesaler or retailer.

2. After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the receiving authority shall:

a) issue a new Certificate of eligibility for pharmacy business which allows trading in drugs subject to special control within 30 days from the day on which the application is received if the applicant is already holding a Certificate of eligibility for pharmacy business and meet Good Practice requirements applied to the operating scope;

b) carry out a site inspection within 30 days from the day on which the application is received if the applicant is not holding a Certificate of eligibility for pharmacy business or the application is holding a Certificate of eligibility for pharmacy business but has not met t Good Practice requirements applied to the operating scope.

4. If the application is not satisfactory, the receiving authority shall request the applicant in writing to complete the application and specify necessary additional documents within 30 days from the day on which the application is received.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the receiving authority shall follow the instructions in Clause 3 of this Article.

6. After the site inspection is done, the receiving authority shall:

a) issue the Certificate of eligibility for pharmacy business within 20 working days from the day on which the site inspection is done and no remedial actions are requested;

b) issue a notification of necessary remedial actions (if any) within 15 working days.

7. Within 20 days from the day on which the notification and documents proving that all necessary remedial actions are taken are received from the applicant, the receiving authority shall issue the Certificate of eligibility for pharmacy business or provide explanation for rejecting the application.

8. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

9. Within 05 working days from the date of issuance of the Certificate of eligibility for pharmacy business, the receiving authority shall update the following information on its website:

a) The name and address of the holder of the Certificate of eligibility for pharmacy business;

b) Full name of the chief pharmacist and his/her pharmacy practice certificate number;

c) Number of the Certificate of eligibility for pharmacy business;

d) The scope of operation.

Article 52. Advisory council responsible for giving counsel on licensing traders of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors

1. Composition of the advisory council of the Ministry of Health

The Minister of Health shall establish an advisory council that consists of at least 05 members to counsel licensing traders of these drugs. To be specific:

a) A representative of the Ministry of Health shall be appointed as the Chairperson;

b) Representatives of the Ministry of Public Security shall be responsible for licensing traders of medicinal ingredients containing narcotic active ingredients, psychotropic active ingredients or drug precursors, narcotic drugs, psychotropic drugs and precursors;

c) Representatives of the Ministry of Science and Technology are responsible for licensing traders of radiopharmaceuticals;

d) Representatives of relevant organizations and relevant individuals (if necessary).

2. Composition of the advisory council of a Department of Health

The Director of the Department of Health shall establish an advisory council that consists of at least 03 members to counsel licensing traders of these drugs. To be specific:

a) A representative of the Department of Health shall be appointed as the Chairperson;

b) Representatives of relevant organizations and relevant individuals (if necessary).

3. The Minister of Health shall specify the structure and operation of advisory councils.

Article 53. Composition of the application for permission to purchase narcotic drugs, psychotropic drugs, precursors or medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors; composition of the

application for permission to sell medicinal ingredients that are active ingredients, psychotropic active ingredients or drug precursors

1. An application for permission to purchase narcotic drugs, psychotropic drugs or precursors consists of:

a) 03 copies of the order for narcotic drugs, psychotropic drugs or precursors according to Form No. 19 in Appendix II enclosed herewith;

b) The report on sales of narcotic drugs, psychotropic drugs and precursors according to Form No. 20 in Appendix II enclosed herewith;

c) A written explanation for purchasing a quantity of drugs that exceeds the previous purchase by over 150%.

2. An application for permission to purchase medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors consists of:

a) 03 copies of the order for medicinal ingredients that contain narcotic active ingredients, psychotropic active ingredients or precursors according to Form No. 19 in Appendix II enclosed herewith;

b) A report on use of medicinal ingredients according to Form No. 10 in Appendix II enclosed herewith;

c) The report on sales of medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors according to Form No. 20 in Appendix II enclosed herewith;

d) A plan for manufacture of drugs from the ingredients to be purchased;

dd) A written explanation for purchasing a quantity of medicinal ingredients that exceed the previous purchase by over 150%.

3. An application for permission to sell medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors consists of:

a) Form No. 21 in Appendix II enclosed herewith;

b) 03 copies of the order for medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors according to Form No. 19 in Appendix II enclosed herewith;

c) A report on sale of drugs and use of medicinal ingredients according to Form No. 10 and Form No. 20 in Appendix II enclosed herewith.

4. Only 01 set of documents specified in Clause 1, 2, 3 of this Article is required.

Article 54. Procedures for granting permission to purchase narcotic drugs, psychotropic drugs, precursors or medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors; procedures for granting permission to sell medicinal ingredients that are active ingredients, psychotropic active ingredients or drug precursors

1. The applicant shall submit an application directly or by post to:

a) the Ministry of Health if the applicant is a manufacturer, the applicant already has a certificate of eligibility for drug export, import and wholesaling, or the applicant is a health facility, a testing laboratory, a rehabilitation center, an establishment providing opioid substitution treatment or an establishment providing training in medicine or pharmacy that needs to purchase drugs for research or testing purposes;

b) The Department of Health of the same province if the applicant is a research institution, a testing laboratory, an establishment providing training in medicine or pharmacy, a drug wholesaler or retailer, a rehabilitation center, an establishment providing opioid substitution treatment (applied to drugs purchased without bidding).

2. When receiving the application, the receiving authority shall give the applicant Form No. 01 in Appendix II enclosed herewith.

3. If the application is satisfactory, the receiving authority shall approve the purchase order or issue a written permission within 30 days from the day on which the application is received.

4. If the application is not satisfactory, the receiving authority shall request the applicant in writing to complete the application and specify necessary additional documents within 30 days from the day on which the application is received.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article.

b) If the supplemented application is satisfactory, the receiving authority shall follow the instructions in Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

Article 55. Documents and procedures for obtaining permission to retail drugs on the list of drugs restricted from retailing

1. If the applicant has not obtained the Certificate of eligibility for pharmacy business that allows drug retailing:

a) The application shall consist of Form No. 22 in Appendix II enclosed herewith and the documents specified in Clause 2d Article 32 hereof;

b) Procedures and time limit for licensing are the same as those specified in Article 33 hereof.

2. If the applicant has obtained a Certificate of eligibility for pharmacy business that allows drug retailing:

a) The application shall consist of Form No. 23 in Appendix II enclosed herewith;

b) Procedures and time limit:

- The applicant shall submit the application directly or by post to the Department of Health of the same province as the applicant's headquarters;

- After receiving the application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

- If the application is satisfactory, the Department of Health shall issue a written permission for retailing drugs on the list of drugs restricted from retailing within 07 working days from the day on which the application is received;

- If the application is not satisfactory, the Department of Health shall request the applicant to complete the application within 05 working days from the day on which the application is received;

- After receiving the supplemented application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the supplemented application is still unsatisfactory, the Department of Health shall inform the applicant in writing within 05 working days from the day on which the application is received. If the supplemented application is satisfactory, the Department of Health shall issue a written permission for retailing drugs on the list of drugs restricted from retailing within 07 working days from the day on which the application is received;

- Within 06 months from the day on which additional documents are requested in writing by the Department of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

3. Within 05 days from the day on which permissions granted, the Department of Health shall publish information about the retailer and the list of drugs permitted for retailing on its website.

Article 56. Responsibility of competent authorities to reporting by traders of drugs subject to special control

1. Competent authorities are entitled to reject applications for permission to purchase drugs or medicinal ingredients, applications for permission to import drugs or medicinal ingredients submitted by traders of drugs subject to special control that fail to submit reports in accordance with Article 47 of this Decree.

2. An application shall only be considered after adequate reports are submitted.

Chapter IV

EXPORT AND IMPORT OF DRUGS AND MEDICINAL INGREDIENTS

Section 1. EXPORT OF DRUGS SUBJECT TO SPECIAL CONTROL, HERBAL INGREDIENTS ON THE LIST OF CONTROLLED RARE AND SPECIAL HERBS

Article 57. Procedures for issuance of the license to export narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors

1. The export of a drug shall only be licensed when one of the following requirements is satisfied:

a) The drug is manufactured in Vietnam, granted a certificate of drug registration in Vietnam and granted an import license by a competent authority of the importing country; or

b) The drug is manufactured overseas, granted a certificate of registration in Vietnam and granted an import license by a competent authority of the importing country.

2. The export of a medicinal ingredient drug shall only be licensed when one of the following requirements is satisfied:

a) The ingredient is manufactured in Vietnam and granted an import license by a competent authority of the importing country regardless of availability of the certificate of registration in Vietnam; or

b) The ingredient is manufactured overseas, granted a certificate of registration in Vietnam and granted an import license by a competent authority of the importing country.

3. Application for the export license:

a) 01 original copy of the purchase order according to Form No. 01 or Form No. 02 in Appendix III enclosed herewith;

b) A report on quantity and origins of drugs/medicinal ingredients according to Form No. 03 in Appendix III enclosed herewith;

c) An original copy of the unexpired license to import drugs/medicinal ingredients issued by a competent authority of the importing country. If the import license is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included. The import license shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law.

4. Only 01 set of documents specified in this Article is required.

Article 58. Requirements and application for the license to export radiopharmaceuticals, drugs or active ingredients on the list of drugs and active ingredients banned from certain fields, toxic drugs or toxic medicinal ingredients

1. The export of a drug or medicinal ingredient shall only be licensed when one of the following requirements is satisfied:

a) The drug or ingredient is manufactured in Vietnam, whether or not granted the certificate of drug registration in Vietnam; or

b) The drug or ingredient is manufactured overseas and has been granted a certificate of drug registration in Vietnam.

2. Application for the export license:

a) 03 original copy of the purchase order according to Form No. 04 or Form No. 05 in Appendix III enclosed herewith;

b) A report on the quantity and origins or drugs/medicinal ingredients to Form No. 03 in Appendix III enclosed herewith, except for toxic drugs, toxic medicinal ingredients and radiopharmaceuticals;

c) A copy (authenticated or bearing the exporter's seal) of the exporter's license to perform radiological works in case of export of radiopharmaceuticals. If a copy bearing the exporter's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 59. Requirements and application for the license to export herbal ingredients on the list of controlled herbs

1. The export of a herbal ingredient on the List of controlled rare and special herbs shall only be licensed if it is naturally obtained and is not on the list of herbs banned from export published by the Minister of Health. In case of export for non-commercial purposes, regulations of law on biodiversity shall apply.

2. Application for the export license:

a) 03 original copies of the purchase order according to Form No. 06 in Appendix III enclosed herewith;

b) A copy of the Certificate of eligibility for pharmacy business which is authenticated or bears the exporter's seal. If a copy bearing the exporter's seal is submitted, the original copy shall be produced for comparison when the application is submitted;

c) A copy of the confirmation of herb origin issued by the People's Committee of the commune which is authenticated or bears the exporter's seal. If a copy bearing the exporter's seal is submitted, the original copy shall be produced for comparison when the application is submitted;

d) A copy of the herbal ingredient purchase order which is authenticated or bears the exporter's seal. If a copy bearing the exporter's seal is submitted, the original copy shall be produced for comparison when the application is submitted;

dd) In case of export for non-commercial purposes, the documents specified in Points c and d of this Clause are not required.

3. Only 01 set of documents specified in this Article is required.

Article 60. Licensing non-commercial export of drugs subject to special control

1. The non-commercial export of a drug subject to special control shall be granted when the drug is licensed for sale in Vietnam and satisfy one of the following requirements:

a) The drug is personal property shipped under a lading bill or the outbound passenger's belongings for treatment of his/her own disease and is not an ingredient of drugs subject to special control;

b) The drug is exported as emergency aid or humanitarian aid;

c) The drug has been granted an import license to serve humanitarian medical services and is not completely used.

2. A license must be obtained before drugs are exported, except for those mentioned in Clause 1a of this Article if the quantity does not exceed:

a) 07 days' dose for narcotic drugs according to the prescription;

b) 10 days' dose for psychotropic drugs and precursors according to the prescription;

c) 30 days' dose for combined drugs that contain narcotic active ingredients or psychotropic active ingredients, toxic drugs, drugs on the list of banned substances in certain fields according to the prescription.

3. An application for export of the drug mentioned in Clause 1a of this Article consists of:

a) Form No. 07 in Appendix III enclosed herewith;

b) Copies of the prescription and outpatient's medical record which is authenticated or bears the applicant's signature (if the applicant is an individual) or seal (if the applicant is an organization). These documents shall specify the patient's name and age; name, concentration and quantity (or doses) of the drug; dosage; the physician's name and signature, address of the hospital or clinic where the physician practices.

If a copy bearing the applicant's signature of seal is submitted, the original copy shall be produced for comparison when the application is submitted;

c) A copy of the applicant's ID card or passport which is authenticated or bears the applicant's signature.

If a copy bearing the applicant's signature is submitted, the original copy shall be produced for comparison when the application is submitted;

d) If any of the documents mentioned in Points b and c of this Clause is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

4. An application for export of the drug mentioned in Clause 1b of this Article consists of:

a) The exporter's written request for issuance of the export license written in either Vietnamese or English language;

b) 03 original copies of the purchase order according to Form No. 01 or Form No. 04 in Appendix III enclosed herewith;

c) The original copy or certified true copy of the written approval for use of drugs for emergency aid or humanitarian aid issued by a competent authority of the importing country;

d) The unexpired license issued by a competent authority of the importing country for import of narcotic drugs, psychotropic drugs, drug precursors or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors;

dd) If any of the documents mentioned in Points c and d of this Clause is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall

be included. The documents shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law.

5. An application for export of the drug mentioned in Clause 1c of this Article consists of:

a) The exporter's written request for issuance of the export license written in either Vietnamese or English language;

b) 03 original copies of the purchase order according to Form No. 01 or Form No. 04 in Appendix III enclosed herewith;

c) A report on quantity of drugs used for humanitarian medical services according to Form No. 08 in Appendix III enclosed herewith.

6. Only 01 set of documents specified in Clause 3, 4, 5 of this Article is required.

Article 61. Requirements and application for export of drugs subject to special control for exhibition

1. The export of a narcotic drug, psychotropic drug, precursor, narcotic active ingredient, psychotropic active ingredient, drug precursor or combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors shall only be licensed when one of the following requirements is satisfied:

a) It is manufactured in Vietnam and granted an import license by a competent authority of the importing country regardless of availability of the certificate of drug registration in Vietnam;

b) It is manufactured overseas, granted a certificate of drug registration in Vietnam and granted an import license by a competent authority of the importing country.

2. An application for export of a narcotic drug, psychotropic drug, precursor, narcotic active ingredient, psychotropic active ingredient, drug precursor or combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors:

a) 01 original copy of the purchase order according to Form No. 01 or Form No. 02 in Appendix III enclosed herewith;

b) An original copy of the unexpired license to import drugs/medicinal ingredients issued by a competent authority of the importing country. If the import license is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included. The import license shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law;

c) Only 01 set of documents specified in this Clause is required.

3. The licensing of export of radiopharmaceuticals, toxic drugs, toxic medicinal ingredients, drugs and active ingredients on the list of substances banned from certain fields for exhibition shall comply with regulations of law on temporary import of goods.

Article 62. Requirements and application for export of drugs subject to special control for the purpose of clinical trial, bioequivalence study, bioavailability assessment, testing, scientific research or as specimens for registration

1. The export of a narcotic drug, psychotropic drug, precursor, narcotic active ingredient, psychotropic active ingredient, drug precursor or combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors shall only be licensed when one of the following requirements is satisfied:

a) It is manufactured in Vietnam and granted an import license by a competent authority of the importing country regardless of availability of the certificate of drug registration in Vietnam;

b) It is manufactured overseas, granted a certificate of drug registration in Vietnam and granted an import license by a competent authority of the importing country.

2. An application for export of a narcotic drug, psychotropic drug, precursor, narcotic active ingredient, psychotropic active ingredient, drug precursor or combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors:

a) 01 original copy of the purchase order according to Form No. 01 or Form No. 02 in Appendix III enclosed herewith;

b) An original copy of the unexpired license to import drugs/medicinal ingredients issued by a competent authority of the importing country. If the import license is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included. The import license shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law;

c) The original copy of the confirmation of the importer that the drug is used for the purpose of clinical trial, bioequivalence study, bioavailability assessment, testing, scientific research or as specimens for registration in the importing country and the quantity thereof. If this document is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included;

d) Only 01 set of documents specified in this Clause is required.

3. The export of a radiopharmaceutical, toxic drug, toxic medicinal ingredient, drug or active ingredient on the list of drugs and active ingredients banned from certain fields shall only be licensed when one of the following requirements is satisfied:

a) It is manufactured in Vietnam, whether or not granted the certificate of drug registration in Vietnam; or

b) It is manufactured overseas and has been granted a certificate of drug registration in Vietnam.

4. An application for export of a radiopharmaceutical, toxic drug, toxic medicinal ingredient, drug or active ingredient on the list of drugs and active ingredients banned from certain fields:

a) 01 original copy of the purchase order according to Form No. 04 or Form No. 05 in Appendix III enclosed herewith;

b) The original copy of the confirmation of the importer that the drug is used for the purpose of clinical trial, bioequivalence study, bioavailability assessment, testing, scientific research or as specimens for registration in the importing country and the quantity thereof. If this document is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

Article 63. Procedures and time limit for licensing export of drugs subject to special control, herbal ingredients on the list of controlled rare and special herbs

1. Procedures and time limit for licensing export of drugs subject to special control, herbal ingredients on the list of controlled rare and special herbs in the cases specified in Articles 57, 58, 59, Clause 1b and Clause 1c Article 60, Clause 1 Article 61 and Article 62 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the export license within 10 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 07 working days from the day on which the application is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the export license in accordance with Point c of this Clause;

e) Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

2. Procedures and time limit for issuing the export license in the case specified in Clause 1a Article 60 hereof:

a) The applicant shall submit an application, directly or by post, to Department of Health of the province where the exit checkpoint is located or where the patient is residing or where the applicant's headquarters are located;

b) After receiving the application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Department of Health shall issue the export license within 07 working days from the day on which the application is received;

d) If the application is not satisfactory, the Department of Health shall request the applicant in writing to complete the application within 05 working days from the day on which the application is received;

dd) After receiving the supplemented application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Department of Health shall request the applicant to complete it in accordance with Point d of this Clause. If the supplemented application is satisfactory, the Department of Health shall issue the export license in accordance with Point c of this Clause;

e) Within 03 months from the day on which additional documents are requested in writing by the Department of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 04 months from the first time it is submitted, the application will be rejected.

3. Within 20 days from the day on which the export license is issued, the Ministry of Health shall publish information about the permission for export of the herbal ingredients on the list of controlled rare and special herbs on its website.

4. The specimens of the export license and permission for export are provided in Form No. 09, 10, 11, 12, 13 in Appendix III enclosed herewith.

Article 64. Management of export and import of drugs and medicinal ingredients

1. Each shipment of narcotic drugs, psychotropic drugs, precursors, combined drugs that contain narcotic active ingredients, psychotropic active ingredients, precursors or medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors is subject to the issuance of an export license; the quantity of exported drugs/medicinal ingredients must not exceed the quantity written on the import license issued by the competent authority of the importing country.

2. Each export of herbal ingredients the list of controlled rare and special herbs is subject to issuance of an export license.

3. Narcotic drugs, psychotropic drugs, precursors, radiopharmaceuticals, combined drugs that contain narcotic active ingredients, psychotropic active ingredients, precursors or medicinal

ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors, herbal ingredients on the list of controlled rare and special herbs other than those specified in Clause 1a Article 60 hereof may only be exported through international checkpoint.

4. A manufacturer of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic substances or drug precursors may export the drugs or medicinal ingredients it manufactures.

5. An exporter or importer of narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic substances or drug precursors may export the drugs or medicinal ingredients it registered.

6. The applicant for permission for non-commercial export of drugs subject to special control specified in Clause 1a Article 60 hereof is responsible for their origin, quality, safety, efficacy and conformity with the importing country' regulations.

7. The exporter shall re-import all the narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors that were temporarily exported for exhibition.

8. Regarding drugs and medicinal ingredients the export of which is not subject to a license granted by the Ministry of Health according to Clause 5 Article 60 of the Law on Pharmacy:

a) The application shall contain 03 copies of the purchase order according to Form No. 14 in Appendix III and an a copy the exporter's Certificate of eligibility for pharmacy business which is authenticated or bear the exporter's seal;

b) Procedures for granting the export license are specified in Clause 1 Article 63 hereof.

Section 2. IMPORT OF DRUGS WITHOUT THE CERTIFICATE OF DRUG REGISTRATION IN VIETNAM

Article 65. Requirements and application for licensing import of drugs containing active ingredients without the certificate of drug registration of drugs or drugs containing herbal ingredients that are used in Vietnam for the first time

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

a) The drug is licensed in one of the following country: manufacturing country, reference country that is a member state of The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or Australia;

b) The drug is used for treatment for a fatal disease, sexually transmitted disease, or dangerous and new epidemic announced by the Minister of Health;

c) There are sufficient clinical data about the safety and efficacy of the drugs in accordance with regulations on drug registration promulgated by the Minister of Health. In case of a vaccine, it is required to submit the result of clinical in Vietnam in accordance with regulations on drug registration promulgated by the Minister of Health.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or a certified true copy of the certificate of pharmaceutical product;

c) A copy of the document about the quality standards and drug testing method of the manufacturer which bears the importer's seal;

d) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

dd) 02 sets of specimens of the label intended to be used in Vietnam and the package insert in Vietnamese language which bear the importer's seal;

e) Clinical data about the safety and efficacy of the drug in accordance with regulations on drug registration promulgated by the Minister of Health. In case of a vaccine, it is required to submit the result of clinical in Vietnam in accordance with regulations on drug registration promulgated by the Minister of Health;

g) A sale report (Form No. 18 in Appendix III enclosed herewith) if the imported drug is a narcotic drug, psychotropic drug, precursor, combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors or a drug on the list of banned substances in certain fields;

h) The original copy or certified true copy of the certificate of GMP of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility;

i) A certified true copy of a copy bearing the importer's seal of the license to perform radiological works in case of import of a radiopharmaceutical. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison.

3. Only 01 set of documents specified in this Article is required.

Article 66. Requirements and application for licensing import of drugs containing active ingredients that already have the certificate of drug registration in Vietnam but are not available in sufficient quantity and drugs containing herbal ingredients that have already been used in Vietnam but are not available in sufficient quantity

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

a) The drug is on the list of drugs not available in sufficient quantity published by the Minister of Health;

b) The drug is licensed in one of the following country: the manufacturing country, a reference country that is a member state of the ICH or Australia.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or a certified true copy of the certificate of pharmaceutical product;

c) Quality documents according to regulations of the Minister of Health on use of ASEAN Common Technical Dossier (ACTD) for drug registration;

d) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

dd) 02 sets of specimens of the labels intended to be used in Vietnam and the package insert in Vietnamese language which bear the importer's seal;

e) Clinical document if required by regulations of the Minister of Health on use of ACTD for drug registration;

g) Regarding a traditional drug that contain a herbal ingredient that has been used in Vietnam as a medicinal ingredient, it is required to have a clinical document proving its safety and efficacy according to Article 89 of the Law on Pharmacy and documents proving the traditional concoction or combination method;

h) A sale report (Form No. 18 in Appendix III enclosed herewith) if the imported drug is a narcotic drug, psychotropic drug, precursor, combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors or a drug on the list of banned substances in certain fields;

i) The original copy or certified true copy of the certificate of GMP of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility;

k) A copy (authenticated or bearing the importer's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 67. Requirements and application for licensing import of drugs to meet urgent need of national defense and security, epidemic control or disaster relief

1. The import of a drug shall only be licensed if it has been licensed in at least one other country and:

a) its import is requested by the Ministry of National Defense to meet urgent need of national defense;

b) its import is requested by the Ministry of Public Security to meet urgent need of security;

c) The drug is approved by the Ministry of Health as suitable for urgent epidemic control or disaster relief.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or certified true copy of the certificate of pharmaceutical product or a confirmation that the drug is licensed in at least one other country issued by the exporting country's competent authority;

c) The original copy or a copy bearing the issuer's seal of the written request or approval issued by any of the competent authorities specified in Clause 1a, 1b or 1c of this Article which specifies: the active ingredients of the modern drug or herbal ingredients of the herbal drug or traditional drug, dosage form, concentration of active ingredients of the modern drug or quantity of herbal ingredients of the herbal drug or traditional drug, package contents, manufacturer and manufacturing country.

3. Only 01 set of documents specified in this Article is required.

Article 68. Requirements and application for licensing import of drugs for special treatment

1. The import of such a drug shall only be licensed when one of the following requirements is satisfied:

a) Its efficacy is considerably superior to another drug sold in Vietnam or there is no other drug to replace it; the drug has been licensed in the manufacturing country or a reference country that is a member state of the ICH or Australia; there is sufficient clinical data about the safety and efficacy of the drug according to regulations on drug registration promulgated by the Minister of Health and the drug is recommend by the certification advisory council;

b) The drug is used for emergency treatment of poison control and does not have the same active ingredients and route of administration as other drugs licensed in Vietnam;

c) The Minister of Health shall decide licensing of vaccines in special cases with limited quantity according to data about its satisfactory quality, efficacy and safety.

2. An application for import of a drug mentioned in Clause 1a of this Article consists of:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) Clinical data about the safety and efficacy of the drug in accordance with regulations on drug registration promulgated by the Minister of Health. In case of a vaccine, it is required to submit the result of clinical in Vietnam in accordance with regulations on drug registration promulgated by the Minister of Health;

c) The original copy or a certified true copy of the certificate of pharmaceutical product;

d) A copy of the document about the quality standards and drug testing method of the manufacturer which bears the importer's seal;

dd) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

e) 02 sets of the specimens of the labels intended to be used in Vietnam and the package insert in Vietnamese language which bear the importer's seal;

g) A sale report (Form No. 18 in Appendix III enclosed herewith) if the imported drug is a narcotic drug, psychotropic drug, precursor, combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors or a drug on the list of banned substances in certain fields;

h) The original copy or certified true copy of the certificate of GMP of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility;

i) A copy (authenticated or bearing the importer's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. An application for import of a drug mentioned in Clause 1b or 1c of this Article consists of:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) Documents proving the quality, safety and efficacy of the vaccine;

c) The original copy of the document written by head of the health facility which contains the reason for import of the drug, the quantity of patients that need to use it and quantity of drug needed, commitment to take responsibility for the use of the drug. The document shall be enclosed with the minutes of meeting of the drug and treatment council regarding the need for drug import (original copy or copy bearing the seal of the health facility). If such a council does not exist, the minutes of meeting are not required;

d) The list of drugs to be imported according to Form No. 10, 20 or 21 in Appendix III enclosed herewith;

dd) A report on the quantity, efficacy (except vaccines) and safety of drugs used according to Form No. 22 in Appendix III enclosed herewith;

e) The original copy of the foreign exporter and manufacturer's commitment to quality, safety and efficacy of the vaccine or biological supplied to the Vietnamese importer according to Form No. 23 in Appendix III enclosed herewith;

g) A copy bearing the importer's seal of the authorization letter or the seller's license or certificate of partnership. The content of such document is specified in Clause 15dd Article 91 hereof.

If such document is not available, the importer shall submit written explanation to the Minister of Health.

4. Only 01 set of documents specified in Clause 2 and 3 of this Article is required.

Article 69. Requirements and application for licensing import of rare drugs

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

a) It is on the list of rare drugs;

b) It is licensed in at least one other country.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or a certified true copy of the certificate of pharmaceutical product;

c) A copy of the document about the quality standards and drug testing method of the manufacturer which bears the importer's seal;

d) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

dd) 02 sets of the specimens of the labels intended to be used in Vietnam and the package insert in Vietnamese language which bear the importer's seal;

e) A sale report (Form No. 18 in Appendix III enclosed herewith) if the imported drug is a narcotic drug, psychotropic drug, precursor, combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors or a drug on the list of banned substances in certain fields;

g) The original copy or certified true copy of the certificate of GMP of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility, unless the certificate of pharmaceutical product already certifies fulfillment of GMP requirements by all of the manufacturers;

h) A copy (authenticated or bearing the importer's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 70. Requirements and application for licensing drugs that have the same trade name, active ingredients, concentration and dosage form as those of a proprietary drug having the certificate of drug registration in Vietnam, are manufactured by the same manufacturer of the proprietary drug or by an authorized manufacturer and are sold at a lower price than that of the proprietary drug sold in Vietnam

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

a) Requirements in Clause 2dd Article 60 of the Law on Pharmacy are satisfied;

b) The intended wholesale price is lower by at least 20% than the successful bid for the proprietary drug having the certificate of registration in Vietnam;

c) The drug is licensed and exported to Vietnam from the manufacturing country, a reference country that is a member state of the ICH or Australia;

d) The drug is not a radiopharmaceutical, vaccine or biological.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The importer's commitment to drug quality and intended wholesale price;

c) Documents proving that the drug is licensed for free sale in the manufacturing country or a reference country;

d) 01 set of specimens of the label and package insert of the drug licensed for free sale in manufacturing country which bear the importer's seal;

dd) 02 sets of specimens of the secondary label and package insert in Vietnamese language which bear the importer's seal. The content of the package insert in Vietnamese language must be consistent with the content of the label of the proprietary drug approved by the Ministry of Health regarding.

3. Only 01 set of documents specified in this Article is required.

Article 71. Requirements and application for licensing import of drugs serving health programs of the State

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

a) The use of the drug for a health program of the State is approved by a competent authority;

b) The drug is licensed in one of the following country: the manufacturing country, a reference country that is a member state of the ICH or Australia.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or a certified true copy of the certificate of pharmaceutical product;

c) Quality documents according to regulations of the Minister of Health on use of ACTD for drug registration;

d) Clinical document if required by regulations of the Minister of Health on use of ACTD for drug registration;

dd) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

e) 02 sets of specimens of the labels intended to be used in Vietnam and the package insert in Vietnamese language which bear the importer's seal;

g) The original copy or certified true copy of the written approval issued by a competent authority for use of the drug for the health program of the State;

h) The original copy or certified true copy of the certificate of GMP of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility;

i) A copy (authenticated or bearing the importer's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 72. Requirements and application for licensing import of drugs as emergency aid or humanitarian aid

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

b) The drug is licensed in the manufacturing country, a reference country that is a member state of the ICH or Australia;

b) The drug meets the need of the aid recipient;

c) The drug is not a narcotic drug, radiopharmaceutical or vaccine.

2. Application for the import license:

a) A written request for permission to import prepared by the importer and enclosed with the list of drugs to be imported as emergency aid or humanitarian aid according to Form No. 24, 25 or 26 in Appendix III enclosed herewith;

b) The original copy of the aid recipient's document specifying the quantity of each type of drugs received as emergency aid or humanitarian aid and the commitment to use the drugs for intended purposes;

c) The original copy or certified true copy of the written approval issued by a competent authority for use of the drug for the health program of the State if the drug is provided through such a program;

d) The original copy or a certified true copy of the certificate of pharmaceutical product;

dd) Quality documents according to regulations of the Minister of Health on use of ACTD for drug registration;

e) Clinical document if required by regulations of the Minister of Health on use of ASEAN Common Technical Dossier (ACTD) for drug registration;

g) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

h) 02 sets of specimens of the secondary label and package insert in Vietnamese language which bear the importer's seal;

i) The original copy or certified true copy of the certificate of good practice of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility;

k) A copy (authenticated or bearing the exporter's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 73. Requirements and application for licensing import of drugs for the purpose of clinical trial, bioequivalence study, bioavailability assessment, testing or scientific research

1. The import of such a drug shall only be licensed when one of the following requirements is satisfied:

a) The drug is used for clinical trial under a research outline approved by the Minister of Health according to Clause 1 Article 94 of the Law on Pharmacy;

b) The drug is used for bioequivalence study or bioavailability assessment in Vietnam under an approved research outline according to Clause 1 Article 100 of the Law on Pharmacy;

c) The drug is used as a reference drug in bioequivalence study. If the reference drug is a new drug, it may only be used under an approved research outline according to Clause 1 Article 100 of the Law on Pharmacy;

d) The drug is used for testing by drug manufacturers or drug-testing laboratories;

dd) The drug is used for scientific research other than those mentioned in Points a, b and c of this Clause.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or certified true copy of the written approval issued by a competent authority or organization in the cases mentioned in Clause 1a, 1b and 1dd of this Article;

c) The original copy or certified true copy of the written approval for the bioequivalence study outline according to Article 100 of the Law on Pharmacy in case of a new drug mentioned in Clause 1c of this Article.

d) The importer's document bearing the importer's seal specifying the purposes and quantity of imported drugs and commitment to use the drugs for intended purposes;

dd) A copy (authenticated or bearing the importer's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 74. Requirements and application for import of drugs for exhibition

1. An application for licensing import of combined drugs that contain narcotic active ingredients, psychotropic substances or precursors for display a medical, pharmaceutical or medical equipment fair or exhibition consists of:

a) 01 original copy of the purchase order according to Form No. 16 in Appendix III enclosed herewith;

b) The importer's commitment to re-export the imported drugs after the exhibition is over.

2. Only 01 set of documents specified in Clause 1 of this Article is required.

3. The import of drugs other than those mentioned in Clause 1 of this Article shall only be licensed when all of the following requirements are satisfied:

a) The drug is used for display a medical, pharmaceutical or medical equipment fair or exhibition;

b) The drug is not a narcotic drug, psychotropic drug, precursor or radiopharmaceutical.

4. The import of the drugs mentioned in Clause 3 of this Article shall comply with regulations of law on temporary import and re-export of goods.

Article 75. Requirements and application for licensing non-commercial import of drugs according to Clause 2i Article 60 of the Law on Pharmacy

1. The non-commercial import of a drug shall only be licensed when one of the following requirements is satisfied:

a) The drug is personal belonging of an inbound person which is shipped under a lading bill, personal belonging of an inbound person for treatment of his/her own disease.

b) The drug is not a narcotic drug, psychotropic drug, precursor and is property of a diplomatic mission, consular office or representative office of an international organization in Vietnam or overseas diplomatic mission of Vietnam, its employees, organizations introduced by a diplomatic mission or overseas diplomatic mission of Vietnam.

2. The import of drugs mentioned in Clause 1 of this Article is subject to issuance of an import license, unless:

a) The quantity of drugs to be imported does not exceed 07 days' dose for narcotic drugs or 10 days' dose for psychotropic drugs and precursors according to the prescription;

b) The drug is not a narcotic drug, psychotropic drug or precursor, the total customs value of a shipment does not exceed USD 200 according to the inter-bank exchange rate on the customs clearance date and not more than 03 shipments are received by an organization or individual in a year.

If the drug is used for treatment of a disease on the list of fatal diseases in the Government's Decree No. 134/2016/ND-CP, the customs value of a shipment must not exceed VND 10,000,000 and not more than 04 shipments are received by an individual in a year.

3. Application for the import license:

a) Form No. 27 in Appendix III enclosed herewith;

b) The applicant's commitment to take responsibility for the origin and quality of the drug to be imported;

c) A certified true copy of a copy bearing the applicant's signature or seal of the prescription or outpatient medical record. These documents shall specify the patient's name and age; name, concentration and quantity (or doses) of the drug; dosage; the physician's name and signature, address of the hospital or clinic where the physician practices.

If a copy bearing the applicant's signature of seal is submitted, the original copy shall be produced for comparison when the application is submitted.

The documents specified in Clause 3c of this Article are not required in the case specified in Clause 1b hereof.

d) If the applicant is an individual, a copy of the applicant's ID or passport which is authenticated or bears the applicant's signature.

If a copy bearing the applicant's signature is submitted, the original copy shall be produced for comparison when the application is submitted.

4. Only 01 set of documents specified in this Article is required.

Article 76. Documents in the application drug import

1. In the cases of drug import specified in Article 65, 66, 69, 71, 72 and Clause 1a Article 68 hereof, a separate purchase order shall be made separately for each drug, unless all of the following elements of the drugs are the same:

a) Drug name;

b) Dosage form and route of administration;

c) Concentration/content of active ingredients of liquid and semi-solid drugs;

d) Quality standards;

dd) Expiration date;

e) Name and address of the manufacturer.

2. If any of the documents in the application is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

3. The following documents shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law:

a) The certificate of pharmaceutical product;

b) Documents proving that the drug is licensed for free sale in the manufacturing country or a reference country;

c) The Certificate of GMP;

d) Label and package insert of the drug licensed for free sale in country in which the certificate of pharmaceutical product is issued.

4. A certificate of pharmaceutical product shall satisfy the following requirements, except for drugs imported to meet urgent need of national defense and security, epidemic control or disaster relief specified in Article 67 hereof:

a) Requirements specified in Clause 2, 3 and 6 of this Article are satisfied;

b) The certificate bears the signer's signature, name and position and the issuer's seal;

c) The signer's signature, name and position and the issuer's seal are certified by a diplomatic missions, consular office or another organization authorized to perform consular tasks in the home country;

d) The certificate of pharmaceutical product undergoing consular legalization is the original copy;

dd) It is certified that the drug is licensed for free sale in country in which the certificate of pharmaceutical product is issued;

e) In the cases where the drug is manufactured by more than one facilities, the certificate must specify the name, address and roles of each facility;

g) The certificate complies with the specimen provided by World Health Organization (WHO) which is applied to the quality certification system or products licensed to be sold internationally.

5. The specimens of the label and package insert of a drug licensed for free sale in the country in which the certificate of pharmaceutical product is issued shall satisfy the following requirements, except for drugs that have the same trade name, active ingredients, concentration and dosage form as those of a proprietary drug having the certificate of drug registration in Vietnam, are manufactured by the same manufacturer of the proprietary drug or by an authorized manufacturer and are sold at a lower price than that of the proprietary drug sold in Vietnam specified in Article 70 hereof:

a) Requirements specified in Clause 3 of this Article are satisfied;

b) The specimens of the label and package insert bear seal of the issuer of the certificate of pharmaceutical product of its home country;

c) The specimens of the labels and package insert undergoing consular legalization are the original copies.

6. Legal documents in the application must be unexpired when the application is submitted.

Article 77. Procedures and deadline for licensing import of drugs without the certificate of drug registration in Vietnam

1. In the cases of drug import specified in Article 65, 66, 69, 71, 72 and Clause 1a Article 68 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the import license within 60 days if clinical documents and documents proving equivalence to reference biologicals are not required, or within 90 days if clinical documents and documents proving equivalence to reference biological are required. The import license shall be issued on the basis of counsel given by the certification advisory council;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 60 days if clinical documents and documents proving equivalence to reference biological are not required, or within 90 days if clinical documents and documents proving equivalence to reference biologicals are required;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Point c of this Clause;

e) Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, it will be rejected;

g) In the cases where drugs are imported for provision of humanitarian medical services approved by a competent authority and the documents mentioned in Point d, dd, e, g or i Clause 2 Article 72 hereof are not submitted but the drugs are essential for disease treatment, the Minister of Health shall consider the application on the basis of counsel given by the certification advisory council.

2. In the cases of drug import specified in Article 67 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the import license within 03 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 03 working days from the day on which the application is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Point c of this Clause;

e) If the applicant fails to provide the documents mentioned in Clause 2b Article 67 hereof but the drugs are essential for disease prevention and treatment, the Minister of Health shall consider the application on the basis of commitments made by relevant Ministries.

3. In the cases of drug import specified in Article 70, 73, Clause 1 Article 74, Clause 1b and Clause 1c Article 68 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the import license within 15 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 15 working days from the day on which it is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Point c of this Clause;

e) Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

4. In the cases of drug import specified in Article 75 hereof:

a) The application shall submit an application, directly or by post, to Department of Health of the province where the entry checkpoint is located or where the patient is residing or where the applicant’s headquarters are located;

b) After receiving the application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Department of Health shall issue the import license within 07 working days from the day on which the application is received;

d) If the application is not satisfactory, the Department of Health shall request the applicant in writing to complete it within 07 working days from the day on which it is received;

dd) After receiving the supplemented application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory,

the Department of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Department of Health shall issue the import license in accordance with Point c of this Clause;

e) Within 03 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 04 months from the first time it is submitted, the application will be rejected.

5. Within 10 working days from the day on which the license for drug import is issued according to Articles 65 through 69 hereof, the Ministry of Health shall publish information on its website in accordance with Clause 6 Article 60 of the Law on Pharmacy.

6. The Ministry of Health shall publish on its website information about drugs used for emergency treatment, poison control and vaccines used in certain cases with limited amounts that are licensed for import according to Clause 1b and Clause 1c Article 68 hereof, including information about the importer, manufacturer, quantity of the drug licensed for import, the drug name, dosage form, route of administration, concentration/content of active ingredients, import license number and date of issuance, and health facilities and vaccination centers in need of the drug.

7. The specimens of the import license and permission for import are provided in Form No. 28, 29, 30, 31, 32 in Appendix III enclosed herewith.

Article 78. Management of import of drugs without the certificate of drug registration in Vietnam

1. The drug that contains an active ingredient that is not granted the certificate of drug registration or a herbal ingredient that is used in Vietnam for the first time or a drug licensed for import according to Article 65 and Article 69 hereof may only be supplied for health facilities.

2. In consideration of the request of the health facility and counsel given by the certification advisory council, the Minister of Health shall decide whether the requirements specified in Clause 1a Article 68 of this Decree are satisfied.

3. Regarding drugs for emergency treatment, poison control and vaccines used in certain cases with limited amounts that are licensed for import according to Clause 1b and Clause 1c Article 68 hereof:

a) These drugs may only be supplied for health facilities and vaccination centers that wish to import them. The health facility or vaccination center shall inform the users, patients or their relatives of information about the drugs licensed for import without adequate legal and technical documents. The drug may only be used with the consent of the user, patient or patient’s relative.

b) The importer, health facility or vaccination center mentioned in Point a of this Clause may sell these drugs to other health facilities and vaccination centers. The buyer shall have adequate

documents specified in Clause 3c and Clause 3d Article 68 hereof and take the responsibility specified in Point a of this Clause.

4. Before being launch, a batch of drug that has the same trade name, active ingredients, concentration/content and dosage form as those of a proprietary drug having the certificate of drug registration in Vietnam, is manufactured by the same manufacturer of the proprietary drug or by an authorized manufacturer and is sold at a lower price than that of the proprietary drug sold in Vietnam specified in Article 70 hereof shall undergo quality inspection by an authority specialized in testing drugs and medicinal ingredients according to quality standards applied to proprietary drugs having the certificate of registration in Vietnam.

5. Drugs licensed for import to serve health programs of the State, clinical trial, research or testing shall be used for intended purposes.

6. Drugs subject to special control that are licensed for import to serve provision of humanitarian medical services and are not completely used shall be re-exported in accordance with Clause 5 Article 60 hereof and must not be used for any other purpose.

7. Drugs licensed for import to be displayed at a medical, pharmaceutical or medical device fair according to Article 74 hereof shall be completely re-exported after the fair is ended and must not be used or sold in Vietnam.

8. The applicant for permission for non-commercial import of drugs according to Article 75 hereof is responsible for their origin and quality.

Section 3. IMPORT OF DRUGS SUBJECT TO SPECIAL CONTROL HAVING THE CERTIFICATE OF DRUG REGISTRATION IN VIETNAM AND MEDICINAL INGREDIENTS SUBJECT TO SPECIAL CONTROL

Article 79. Composition of the application for licensing import of drugs subject to special control having the certificate of drug registration in Vietnam

An application for the license to import narcotic drugs, psychotropic drugs, precursors, combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors or drugs on the list of banned substances in certain fields having an unexpired certificate of drug registration in Vietnam consists of:

1. 01 original copy of the purchase order according to Form No. 33 or 34 in Appendix III enclosed herewith.

2. A report on sale of the drug according to Form No. 18 in Appendix III enclosed herewith, except for toxic drugs.

3. A copy (authenticated or bearing the importer’s seal) of the importer’s license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer’s

seal is submitted, the original copy shall be produced for comparison when the application is submitted.

4. Only 01 set of documents specified in this Article is required.

Article 80. Composition of the applications for licensing import of medicinal ingredients subject to special control

1. An application for the license to import medicinal ingredients subject to special control consists of:

a) 01 original copy of the purchase order according to Form No. 35 or 36 in Appendix III enclosed herewith;

b) A copy of the document about the quality standards and medicinal ingredient testing method of the manufacturer which bears the importer's seal;

c) A certified true copy of the manufacturing license issued by a competent authority of the exporting country. The manufacturing license shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law;

d) A report on use of medicinal ingredients other than toxic medicinal ingredients according to Form No. 37 in Appendix II enclosed herewith and the report on sale of medicinal ingredients other than toxic medicinal ingredients according to Form No. 38 in Appendix III enclosed herewith;

dd) The plan for production of use of the ingredients and plan for sale of products derived from such ingredients, except toxic ingredients;

e) If ingredients are imported for testing or research, the ingredients are already granted the certificate of registration in Vietnam or the ingredients on the list of active ingredients, excipients or semi-finished drugs used for production of drugs that are already granted the certificate of drug registration in Vietnam, the documents specified in Points b and c of this Clause are not required;

g) If the medicinal ingredients have to be imported for testing or research, the original copy of the importer's document specifying the purposes and quantity of ingredients to be imported and the commitment to use them for intended purposes;

h) In the cases where a medicinal ingredient subject to special control that does not have the certificate of registration in Vietnam or not on the list of active ingredients, excipients or semi-finished drugs used for production of drugs that are already granted the certificate of drug registration in Vietnam is imported to concoct prescription drugs by pharmacies or health facilities serving epidemic control, the concocting facility's written request according to Form No. 39 in Appendix III enclosed herewith.

2. If any of the documents mentioned in Clause 1b and 1c of this Article is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

3. Only 01 set of documents specified in Clause 1 and 2 of this Article is required.

4. Import of medicinal ingredients that are narcotic active ingredients, psychotropic substances or drug precursors for exhibition shall not be licensed.

5. Procedures for import of toxic medicinal ingredients and active ingredients on the list of substances banned from certain fields for exhibition are specified in Article 83 hereof.

Article 81. Procedures and deadlines for licensing import of drugs subject to special control having an unexpired certificate of drug registration in Vietnam and medicinal ingredients subject to special control

1. The applicant shall submit an application to the Ministry of Health directly or by post.

2. After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the Ministry of Health shall issue the import license within 15 working days from the day on which the application is received.

4. If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 15 working days from the day on which it is received.

5. After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the supplemented application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Clause 4 of this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

7. The specimens of the import license and permission for import are provided in Form No. 28, 29, 30, 40, 44 in Appendix III enclosed herewith.

Section 4. IMPORT OF MEDICINAL INGREDIENTS WITHOUT THE CERTIFICATE OF REGISTRATION IN VIETNAM OTHER THAN MEDICINAL INGREDIENTS SUBJECT TO SPECIAL CONTROL; IMPORT OF REFERENCE MATERIALS AND PRIMARY PACKAGES OF DRUGS

Article 82. Requirements and application for licensing import of active ingredients, herbal ingredients, semi-finished drugs and semi-finished herbal ingredients as samples for testing or research

1. Import of an active ingredient, herbal ingredient, semi-finished drug or semi-finished product used for production of herbal drugs in the form of glue, powder, extract, essential oil, resin, gum, gel or agar (hereinafter referred to as "semi-finished herbal ingredient") without a certificate of registration in Vietnam shall be licensed if:

a) it is used for testing or research by a drug manufacturer or a facility specialized in testing or researching drugs or medicinal ingredients; or

b) it is used for a scientific research approved by a competent authority.

2. The application for import consists of:

a) 03 original copy of the purchase order according to Form No. 36 or 41 in Appendix III enclosed herewith;

b) The importer's document specifying the purposes and quantity of ingredients to be imported and the commitment to use them for intended purposes;

c) The original copy or certified true copy of the written approval issued by a competent authority in the cases mentioned in Clause 1b of this Article.

3. Only 01 set of documents specified in this Article is required.

Article 83. Import of active ingredients, semi-finished drug, herbal ingredients and semi-finished herbal ingredients for exhibition

1. Medicinal ingredients may only be imported for display a medical, pharmaceutical or medical equipment fair or exhibition.

2. The import of medicinal ingredients for exhibition shall comply with regulations of law on temporary import of goods.

3. The medicinal ingredients that are licensed for import in accordance with this Article must be completely re-exported after the exhibition or fair is ended and must not be sold in Vietnam.

Article 84. Composition of the application for licensing import of active ingredients, herbal ingredients, semi-finished drugs and semi-finished herbal ingredients for manufacture of drugs for export

1. The application for import consists of:

a) 03 original copy of the purchase order according to Form No. 36 or 41 in Appendix III enclosed herewith;

b) A copy of the document about the quality standards and medicinal ingredient testing method of the manufacturer which bears the importer's seal. If this document is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included;

c) A commitment to use the medicinal ingredients for intended purposes and export drugs derived from such ingredients.

2. Only 01 set of documents specified in this Article is required.

Article 85. Requirements and application for licensing import of active ingredients, semi-finished drug, herbal ingredients and semi-finished herbal ingredients to produce drugs serving national defense and security, epidemic control or disaster relief

1. The import of a medicinal ingredient drug shall only be licensed if it is imported to manufacture:

a) drugs serving national defense;

b) drugs serving security protection; or

c) drugs serving epidemic control or disaster relief, including drugs concocted according to prescriptions by pharmacies or health facilities. The import of herbal ingredients for concoction of drugs according to prescriptions by pharmacies and health facilities shall comply with Article 87 hereof.

2. The application for import consists of:

a) 03 original copy of the purchase order according to Form No. 36 or 41 in Appendix III enclosed herewith;

b) If the ingredient is imported for production of drugs serving national defense and security, the original copy of the written request of the Ministry of National Defense or the Ministry of Public Security which specifies the drug name, the manufacturer's name, active ingredients and concentration/content thereof, dosage form, package contents, route of administration and indications;

c) If the ingredient is imported for production of drugs serving epidemic control or disaster relief, a written approval for the list of drugs issued by the Ministry of Health which specifies the drug name, the manufacturer's name, active ingredients and concentration/content thereof, dosage form, package contents, route of administration and indications;

d) If the ingredient is importer for production or concoction of drugs according to prescriptions at pharmacies or health facilities, the written request of the manufacturing facility or concocting facility according to Form No. 42 in Appendix III enclosed herewith;

dd) The commitment to use the ingredient for intended purposes by the importer and the facility using the ingredient.

e) A copy of the document about the quality standards and medicinal ingredient testing method of the manufacturer which bears the importer's seal;

g) A certified true copy of the manufacturing license issued by a competent authority of the exporting country. The manufacturing license shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law;

h) If any of the documents mentioned in Points e and g of this Clause is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

3. Only 01 set of documents specified in this Article is required.

Article 86. Composition of the application for licensing import of excipients, softgel shells, primary packages of drugs or reference materials

1. An application for the import license consists of:

a) 03 original copy of the purchase order according to Form No. 43 in Appendix III enclosed herewith;

b) A copy of the document about the quality standards and method for testing excipients, softgel shells or primary packages of drugs of the manufacturer which bears the importer's seal. If this document is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

2. Only 01 set of documents specified in this Article is required.

Article 87. Composition of the application for licensing import of herbal ingredients other than those specified in Articles 82 through 85 hereof

1. An application for the import license consists of:

a) 03 original copy of the purchase order according to Form No. 41 in Appendix III enclosed herewith;

b) Documents proving that quality standards of the herbal ingredient are conformable with the National Technical Regulation on herbal ingredients according to Vietnam's pharmacopoeia or a foreign pharmacopoeia recognized by the Ministry of Health.

If the National Technical Regulation on the herbal ingredient is not available in Vietnam's pharmacopoeia or a foreign pharmacopoeia recognized by the Ministry of Health, the applicant shall provide quality standards including the testing method which has been evaluated by a state-owned testing laboratory;

c) Certified true copy of the certificate of registration of the representative office in Vietnam of the foreign exporter or the license for pharmacy business of the state-owned enterprise in Vietnam which is licensed to trade in herbal ingredients, prepared and processed herbal ingredients;

d) Certified true copy of the exporter's business license which allows export of herbal ingredients and is issued by a competent authority of the exporter's home country;

dd) Certified true copy of the manufacturer's certificate of GMP which allows production of herbal ingredients and is issued by a competent authority of the manufacturer's home country;

e) A copy bearing the importer's seal of the manufacturer's document authorizing the foreign exporter to export herbal ingredients, unless the manufacturer is also the exporter. The content of such document is specified in Clause 15dd Article 91 hereof.

2. Only 01 set of documents specified in this Article is required.

Article 88. Procedures and deadlines for licensing import of medicinal ingredients without the certificate of registration in Vietnam other than medicinal ingredients subject to special control; import of reference materials and primary packages of drugs

1. Procedures and deadlines for licensing import of medicinal ingredients, primary packages of drugs and reference materials specified in Articles 82, 84, 86 and 87 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the import license within 15 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 15 working days from the day on which it is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the

Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Point c of this Clause;

e) Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

2. In the cases of import of medicinal ingredients specified in Article 85 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the import license within 03 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 03 working days from the day on which it is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Point c of this Clause.

3. The specimens of the import license and permission to import medicinal ingredients are provided in Form No. 44 or Form No. 45 in Appendix III enclosed herewith.

Section 5. EXPORT AND IMPORT OF DRUGS AND MEDICINAL INGREDIENTS

Article 89. Effective periods of the license to export drugs/medicinal ingredients and the license to import drugs/medicinal ingredients

1. Effective periods of licenses to export drugs/medicinal ingredients:

a) A license to export drugs/medicinal ingredients issued according to Articles 57, 59, 60, 62 and Clause 1 Article 61 hereof is effective for up to 01 year;

b) A license to export drugs/medicinal ingredients issued according to Articles 58 and Clause 8 Article 64 hereof is effective for up to 02 years;

2. Effective periods of licenses and written permissions to import drugs/medicinal ingredients:

a) A license or written permission to import drugs is effective for up to 01 year;

b) A license to import narcotic drugs, psychotropic drugs, precursors, medicinal ingredients that are narcotic active ingredients, psychotropic substances or drug precursors is effective for up to 01 year and expires after the import is completed;

c) A license or written permission to import medicinal ingredients other than those mentioned in Point b of this Clause is effective for up to 02 years.

3. The effective period of a license or permission must be specified therein

Article 90. Remaining shelf life of imported drugs/medicinal ingredients when customs clearance is granted

1. Minimum remaining shelf life of imported modern drugs, herbal drugs, traditional drugs, medicinal ingredients other than those specified in Clause 3 of this Article when customs clearance is granted:

a) 18 month if the official shelf life is longer than 24 months;

b) 1/2 of the official shelf life if it does not 24 months.

2. The minimum remaining shelf life of imported vaccines and biologicals other than those specified in Clause 3 of this Article when customs clearance is granted is 1/2 of the official shelf life.

3. Imported drugs/medicinal ingredients specified in Articles 67, 73, 74, 75, 82, 83, 84, 85, 86 and Clause 1b Article 68 hereof must be unexpired when customs clearance is granted.

4. The Minister of Health shall consider permitting import of drugs/medicinal ingredients whose remaining shelf life is shorter than those specified in Clause 1 or Clause 2 of this Article but they are essential for prevention and treatment of diseases.

5. An application for the permission to import a drug/medicinal ingredient mentioned in Clause 4 of this Article consists of:

a) The importer’s written request which specifies: name of the drug/medicinal ingredient, remaining shelf life when customs clearance is granted and explanation as to why its remaining shelf life is shorter than those specified in Clause 1 or Clause 2 of this Article;

b) Documents proving that the remaining shelf life of the batch of drug/medicinal ingredient when customs clearance is granted is shorter than those specified in Clause 1 or Clause 2 of this Article.

6. Procedures for granting permission to import a drug/medicinal ingredient mentioned in Clause 4 of this Article:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the written permission to import within 15 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 15 working days from the day on which it is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the written permission to import in accordance with Point c of this Clause;

e) Within 03 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 04 months from the first time it is submitted, the application will be rejected.

Article 91. Import of drugs and medicinal ingredients

1. The list of medicinal ingredients that are active ingredients excipients, semi-finished drug other than semi-finished herbal ingredients for production of drugs under an application for registration of drugs having the certificate of drug registration in Vietnam shall be specified by the Minister of Health according to Form No. 46 in Appendix III enclosed herewith within 15 days from the day on which the certificate of drug registration in Vietnam is granted or renewed. Medicinal ingredients that are active ingredients, excipients or semi-finished drug on the list published by the Ministry of Health may be imported without a license, except ingredients of drugs subject to special control.

2. The list of drugs and medicinal ingredients banned from import and production is provided in Appendix V hereof.

3. Medicinal ingredients that have the certificate of registration in Vietnam, including herbal ingredients, semi-finished herbal ingredients, excipients, softgel shells and semi-finished drug other than semi-finished drugs subject to special control may be imported without license.

4. Institutions providing medical or pharmaceutical training, drug testing laboratories and drug research institutions may import drugs, medicinal ingredients and reference materials to serve their operation.

5. Representative offices in Vietnam of manufacturers, holders of the certificate of free sale of drugs undergoing clinical trial, bioavailability study or bioequivalence study; providers of

clinical trial, bioavailability study or bioequivalence study services may import medicinal ingredients and reference materials to serve their operation.

6. Traders may import primary packages of drugs.

7. Drugs and medicinal ingredients may only be imported through international checkpoints, except for non-commercial import of drugs specified in Article 75 hereof.

8. The Minister of Health shall decide the quantity of drugs/medicinal ingredients licensed for import as follows:

a) The licensed import quantity of drugs that contains an active ingredient that is not granted the certificate of drug registration or a herbal ingredient that is used in Vietnam for the first time specified in Article 65 hereof depends on the developments of the fatal disease, sexually transmitted disease or dangerous and new epidemic;

b) The licensed import quantity of drugs containing active ingredients that already have the certificate of drug registration in Vietnam but are not available in sufficient quantity, drugs containing herbal ingredients that have already been used in Vietnam but are not available in sufficient quantity and drugs for special treatment specified in Article 66 and Article 68 hereof depend on the need of the health facility;

c) The licensed import quantity of drugs serving urgent need for national defense and security, epidemic control or disaster relief specified in Article 67 hereof depends on their purposes;

d) The licensed import quantity of rare drugs specified in Article 69 hereof depends on the importer's business plan;

dd) The licensed import quantity of drugs that have the same trade name, active ingredients, concentration and dosage form as those of a proprietary drug having the certificate of drug registration in Vietnam, are manufactured by the same manufacturer of the proprietary drug or by an authorized manufacturer and are sold at a lower price than that of the proprietary drug sold in Vietnam as specified in Article 70 hereof depends on the possibility of achieving the price stabilization target;

e) The licensed import quantity of drugs serving a health program of the State specified in Article 71 hereof depends on the need for drugs of such program;

g) The licensed import quantity of drugs as emergency aid or humanitarian aid specified in Article 72 hereof depends on the recipient's need;

h) The licensed import quantity of drugs imported for the purpose of clinical trial, bioequivalence study, bioavailability assessment, testing or scientific research specified in Article 73 hereof depends on the approved research outline of the laboratory's need;

i) The licensed quantity of drugs imported for non-commercial purposes specified in Article 75 hereof depends on the owner's need for disease treatment;

k) The licensed import quantity of drugs subject to special control specified in Articles 79 and 80 hereof depends on the importer's business plan;

The licensed import quantity of reference materials, primary packages of drugs, medicinal ingredients without the certificate of registration in Vietnam specified in Articles 82, 84, 85, 86 and 87 hereof depends on the importer's need, except drugs subject to special control.

9. Imported medicinal ingredients and reference materials specified in the Law on Pharmacy and this Decree are exempt from procedures for declaration of chemicals.

10. The entities that are entitled to import but not entitled to distribute drugs and medicinal ingredients in Vietnam must do activities related to distribution of drugs and medicinal ingredients in Vietnam except for drugs and medicinal ingredients they manufacture in Vietnam, including:

a) Selling drugs and medicinal ingredients, delivery drugs and medicinal ingredients to health facilities, retailers, individuals and organizations other than wholesalers of drugs and medicinal ingredients;

b) Receiving orders or payments for drugs and medicinal ingredients from health facilities, retailers, individuals and organizations other than wholesalers of drugs and medicinal ingredients;

c) Providing drug/medicinal ingredient transport or storage services;

d) Impose prices for drugs or medicinal ingredients distributed by other pharmaceutical-trading establishment;

dd) Deciding the strategy or policy on selling drugs/medicinal ingredients distributed by other pharmaceutical-trading establishment;

e) Developing the plan for supply of drugs and medicinal ingredients of health facilities in Vietnam;

g) Provide financial assistance for buyers of drugs/medicinal ingredients to control the distribution of imported drugs and medicinal ingredients;

h) Other activities related to drug distribution defined by law.

11. Wholesalers of drugs and medicinal ingredients imported by importers that are not entitled to distribute drugs and medicinal ingredients in Vietnam must be capable of distributing drugs and medicinal ingredients to health facilities and drug-trading establishments without being

controlled by entities that are not entitled to distributed drugs and medicinal ingredients in the manners mentioned in Clause 10 of this Article.

12. The importer that is not entitled to distribute drugs and medicinal ingredients in Vietnam shall notify the Ministry of Health in writing before it starts to sell or stops selling drugs to a wholesaler that distributes the drugs or medicinal ingredients it imported.

Within 03 days from the day on which the importer's notification is received, the Ministry of Health shall publish information about the wholesaler on its website.

13. The import of herbal ingredients that are specimens of a species on the list of endangered species for testing or pharmaceutical research shall comply with regulations of law on biodiversity.

14. Testing certificate of the batch of imported drugs/medicinal ingredients:

a) The testing certificate shall be written in Vietnamese or English language. If it is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included;

b) If a batch is manufactured by more than one facilities, it is required to have the testing certificate of the final manufacturing or releasing facility;

c) The testing certificate shall contain: name and address of the manufacturing facility, testing certificate number, name and signature of the responsible for person, date of issue of the testing certificate, product name, batch number, shelf life, applied quality standards and requirements, testing results, conclusion.

15. To be allowed to sign a contract with an importer, the foreign supplier of drugs/medicinal ingredients has to be either:

a) A manufacturer of the drug or active ingredients.

b) The owner of the product or holder of the certificate of free sale of the drug or active ingredient written on the certificate of pharmaceutical product, whether or not the drug is granted the certificate of registration in accordance with the Law on Pharmacy;

c) The applicant for registration of the drug or medicinal ingredient having the certificate of drug registration in Vietnam which is unexpired when customs clearance is granted other than the entities mentioned in Point a and Point b of this Clause;

d) An establishment granted the license to do trade in drugs, medicinal ingredients, vaccines, biologicals or ingredients thereof in Vietnam;

dd) In the cases in Point c or Point d of this Clause, it is required to be authorized in writing by the entity mentioned in Point a or Point b of this Clause to supply drugs in Vietnam.

The authorization document may be an authorization letter, seller's license or certificate of partnership. The authorization document shall be written in Vietnamese or English and contain: name and address of the authorizing party and authorized party; scope of supply of drugs/medicinal ingredients in Vietnam; authorization period; responsibilities of the parties for quality and origins of drugs/medicinal ingredients supplied in Vietnam; signatures of the parties;

e) Regulations of this Clause do not apply to suppliers of imported drugs specified in Article 67, 73 and Clause 1 Article 74 hereof.

g) Regulations of Point dd of this Clause do not apply to suppliers of imported drugs specified in Article 70 hereof.

16. g) Regulations of Clause 15 of this Article do not apply to suppliers of imported excipients, softgel shells, primary packages of drugs and reference materials.

17. The license to import drugs shall be revoked in the following cases:

a) The imported drug is recalled because of a first-degree violations according to Clause 2a Article 63 of the Law on Pharmacy;

b) The certificate of registration of the imported drug is revoked by the competent authority of the manufacturing country, member state of the ICH or Australia;

c) A competent authority concludes that fraudulent documents are used in the application for licensing drug import;

d) The location where the imported drug is manufactured is not consistent with the address on the application for licensing drug import;

dd) The drug contains an imported active ingredient or herbal ingredient that is not recommended by WHO, a competent authority of Vietnam or the country of origin;

e) The manufacturer or importer requests revocation of the license;

g) A pharmacy authority of the exporting country issues a request for recall of the imported batch.

18. The license to import medicinal ingredients shall be revoked in the following cases:

a) The medicinal ingredient is recalled according to Clause 2a, 2b, 2d, 2dd or 2e Article 62 of the Law on Pharmacy;

b) The imported active ingredient or herbal ingredient is not recommended by WHO, a competent authority of Vietnam or the country of origin of the active ingredient or herbal ingredient;

19. An importer of drugs/medicinal ingredients must not submit the application for the license to import drugs for 01 – 02 years if

a) Any of the violations mentioned in Clause 17a, 17c and 17d of this Article is committed;

b) Within 12 months, 02 or more batches of the imported drug are recalled because of second-degree violations specified in Clause 2b Article 63 of the Law on Pharmacy or 03 or more batches of the imported drug fails to meet quality standards;

c) Information in the application for the import license is not based on research findings or the manufacturer's capacity;

d) Information about the efficacy and safety of the imported drug is not updated on its label or package insert as requested by the Ministry of Health.

20. The entire batch of drug or medicinal ingredient shall be suspended from import if its manufacturer:

a) commits a serious violations against GMP requirements as prescribed by the Minister of Health;

b) produces 02 or more batches that constitute first-degree violations specified in Clause 2a Article 63 of the Law on Pharmacy within 12 months;

c) produces 03 or more batches that constitute second-degree violations specified in Clause 2b Article 63 of the Law on Pharmacy within 12 months or produces 04 or more batches that fail to meet quality standards;

d) The duration of suspension shall be 01 – 02 years for the violations mentioned in Points a and b of this Clause; 06 – 12 months for the violations mentioned in Point c of this Clause.

21. Reporting export and import of drugs/medicinal ingredients other than drugs subject to special control:

a) Within 10 days from the date of import of a vaccine that is already granted the certificate of registration in Vietnam or a drug that is not granted a certificate of drug registration in Vietnam, the importer shall submit a report on each shipment to the Ministry of Health and National Institute for Control of Vaccines and Biologicals (for vaccines) according to Form No. 47 or Form No. 48 in Appendix III enclosed herewith.

b) By the 15th of July and 15th of January, the importer shall prepare biannual and annual reports on import of drugs and medicinal ingredients according to Form No. 49 or Form No. 50 in Appendix II enclosed herewith and send them to the Ministry of Health.

Article 92. Documents to be produced and submitted upon customs clearance of drugs and medicinal ingredients

Apart from the documents to be submitted according to regulations of law on customs, the following documents shall be produced and submitted upon customs clearance of drugs and medicinal ingredients:

1. Regarding export drugs and medicinal ingredients:

a) A copy of the Certificate of eligibility for pharmacy business which bears the exporter's seal if the exporter is a pharmacy business establishment (the original copy or certified true copy shall be produced for comparison);

b) A copy of the export license of export of herbal ingredients on the list of controlled rare and special herbs or drugs subject to special control except for those in Point c of this Clause;

c) Copies of the prescription and outpatient's medical record which is authenticated or bears the applicant's signature (if the applicant is an individual) or seal (if the applicant is an organization) if the drug is personal property shipped under a lading bill or an outbound passenger's belongings for his/her treatment and the quantity does not exceed 07 days' dose if the drug is narcotic; 10 days if the drug is psychotropic, 30 days if the drug is a combined drug that contains a narcotic active ingredient, psychotropic active ingredient or precursor, toxic drug or a drug on the list of substances banned from certain fields.

2. Regarding import of drugs/medicinal ingredients having the certificate of registration in Vietnam, medicinal ingredients on the list of active ingredients, excipients or medicinal semi-finished products used for drug production having the certificate of drug registration in Vietnam, except for herbal ingredients:

a) A copy of the Certificate of eligibility for pharmacy business which bears the importer's seal if the importer is a pharmacy business establishment (the original copy or certified true copy shall be produced for comparison;

b) A copy of the import license bearing the importer's seal in case of import of drugs subject to special control;

c) The original copy or a copy bearing the importer's seal of the testing certificate of each batch of imported drug or medicinal ingredient (the original copy must be produced for comparison if a copy is submitted;

d) A copy bearing the importer's seal of the authorization letter or the seller's license or certificate of partnership according to Clause 15dd Article 91 hereof, except for import of excipients or softgel shells;

dd) In case of import of a drug or medicinal ingredient specified in Clause 1dd Article 59 hereof, the importer shall produce the bill of lading proving that the shipment is sent from the exporting country's port before the expiration date of the certificate of registration.

3. Regarding import of herbal ingredients and semi-finished herbal ingredients, regardless of availability of the certificate of registration in Vietnam:

a) A copy bearing the importer's seal of the Certificate of eligibility for pharmacy business if the importer is a pharmacy business establishment (the original copy or certified true copy shall be produced for comparison);

b) Regarding herbal ingredients and semi-finished herbal ingredients having the certificate of registration in Vietnam, a copy of the certificate of registration bearing the importer's seal (the original copy or certified true copy shall be produced for comparison);

c) Regarding herbal ingredients and semi-finished herbal ingredients without the certificate of registration in Vietnam, a copy bearing the importer's seal of the license to import herbal ingredients (the original copy or certified true copy shall be produced for comparison);

d) A copy bearing the importer's seal of the manufacturer's document authorizing the foreign exporter to export herbal ingredients, unless the manufacturer is also the exporter. The content of such document is specified in Clause 15dd Article 91 hereof.

dd) The original copy or a copy bearing the importer's seal of the testing certificate of each batch of the imported herbal ingredient or semi-finished herbal ingredients (the original copy must be produced for comparison if a copy is submitted);

e) In case of import of a herbal ingredient or semi-finished herbal ingredient mentioned in Clause 1dd Article 59 of the Law on Pharmacy, the bill of lading proving that the shipment is sent from the exporting country's port before the expiration date of the certificate of registration;

g) In case of import of herbal ingredients and semi-finished herbal ingredients specified in Article 82 and Article 83 hereof, the documents specified in Points b, d, dd and e of this Clause are not required.

4. Grant of customs clearance to imported drugs and medicinal ingredients without the certificate of registration in Vietnam other than herbal ingredients:

a) A copy of the Certificate of eligibility for pharmacy business which bears the importer's seal if the importer is a pharmacy business establishment (the original copy or certified true copy shall be produced for comparison);

b) A copy of the import license bearing the importer's seal (the original copy or a certified true copy shall be produced for comparison);

c) The original copy or a copy bearing the importer's seal of the testing certificate of each batch of imported drug or medicinal ingredient in case of import of any of the drugs and medicinal ingredients specified in Articles 65, 66, 69, 71, 72, 79, 80, 84, 85, 86 and Clause 1a and Clause 1c Article 68 hereof (the original copy must be produced for comparison if a copy is submitted);

d) Copies of the prescription and outpatient's medical record which is authenticated or bears the applicant’s signature (if the applicant is an individual) or seal (if the applicant is an organization) in any of the following cases:

The quantity of drugs to be imported does not exceed 07 days’ dose for narcotic drugs or 10 days’ dose for psychotropic drugs and precursors according to the prescription;

The drug is not a narcotic drug, psychotropic drug or precursor, the total customs value of a shipment does not exceed USD 200 according to the inter-bank exchange rate on the customs clearance date and not more than 03 shipments are received by an organization or individual in a year. If the drug is used for treatment of a disease on the list of fatal diseases in the Government's Decree No. 134/2016/ND-CP, the customs value of a shipment must not exceed VND 10,000,000 and not more than 04 shipments are received by an individual in a year.

The original copies the prescription and outpatient's medical record shall be produced upon customs clearance for comparison with the copies submitted.

dd) A copy bearing the importer’s seal of the authorization letter or the seller’s license or certificate of partnership according to Clause 15dd Article 91 hereof, except for import of drugs specified in Articles 67, 70, 73 and Clause 1 of Article 74 hereof, primary packages of drugs, reference materials, medicinal ingredients granted the import license according to Articles 82, 83, 86 hereof and medicinal ingredients subject to special control that are imported for testing or research.

Chapter V

REGISTRATION OF HERBAL INGREDIENTS, EXCIPIENTS, SOFTGEL SHELLS AND ASSESSMENT OF OVERSEAS DRUG MANUFACTURERS

Section 1. REGSITRATION OF HERBAL INGREDIENTS, EXCIPIENTS, SOFTGEL SHELLS

Article 93. Herbal ingredients for which registration is mandatory and conditions for registration

1. A herbal ingredient shall be registered before being sold in Vietnam if:

a) it is on the list of toxic herbal ingredients;

b) it is used as a medicinal ingredient in Vietnam for the first time;

c) it is likely to cause confusion or subject to counterfeiting;

d) it contains an active ingredient whose quality is easily affected during its manufacture, processing or sale;

dd) it is on the list of herbal ingredients that can be domestically obtained with adequate quantity and at rational prices; or

e) it is a semi-finished herbal ingredient unless it is meant to be processed into drugs by its manufacturer.

The Minister of Health shall compile the list of herbal ingredients for which registration is mandatory.

2. Applied standards of herbal ingredients other than those specified in Clause 1 of this Article shall be declared in accordance with Clause 2 Article 68 of the Law on Pharmacy. Procedures for registration are specified in Section 1 of Chapter V hereof.

3. In the cases where quality standards applied to an excipient that are established by the manufacturer are not included in Vietnam's pharmacopoeia or any Vietnam's pharmaceutical standards or any foreign pharmacopoeia specified by the Minister of Health, such excipient must be registered unless it is used for production of a drug that has an unexpired certificate of registration in Vietnam. Procedures for registration are specified in Section 1 of Chapter V hereof.

4. Softgel shells shall be registered unless they are used for production of a drug that has an unexpired certificate of registration in Vietnam. Procedures for registration are specified in Section 1 of Chapter V hereof.

5. The following entities may apply for registration of herbal ingredients, excipients or softgel shells:

a) The establishments specified in Clause 3 Article 54 of the Law on Pharmacy;

b) The establishments specified in Clause 1c Article 35 of the Law on Pharmacy that are permitted to apply for registration of herbal ingredients;

6. Registration method, rights and obligations of applicants for registration of herbal ingredients, excipients and softgel shells are specified in Article 55 and Article 57 of the Law on Pharmacy.

Article 94. Power, documents, procedures and deadline for issuing, renewing, adjusting and revoking the certificate of registration of herbal ingredients, excipients and softgel shells

The power, documents, procedures and deadline for issuing, renewing, adjusting and revoking the certificate of registration of herbal ingredients, excipients and softgel shells are specified in Article 56 and Article 58 of the Law on Pharmacy, with the following exceptions:

1. If the applicant is a manufacturer of herbal ingredients without the Certificate of eligibility for pharmacy business, a certified true copy of the certificate of enterprise registration shall be included in the application.

2. The certificate of registration of herbal ingredients, excipients and softgel shells shall be issued within 06 months from the day on which the satisfactory application is received.

Section 2. INSPECTION OF FULFILLMENT OF GMP REQUIREMENTS BY OVERSEAS MANUFACTURERS OF DRUGS/MEDICINAL INGREDIENTS WHEN THEY APPLY FOR REGISTRATION IN VIETNAM

Article 95. Applying for inspection of overseas manufacturers of drugs/medicinal ingredients when they apply for registration in Vietnam

1. If a drug or medicinal ingredient has not been granted a certificate of registration, the applicant shall submit an application for GMP inspection in addition to the application for the certificate of registration of the drug or medicinal ingredient in the following cases:

a) The foreign manufacturer applies for drug registration in Vietnam for the first time;

b) The production line of the drug has not undergone inspection by the Ministry of Health;

c) The medicinal ingredient is an active ingredient that is registered in Vietnam for the first time;

d) The foreign manufacturer applies for herbal ingredient registration in Vietnam for the first time.

2. If the certificate of registration of a drug or medicinal ingredient is issued before the effective date of this Decree and its manufacturer has not undergone inspection by the Ministry of Health, an application GMP inspection shall be submitted when:

a) applying for renewal of the certificate of registration of the drug or medicinal ingredient according to Clause 4 Article 55 of the Law on Pharmacy;

b) applying for issuance of the certificate of registration the drug or medicinal ingredient because of relocation of the factory according to Clause 2b or Clause 2c Article 55 of the Law on Pharmacy.

3. If the drug or medicinal ingredient is manufactured by multiple factories, the applicant shall apply for inspection of all of the factories that participate in the production.

Article 96. Inspection methods

1. Inspection of documents about the manufacturing conditions shall be carried out in the cases specified in Clause 2 and Clause 3b of this Article.

2. The inspection result given by a pharmacy authority shall be recognized in the following cases:

a) The manufacturer is of a country that has agreement with Vietnam on mutual recognition of GMP inspections according to the list compiled by the Ministry of Health, except for the cases specified in Clause 3 of this Article;

b) The manufacturer is of a member state of ICH or Australia, undergoes GMP inspection and granted the certificate of GMP by either US Food and Drug Administration (USFDA), European Union, European Medicines Agency (EMA), Australia's Therapeutic Goods Administration (TGA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA) or Health Canada, except for the cases specified in Clause 3 of this Article.

3. A site inspection shall be carried out when:

a) The application for registration of drug or medicinal ingredient is suspected of falsification or inaccuracy;

b) The manufacturer commits a first-degree violation according to conclusion of the Ministry of Health;

c) The Ministry of Health concludes that documents submitted by the manufacturer are not sufficient for proving its fulfillment of GMP requirements.

Article 97. Inspection contents

1. Documents that are basis for inspection:

a) The GMP requirements applied to drugs and medicinal ingredients prescribed by the Minister of Health;

b) Effective regulations on registration of drugs and medicinal ingredients and quality control.

2. Document inspection contents:

a) Legitimacy of the certificate of GMP, the manufacturing license or the report on GMP inspection;

b) Suitability of the certificate of GMP, the manufacturing license or the report on GMP inspection for the dosage form of the registered drug or medicinal ingredient;

c) Suitability of the factory, including the floor plan, production line, building materials, environmental conditions, movement of employees, ingredients, semi-finished products and finished products, movement of equipment for manufacturing, testing, storing drugs/medicinal ingredients;

d) Establishment and operation of the manufacturer's quality control system;

dd) Comments of the pharmacy authority of the manufacturer's home country or other countries; discovered weaknesses and remedies taken by the manufacturer.

3. Contents of inspection in the form of mutual recognition of GMP inspection by foreign pharmacy authorities:

a) Legitimacy of the certificate of GMP, the manufacturing license or the report on GMP inspection;

b) Suitability of the certificate of GMP, the manufacturing license or the report on GMP inspection for the dosage form of the registered drug or medicinal ingredient.

4. Contents of site inspection:

a) Legitimacy of the certificate of GMP, the manufacturing license or the report on GMP inspection;

b) Conditions of the factory, including the floor plan, production line, building materials, environmental conditions, movement of employees, ingredients, semi-finished products and finished products, movement of equipment for manufacturing, testing, storing drugs/medicinal ingredients;

c) Operation of the production line for the drug or medicinal ingredient registered;

d) Establishment and operation of the manufacturer's quality control system;

dd) Application of GMP requirements to the production, testing, storage of drugs/medicinal ingredients by the manufacturer.

Article 98. Composition of the application for GMP inspection

1. The application for GMP inspection submitted by a manufacturer of drugs/medicinal ingredients that are active ingredients in any of the cases specified in Clause 2 Article 96 hereof consists of:

a) The certificate of GMP, the manufacturing license or the report on GMP inspection which contains sufficient information about the dosage form of the drug or medicinal ingredient issued by a competent authority of the manufacturer's home country;

b) The drug master file (DMF) prepared by the manufacturer according to instructions of EU, Pharmaceutical Inspection Co-operation Scheme (PIC/S) or WHO.

2. The application for GMP inspection submitted by a manufacturer of drugs/medicinal ingredients that are active ingredients in any of the cases specified in Clause 1 and Clause 3 Article 96 hereof consists of:

a) The certificate of GMP, the manufacturing license or the report on GMP inspection which contains sufficient information about the dosage form of the drug or medicinal ingredient issued by a competent authority of the manufacturer's home country; the certificate of GMP or report on GMP inspection issued by the pharmacy authority of a member state of EU or PIC/S (if any);

b) The drug master file (DMF) prepared by the manufacturer according to instructions of EU, Pharmaceutical Inspection Co-operation Scheme (PIC/S) or WHO;

c) A list of GMP inspections carried out by pharmacy authorities of the manufacturer's home country over the last 03 years before the application is submitted and the report on the latest GMP inspection that involves the registered drug or medicinal ingredient or the dosage form thereof;

d) A list of drugs and dosage forms thereof and medicinal ingredients that have been exported or intended for export to Vietnam;

dd) Procedures for release of the drug or medicinal ingredient to be registered in Vietnam;

e) A report on periodic quality inspection if the registered drug or medicinal ingredient is in sterile form;

3. The application for GMP inspection submitted by a manufacturer of excipients or softgel shells consists of:

a) The certificate of GMP, the manufacturing license or the report on GMP inspection which contains sufficient information about the excipient of softgel shells issued by a competent authority of the manufacturer's home country;

b) The quality manual according to ISO/TR 10013:2001 of updates thereof or the DMF prepared by the manufacturer according to instructions of EU, PIC/S or WHO;

c) A manufacturer of excipients or softgel shells specified in Clause 2 Article 96 hereof shall submit only documents specified in Point a of this Clause.

4. The application for GMP inspection submitted by a manufacturer of herbal ingredients consists of:

a) The certificate of GMP or the report on GMP inspection;

b) The quality handbook according to ISO/TR 10013:2001 of updates thereof or the DMF prepared by the manufacturer according to instructions of EU, PIC/S or WHO;

c) A list of herbal ingredients that have been exported or intended for export to Vietnam;

d) Documents about the area(s) where herbal ingredients have been exported or intended for export to Vietnam are obtained;

dd) A manufacturer of herbal ingredients specified in Clause 2 Article 96 hereof shall submit only documents specified in Points a, c and d of this Clause.

5. An application for GMP inspection shall satisfy the following requirements:

a) The application is written in English or Vietnam language; documents in the application are clearly printed and arranged in the order specified in Clause 1 through 4 of this Article, the parts are clearly separated; the application has covers and a list of documents;

b) The certificate of GMP and report on GMP inspection mentioned in Clause 1 through 4 of this Article and the manufacturing license mentioned in Clause 1 through 3 of this Article shall be original copies or certified true copies and have to be unexpired when the application is submitted. If the expiration date is not specified, it must be issued within the last 03 years from the day on which the application is submitted.

Article 99. Receipt of applications and time of inspection

1. The Ministry of Health shall receive applications for GMP inspection, carry out the inspections, prepare GMP inspection reports and notify the results:

a) within 30 days from the day on which the satisfactory application is received in case of mutual recognition of GMP inspection;

b) within 60 days from the day on which the satisfactory application is received in case of document inspection;

c) within 90 days from the day on which the satisfactory application is received in the case specified in Clause 3b Article 96 of this Decree or the date of notification of the result of verification of the application for drug registration or application for GMP inspection and the plan for site inspection in the cases specified in Clause 3a and Clause 3c Article 96 of this Decree.

2. If the applicant wishes to change the site inspection date, the time limit specified in Clause 1c of this Article shall begin when the applicant’s request is received.

3. If the certificate of GMP or the manufacturing license is expired on the inspection date or the report on GMP inspection was issued more than 03 years before the inspection date or the DMF does not contain sufficient information, the Ministry of Health shall request the applicant to complete the application.

a) The supplementary DMF shall be submitted within 90 days, the certificate of GMP, manufacturing license or GMP inspection report within 06 months;

b) The Ministry of Health shall notify the applicant of the result within 30 days from the day on which supplementary documents are received.

4. Within 10 working days from the day on which the result is available, the Ministry of Health shall publish information about the inspected and recognized manufacturers on its website.

Article 100. Responsibilities of applicants for registration of drugs/medicinal ingredients of foreign manufacturers in GMP inspection; cases in which applications for registration of drugs/medicinal ingredients are rejected

1. During the GMP inspection, the applicant for registration of a drug or medicinal ingredient of a foreign manufacturer shall:

a) Submit the application for GMP inspection as prescribed;

b) Take responsibility for the adequacy and accuracy of documents in the application for GMP inspection; provide supporting documents requested by the Ministry of Health;

c) Cooperate with the manufacturer in complying with requests of the Ministry of Health;

d) Submit a report to the Ministry of Health on the manufacturer's fulfillment of GMP requirements. In the cases where the manufacturing license is revoked or the manufacturer fails to fulfill GMP requirements in its home country, the applicant shall submit a report within 15 days from the day on which a notification is issued by a competent authority of the manufacturer's home country;

d) Pay the cost of GMP inspection as prescribed by law.

2. The application for issuance or renewal of the certificate of drug/medicinal ingredient registration shall be rejected if the applicant or the manufacturer commits any of the following violations:

a) Any of the violations that result in revocation of the certificate of drug/medicinal ingredient registration specified in Points a, b, d, dd Clause 1 Article 58 of the Law on Pharmacy;

b) Ingredients of unknown origins or expired ingredients are used for drug production;

c) At least 02 batch of drug or medicinal ingredient fail to meet Level 2 quality standards or at least 03 batches of drug or medicinal ingredient fail to meet quality standards within 01 years according to conclusion given by a competent authority;

d) Information about technical documents is provided without research or production in reality;

dd) No report is submitted to the Ministry of Health within 15 days from the day on which a competent authority of the manufacturer's home country issues a notification of revocation of the manufacturing license or the manufacturer's failure to meet GMP requirements;

e) Shelf life of drug is falsified, except for the case specified in Clause 3 Article 61 of the Law on Pharmacy;

g) No report is submitted to the Ministry of Health within 15 days from the day on which a competent authority issues a notification that the registered drug or medicinal ingredient is recalled or has the certificate of registration revoked in any country in the world;

h) Information about the drug on the label or package insert or summary of drug characteristics is not updated as requested by the Ministry of Health.

3. From the day on which the violation is notified by a competent authority, the applicant shall be suspended from submitting the application for issuance or renewal of the certificate of drug/medicinal ingredient registration for:

a) 03 – 05 years in the cases specified in Clause 1d Article 58 of the Law on Pharmacy;

b) 01 – 02 years in the cases specified in Clause 1a and 1 dd Article 58 of the Law on Pharmacy and Points b, c, d, dd, e of Clause 2 of this Article;

c) 06 months – 01 year in the cases specified in Clause 1b Article 58 of the Law on Pharmacy, Clause 2g and Clause 2h of this Article.

4. Applications submitted by applicants that commit any of the violations specified in Points a, b, c, d, đ, e Clause 2 of this Article before the violations are dealt with will be invalidated. At the end of the periods specified in Clause 3 of this Article, the application may be submitted in accordance with the Law on Pharmacy.

Chapter VI

RECALL OF MEDICINAL INGREDIENTS AND HANDLING OF RECALLED MEDICINAL INGREDIENTS

Article 101. Types and scale of recall

1. Types of recall:

a) Mandatory recall: under a decision of a competent authority;

b) Voluntary recall: by the applicant for registration, manufacturer or importer of medicinal ingredients.

2. Scale of recall:

a) Medicinal ingredients shall be recalled from establishments that sell or use them, except for the case in Point b of this Clause;

b) If the ingredient fails to meet quality standards because of an error during the process of storage, transport or distribution, or used for unintended purposes, only the affected ingredient at establishments that sell or use it shall be recalled;

c) The scale of recall must be specified in the decision on recall issued by the competent authority (in case of mandatory recall) or by the applicant for registration, the manufacturer or the importer (in case of voluntary recall).

Article 102. The power to recall and procedures for recalling medicinal ingredients

1. Power to issue the decision on recall:

a) The Ministry of Health shall decide the recall of medicinal ingredients and issue the decision on recall in case of mandatory recall;

b) Domestic manufacturers and importers of medicinal ingredients shall decide the recall of medicinal ingredients and issue the decision on recall in case of voluntary recall.

2. Procedures for recalling medicinal ingredients:

a) Within 48 hours from the time a recall is decided, the Ministry of Health or the establishment mentioned in Clause 1b of this Article shall issue the decision on recall and inform the Ministry of Health of the recall. Decision on mandatory recall shall be sent to domestic manufacturers of medicinal ingredients, importers of medicinal ingredients, Departments of Health of provinces and posted on the website of the Ministry of Health.

b) Within 05 working days from the day on which the decision on recall is issued, the domestic manufacturer or importer of medicinal ingredients inform buyers of the ingredients of the recall and organize receipt of the ingredients returned;

c) The recall of medicinal ingredients must be finished within 30 days from the day on which the decision on recall is issued;

d) Within 10 days from the day on which the recall is finished, the establishment responsible for the recall shall submit a report to the Ministry of Health which is enclosed with copies of the documents about the recall bearing the establishment's seal. Documents about the recall are documents that specify quantity of ingredients manufactured or imported, quantity of ingredients recall, time of manufacture, date of import, list of buyers and evidence that ingredients have been returned by the buyers and users;

dd) The Ministry of Health shall verify the report, assess the effectiveness of the recall or enforce the recall if the domestic manufacturer or importer fails to carry out the recall in accordance with Point b or Point c of this Clause.

Article 103. Responsibility to recall medicinal ingredients

1. The domestic manufacturer or importer of the recalled medicinal ingredient shall:

a) Give a conclusion that the ingredient has to be recalled and issue a decision on recall in case of voluntary recall;

b) Stop selling the recalled ingredient;

c) Take charge and cooperate with relevant entities in publishing information about the recalled ingredient, organize the recall and receipt of recalled ingredient;

d) Handle the recalled ingredient;

dd) Pay for the recall and handling of recalled ingredient (even if the recall is enforced) and pay damages as prescribed by law;

e) Submit a report on the recall to the Ministry of Health.

2. Each distributor of the recalled ingredient shall:

a) Stop buying and selling the recalled ingredient;

b) Announce the recall, organize the recall and receive the ingredient returned by buyers;

c) Return the ingredient to its supplier;

d) Pay for the recall and handling of recalled ingredient (even if the recall is enforced) and pay damages if the distributor is as fault.

3. The manufacturer that uses the recalled ingredient shall:

a) Stop using the ingredient;

b) Return the ingredient to its supplier.

4. The Ministry of Health shall:

a) Draw a conclusion that the medicinal ingredient has to be recall and issue the decision on recall in case of mandatory recall;

b) Verify the report on recall and comment on the handling and recycling of the recalled ingredient;

c) Inspect and supervise the recall; take actions against violators as prescribed by law;

d) Instruct the Department of Health of the province to inspect and supervise recall of medicinal ingredients and take actions against violators in its province;

dd) Decide enforcement of recall if the domestic manufacturer or importer fails to carry out the recall as requested;

e) Publish information about the recalled medicinal ingredients on its website if they have to be destroyed.

5. The Department of Health of the province shall:

a) Inform manufacturers and sellers in the province of the recall;

b) Inspect and supervise recall of medicinal ingredients and take actions against violators in the province;

c) Inform the Ministry of Health of the establishments that fail to properly recall medicinal ingredients.

Article 104. Handling recalled ingredients

1. Recalled medicinal ingredients that are herbal ingredients or active ingredients shall be destroyed in the following cases:

a) The medicinal ingredients are not meant for human use but labeled for human use;

b) The certificate of registration was obtained by submission of fraudulent documents;

c) The origin of the ingredients is unknown;

d) The active ingredient is displayed or labeled under another manufacturer or manufacturing country or country of origin;

dd) The herbal ingredient is counterfeit;

e) The herbal ingredient does not have a certificate of registration or applied quality standards as prescribed;

g) The medicinal ingredients are used to produce drugs that are not recommended by WHO.

2. Medicinal ingredients may be recycled in the following cases:

a) The medicinal ingredients are recalled because they fail to comply with regulations on labels or medicinal ingredients specified in Article 61 of the Law on Pharmacy or relevant regulations of law;

b) The medicinal ingredients are recalled because they are produced at factory other than the registered factory but the former is granted a manufacturing license by a competent authority.

3. Recalled medicinal ingredients that are not psychotropic active ingredients, narcotic substances, drug precursors and are not those mentioned in Clause 1 and Clause 2 of this Article

may be recycled if they are domestically produced or re-exported if they are imported or repurposed under the procedures in Clause 4 of this Article.

Recalled medicinal ingredients that are not recycled, re-exported or repurposed shall be destroyed.

4. Procedures for recycling, re-exporting and repurposing medicinal ingredients:

a) A written request for permission to repurpose, recycle or re-export the medicinal ingredients which specifies the new purposes, the remedies or the recycling process shall be sent to the Ministry of Health.

b) The remedy, recycling or re-export of medicinal ingredients must not be carried without the consent of the Ministry of Health;

c) The Ministry of Health shall respond in writing within 03 months from the day on which such a request is received. In the cases where re-export of medicinal ingredients is permitted, the Ministry of Health shall inform a competent authority of the importing country.

5. Procedures for destroying medicinal ingredients:

a) The head of the establishment whose medicinal ingredients have to be destroyed shall establish a drug destruction council. The council consists of at least 03 persons, including the head and the chief pharmacist of the establishment;

b) The destruction of medicinal ingredients must ensure long-term health of human and animals and avoid causing environmental pollution in accordance with regulations of law on environmental protection;

c) The establishment having the recalled medicinal ingredients shall pay for their destruction;

d) Destruction of medicinal ingredients subject to special control shall comply with regulations of Article 48 of this Decree.

Chapter VII

CERTIFICATION OF DRUG INFORMATION AND DRUG ADVERTISEMENTS

Section 1. CERTIFICATION OF DRUG INFORMATION

Article 105. Methods of provision of drug information

Information shall be provided for medical practitioners by using the following methods:

1. Provision of drug information via sale representatives.

2. Publishing of documents containing drug information.

3. Holding pharmaceutical conferences.

Article 106. Applicants for certification of drug information

1. The following entities may apply for certification of drug information:

a) Establishments applying for drug registration in Vietnam;

b) Representative offices in Vietnam authorized by the overseas establishments that apply for drug registration in Vietnam;

c) Vietnamese pharmacy business establishments authorized by the establishments mentioned in Clause 1a of this Article;

d) Vietnamese drug importers, which may only provide information about the drugs they import using the method specified in Clause 3 Article 105 of this Decree.

2. Applicants for drug registration, including those authorizing the entities mentioned in Clause 1b or 1c of this Article to apply for certification of drug information, and Vietnamese drug importers applying for certification of drug information shall take responsibility for the information provided.

Article 107. Issuance and reissuance of the certification of drug information and adjustment of certified drug information

1. The certification of drug information shall be issued in the following cases:

a) The certification of drug information is applied for the first time;

b) The certification of drug information was issued but the applicant for drug registration, drug name, ingredients, concentration, dosage form, indications, contraindications, dosage, uses for special cases, warnings or drug safety information is changed.

2. The certification of drug information shall be reissued in the following cases:

a) The certification of drug information is lost or damaged;

b) The issuer makes an error on the certification of drug information.

3. Certified drug information may be adjusted in case of changes other than those specified in Clause 1b of this Article.

Article 108. Application for the certification of drug information

1. An application for the certification of drug information which is provided using the method mentioned in Clause 2 Article 105 of this Decree consists of:

a) Form No. 01 in Appendix VI enclosed herewith;

b) A design of the document containing drug information;

c) Specimens of the label and package insert approved by the Ministry of Health;

d) Reference documents about the drug information to be certified (if any);

dd) The certificate of drug registration;

e) The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; the certificate of eligibility for drug business if the applicant is a Vietnamese pharmacy business establishment;

g) In case the applicant for certification of drug information is authorized by the applicant for drug registration, the authorization document.

2. An application for the certification of drug information which is provided using the method mentioned in Clause 3 Article 105 of this Decree consists of:

a) Form No. 02 in Appendix VI enclosed herewith;

b) Drug information;

c) Specimens of the label and package insert approved by the Ministry of Health;

d) Reference documents about the drug information to be certified (if any);

dd) the certificate of drug registration or the license for drug import;

e) The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; the certificate of eligibility for drug business if the applicant is a Vietnamese pharmacy business establishment;

g) In case the applicant for certification of drug information is authorized by the applicant for drug registration, the authorization document;

h) The agenda of the pharmaceutical conference.

Article 109. Composition of the application for reissuance of the certification of drug information

1. Form No. 03 in Appendix VI enclosed herewith.

2. A design of the drug information sheet or the drug information.

3. A confirmation that the error is made by the issuer in the case mentioned in Clause 2b Article 107 of this Decree.

Article 110. Composition of an application for adjustment to certified drug information

1. Form No. 04 in Appendix VI enclosed herewith which specifies the adjustment and reasons for adjustment.

2. Documents proving the adjustment.

Article 111. Documents in the applications for issuance and reissuance of the certification of drug information and application for adjustment of certified drug information

1. Documents mentioned in Clause 1c, Clause 1dd, Clause 2c and Clause 2dd of Article 108 shall be copies.

2. Documents mentioned in Clause 1d, Clause 1e, Clause 2d, Clause 2e of Article 108 and Clause 2 of Article 110 of this Decree shall be copies bearing the seal of the applicant if they are issued by the Ministry of Health or certified true copies if they are not issued by the Ministry of Health.

3. Documents mentioned in Clause 1g and Clause 2g of Article 108 of this Decree shall be original copies or certified true copies.

4. Documents mentioned in Clause 3 of Article 109 of this Decree shall be original copies.

5. Documents mentioned in Clause 1b and Clause 2b of Article 108 and Clause 2 of Article 109 of this Decree are 02 original copies.

6. Each application for issuance or reissuance of the certification of drug information shall contain:

a) 01 specimen of the design mentioned in Clause 1 Article 108 of this Decree or 01 sheet of drug information mentioned in Clause 2 Article 108 of this Decree for a drug;

b) 01 specimen of the design mentioned in Clause 1 Article 108 of this Decree or 01 sheet of drug information mentioned in Clause 2 Article 108 of this Decree for more than one drug that have the same active ingredients and route of administration, the same manufacturer but different concentrations or dosage forms.

7. Documents shall be printed on A4 pages and bear fan stamping of the applicant for the certification of drug information.

Article 112. Presentation of drug information

1. Drug information shall satisfy the following requirements:

a) Information is sufficient according to Clause 5a Article 76 of the Law on Pharmacy; information and images not related to the drug or use of the drug and similar information and images specified in Article 126 of this Decree are not permitted;

b) Reference documents and extracts therefrom are specified. The extracts must be accurate without addition or removal of information which leads to misunderstanding of the safety and efficacy of the drug;

c) The drug information is written in Vietnamese language, except for untranslatable information;

d) Minimum font size: 12; Font: VnTime or Times New Roman; Page: A4.

2. The text "Tài liệu thông tin thuốc" ("Drug information") must be displayed on the top of all pages. Pages of a multi-page document must be numbered. The first page must contain the table of content and the text "Số Giấy xác nhận nội dung thông tin thuốc của Bộ Y tế…/XNTT/…, ngày ... tháng ... năm ..." ("Number and date of the certification of drug information issued by the Ministry of Health: …")

3. In case of a pharmaceutical conference, the drug information must include the names and academic ranks of the speakers, whose medical or pharmaceutical qualifications are suitable for the drug introduced.

Article 113. Procedures for issuance of the certification of drug information

1. The applicant shall submit the application for the certification of drug information to the competent authority specified in Article 116 of this Decree.

2. Within 15 days from the day on which the satisfactory application is received, the receiving authority shall give the applicant Form No. 05 or Form No. 06 in Appendix VI enclosed herewith. If the application is rejected, the receiving authority shall respond and provide explanation in writing.

3. If the application is not satisfactory, the receiving authority shall request the applicant in writing to complete the application. To be specific:

a) The written request shall specify necessary adjustments and/or additions;

b) Within 15 days from the day on which the supplemented application is received, the receiving authority shall give the applicant Form No. 05 or Form No. 06 in Appendix VI enclosed herewith or reject the application and provide explanation.

c) Within 90 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. Otherwise, the application will be rejected.

4. While the application is being processed, the receiving authority shall suspend granting the confirmation and issue a notification of the suspension if the information about drug safety and efficacy in the package insert is found unsatisfactory or not updated as requested by competent authority or according to instructions given or recognized by the Ministry of Health. The suspension will be lifted when the applicant submits adjusted or updated information that ensures safety of drug users.

5. At least 03 days before providing drug information using the method mentioned in Clause 3 Article 105 of this Decree, the holder of the certification of drug information shall send a notification of the time and location and a copy of the certification of drug information to the Department of Health of the province where drug information is provided.

If the time or location is changed, the Department of Health shall be informed at least 01 working day before drug information is provided.

6. The application will be rejected if the applicant, including authorized applicants mentioned in Clause 1b and Clause 1c Article 106 of this Decree, commits any of the following violations:

a) Legal documents issued by regulatory authorities in the application for certification of drug information are falsified or forged;

b) The drug information is provided or the drug advertisement is run before its contents are certified by a competent authority or against the contents certified by a competent authority;

c) A certificate not recognized by the Ministry of Health, another organization's or individual's name, symbol, images, letters or reputation is included in the drug information or advertisement.

d) A clinical trial result, pre-clinical trial result, test result or bioequivalence study result not recognized by the Ministry of Health is included in the drug information or advertisement;

dd) Drug information is provided or drug advertisement is run despite the change in its contents that requires another certification of drug information or drug advertisement specified in Clause 1b Article 107 or Clause 1b Article 120 of this Decree.

7. From the day on which the violation is notified by a competent authority, the applicant shall be suspended from submitting the application for the certification of drug information or drug advertisement for:

a) 01 – 02 years in the cases specified in Clause 6a of this Article;

b) 06 – 12 months in the cases specified in Clause 6b, Clause 6c or Clause 6d of this Article;

c) 03 – 06 months in the cases specified in Clause 6dd of this Article.

Article 114. Procedures for reissuance of the certification of drug information

1. The applicant for reissuance of the certification of drug information shall submit an application to the competent authority in accordance with Article 116 of this Decree.

2. Within 10 working days from the day on which the satisfactory application is received, the receiving authority shall give the applicant Form No. 05 or Form No. 06 in Appendix VI enclosed herewith.

Article 115. Procedures for adjusting certified drug information

1. The applicant for adjustment to certified drug information shall submit an application to the competent authority in accordance with Article 116 of this Decree.

2. Within 07 working days from the day on which the application is received, the applicant may make the adjustment if no response is given by the receiving authority. If the adjustment is rejected, the receiving authority shall respond and provide explanation in writing.

Article 116. Power to issue, reissue the certification of drug information and adjust certified drug information

1. The Ministry of Health has the power to issue, reissue the certification of drug information and adjust information it confirms in the cases specified in Clause 2 Article 105 of this Decree.

2. Departments of Health of provinces have the power to issue, reissue the certification of drug information and adjust information they confirm in the cases specified in Clause 3 Article 105 of this Decree.

Article 117. Effect of the certification of drug information

1. The certification of drug information is effective nationwide.

2. The certification of drug information does not have a specific expiration date and shall be invalidated in the following cases:

a) The certificate of drug registration or the license for drug import is revoked;

b) A change to drug information is made that requires issuance of another certification of drug information according to Clause 1b Article 107 of this Decree.

Section 2. CONFIRMATION OF DRUG ADVERTISEMENT CONTENTS

Article 118. Means of advertising drugs

Drugs may be advertised through the means of advertising defined by advertising laws.

Article 119. Applicants for confirmation of drug advertisement contents

1. The following entities may apply for confirmation of drug advertisement contents:

a) Establishments applying for drug registration in Vietnam;

b) Representative offices in Vietnam authorized by the overseas establishments that apply for drug registration in Vietnam;

c) Vietnamese pharmacy business establishments authorized by the establishments mentioned in Clause 1a of this Article.

2. Applicants for drug registration, including those authorizing the entities mentioned in Clause 1b or 1c of this Article to apply for confirmation of drug advertisement contents, shall take responsibility for the drug advertisement contents.

Article 120. Issuance and reissuance of the certification of drug advertisement contents and adjustment thereto

1. The certification of drug advertisement contents shall be issued in the following cases:

a) The certification of drug advertisement contents is applied for the first time;

b) The certification of drug advertisement contents was issued but the applicant for drug registration, drug name, ingredients, concentration, dosage form, indications, contraindications, dosage, uses for special cases, warnings or drug safety information is changed.

2. The certification of drug advertisement contents shall be reissued in the following cases:

a) The certification of drug advertisement contents is lost or damaged;

b) The issuer makes an error on the confirmation of drug advertisement contents.

3. Certified drug advertisement contents may be adjusted in case of changes other than those specified in Clause 1b of this Article.

Article 121. Application for the certification of drug advertisement contents

1. An application for the certification of drug advertisement contents, except for advertisements in the form of conferences, conventions or events, consists of:

a) Form No. 01 in Appendix VI enclosed herewith;

b) The graphic design of the drug advertisement; the audio or video track of the advertisement on audio or video news and other means of audio and video advertisements defined by advertising laws;

c) Specimens of the label and package insert approved by the Ministry of Health;

d) Reference documents about the drug advertisement contents to be certified (if any);

dd) The certificate of drug registration;

e) The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; the certificate of eligibility for drug business if the applicant is a Vietnamese pharmacy business establishment;

g) In case the applicant for the confirmation of drug advertisement contents is authorized by the applicant for drug registration, the authorization document.

2. An application for the certification of contents of drug advertisement in the form of a conference, convention or event consists of:

a) Form No. 02 in Appendix VI enclosed herewith;

b) The drug advertisement contents;

c) Specimens of the label and package insert approved by the Ministry of Health;

d) Reference documents about the drug advertisement contents to be certified (if any);

dd) The certificate of drug registration;

e) The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; the certificate of eligibility for drug business if the applicant is a Vietnamese pharmacy business establishment;

g) In case the applicant for the confirmation of drug advertisement contents is authorized by the applicant for drug registration, the authorization document;

h) The agenda of the conference.

Article 122. Application for reissuance of the certification of drug advertisement contents

1. Form No. 03 in Appendix VI enclosed herewith.

2. The graphic design, audio or video track of the advertisement or contents of the advertisement to be certified.

3. An confirmation that the error is made by the issuer in the case mentioned in Clause 2b Article 120 of this Decree.

Article 123. Composition of an application for adjustment to certified drug advertisement contents

1. Form No. 04 in Appendix VI enclosed herewith which specifies the adjustment and reasons for adjustment.

2. Documents proving the adjustment.

Article 124. Documents in the application for certification of drug advertisement contents and adjustment thereto

1. Documents mentioned in Clause 1c, Clause 1dd, Clause 2c and Clause 2dd of Article 121 shall be copies.

2. Documents mentioned in Clause 1d, Clause 1e, Clause 2d, Clause 2e of Article 121 and Clause 2 of Article 123 of this Decree shall be copies bearing the seal of the applicant if they are issued by the Ministry of Health or certified true copies if they are not issued by the Ministry of Health.

3. Documents mentioned in Clause 1g and Clause 2g of Article 121 of this Decree shall be original copies or certified true copies.

4. Documents mentioned in Clause 3 of Article 122 of this Decree shall be original copies.

5. Documents mentioned in Clause 1b and Clause 2b of Article 121 and Clause 2 of Article 122 of this Decree are 02 original copies.

6. Each application for issuance or reissuance of the confirmation of drug advertisement contents shall contain:

a) 01 specimen of the graphic design or audio track or video track of the advertisement mentioned in Clause 1 Article 121 of this Decree or 01 specimen of the drug advertisement mentioned in Clause 2 Article 121 of this Decree for a drug;

b) 01 specimen of the graphic design or audio track or video track of the advertisement mentioned in Clause 1 Article 121 of this Decree or 01 specimen of the drug advertisement mentioned in Clause 2 Article 121 of this Decree for more than one drug that have the same active ingredients and route of administration, the same manufacturer but different concentrations or dosage forms.

7. The documents shall be printed on A4 papers. In case of advertisements on billboards, the drug advertisement contents may be printed on an A3 paper with specific ratio. All documents in

the application must bear the applicant's seal. If the advertisement object is three-dimensional, a description on A3 paper with the following information shall be included:

a) The object;

b) Numbers and dimensions of the sides;

c) The ratio of the specimen to the real object.

Article 125. Requirements applied to drug advertisement contents

1. The drug advertisement contents shall comply with the following documents:

a) The label and package insert approved by the Ministry of Health;

b) The treatise on the drug in the National Pharmacopoeia of Vietnam;

c) Related instructions provided or recognized by the Ministry of Health.

2. The drug advertisement contents have the following compulsory information:

a) Drug name;

b) Active ingredients or herbal ingredients in the approved package insert. Names of herbal ingredients must be written in Vietnamese language. Names of untranslatable foreign herbal ingredients may be written in Latin language;

c) Indications;

d) Uses;

dd) Dosage;

e) Contraindications and warnings for special users (pregnant women, breast-feeding women, children, old people, people having chronic diseases);

g) Cautions and what to avoid when using the drug;

h) Side effects and adverse effects;

i) Name and address of the manufacturer;

k) The text "Đọc kỹ hướng dẫn sử dụng trước khi dùng" ("Read the instructions carefully before use");

l) The text “Số Giấy xác nhận nội dung quảng cáo thuốc của Bộ Y tế: .../XNQC..., ngày ... tháng ... năm...;” (“Number and date of the certification of drug advertisement contents issued by the Ministry of Health: …”) at the end of the first page;

m) Pages of a multi-page document must be numbered. The first page must specify the number of pages and contain the table of content;

n) Reference documents and extracts therefrom are specified. The extracts must be accurate without addition or removal of information which leads to misunderstanding of the safety and efficacy of the drug.

3. The contents of an audio or video advertisement must contains sufficient information specified in Points a, b, c, e, i, k Clause 2 of this Article. Information mentioned in Points a, b, c, e, k Clause 2 of this Article must be read aloud. If the drug consists of 03 or more active ingredients, each of them or the groups of vitamins, minerals and herbal ingredients must be read aloud.

4. Contents of advertisements on online newspapers, websites, electronic devices, advertising screens and other means of advertising defined by advertising laws:

a) The contents of an advertisement that has sounds shall comply with regulations of Clause 3 of this Article;

b) The contents of an advertisement without sounds shall comply with regulations of Clause 2 of this Article.

If the advertisement is an audio or video track that has multiple pages or footages, the pages or footages must be continuous and stay still for viewers to read all information; the page or footage that contains product information must be still for viewers to read such information. The script must specify how the pages of a multi-page advertisement are shown.

Such an advertisement must not advertise more than one drugs to avoid confusion.

5. The contents of an outdoor advertisement shall be shown on one side of the board and contains the information specified in Points .a, b, i, k, l Clause 2 of this Article. If the advertisement contains information about the effects and indications of the drug, sufficient information specified in Clause 2 of this Article must be provided.

6. Voice and text in a drug advertisement shall comply with the Law on Advertising.

7. Minimum font size: 12; Font: VnTime or Times New Roman; Page: A4.

8. The script must clearly describe the graphics, dialogues, text and music.

9. A drug advertisement may only provide information about the drug and may not provide information not related to the drug.

Article 126. Information and images banned from drug advertisements

1. Information and images prescribed in the Law on Advertising.

2. Information that causes misunderstanding about the ingredients, effects, indications or origin of the drug.

3. Information causing the viewers to believe that the drug is the best, the drug can be used without physician's counsel, the drug is completely harmful, the drug has no contraindications or adverse effects.

4. Words or images that exaggerate the effects of the drug.

5. Information that equates effects of some ingredient of the drug with effects of the drug.

6. The following words and phrases: "điều trị tận gốc", "tiệt trừ", "chuyên trị" ("complete treatment"), "hàng đầu", "đầu bảng", "đầu tay" ("best", "top"), "lựa chọn", "chất lượng cao" ("high-quality"), "đảm bảo 100%" ("100% guarantee"), "an toàn" ("safe"), "dứt", "cắt đứt", "chặn đứng" ("stop", "end"), "giảm ngay", "giảm liền", "giảm tức thì" ("relieve instantly"), "khỏi ngay", "khỏi hẳn" ("treat instantly"), "yên tâm", "không lo", "khỏi lo" ("no worries"), "khuyên dùng" ("recommended"), "hotline", "điện thoại tư vấn" ("hotline").

7. The following indications:

a) Treatment of tuberculosis or leprosy;

b) Treatment of sexually transmitted diseases;

c) Treatment of insomnia;

d) Aphrodisiac indications;

dd) Treatment of cancers or tumors;

e) Drug detoxification;

g) Treatment of diabetes mellitus or similar metabolic disorders;

h) Treatment of viral hepatitis or new dangerous diseases.

8. Drug or medicinal ingredient quality test results.

9. Pre-clinical study results.

10. Clinical study results or bioequivalence study results that have not been recognized by the Ministry of Health.

11. Names, positions, letters of other organizations or individuals used for advertising purposes.

12. Origin of the drug or medicinal ingredient used for advertising purposes.

13. Image, name or symbol of a health worker.

14. Images of an animal or plant on the list of endangered species.

15. Words that are expressed as advice or tips that recommend the drug.

16. Images of patients used for description of symptoms or effects of the drug that are not conformable with relevant documents and instructions provided or recognized by the Ministry of Health.

Article 127. Procedures for issuance and reissuance of the certification of drug advertisement contents and adjustment to certified drug advertisement contents

1. The applicant for the certification of drug advertisement contents or adjustment to certified drug advertisement contents shall submit an application to the Ministry of Health.

2. Procedures for issuance and reissuance of the certification of drug advertisement contents or adjustment to certified drug advertisement contents are the same as the procedures specified in Article 113, Article 114 and Article 115 of this Decree.

Article 128. Power to issue, reissue the certification of drug advertisement contents and adjust certified drug advertisement contents

The Ministry of Health has the power to issue, reissue the certification of drug advertisement contents and adjust certified drug advertisement contents.

Article 129. Effect of certification of drug advertisement contents

1. The certification of drug advertisement contents does not have a specific expiration date and shall be invalidated in the following cases:

a) The certificate of drug registration expires;

b) The certificate of drug registration is revoked;

c) A change to drug information is made that requires issuance of another certification of drug advertisement contents according to Clause 1b Article 120 of this Decree;

d) A regulatory body recommends that the use of the drug should be restricted or supervised by medical practitioners;

dd) The drug contains an active ingredient or herbal ingredient that has been removed from the list of OTC drugs promulgated by the Minister of Health.

2. When the certificate of drug registration is renewed, the certification of drug advertisement contents will be automatically renewed with the same duration as that of the certificate of drug registration.

Chapter VIII

MEASURES FOR DRUG PRICE MANAGEMENT

Section 1. DECLARATION AND RE-DECLARATION OF DRUG PRICES

Article 130. Declaration and re-declaration of drug prices

1. Declarations of drug prices include:

a) The declaration of imported drug prices according to Form No. 01 in Appendix VII enclosed herewith;

b) The declaration of domestic drug prices according to Form No. 02 in Appendix VII enclosed herewith.

2. Re-declarations of drug prices include:

a) The re-declaration of imported drug prices according to Form No. 03 in Appendix VII enclosed herewith;

b) The re-declaration of domestic drug prices according to Form No. 04 in Appendix VII enclosed herewith.

3. The declaration of drug prices in case of change to the certificate of drug registration is the same as that specified in Clause 1 of this Article.

4. Documents to be submitted in case of adjustment to information about a drug whose price has been declared or re-declared while the drug price is not adjusted (except for the case in Clause 3 of this Article):

a) The information adjustment form according to Form No. 05 in Appendix VII enclosed herewith;

b) A copy of the document permitting the information adjustment issued by a competent authority.

5. The documents shall be made into 02 sets, one of them shall be sent to the Ministry of Health or the People's Committee of the province in case of declaration of domestic drug prices, and the other is retained by the declaring establishment.

6. Drug prices shall be expressed in VND, inclusive of VAT. The unit price shall be the price for the smallest pack. The declaration or re-declaration of imported drug prices shall specify the exchange rate applicable at that time. The exchange rate is that applied by the drug-trading establishment and the transacting bank when borrowing or buying the foreign currency. If the drug-trading establishment has not paid the bank, the selling exchange rate quoted by the commercial bank from which foreign currency is borrowed or bought shall be applied.

Article 131. Receipt of declarations and re-declarations of drug prices, adjustment to declared drug prices and verification of declared drug prices

1. Regarding imported drugs:

a) The importer shall declare the intended wholesale price and retail price for the imported drug (in case of retailing) before launching the first shipment in Vietnam. Price declaration is not required for the next shipments if the price declared is not adjusted;

b) The importer shall re-declare the intended wholesale price and retail price if the price that was declared/re-declared and posted on the website of the Ministry of Health is increased.

c) A drug price declaration shall be submitted when the certificate of drug registration is adjusted and before the first shipment of imported drug is launch in Vietnam;

b) During business operation, if the importer decreases the wholesale price and retail price that was declared/re-declared, the decreased price shall be re-declared.

2. Regarding domestic drugs:

a) The manufacturer or outsourcing entity (in case of outsourcing manufacturing) shall declare the intended wholesale price and retail price (in case of retailing) before launching the first batch in Vietnam. Price declaration is not required for the next batches if the price declared is not adjusted;

b) The manufacturer or outsourcing entity (in case of outsourcing manufacturing) shall re-declare the intended wholesale price and retail price if the price that was declared/re-declared and posted on the website of the Ministry of Health is increased.

c) A drug price declaration shall be submitted when the certificate of drug registration is adjusted and before the first batch of drug is launch in Vietnam;

d) During business operation, if the manufacturer or outsourcing entity (in case of outsourcing manufacturing) decreases the wholesale price and retail price that was declared/re-declared, the decreased price shall be re-declared.

3. Power to receive declarations and re-declarations of drug prices:

a) The Ministry of Health shall receive and verify declarations and re-declarations of imported drug prices, declarations of domestic drug prices and declarations of adjustment to information of drugs whose prices have been declared/re-declared;

b) The People's Committees of provinces shall receive and verify re-declarations of domestic drug prices from establishments in their provinces.

4. Organization of receipt, verification and publishing of declarations and re-declarations of drug prices:

a) The importer or outsourcing entity (in case of outsourcing manufacturing) shall submit an application in accordance with Clause 1 through 4 Article 130 of this Decree to the competent authority specified in Clause 3 of this Article;

b) The receiving authority shall give Form No. 06 (if the receiving authority is the Ministry of Health) or Form No. 07 (if the receiving authority is the People's Committee of the province) in Appendix VII enclosed herewith;

c) Within 45 days for declarations of drug prices 30 days for declarations of imported drug prices, 15 days for adjustment to information of drugs whose prices have been declared or re-declared, the Ministry of Health shall verify and publish the declared/re-declared drug prices and adjustments to drug information on its website if the declared/re-declared prices are found rational. If the declared/re-declared prices are not rational or the application for adjustment to drug information is not satisfactory, the Ministry of Health shall request the declaring establishment to review the prices or supplement the application and provide explanation by the deadline specified in this Point;

d) Regarding re-declarations domestic drug prices, within 25 days from the day on which adequate documents are received, the People's Committee of the province shall verify the prices and submit a report (Form No. 08 in Appendix VII enclosed herewith) to the Ministry of Health if the prices are found rational. If the declared/re-declared prices are not rational, the People's Committee of the province shall request the declaring establishment to review the prices and provide explanation by the deadline specified in this Point.

Within 05 working days from the day on which the report is received from the People's Committee, the Ministry of Health shall post it on its website.

dd) Within 06 months from the day on which the competent authority comments on the declared/re-declared prices or requests supplementation of the application, the declaring establishment shall send a written response and relevant documents to prove the prices are rational, adjust the prices or supplement the application. If not response is made by the aforementioned deadline, the documents will be invalidated;

e) Regarding declarations and re-declarations of imported drug prices, within 25 days from the day on which a response is received from the declaring establishment, the Ministry of Health shall verify the prices and publish them on its website if they are proved rational or reasonably adjusted. If the declaring establishment fails to prove that the declared/re-declared prices are rational or fails to adjust the prices, the Ministry of Health shall request the declaring establishment in writing to review the prices and provide explanation by the deadline specified in this Point;

g) Regarding re-declarations domestic drug prices, within 20 days from the day on which a response is received from the declaring establishment, the People's Committee of the province shall verify the prices and submit a report (Form No. 08 in Appendix VII enclosed herewith) to the Ministry of Health if the declaring establishment is able to prove that the re-declared prices are rational or adjusts the prices. If the declared/re-declared prices are not rational, the People's Committee of the province shall request the declaring establishment to review the prices and provide explanation by the deadline specified in this Point.

Within 05 working days from the day on which the report is received from the People's Committee, the Ministry of Health shall post it on its website.

Article 132. Responsibilities of drug pricing authorities for implementation of regulations on declaration and re-declaration of drug prices

1. Whenever a declared/re-declare drug price is found irrational, the competent authority specified in Clause 3 Article 131 of this Decree shall request the declaring establishment to review it and provide explanation.

2. During drug price inspection, the drug pricing authority or competent person shall take actions against drug-trading establishments that violate regulations on drug pricing or transfer the case to a competent authority for actions in the following cases:

a) Failure to declare/re-declare drug prices; failure to declare drug price adequately;

b) Failure to adjust drug prices at the request of a drug pricing authority;

c) Selling drugs at higher prices than the declared/re-declared prices applicable.

3. If a pharmacy business establishment has committed violations more than one time or has more than one unconformable product in a year, the drug pricing shall consider:

a) Rejecting applications for the certification of drug information or drug advertisement contents;

b) Rejecting receiving applications for permission to import drugs without the certificate of drug registration in Vietnam;

c) Rejecting receiving applications for issuance or renewal of the certificate of drug/medicinal ingredient registration.

4. The period over which the applications mentioned in Clause 3 of this Article are rejected is 3 – 12 months from the day on which the violation notice is issued by a competent authority.

Article 133. Responsibilities of pharmacy business establishments for implementation of regulations on declaration and re-declaration of drug prices

1. Every pharmacy business establishment shall implement regulations on declaration and re-declaration of drug prices, other regulations on drug pricing of this Decree and relevant legislative documents; take legal responsibility for the declared and re-declared prices, accuracy of the reports and information provided.

2. A pharmacy business establishment must not sell a drug before its price is declared by the manufacturer, outsourcing entity or importer and posted on the website of the Ministry of Health.

3. A pharmacy business establishment must not sell a drug wholesale or retail at a price higher than the price declared by the manufacturer, outsourcing entity or importer and posted on the website of the Ministry of Health.

4. In the cases where a competent authority requests a pharmacy business establishment to review a declared price which has been posted on the website of the Ministry of Health, it shall send a written response and relevant documents to the requesting authority to prove that the declared price is rational or adjust the price within 60 days from the day on which the request is issued. If no response is made by the aforementioned deadline, the price will be invalidated and removed from the website of the Ministry of Health.

Article 134. Rules for reviewing and publishing declared/re-declared drug prices

1. Rationality declared/re-declared drug prices shall be considered on the following basis:

a) The average drug price of similar domestic drugs or foreign drugs (if domestic drugs are not available) with the same technical criteria;

If the declared price is higher than the average price, the competent authority shall consider rationality of the price on the basis of the documents provided by the declaring establishment about the efficacy of the drug, the relation between price and efficacy, production technologies and pricing structure according to Form No. 09 and Form No. 10 in Appendix VII enclosed herewith, and relevant documents.

b) Changes in cost of ingredients, cost of fuel, exchange rates, and relevant costs in case of price increase. The competent authority shall consider the re-declared price on the basis of the documents provided by the declaring establishment about the changes in costs of ingredients, fuel, employment, exchange rates and relevant costs to explain the increase in price, provided the rate of increase in price does not exceed the rate of increase in the costs;

c) Import price and prime cost of the drug;

d) The relation between supply and demand, competitiveness, drug quality, availability of bioequivalence study results, other elements affecting the drug price and assurance of drug supply.

2. A declared drug price will be posted on the website of the Ministry of Health if the following criteria are satisfied:

a) The price is not higher than the declared price for the same product or another product that has a different trade name but has the same active ingredients, concentrations and dosage form of the same manufacturer and has been posted on the website of the Ministry of Health;

b) The price is not higher than the highest price for a drug that has the same active ingredients, concentrations and dosage form, technical criteria that has been declared over the last 03 years and has been posted on the website of the Ministry of Health, with account taken of possibility of price rise announced by General Statistics Office when such highest price is declared/re-declared;

c) If the drug whose price is declared does not have the same active ingredients, concentration and dosage form as those of any domestic drug, the declared import price or wholesale price is not higher than the average import price or wholesale price among ASEAN member states into which the drug is imported;

d) The import price for a foreign drug shall be consistent with the import price written on the customs declaration.

3. An increased price will be published if it satisfies the criteria specified in Clause 1b and Clause 1d of this Article. A decreased price will be posted on the website of the Ministry of Health.

4. In the cases where a declared drug price is not rational and not posted on the website of the Ministry of Health if the following criteria:

a) If the price is adjusted and the adjusted price satisfies the criteria in Clause 2 of this Article, it will be posted on the website of the Ministry of Health;

b) If the declaring establishment does not adjust the price and provide documentary explanation according to Clause 1 of this Article, the documents provided by the declaring establishment shall be the basis for determining whether the price is rational and posted on the website of the Ministry of Health.

5. Drug pricing authorities shall establish drug pricing department to review rationality of declared and re-declared drug prices.

6. The Minister of Health shall establish a drug pricing council, which consists of representatives of the Ministry of Health, the Ministry of Finance, Social Security Administration of Vietnam

and relevant organizations, to give counsel to the Minister of Health on review of drug prices and rationality of declared and re-declared drug prices in the following cases:

a) The concentrations/contents of the drug are different from those of other drugs posted on the website of the Ministry of Health;

b) The dosage form of the drug is different from that of other drugs posted on the website of the Ministry of Health and its price exceeds the highest price of the drug having the same active ingredients, concentrations and dosage form, technical criteria posted on the website of the Ministry of Health over the last 03 years;

c) The drug is a new drug.

d) The drug is on the list of drugs undergoing price negotiation, the drug is a proprietary drug, a drug manufactured according to EU-GMP or PIC/S-GMP standards by a manufacturer in a member state of the ICH or Australia, a drug manufactured according to WHO-GMP standards certified by the Ministry of Health of Vietnam and granted the certificate of free sale in a member state of the ICH or Australia with the following increase rates:

- Over 10% if the drug price is exceeding VND 5,000 but not exceeding VND 100,000 per smallest pack.

- Over 7% if the drug price is exceeding VND 100,000 but not exceeding VND 1,000,000 per smallest pack.

- Over 5% if the drug price is exceeding VND 1,000,000.

7. The Minister of Health shall specify the organizational structure and operation of the drug pricing council.

Section 2. LISTING OF DRUG PRICES, RETAIL SURPLUS APPLIED TO RETAILERS IN HEALTH FACILITIES

Article 135. Listing of drug prices

1. Responsibility to list drug price:

a) Drug wholesalers shall list the wholesale price of each drug at the wholesale stores;

b) Drug retailers shall list the retail price of each drug at the retail stores;

c) Drug wholesalers and retailers must not sell drugs at prices higher than listed prices.

2. Price listing:

a) Prices may be listed on a table or paper or in other forms as long as it is suitable and noticeable by buyers and the authorities;

b) The retail price must be printed, written or stuck on the primary package or secondary package of the drug, written on a board or paper or in other forms as long as it does not block the drug label, is suitable and noticeable by buyers and the authorities;

c) The listed currency shall be VND;

d) The listed price shall be inclusive of taxes and charges (if any).

Article 136. Retail margins applied to retailers in health facilities

1. The retail price equals (=) buying price according to the invoice plus (+) the retail margin percent rate multiplied by (x) buying price. Formula:

Retail price equals = buying price + retail margin percent (%) x buying price

2. The drug retailer within the premises of a health facility may only buy drugs from suppliers that are awarded contracts for supply of drugs to such health facility and drugs published on the website of the Ministry of Health over the last 12 months before the purchase. The buying prices are specified below:

a) The buying price for a drug on the list of drugs supplied by successful bidders bidding of the health facility must not exceed the successful bid at the same time;

b) The buying price for a drug that is not included in the list … of the health facility must not exceed the successful bid published on the website of the Ministry of Health over the last 12 months before the purchase.

3. Maximum retail margin percents applied to drug retailers in health facilities:

a) If the buying price is not exceeding 1,000 VND per smallest pack: 15%;

b) If the buying price is exceeding VND 1,000 but not exceeding VND 5,000 per smallest pack: 10%;

c) If the buying price is exceeding VND 5,000 but not exceeding VND 100,000 per smallest pack: 7%;

d) If the buying price is exceeding VND 100,000 but not exceeding VND 1,000,000 per smallest pack: 5%;

dd) If the buying price is exceeding VND 1,000,000 per smallest pack: 2%.

4. Definitions of smallest pack:

a) If the dosage form is tablets, pills or capsules, the smallest pack is a tablet, pill or capsule;

b) If the dosage form is liquid, the smallest pack is a pre-filled tube, bottle, jar or syringe;

c) If the dosage form is powder for solution for injection, the smallest pack is a pre-filled tube, bottle, jar, bag, or syringe;

b) If the dosage form is orally administered powder or granules, the smallest pack is a bag, bottle or;

dd) If the dosage form is cream, salve or gel for topical administration, the smallest pack is a tube or jar;

e) If the dosage form is transdermal patch, the smallest pack is a patch;

g) IF the dosage form is aerosol, the smallest pack is a bottle;

h) If the dosage form is a kit, the smallest pack is a kit.

Section 3. Bidding for drug purchase, drug price negotiation and measures for drug price stabilization

Article 137. Bidding for drug purchase

1. Bidding for drug purchase from state capital, health insurance fund, revenue from provision of medical services and other lawful sources of revenue of public health facilities shall comply with regulations of law on bidding, the principles in Clause 4 Article 7 and Clause 6 Article 107 of the Law on Pharmacy.

2. Criteria for determination or ration prices as the basis for promulgation of the list of domestic herbal ingredients that can be domestically obtained with adequate quantity and at rational prices:

a) The successful bid and actual selling prices of domestic herbal ingredients and imported herbal ingredients;

b) Fulfillment of Good Agricultural and Collection Practices (GACP) by domestic manufacturer of traditional drugs or herbal drugs; active ingredients of herbs and concentrations thereof.

3. The Minister of Health shall provide guidelines for bidding for the drugs specified in Clause 1 and Clause 2 of this Article; publish the list of proprietary drugs; promulgate regulations on purchase of proprietary drugs that are not on the list of drugs and herbal ingredients eligible for price negotiation specified in Article 138 of this Decree by selecting suitable contractors according to bidding laws.

Article 138. List of drugs and herbal ingredients eligible for price negotiation

The Minister of Health shall promulgate the list of drugs and herbal ingredients eligible for price negotiation according to Clause 6 Article 107 of herbal ingredients on the basis of counsel of the National Advisory Council for Drug Bidding.

Article 139. Drug price negotiation

Regulations of the Law on Pricing and its instructional documents shall apply to implementation of measures for drug price stabilization, power responsibility to implement of measures for drug price stabilization.

Chapter IX

IMPLEMENTATION CLAUSES

Article 140. Deadlines for obtaining the pharmacy practice certificate

1. From January 01, 2019, every chief pharmacist and person in charge of drug quality assurance of manufacturers of active ingredients other than sterile active ingredients shall have the pharmacy practice certificate. From January 01, 2021, every chief pharmacist and person in charge of drug quality assurance of manufacturers of excipients or softgel shells, manufacturers and processors of herbal ingredients or traditional ingredients shall have the pharmacy practice certificate.

2. From July 01, 2018, every person in charge of quality assurance of manufacturers of modern drugs, herbal drugs or traditional drugs, except manufacturers of traditional ingredients, vaccines and biologicals, shall have the pharmacy practice certificate.

3. From January 01, 2021, every person in charge of clinical pharmacology of the hospitals specified in Clause 3 Article 116 of the Law on Pharmacy shall have the pharmacy practice certificate.

4. From the effective date of this Decree, every chief pharmacist of pharmacy business establishments and person in charge of drug quality assurance of manufacturers of drugs or medicinal ingredients shall have the practising certificate, except for the cases specified in Clause 1 and Clause 2 of this Article.

5. Chief pharmacists of pharmacy business establishments and owners of drug retailing stores who have been granted the Certificate of eligibility for pharmacy business according to the Law on Pharmacy No. 34/2005/QH11 shall keep holding the position of chief pharmacist.

Article 141. Deadlines for fulfillment of Good Practice requirements by pharmacy business establishments

1. From the effective date of this Decree, manufacturers of modern drugs, herbal drugs, vaccines or biologicals, importers, exporters, wholesalers, retailers that are drugstores or dispensaries, providers of testing services, storage services, bioequivalence study services or clinical trial

services, manufacturers of medicinal ingredients that are sterile active ingredients shall fulfill corresponding Good Practice requirements, except for the cases specified in Clause 2 and Clause 5 of this Article.

2. From January 01, 2019, manufacturers of medicinal ingredients that are active ingredients other than sterile active ingredients mentioned in Clause 1 of this Article shall fulfill GMP standards.

3. From the effective date of this Decree, drug counters shall fulfill corresponding GPP requirements to be granted the Certificate of eligibility for pharmacy business.

From July 01, 2019, drug counters that have obtained the Certificate of eligibility for pharmacy business before the effective date of this Decree shall fulfill corresponding GPP requirements. By this deadline, the business conditions specified in the Certificate must be maintained.

4. From the effective date of this Decree, manufacturers of traditional drugs, except manufacturers of traditional ingredients, shall fulfill GMP requirements applied to traditional drugs to be granted the Certificate of eligibility for pharmacy business.

From July 01, 2019, manufacturers of orient drugs that have obtained the Certificate of eligibility for pharmacy business before the effective date of this Decree shall fulfill GMP requirements applied to traditional drugs. By this deadline, the business conditions specified in the Certificate must be maintained.

5. From January 01, 2021, manufacturers of excipients or softgel shells, manufacturers and processors of herbal ingredients or traditional ingredients shall meet corresponding GMP requirements.

Article 142. Deadlines for fulfillment of Good Practice requirements by non-commercial pharmacy business establishments

1. From the effective date of this Decree, non-commercial establishments specified in Clause 1a Article 35 of the Law on Pharmacy that have not fulfilled Good Practice requirements may operate within a scope corresponding to their fulfillment of Good Practice requirements and have to fulfill all corresponding Good Practice requirements by the following deadlines:

a) Establishments that store and supply vaccines shall fulfill corresponding Good Practice requirements from July 01, 2019;

b) Non-commercial pharmacy establishments other that those mentioned in Point a of this Clause shall fulfill corresponding Good Practice requirements from January 01, 2021.

2. From the effective date of this Decree, non-commercial establishments specified in Clause 1a Article 35 of the Law on Pharmacy that have just been inaugurated or changed its scope of operation shall fulfill corresponding Good Practice requirements.

Article 143. Transition clauses

1. Applications submitted according to regulations of the Law on Pharmacy No. 34/2005/QH11 and its instructional documents shall apply regulations thereof, except for applications that are submitted according to Clause 2 Article 115 of the Law on Pharmacy No. 105/2016/QH13 before the effective date of this Decree, unless the applicant wishes to apply regulations of the Law on Pharmacy No. 105/2016/QH13.

2. From July 01, 2019, the application for GMP inspection is mandatory when applying for renewal of the certificate of registration of imported drugs.

3. Licenses to export or import drugs/medicinal ingredients, orders for exported or imported drugs/medicinal ingredients issued according to the Law on Pharmacy No. 34/2005/QH11 and its instructional documents shall remain effective until their expiration dates.

Regarding drugs and medicinal ingredients mentioned in this Clause that are imported or exported and granted customs clearance before January 01, 2018, customs clearance documents shall comply with regulations of the Law on Pharmacy No. 34/2005/QH11 and instructional documents or regulations of this Decree from the effective date of this Decree.

4. Regarding drugs and medicinal ingredients that have been granted registration numbers or published before the effective date of this Decree, imported and granted customs clearance before January 01, 2018, customs clearance documents shall comply with regulations of the Law on Pharmacy No. 34/2005/QH11 and instructional documents or regulations of this Decree from the effective date of this Decree.

5. Establishments trading in drugs subject to special control shall apply the following regulations:

a) An establishment trading in drugs subject to special control specified in Clause 26a and Clause 26b Article 2 of the Law on Pharmacy may keep operating until the end of June 30, 2018. After this day, it shall obtain the Certificate of eligibility for pharmacy business that permits trading in drugs subject to special control in accordance with Section 4 Chapter III of this Decree if it wishes to keep operating;

b) An establishment trading in drugs subject to special control specified in Clause 26c and Clause 26d Article 2 of the Law on Pharmacy may keep operating until the expiration date written on its Certificate of eligibility for pharmacy business or the Certificate of Good Practice if the Certificate of eligibility for pharmacy business does not specifies an expiration date. After this day, it shall obtain the Certificate of eligibility for pharmacy business that permits trading in drugs subject to special control in accordance with Section 4 Chapter III of this Decree if it wishes to keep operating.

6. From July 01, 2018, retailers of drugs on the list of drugs restricted from retailing shall comply with regulations of Clause 2 Article 55 of this Decree.

7. From March 01, 2018, the certificate of registration or declaration of applied standards shall be obtained in accordance with Clause 1 and Clause 2 Article 93 of this Decree before herbal ingredients are sold in Vietnam.

8. From January 01, 2019, the certificate of registration shall be obtained in accordance with Clause 4 Article 93 of this Decree before softgel shells are sold in Vietnam. From January 01, 2021, the certificate of registration shall be obtained in accordance with Clause 3 Article 93 of this Decree before excipients are sold in Vietnam.

9. From January 01, 2018, drug retailers in the premises of health facilities shall comply with regulations of Article 136 of this Decree.

10. Certifications of drug information and certifications of drug advertisement contents issued before the effective date of this Decree shall remain effective until their expiration dates.

11. A foreign enterprise whose license to trade in drugs and medicinal ingredients in Vietnam or license to trade in vaccines, biologicals and ingredients thereof in Vietnam expires after December 31, 2016 may keep supplying drugs in Vietnam until the effective date of this Decree and may keep supplying medicinal ingredients in Vietnam until January 01, 2018.

12. From January 01, 2021, medicinal ingredients that are excipients for production of drugs under an application for registration of drugs having the certificate of drug registration in Vietnam may be imported under a published list in accordance with regulations of the Minister of Health without the import license.

Article 144. Effect

1. This Decree comes into force as of July 01, 2017.

2. The following regulations and documents are annulled:

a) Regulations on drug advertising in Article 3 of the Government's Decree No. 181/2013/ND-CP;

b) The Government's Decree No. 79/2006/ND-CP;

c) The Government's Decree No. 89/2012/ND-CP;

d) The Government's Decree No. 102/2016/ND-CP.

3. In the cases where a legislative document or regulation referred to in this Decree is changed or replaced, the newer one shall apply.

Article 145. Responsibility for organization of implementation of this Decree

1. The Minister of Health is responsible for providing guidance and organizing the implementation of this Decree.

2. Presidents of the People's Committees of provinces shall request Departments of Health to organize the receipt and verification of re-declarations of prices of domestic drugs submitted by establishments in their provinces.

3. Electronic licensing shall apply the roadmap established by the Minister of Health.

4. Ministers, Heads of ministerial agencies, Heads of Governmental agencies, the People's Committees of provinces are responsible for the implementation of this Decree./.

PP THE GOVERNMENT
THE PRIME MINISTER

Nguyen Xuan Phuc

GOVERNMENT

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No. 155/2018/ND-CP

Hanoi, November 12, 2018

DECREE

ON AMENDMENTS TO SOME ARTICLES RELATED TO BUSINESS CONDITIONS UNDER STATE MANAGEMENT OF THE MINISTRY OF HEALTH

Pursuant to the Law on organization of the Government dated June 19, 2015;

At the request of the Minister of Health;

The Government promulgates the Decree on amendments to some articles related to business conditions under state management of the Ministry of Health.

Chapter I

FOOD SAFETY

Article 1. Annulment of some documents and regulations on food safety The documents and regulations below are annulled:

1. Article 2, Chapter I, Chapter IV and Chapter V of the Government's Decree No. 67/2016/ND-CP dated July 01, 2016 on requirements for food manufacturing and trading under specialized management of the Ministry of Health.

2. Clause 2c, Article 5 of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 on elaboration of some articles of the Law on Food Safety (hereinafter referred to as "Decree No. 15/2018/ND-CP).

3. Circular No. 15/2012/TT-BYT dated September 12, 2012 of the Minister of Health providing food safety requirements applied to food manufacturers and sellers.

4. Circular No. 16/2012/TT-BYT dated October 22, 2012 of the Minister of Health on food safety conditions applicable to food manufacturers and sellers and food packing instruments and materials under the management of the Ministry of Health.

5. Circular No. 26/2012/TT-BYT dated November 30, 2012 of the Minister of Health on granting of food safety certificates for manufacturers and sellers of functional food, food with micronutrients, food additives and food processing aids; still mineral water, bottled water; food packaging instruments and materials under the management of the Ministry of Health.

6. Circular No. 30/2012/TT-BYT dated December 05, 2012 of the Minister of Health on food safety conditions applied to street food vendors.

7. Circular No. 47/2014/TT-BYT dated December 11, 2014 of the Minister of Health providing guidance on management of food safety of food and beverage establishments.

8. Clause 1 and 3, Article 14, clause 1 of Article 15 of Circular No. 43/2014/TT-BYT dated November 24, 2014 of the Minister of Health on management of functional foods.

Article 2. Amendments to some articles of the Government's Decree No. 67/2016/ND-CP dated July 01, 2016 on requirements for food manufacturing and trading under specialized management of the Ministry of Health

1. Article 1, Chapter I is amended as follows:

"This Decree deals with requirements for food manufacturing and trading, application documents and procedures for issuance of food safety certificates (hereinafter referred to as "Certificates") under specialized

management of the Ministry of Health. Such certificates are provided for the facilities manufacturing and trading the products and foods specified in Appendix II enclosed with the Circular 15/2018/ND-CP (hereinafter referred to as "food manufacturers and sellers) and for the food and beverage establishments. Requirements for food manufacturing and trading, application documents and procedures for issuance or re-issuance of food safety certificates for the eligible facilities applying GMP principle in producing health supplements, and requirements for food additive production and business must be satisfied according to the regulations in the Decree No. 15/2018/ND-CP."

2. Chapter II is amended as follows:

"Chapter II

FOOD SAFETY REQUIREMENTS FOR FOOD MANUFACTURERS AND SELLERS UNDER MANAGEMENT OF THE MINISTRY OF HEALTH AND THE FOOD AND BEVERAGE ESTABLISHMENTS

Article 4. Food manufacturers and sellers under management of the Ministry of Health

1. Comply with the regulations in Articles 19, 20, 21, 22, 25, 26 and 27 of the Law on Food Safety and the following specific requirements:

a. Food manufacturing process shall be designed to provide an operational flow through pattern and follow a sequence from raw materials to finished products.

b. Walls, ceilings and floors of the production, trading and storage areas must be water-resistant, without flaws and moisture-resistant.

c. Equipment and tools in direct contact with food must be easy to clean, not release harmful substances into the food and not contaminate it.

d. There must be boots, shoes or sandals for personal use in the food production area.

dd. There must be no invasion of harmful insects and animals in the food production area and the food and ingredient storage area; rodenticides, insecticides and pesticides must not be used within the food production area, as well as the food and ingredient storage area.

e. Do not display and sell chemicals for other purposes in the facilities trading additives and food processing aids.

2. The persons who directly produce and trade food must be trained and provided with knowledge on food safety, as well as be authorized by the facility owner and must not contract any of the following diseases during food manufacturing and trading process: cholera, hepatitis A and E, skin infection, tuberculosis and diarrhoea epidemic.

Article 5. Food and beverage establishments

1. Comply with the regulations in Articles 28, 29 and 30 of the Law on Food Safety and the following specific requirements:

a. Carry out three-step food checking and store food sample according to the guidelines of the Ministry of Health.

b. Equipment and vehicle used for food transport and preservation must ensure hygiene and must not contaminate such food.

2. The person in charge of the processing of food must be trained in food safety, and confirmed by the establishment owner that he/she does not contract any of the following diseases during food manufacturing and trading process: cholera, hepatitis A and E, skin infection, tuberculosis and diarrhoea epidemic."

3. Chapter III is amended as follows:

"Chapter III

APPLICATION DOCUMENTS AND PROCEDURES FOR AND AUTHORITY TO ISSUE FOOD SAFETY CERTIFICATES FOR THE FOOD MANUFACTURING FACILITIES UNDER MANAGEMENT OF THE MINISTRY OF HEALTH AND THE FOOD AND BEVERAGE ESTABLISHMENTS

Article 6. Application documents and procedures for and authority to issue the Certificates

1. Authority to issue the Certificate:

The Ministry of Health shall issue the Certificates for the facilities manufacturing different types of foods under its management or decentralize or authorize another unit to issue such Certificate according to the regulations in clause 5, Article 37 and in Appendix II of Decree No. 15/2018/ND-CP.

2. The application for the Certificate must be made in accordance with the regulations in clause 1, Article 36 of the Law on Food Safety and must contain:

a. An application form for the Certificate using form No.01 in Appendix I hereto.

b. A copy of the Business Registration Certificate or the Enterprise Registration Certificate which specifies the business suitable to the types of food manufactured by the facility (must be confirmed by such facility).

c. A list of food producers and food service providers who are trained and provided with food safety knowledge. Such list must be confirmed by the facility owner.

3. The procedures for issuance of the Certificate must be carried out in accordance with clause 2, Article 26 of the Law on Food Safety and the following requirements:

a. Send the application specified in clause 2 of this Article through the online public service system or by post or in person at the receiving authority.

b. If the application is not satisfactory, the receiving authority shall send a written notification to the facility within 05 working days from the date on which the complete application is received.

After 30 days from the date on which such notification is received, if the facility does not provide additional documents and complete the application as requested, such application will be invalidated. If needed, organizations and individuals shall submit new application to receive the Certificate.

c. If the application is satisfactory, within 15 working days from the date on which the complete application is received, the receiving authority shall establish an appraisal team or authorize another appraisal unit to write an appraisal document using form No. 02 in Appendix hereto. If the receiving authority authorizes its inferior competent agency, it must provide an authorization document.

The appraisal team, which receives a Certificate from the competent agency or authorized by it to carry out the appraisal tasks, shall be established with 03 to 05 members. At least 03 members must carry out food safety tasks (may invite experts who are suitable for the food production of the facility to participate in the appraisal).

d. If the appraisal results satisfy the requirements, within 05 working days from the date on which such results are received, the receiving authority shall issue the Certificate by using form No. 03 in Appendix hereto.

dd. If the appraisal results are not satisfactory and the weaknesses are rectifiable, the appraisal team must specify the necessary rectifications and allow a period of 30 days for rectification.

After receiving the rectification report from the facility, within 05 working days, the appraisal team must evaluate such rectification result and write the conclusion in the appraisal document. If the rectification result is satisfactory, the facility will be granted a Certificate according to point d of this clause. If the rectification result is not satisfactory, the receiving authority shall send a written notification of the appraisal result to the facility and the local regulatory agency.

e. If the appraisal result is not satisfactory, the receiving authority shall send a written notification to the local regulatory agency for it to carry out supervision and request the facility not to operate until such facility receives the Certificate.

4. If the name of the enterprise, the facility owner or the address is changed without changing the location and the food manufacturing and service process, and the Certificate does not expire, the facility must write a notification about the adjusted Certificate and attach with it a legal copy specifying such changes, then send both of them to the receiving authority through an online public service system or by post or in person.

5. Any certificate issued before this Decree comes into effect may be used until its expiry date.”

Article 3. Amendments to some Articles of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 providing guidelines on implementation of some articles of the Law on Food Safety.

1. Point a, clause 2, Article 5 is amended as follows:

a. Organizations or individuals shall announce the product declaration through mass media or post it on their websites or publicly post it up at their offices and make public through the food safety data system (if such system has not been established, organizations or individuals shall send 01 application by post or in person to the regulatory agency assigned by the People's Committees of provinces and central-affiliated cities (hereinafter referred to as "receiving authority"), in order for it to retain the application documents and post the self-declaration, including names of organizations or individuals and product information, on its website. If the organizations or individuals have more than 02 facilities which manufacture the same product, they shall only submit the application at the regulatory agency in their locality where the manufacturing facility is selected by them. After selecting the regulatory agency for submitting the application, the next self-declared documents must be submitted at the previously selected agency.)

2. Clause 6, Article 40 is amended as follows:

"6. Issue the Certificate of Eligibility for Food Safety to the facilities producing bottled water, still mineral water, ready-to-use ice and ice used for food processing and the facilities producing supplement food, medical food, food for special dietary uses, nutrition products used for children of 36 months old, additives, food processing aids and food micronutrients, other food manufacturing facilities which are not specified in the list of the Ministry of Industry and Trade and the Ministry of Agriculture and Rural Development, and the food and beverage establishments.

Chapter II

PHARMACEUTICAL PRODUCTS

Article 4. Annulment of the following regulations of the Government's Decree No. 54/2017/ND-CP dated May 08, 2017 providing guidelines on some articles on methods for implementing the Law on Pharmacy

1. Clause 1c and Clause 1g, Article 3.

2. Clause 1b, Article 4.

3. Articles 9, 10, 11, 12 and 13.

4. Clause 1, clause 3 and clause 4, Article 14.

5. Clause 4, Article 19.

6. Points a, b, c, d, dd and e, clause 2, Article 21.

7. Clause 2, Article 23.

8. Article 24.

9. Article 25.

10. Article 26.

11. Article 27.

12. Clause 1, Article 28.

13. Additional requirements: specialized technical documents and human resource documents according to the Good Distribution Practices. Such documents must be provided by the facility registering for the Certificate of Eligibility for Pharmacy Business that allows sale of drugs and medicinal ingredients imported to retailers and health facilities specified in Clause 2b, Article 32.

14. Clause 3, Article 32.

15. Clause 5, Article 38.

16. Clause 2, Article 40.

17. Clause 1d; Clause 2dd; Clause 3b and 3c; Clause 4d; Clause 5c; Clause 7d; Clause 10b and 10d; Clause 11b and 11c, Article 43.

18. The storage facility and separate areas must have solid walls and ceilings which are made from solid materials specified in Clause 1a, Clause 2a, Clause 5a and Clause 7a, Article 43.

19. Clause 1c; Clause 2c; Clause 3b; Clause 4b; Clause 5; Clause 6c; Clause 7; Clause 12b, Article 44.

20. Clause 2, Article 49.

21. Article 50.

22. Article 52.

23. Clause 1b, Article 53.

24. Clause 2b and 2c, Article 58.

25. Clause 3c, Clause 4a, and Clause 5a, Article 60.

26. Clause 2c, Clause 4b, Article 62.

27. Clause 1c, Clause 2i, Article 65.

28. A report on the pharmacy business results must be included in the application for Drug Import License. The licensed drugs are specified in the List of Inhibited Drugs and Active Ingredients in certain fields mentioned in Clause 2g, Article 65, Clause 2h, Article 66, Clause 2e, Article 69.

29. The drug importer must include a GMP Certificate in the application for Drug Import License as specified in Clause 2h, Article 65, Clause 2i, Article 66, Clause 2g, Article 69, Clause 2h, Article 71, Clause 2i, Article 72, if the Certificate of Pharmaceutical Products confirms that the importer satisfies the GMP principles and standards.

30. Clause 2k, Article 66.

31. Clause 1a; Clause 2, Article 68.

32. If biologicals are imported, there must be an original copy of the foreign exporter and manufacturer's commitment to quality, safety and efficacy as specified in Clause 3e, Article 68.

33. Clause 2h, Article 69.

34. Clause 2b, Article 70.

35. Clause 2i, Article 71.

36. Clause 2dd, Article 73.

37. Clause 1b, Article 74.

38. Clause 3b and 3d, Article 75.

39. If drugs are imported as specified in Article 72, there must be a separate purchase order as mentioned in Clause 1, Article 76.

40. Clause 3b, Article 76.

41. The drug labels must be consularly legalized according to Clause 3d, Article 76.

42. The Certificate of Pharmaceutical Products must confirm that the drugs are licensed in the country in which the Certificate is issued, according to Clause 4dd, Article 76.

43. Clause 2, Article 78.

44. Clause 2b, Article 82.

45. Clause 1b and 1c, Article 84.

46. Clause 2dd, Article 85.

47. Clause 1b, Article 86.

48. The facility which provides controlled drugs imported for testing, research and production of exported drugs as specified in Article 80; provides imported medicinal ingredients specified in Article 82, 83, 84, 85; and drugs as emergency aid or humanitarian aid must implement the regulations specified in clause 15, Article 91.

49. If the drugs are imported in accordance with the regulations in Clause 1a and 1b, Article 72, the importer must submit an original copy or a certified true copy of the testing certificate of the batch of imported drugs/medicinal ingredients.

50. There must be a copy bearing the importer's seal of the authorization letter or the seller's license or the certificate of partnership which are specified in point d, clause 2, Article 92, with regards to drugs as emergency aid or humanitarian aid.

51. There must be a copy bearing the importer's seal of the authorization letter or the seller's license or the certificate of partnership which are specified in Clause 4dd, Article 92, with regards to imported drugs specified in Article 68 and 72, controlled drugs imported for production of exported drugs specified in Article 80, imported medicinal ingredients specified in Article 84, 85.

52. Clause 1a, 1c, 1d and the sentence "Minister of Health shall compile the list of herbal ingredients for which registration is mandatory" in Article 93.

53. Clause 2d and 2dd, Clause 3b and 3c, Clause 4c, Article 98.

54. Clause 2h, Article 100.

55. Procedures for re-exporting medicinal ingredients specified in Clause 4, Article 104.

56. Clause 2 and Clause 3, Article 107.

57. Clause 1dd; Clause 2dd, Article 108.

58. Article 109.

59. Article 110.

60. Clause 4, Article 111.

61. Article 114.

62. Article 115.

63. Clause 2 and clause 3, Article 120.

64. Clause 1dd and Clause 2dd, Article 121.

65. Article 122.

66. Article 123.

67. Clause 4, Article 124.

68. Clause 4b, Article 130.

69. Clause 4dd, 4e, 4g of Article 131.

70. Clause 2, clause 3, clause 4, Article 134.

71. Deadlines for the person in charge of drug quality assurance of the manufacturer to obtain the pharmacy practice certificate are specified in clause 1, clause 4, Article 140.

72. Forms No. 08, 09, 10, 11, 13, 14, 14, 16 and 17 in Appendix I.

73. Sentence 120 and 159 of Appendix V.

74. Forms No. 03 and 04 in Appendix VI.

Article 5. Amendments to some articles of the Government's Decree No. 54/2017/ND-CP dated May 08, 2017 providing guidelines for some articles on implementation of the Law on Pharmacy

1. Clause 2, Article 2 is amended as follows:

“2. Pharmaceutical conference means a conference where a drug is introduced or drug-related issues are discussed among medical or pharmaceutical practitioners.”

2. Clause 1a, Article 3 is amended as follows:

“a. The application form for the Pharmacy Practice Certificate must be made by using form No.02 in Appendix I hereto."

3. Clause 1a, Article 4 is amended as follows:

“a. The application form for re-issuance of the Pharmacy Practice Certificate must be made by using form No. 04 in Appendix I hereto."

4. Clause 1a, Article 5 is amended as follows:

"a. Application form for amendments to the Pharmacy Practice Certificate must be made by using form No. 05 in Appendix I hereto.”

5. Clause 3a and 3c, Article 6 are amended as follows:

a. Point a is amended as follows:

“a. The Pharmacy Practice Certificate must be issued within 15 days from the date on which the application is received; if the application is rejected, provide explanations in writing."

b. Point c is amended as follows:

“c. Re-issue or amend the Pharmacy Practice Certificate within 05 working days from the date on which the application is received; if the application is rejected, provide explanations in writing.

6. Article 8 is amended as follows:

“Article 8. Institutions offering refresher training courses in pharmacy

1. The institutions offering refresher training courses must be one of the following organizations: a vocational education institution licensed to provide training in medicine or pharmacy; an education institution licensed to provide training in health science; a research institute licensed to provide training in medicine or pharmacy; an institution licensed to provide training for health workers or a pharmacy association.

2. The institutions providing refresher training courses in pharmacy must develop their training programs with the following principal contents:

a. The training contents include:

- Professional knowledge.

- Pharmacy law and management.

b. Duration of the refresher course: at least 08 hours."

7. Clause 1a and Clause 2a, Article 15 are amended as follows:

Clause 1a is amended as follows:

“a. Inspect and supervise the refresher training institutions specified in Article 8 hereof"

b. Clause 2a is amended as follows:

“a. Inspect, supervise and cooperate with the pharmacy refresher training institutions in its provinces in providing refresher trainings in pharmacy.

8. Clause 2, Article 21 is amended as follows:

"2. The specific internship durations at the pharmacy which comply with the regulations in Articles 15, 16, 17, 18, 19, 20, 21 and 22 shall be reduced for:

a. 3/4 of the duration for holders of PhDs or SL2 degrees in the field related to the specific internship.

b. 1/2 of the duration for holders of Master Degrees or SL1 degrees in the field related to the specific internship.”

9. Clause 3, Article 28 is amended as follows:

“3. The Ministry of Health shall assign the eligible examination centers specified in Article 23 hereof to administer tests and issue the Pharmacy Practice Certificate if there are no centers carrying out such tasks.”

10. Article 31 is amended as follows:

a. Clause 5b, Article 31 is amended as follows:

"b. The retailer has an isolated and fixed store which is firmly built; the store area is suitable to its scope of business, located in a high, dry, airy and safe area, at an adequate distance from sources of pollution."

b. Clause 5c, Article 31 is amended as follows:

“The storage area and equipment must satisfy the storage requirements written on the labels.

Toxic herbal ingredients (if any) shall be displayed and stored in a separate area. Otherwise, they must be separated from other herbal ingredients and labeled as “dược liệu độc (“toxic ingredients”) to avoid confusion.

The retailer of herbal drugs, traditional drugs or herbal ingredients shall have suitable storage areas to store such drugs and ingredients.”

11. Clause 2a, Article 32 is amended as follows:

“a. If the applicant is a manufacturer of drugs or medicinal ingredients: documents about the location, factory, testing laboratory, storage area, auxiliary systems, machinery for manufacturing and storing drugs, quality control system, documents about technologies and personnel according to Good Manufacturing Practice (GMP) requirements applied to drugs and medicinal ingredients.

If the applicant applies for a Certificate of Eligibility for Pharmacy Business that allows sale and delivery of drugs or medicinal ingredients manufactured by the applicant to wholesalers, retailers and health facilities, documents on technologies and personnel according to GPD requirements applied to drugs and medicinal ingredients are required, unless such products are delivered at the storage facility of the applicant.

12. Heading, Clause 3a and Clause 4 of Article 33 are amended as follows:

“3. The receiving authority shall:

“a. Issue the Certificate of eligibility for pharmacy business within 20 days from the date on which the application is received without a site inspection at the applicant’s premises, if the applicant’s facilities and personnel are conformable with relevant Good Practice requirements.

4. If the application is deemed unsatisfactory according to Clause 3a of this Article, within 07 working days from the date on which the application is received, the receiving authority shall request the applicant in writing to complete the application and specify necessary additional documents.”

13. Clause 3a, Article 34 is amended as follows:

“a. Re-issue or adjust the Certificate of Eligibility for Pharmacy Business within 15 days from the date on which the application is received, in the case mentioned in Clause 2a and Clause 3, Article 36 of the Law on Pharmacy.”

14. Clause 3, Article 40 is amended as follows:

“3. Within 05 working days from the date on which the notification from the applicant is received, the Department of Health shall publish information about the mobile drugstore on its website and inform the district health offices for supervision and inspection.”

15. Clause 2, Article 41 is amended as follows:

a. The heading of clause 2, Article 31 is amended as follows:

“2. Publication of the list of drugs and active ingredients banned from certain fields:

b. Clause 2b, Article 41 is amended as follows:

“b. After receiving the list of banned substances from the ministries and ministerial agencies, the Ministry of Health shall promulgate the list of banned drugs and active ingredients in certain fields on its website."

16. Clause 2, Article 42 is amended as follows:

“2. If there are no establishments trading controlled drugs in the province, the Department of Health shall appoint a wholesaler or a retailer to conduct such trading or the pharmacy department of the health facility to sell the controlled drugs in order to ensure adequate supply of drugs for patients."

17. Clause 4a, Article 43 is amended as follows:

“a. Have a separate storage facility or area that meets GSP requirements. Such separate storage facility or area must have robust doors with locks to store narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors.”

18. Clause 6, Article 43 is amended as follows:

“6. An exporter, importer or wholesaler of radiopharmaceuticals shall have a documentary management system according to the regulations of the Minister of Health.”

19. Clause 8a, Article 43 is amended as follows:

“a. The narcotic drugs, psychotropic drugs or precursors must be stored in a separate and locked cabinet or drawer.”

20. Clause 12, Article 43 is amended as follows:

“12. A provider of clinical trial services, bioequivalence study services, controlled drug testing services, except for those mentioned in Clause 11 of this Article, shall store the narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors, combination drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors in a separate and locked area or separate and locked cabinets or drawers.”

21. Article 44 is amended as follows:

Change the phrase “02 years” with the phrase “12 months” in clauses 1, 2, 4, 6 and 10.

22. Clause 9, Article 44 is amended as follows:

“9. As for the retailer of radiopharmaceuticals: the person responsible for retailing such drugs must have at least an associate degree in pharmacy.”

23. Clause 2c, Article 46 is amended as follows:

“c. An establishment that has the Certificate of Eligibility for Pharmacy Business that allows export, import and wholesaling of drugs may only sell drugs to other establishments that have such Certificates, health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy, drugstores nationwide; and may select 01 wholesaler in a province to sell all of its products.”

24. Clause 2d, Article 46 is amended as follows:

"d. A wholesaler may only sell drugs to health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, institutions providing training in medicine or pharmacy, other non-commercial pharmacy establishments and drugstores in the same province."

25. Clause 2dd, Article 46 is amended as follows:

"dd. Health facilities, rehabilitation centers and establishments providing opioid substitution treatment may purchase drugs from the establishments specified in Points a, b, c, d of this Clause based on their bidding results or according to the bidding plan approved by the competent authority.

26. Clause 2a, Article 48 is amended as follows:

“a. The application shall be sent in person or by post to the Ministry of Health if the applicant is a manufacturer, exporter or importer, or to the Department of Health of the same province if the applicant is a pharmacy business establishment other than the aforesaid entities; or at the Military Medicine Department (Ministry of National Defense) if the applicant is under the management of such Ministry.

27. Clause 2a and 2d, Article 48 are amended as follows:

“a. If the application is satisfactory, the receiving authority shall issue a written permission for destruction within 20 days from the date on which the application is received.

d. If the application is not satisfactory, the receiving authority shall request the applicant in writing to complete the application within 20 days from the date on which the application is received."

28. Clause 3, Article 48 is amended as follows:

“3. The destruction of narcotic drugs, psychotropic drugs, precursor drugs or medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors may only be carried out after receiving the written permission from the Ministry of Health or the Department of Health in the same province, or from the Military Medicine Department (Ministry of National Defense).”

29. Clause 4b, Article 48 is amended as follows:

“b. The destruction must be witnessed by representatives of the Department of Health of the same province or the Military Medicine Department (Ministry of National Defense) and be recorded using form No. 16 in Appendix II hereto.

30. Clause 4c, Article 48 is amended as follows:

“17. Within 10 days from the date on which the destruction is done, a destruction report (using form No. 17 in Appendix II) enclosed with a destruction record shall be submitted to the Ministry of Health or Department of Health or Military Medicine Department (Ministry of National Defense).”

31. Clause 1, Article 49 is amended as follows:

“19. Documents proving that the establishment has taken measures to ensure security and prevent loss of controlled drugs according to Form No. 18 in Appendix hereto."

32. Article 51 is amended as follows:

"Article 51. Procedures for issuance of the Certificate of Eligibility for Pharmacy Business to traders of controlled drugs

1. The procedures for issuance of the Certificate of Eligibility for Pharmacy Business to the traders of controlled drugs shall be completed in accordance with Article 33 hereof.

2. If the trader already has such Certificate or satisfies the Good Practice requirements according to Article 33 of the Law on Pharmacy and requests for the permission for trading controlled drugs, the receiving authority shall only evaluate the application mentioned in Article 49 of the Decree No. 54/2017/ND-CP.

33. Article 53 is amended as follows:Clause 2a is amended as follows:

“a. 01 order for medicinal ingredients that contain narcotic active ingredients, psychotropic active ingredients or drug precursors using form No. 19 in Appendix II hereto.

b. Clause 3b is amended as follows:

“b. 01 sale order for medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors using form No. 19 in Appendix II hereto."

34. Clause 1, Article 54 is amended as follows:

a. Clause 1b is amended as follows:

"b. Department of Health of the same province if the applicant is a drug wholesaler, a retailer, a private health facility, a research and testing institution, an institution providing training in medicine or pharmacy, a rehabilitation center, an establishment providing opioid substitution treatment and a non-commercial pharmacy establishment.”

b. Clause 1c is added as follows:

“c. Military Medicine Department (Ministry of National Defense) if the applicant is under the management of the Ministry of National Defense."

35. Article 65 is amended as follows:

a. Clause 1a and 1b, Article 65 are amended as follows:

"a. The drug is licensed in one of the following country: manufacturing country, reference country that is a member state of The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) or Australia;

b. The drug is used for the following cases:

- The drug is specified in the guidelines for disease diagnosis, prevention and treatment which are promulgated and approved by the Ministry of Health.

- The drug is used for emergency of poison control and as an anti-rejection medication.

- The drug is used for diagnosis, prevention or treatment for class-A communicable disease, cancers, HIV/AIDS, hepatitis, tuberculosis, malaria; other diseases announced by the Minister of Health."

b. Clause 2d and 2e, Article 65 are amended as follows:

"d. The original copy of 01 set of samples of the label and package insert from the drug production country or the exporting country, unless such package insert or the summary of product characteristics is attached to the Certificate of Pharmaceutical Product.

e. Clinical data about the safety and efficacy of the drug according to the regulations on drug registration of the Minister of Health.

Documents specified in this point are not required to be submitted in cases where the drug are licensed for import according the regulations in this Article and no changes are made to the information related to the indication, dosage and user.

36. Clause 2c, 2d and 2e, Article 66 are amended as follows:

"c. Quality documents according to the regulations of the Minister of Health on the use of ASEAN Common Technical Dossier (ACTD) in drug registration or quality standards and results of bioequivalence study according to clause 7, Article 76 hereof."

d. The original of 01 set of samples of the label and package insert from the drug production country or the exporting country, unless both of them or the summary of product characteristics are attached to the Certificate of Pharmaceutical Product.

e. Clinical document if required by the regulations of the Minister of Health on drug registration.

Documents specified in this point are not required to be submitted in cases where the drug has been licensed for import according the regulations in this Article and no changes have been made to the information about the indication, dosage and user."

37. Clause 2c, Article 67 is amended as follows:

"c. An original copy or a copy bearing the issuer's seal of the written request or approval issued by any of the competent authorities specified in Clause 1a, 1b or 1c of this Article which specifies: the active ingredients of the modern drug or biologicals or herbal ingredients of the herbal drug or traditional drug, dosage form, concentration of active ingredients of the modern drug or biologicals or quantity of herbal ingredients of the herbal drug or traditional drug, package contents, manufacturer and manufacturing country."

38. Article 68 is amended as follows:

Clause 1b, Article 68 is amended as follows:

"b. The drug does not satisfy the treatment requirements and is:

- Used for emergency of poison control and as anti-rejection medication.

- Included in the List of Rare Drugs.

- Specified in the guidelines on prevention and treatment for anaphylactic shock. Such guidelines are promulgated and approved by the Ministry of Health.

- Used for a specific patient who is receiving treatment at the health facility for: class-A communicable disease, cancer, HIV/AIDS, tuberculosis, malaria and other fatal diseases announced by the Minister of Health."

b. Clause 3c, Article 68 is amended as follows:

"c. An original copy of the document of the health facility which contains the reason for importing the drug, the quantity of patients who need to use it and quantity of drug needed, as well as the commitment to assume responsibility for the use of the imported drug. The document shall be enclosed with the original copy or the copy bearing the seal of the health facility, as well as the minutes of meeting of the Drug and Treatment Council about the import demand of such drug. If such Council does not exist or the drug used for the emergency of poison control is needed for patients who are clearly listed by the health facility, then the minutes of meeting are not required."

c. Clause 3g, Article 68 is amended as follows:

"g. The drug provider is not required to implement the regulations in clause 15, Article 91 hereof, if it has a copy of the Pharmacy Business License which is issued by the competent agency of the home country and is certified and consularly legalized according to the regulations."

39. Clause 2d, Article 69 is amended as follows:

"d. The original copy of 01 set of samples of the label and package insert from the drug production country or the exporting country, unless both of them are attached to the Certificate of Pharmaceutical Product."

40. Article 71 is amended as follows:

Clause 1b, Article 71 is amended as follows:

"b. The drug is licensed in one of the following countries: the manufacturing country, the member state of the ICH or Australia."

b. Clause 2c, 2d and 2dd, Article 71 are amended as follows:

"c. Quality documents according to the regulations of the Minister of Health on the use of ACTD in drug registration or quality standards and results of bioequivalence study according to Clause 7, Article 76 hereof."

d. Clinical document if required in some cases by the regulations of the Minister of Health on drug registration.

The documents specified in this point are not required to be submitted in cases where the drug has been licensed for import according the regulations in this Article and no changes have been made to the information about the indication, dosage and user.

dd. The original copy of 01 set of samples of the label and package insert from the drug production country or the exporting country, unless both of them are attached to the Certificate of Pharmaceutical Product."

41. Article 72 is amended as follows:

a. Clause 1, Article 72 is amended as follows:

"1. The import of such drug shall only be licensed in the manufacturing country or the country which is the member state of ICH or Australia, when:

a. The drug as an emergency aid is carried by the foreign humanitarian medical team to use for their humanitarian medical services.

b. The drug as an emergency aid is used for treating a specific patient who is required to stay in the health facility.

c. The drug as an emergency aid is used for the state medical programs or projects.

d. The drug as an emergency aid is not specified in points a, b and c of this clause and is not narcotic drug, radiopharmaceutical or vaccine."

b. Points a, c, dd, e, g, h and k, clause 2, Article 72 are amended as follows:

"a. The import order using form No. 24, 25 or 26 in Appendix III hereto.

c. The original copy or the certified true copy of the written approval issued by a regulatory agency for the use of foreign drugs as an emergency aid in state medical programs or projects; if the drugs are imported, the

original copy of the written approval issued by the regulatory agency for humanitarian medical services is required, according to Clause 1a of this Article.

dd. Quality documents according to the regulations of the Minister of Health on the use of ACTD in drug registration or quality standards and results of bioequivalence study according to clause 7, Article 76 hereof."

e. Clinical document if required in some cases by the regulations of the Minister of Health on drug registration.

The documents specified in this point are not required to be submitted in cases where the drug has been licensed for import according the regulations in this Article and no changes have been made to the information about the indication, dosage and user."

g. The original of 01 set of specimens of the label and package insert from the drug production country or the exporting country, unless both of them are attached to the Certificate of Pharmaceutical Product."

h. 02 sets of samples of the label and package insert in Vietnamese which bear the importer's seal.

k. The documents specified in points d, dd, e, g, h and i are not required in cases where the drug is imported in accordance with Clause 1a and 1b of this Article. However, there must be a written commitment about the drug licensed in the manufacturing country or the member state of ICH or Australia. Also, the written commitment of the facility receiving humanitarian aids must clearly specify the list of patients in need of the drug according to Clause 1b of this Article."

42. Article 76 is amended as follows:

a. Clause 3d is amended as follows:

"d. The package insert of the drug licensed in the manufacturing country or the exporting country, except for the cases specified in Clause 2d, Article 66, Clause 2d, Article 69, Clause 2dd, Article 71 and Clause 2g, Article 72 hereof."

b. The heading of clause 5, point b and c, clause 5, Article 76 are amended as follows:

"5. The samples of the label and package insert of a drug licensed in the manufacturing country or the exporting country must satisfy the following requirements, except the drugs that have the same trade name, active ingredients, concentration and dosage form as those of a proprietary drug having the certificate of drug registration in Vietnam, are manufactured by the same manufacturer of the proprietary drug or by an authorized manufacturer and are sold at a lower price than that of the proprietary drug sold in Vietnam according Article 70 hereof:

b. The sample of the package insert bearing the seal of the competent authority which issues the Certificate of Pharmaceutical Product in the manufacturing country or the exporting country, except for the cases specified in Clause 2d, Article 66, Clause 2d, Article 69, Clause 2dd, Article 71 and Clause 2g, Article 72.

c. The original of the sample of package insert undergoing consular legalization."

c. Clause 5d, Article 76 is amended as follows:

"d. The sample of the label specified in Clause 2d, Article 65; samples of the label and the package insert which are specified in Clause 2d, Article 66, Clause 2d, Article 69, Clause 2dd, Article 71 and Clause 2g, Article 72 must bear the seal of the manufacturer or the owner of the product or product license (stamped on the Certificate of Pharmaceutical Product) and the importer."

d. Clause 7, Article 76 is amended as follows:

"7. Quality standards and results of the bioequivalence study:

a. Must provide copies which bear the seal of the manufacturer or the owner of the product or product license (stamped on the Certificate of Pharmaceutical Product) and of the importer.

b. Results of bioequivalence study shall only be submitted if required by the regulations of the Minister of Health on drug registration.

The documents specified in this point are not required in cases where drugs are produced and licensed (specified on the Certificate of Pharmaceutical Product) in the country that is the permanent member or founder of ICH or Australia."

43. Article 77 is amended as follows:

a. Heading of Clause 1, Clause 1g, Article 77 are amended as follows:

"1. In cases of drug import specified in Articles 65, 66, 69, 71, Clause 1c and 1d, Article 72 hereof:

g. In cases where drugs imported for provision of humanitarian medical services are approved by the competent authority and the documents specified in Points d, dd, e, g, h, i, clause 2, Article 72 hereof are not mentioned but the drugs are essential for the disease treatment, the Minister of Health shall consider approving the application on the basis of counsel given by the certification advisory council."

b. Heading of Clause 3, Article 77 is amended as follows:

"3. In cases of drug import specified in Clause 1b and 1c, Article 68, Article 70, Clause 1a and 1b, Article 72, 73, Clause 1, Article 74 hereof."

c. Clause 4e, Article 77 is amended as follows:

"e. Within 03 months, from the date on which the additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforesaid deadline or the application is not satisfactory within 04 months, from the first time it is submitted, such application will be rejected."

44. Clause 3, Article 78 is amended as follows:

a. The heading of Clause 3, Article 78 is amended as follows:

"3. As for drugs used for emergency treatment and poison control, and vaccines used in some special cases with limited amounts and other drugs licensed for import according to Clause 1b and 1c, Article 68 hereof:"

b. Clause 3c is added to Article 78 as follows:

"c. The regulations in clause 4, Article 103 of the Law on Pharmacy are not required to be implemented. The importer of drugs requiring cold or deep freezing storage shall retain the data sheets which record the storage conditions (cold chain) during the transport process of imported batch of drugs (bearing the seal of the importer). Such storage conditions are recorded by using the temperature data logger and from the freeze indicator (if any).

45. Clause 3, Article 79 is amended as follows:

"3. For the drugs specified in the list of drugs and active ingredients banned from certain fields, a written explanation enclosed with proof documents are required if the total quantity of imported drugs and remaining drugs specified in the order form and the quantity of drugs to be imported according to the issued Import License

46. Points a, d, dd, e, clause 1, Article 80 are amended as follows:

"a. 01 original of the purchase order using form No. 35 or 36 in Appendix III hereto.

d. A report on the use of medicinal ingredients other than toxic medicinal ingredients using form No. 37 in Appendix II hereto, and a report on the sale of semi-finished drugs produced from medicinal ingredients other than toxic medicinal ingredients, using form No. 38 in Appendix III hereto.

The sale report specified in this point is not required in cases where medicinal ingredients and reference materials are imported for testing or research.

dd. The plan for production, use or sale of imported medicinal ingredients and the plan for sale of semi-finished drugs produced from imported medicinal ingredients other than toxic medicinal ingredients.

The sale report specified in this point is not required in cases where semi-finished drugs produced from medicinal ingredients and reference materials which are imported for testing or research.

For the imported drugs specified in the list of drugs and active ingredients banned from certain fields, a written explanation enclosed proof documents are required if the total quantity of imported drugs and

remaining drugs specified in the order form and the quantity of imported ingredients which have been granted the Import License exceed 150% compared to the total demand of trading and use of drugs in the previous year, by the time of making the order, then proof documents shall be provided.

e. If medicinal ingredients and reference materials are imported for testing or research; toxic medicinal ingredients and active ingredients specified in the List of Drugs and Active Ingredients Banned from Certain fields are imported for production of exported drugs; the medicinal ingredients are granted the certificate of registration in Vietnam or the ingredients on the list of active ingredients, excipients or semi-finished drugs used for production of drugs are granted the certificate of drug registration in Vietnam, the documents specified in Points b and c of this Clause are not required."

47. Article 87 is amended as follows:

a. Heading of Article 87 is amended as follows:

"Article 87. Composition of the application for licensing import of herbal ingredients in the cases other than those specified in Articles 82 through 86 hereof"

b. Clause 1d and 1dd, Article 87 are amended as follows:

"d. The foreign provider of herbal ingredients is not required to implement the regulations in clause 15, Article 91 hereof, if it has a certified true copy of the Pharmacy Business License issued and consularly legalized by a competent authority of its home country.

dd. Certified true copy of the manufacturer's certificate of GMP issued by the competent authority of their home country."

48. Article 91 is amended as follows:

a. Clause 5, Article 91 is amended as follows:

"5. Representative offices in Vietnam of manufacturers, holders of the certificates of free sale of drugs undergoing clinical trial, bioavailability study or bioequivalence study; providers of clinical trial, bioavailability study or bioequivalence study services may import medicinal ingredients, primary packages of drugs and reference materials for provision of the aforesaid services and register for the license to perform testing and research on drugs and medicinal ingredients.

b. Clause 5a is added to clause 91 as follows:

"5a. The following agencies and organizations, which satisfy the requirements in Article 35 of the Law on Pharmacy, may:

a. Import drugs which are specified in Article 67 hereof, if assigned by the Ministry of National Defense, Ministry of Public Security or Ministry of Health in a written request.

b. Import drugs as emergency aid or humanitarian aid, if approved by the regulatory agency.

c. Clause 8a, Article 91 is amended as follows:

"a. The licensed import quantity of drugs that contain an active ingredient which is not granted the certificate of drug registration or a herbal ingredient that is used in Vietnam for the first time as specified in Article 65 hereof, depends on the business demand of the importer."

d. Clause 15, Article 91 is amended as follows;

"15. To be allowed to sign a contract with the importer, the foreign supplier of drugs/medicinal ingredients must be:

a. A manufacturer of imported drugs/medicinal ingredients.

b. The owner of the product or holder of the certificate of free sale of the imported drug or active ingredient written on the Certificate of Pharmaceutical product, whether or not the drug is granted the Certificate of Registration in accordance with the Law on Pharmacy.

c. The applicant for registration of the drug or medicinal ingredient has the certificate of registration in Vietnam which does not expire at the time customs clearance is granted. This applicant must be other than those mentioned in Points a and b of this Clause.

d. An establishment granted the License to trade drugs, medicinal ingredients, vaccines, biologicals or ingredients thereof in Vietnam.

dd. In cases specified in Points c, d or h of this clause, they are required to be authorized in writing by the entity mentioned in Point a or b of this Clause to supply drugs in Vietnam. Except for those specified in points d and h of this clause, they are specified in point a or b of this clause.

The authorization document may be an authorization letter, seller's license or certificate of partnership. The authorization document must be written in Vietnamese or English and contain: name and address of the authorizing party and authorized party; scope of supply of drugs/medicinal ingredients in Vietnam; authorization period or sale period; responsibilities of the parties for the quality and origins of drugs/medicinal ingredients supplied in Vietnam; signatures of the parties.

e. Regulations of this Clause do not apply to suppliers of imported drugs specified in Articles 67, 73 and Clause 1, Article 74 hereof.

g. Regulations of Point dd of this Clause do not apply to suppliers of imported drugs specified in Articles 68 and 70 hereof.

h. Establishments specified in Clause 22 hereof."

dd. Clause 16, Article 91 is amended as follows:

"16. Regulations of Clause 15 of this Article do not apply to suppliers of imported excipients, capsule shells, primary packages of drugs, reference materials and medicinal ingredients used for producing controlled drugs which are imported for testing, research or production of exported drugs according to Article 80 hereof; medicinal ingredients used for producing imported drugs according to Articles 82, 83, 84, 85 hereof; drugs as emergency aid or humanitarian aid.

e. Clauses 22, 23, 24 are added to Article 91 as follows:

"22. If the Ministry of Health receives a written document from the competent authority of the exporting country requesting the announcement of the list of manufacturers and sellers which register for supplying drugs and medicinal ingredients in Vietnam, the Ministry of Health shall:

a. Within 30 days from the date on which the written request of the aforesaid competent authority is received, the Ministry of Health shall post the list of foreign manufacturers and sellers which register for supplying drugs and medicinal ingredients in Vietnam on its website.

b. If the Ministry of Health receives the written document from the aforesaid authority requesting it to change the announced information about the foreign suppliers, the Ministry of Health shall implement point a of this clause.

23. The competent authority of the exporting country specified in clause 23 of this Article shall send a written notification to the Ministry of Health as follows:

a. The written notification must be sent within 01 month, from the date on which the written request for changes to the name, address and business scope of the supplier is received.

b. The written notification must be sent within 15 days from the date on which the document about the termination or suspension imposing to the foreign suppliers in its home country is received.

24. The written documents of the competent authority specified in clauses 23 and 24 hereof must:

a. Clearly specify the name, address and contact information of the competent authority of the exporting country; information about the country or territory which register for supplying drugs and medicinal ingredients in Vietnam; name of the supplier, address, business scope and contact information of the manufacturer and seller<0}

b. Be the original copies which are written in English or Vietnamese. If the copies cannot be written in English or Vietnamese, provide the certified translated documents in one of these languages.

49. Article 92 is amended as follows:

a. Clause 2dd, Article 92 is amended as follows:

“dd. In case of import of a drug or medicinal ingredient specified in Clause 1dd, Article 59 of the Law on Pharmacy and such case does not require the import license, the importer shall provide the bill of lading in order to prove that the shipment is sent from the exporting country's port before the expiration date of the Certificate of Registration.”

b. Points e, g and h, clause 2, Article 92 are added as follows:

“e. In case of import of a drug or medicinal ingredient specified in Clause 1dd, Article 59 of the Law on Pharmacy and if such case does not require the import license, the importer shall provide the bill of lading to prove that the shipment is sent from the exporting country’s port before the expiration date of the Certificate of Registration.”

g. In case of import of medicinal ingredients specified in the list of active ingredients, excipients, semi-finished drugs used for production of drugs that are granted the Certificate of Drug Registration in Vietnam and if such case does not require the import license, the importer shall provide the bill of lading to prove that the shipment is sent from the exporting country’s port before the expiration date of the Certificate of Drug Registration which is used to declare the expired ingredients (if such certificate is used to declare the expired ingredients during customs clearance).

h. In case of import of medicinal ingredients specified in the list of active ingredients, excipients, semi-finished drugs used for production of drugs that are granted the Certificate of Drug Registration in Vietnam and if such case does not require the import license, the importer shall provide the bill of lading to prove that the shipment is sent from the exporting country’s port before the expiration dates of the Certificate of Drug Registration used to declare the expired ingredients and the import license (if such certificate and license expire by the time of customs clearance).

c. Clause 3e, Article 92 is amended as follows:

“e. In case of import of medicinal ingredients and semi-finished products specified in Clause 1dd, Article 59 hereof and if such case does not require the import license, the importer shall provide the bill of lading in order to prove that the shipment is sent from the exporting country's port before the expiration date of the Certificate of Registration.”

d. Clause 3h and 3i, Article 92 are added as follows:

“h. In case of import of medicinal ingredients and semi-finished products specified in Clause 1dd, Article 59 of the Law on Pharmacy and if such case does not require the import license, the importer shall provide the bill of lading in order to prove that the shipment is sent from the exporting country's port before the expiration date of the Certificate of Registration and the Import License.”

“i. In case of import of medicinal ingredients and semi-finished products in the form of import license but without a certificate of registration in Vietnam and such import license expires by the time of customs clearance, the importer shall provide the bill of lading in order to prove that the shipment is sent from the exporting country's port before the expiration date of the Import License.”

dd. Clause 4e, Article 92 is amended as follows:

“e. In case of import of drugs, medicinal ingredients in the form of import license but without a certificate of registration in Vietnam and such import license expires by the time of customs clearance, the importer shall provide the bill of lading in order to prove that the shipment is sent from the exporting country’s port before the expiration date of the Import License.”

50. Clause 1dd, Article 93 is amended as follows:

“dd. It is on the list of herbal ingredients that can be domestically obtained with adequate quantity for the treatment demand and at reasonable prices; or"

51. Clause 5b, Article 98 is amended as follows:

“b. The certificate of GMP and report on GMP inspection mentioned in Clause 1 through 4 of this Article and the manufacturing license mentioned in Clause 1 through 3 of this Article must be original copies or certified true copies and must be unexpired when the application is submitted. If the expiration date is not specified, they must be issued within the last 03 years, from the date on which the application is submitted.

The Certificate of GMP or the Manufacturing License are not required if they are posted on the website of the pharmacy authority.

52. Clause 1a and 1b, Article 99 are amended as follows:

"a. Within 20 days from the date on which the satisfactory application is received in case of mutual recognition of GMP inspection.

b. Within 40 days from the date on which the satisfactory application is received in case of document inspection.

53. Clause 2a, Clause 3c and Clause 4, Article 100 are amended as follows:

a. Clause 2a is amended as follows:

"a. Any of the violations that result in revocation of the Certificate of Drug/Medicinal Ingredient Registration specified in Points a, d, dd, Clause 1, Article 58 of the Law on Pharmacy."

b. Clause 3c is amended as follows:

"c. From 06 months to 01 year in cases specified in clause 1b, Article 58 of the Law on Pharmacy, Clause 2g of this Article."

c. Clause 4 is amended as follows:

"4. Applications submitted by applicants that commit any of the violations specified in Points a, b, d, dd, e, Clause 2 of this Article before the violations are dealt with will be invalidated. At the end of the periods specified in Clause 3 of this Article, the application may be submitted in accordance with the Law on Pharmacy."

54. Article 105 is amended as follows:

"Article 105. Methods of provision of drug information

Information shall be provided for medical and pharmaceutical practitioners by using the following methods:

1. Provision of drug information via sale representatives.

2. Publishing of documents containing drug information.

3. Holding pharmaceutical conferences."

55. The heading of Article 107 is amended as follows:

"Article 107. Cases in which the Certification of Drug Information is required"

56. Clause 1e and Clause 2e, Article 108 are amended as follows:

"e. The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; or the Certificate of Eligibility for Drug Business if the applicant is a Vietnamese pharmacy business establishment. The Certificate of Eligibility for Drug Business is not required if the applicant is a Vietnamese pharmacy business establishment.

57. Article 111 is amended as follows:

a. The heading is amended as follows:

"Article 111. Documents included in the application for issuance of the Certification of Drug Information"

b. Clause 2, clause 5 and clause 6, Article 111 are amended as follows:

"2. Documents mentioned in Clause 1d, Clause 1e, Clause 2d, Clause 2e of Article 108 shall be copies bearing the seal of the applicant if they are issued by the Minister of Health or certified true copies if they are not issued by the Ministry of Health.

5. Documents mentioned in Clause 1b and Clause 2b of Article 108 hereof are 02 original copies.

6. Each application for issuance of the Certification of Drug Information shall contain:

58. Clause 2, Article 113 is amended as follows:

"2. Within 10 days from the date on which the satisfactory application is received, the receiving authority shall issue the Certificate to the applicant by using Form No. 05 or Form No.06 in Appendix hereto. If the application is rejected, the receiving authority must respond and provide explanation in writing."

59. Clause 3, Article 113 is amended as follows:

"3. If the application is not satisfactory, within 10 days from the date on which the application is received, the receiving authority shall request the applicant in writing to complete the application. To be specific:

a. The written request shall specify necessary adjustments and/or additions.

b. Within 10 days from the date on which the amended application is received, the receiving authority shall issue the Certificate by using form No. 05 or No. 06 in appendix VI hereto, or reject the application and provide explanation.

c. Within 90 days from the date on which the additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. Otherwise, the application will be rejected."

60. Article 116 is amended as follows:

"Article 116. Power to issue the Certification of Drug Information

1. The Ministry of Health has the power to issue the Certification of Drug Information in cases specified in clause 2, Article 105 hereof.

2. Departments of Health of provinces have the power to issue the Certification of Drug Information in cases specified in Clause 3, Article 105 hereof."

61. The heading of Article 120 is amended as follows:

"Article 120. Issuance of the Certification of Drug Advertisement Contents"

62. Clause 1e, Clause 2e, Article 121 are amended as follows:

"e. The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; or the Certificate of Eligibility for Drug Business if the applicant is a Vietnamese pharmacy business establishment. The Certificate of Eligibility for Drug Business is not required if the applicant is a Vietnamese pharmacy business establishment."

63. Article 124 is amended as follows:

a. Heading of Article 124 is amended as follows:

"Article 124. Documents included in the application for the Certification of Drug Advertisement Contents"

b. Clause 2, clause 5 and clause 6, Article 124 are amended as follows:

"2. Documents mentioned in Clause 1d, Clause 1e, Clause 2d, Clause 2e of Article 121 must be copies which bear the seal of the applicant if they are issued by the Ministry of Health or certified true copies if they are not issued by such Ministry.

5. Documents mentioned in Clause 1b and Clause 2b of Article 121 hereof are 02 original copies.

6. Each application for issuance of the Certification of Drug Advertisement Contents shall contain:"

64. Article 127 is amended as follows:

Article 127. Procedures for issuance of the Certification of Drug Advertisement Contents

1. The applicant for the Certification of Drug Advertisement Contents shall submit an application to the Ministry of Health.

2. Procedures for issuance of the Certification of Drug Advertisement Contents are the same as the procedures in Article 113 hereof."

65. Article 128 is amended as follows:

"Article 128. Power to issue the Certification of Drug Advertisement Contents

The Ministry of Health has the power to issue the Certification of Drug Advertisement Contents."

66. Article 129a is added to Article 129 as follows:

Article 129a. Adjustment to the contents which are granted the certification

1. If the information specified on the Certification of Drug Information and Drug Advertisement is incorrect due to the mistakes made by the issuer, the applicant must send a written notification to the issuer and clearly specify the incorrect information that requires to be modified. After receiving the written notification, the issuer must send a written confirmation which specifies the contents to be adjusted to the applicant. Such confirmation must be made by using form No. 07 in Appendix VI hereto. The applicant may operate according to the adjusted contents and shall be responsible for such contents.

2. If the amended contents are granted the certification but this case is not specified in clause 1b, Article 107 or clause 1b, Article 120 of the Decree No. 54/2017/ND-CP, the applicant shall notify the issuer of the adjusted contents in writing. The applicant may change the contents themselves and shall be responsible for such changes.

67. Clause 3, Article 130 is amended as follows:

"3. The declaration of drug prices in case of change to the Certificate of Drug Registration specified in Clause 2b, Article 55 of the Law on Pharmacy shall be made in accordance with clause 1 of this Article."

68. Clause 1c, Article 131 is amended as follows:

"c. A drug price declaration shall be submitted when the Certificate of Drug Registration specified in Clause 2b, Article 55 of the Law on Pharmacy is adjusted, or the Drug Import License is also adjusted and before the first shipment of imported drug is launched in Vietnam.

If adjustment is made to the Certificate of Drug Registration unspecified in Clause 2b, Article 55 of the Law on Pharmacy or to the Drug Import License without adjusting the expected sale and retail prices of the drug according to the declaration, the declarant is not required to submit the declaration of drug prices but shall submit the application specified in clause 4, Article 130 hereof."

69. Clause 2c, Article 131 is amended as follows:

"c. A drug price declaration shall be submitted when the Certificate of Drug Registration specified in Clause 2b, Article 55 of the Law on Pharmacy is adjusted and before the first batch of drugs is launched in Vietnam.

If adjustment is made to the Certificate of Drug Registration unspecified in Clause 2b, Article 55 of the Law on Pharmacy without adjusting the expected sale and retail prices of the drug according to the declaration, the applicant is not required to submit the declaration of drug prices but shall submit the application specified in clause 4, Article 130 hereof."

70. Clause 4b, 4c, 4d are amended as follows:

"b. The receiving official shall examine the application documents and their quantity if such application is completed. He/she shall append a seal on the received documents, specify the date of receipt and return 01 dossier in person or by post to the applicant. If the Ministry of Health is the receiving authority, such dossier must be enclosed with a receipt note, using form No.06 in Appendix VII hereto. If the People's of Committees in provinces and central-affiliated cities are the receiving authorities, the receipt note must be made by using form No. 07 in Appendix VII hereto. Also, the receiving official shall send 01 dossier to the heads of competent agencies and technical service sections.

If the application is rejected, the receiving official shall provide explanation in writing, specify the required additional contents and immediately return the application to the applicant in person; or within 02 working days from the date on which the application is received in paper form.

c. Within 07 days from the date on which the complete declarations which specify the declared/re-declared drug prices are received, the Ministry of Health shall announce such declared/re-declared drug prices; and additional drug information on its website.

d. As for the re-declarations of domestic drug prices:

- Within 03 working days from the date on which the complete application is received, the People's Committees of provinces and central-affiliated cities must send reports on the re-declared drug prices to the Ministry of Health, using form No.08 in Appendix hereto.

- Within 04 working days from the date on which the reports from the People's Committees of provinces and central-affiliated cities are received, the Ministry of Health shall publish the summarization of these reports on its website.

- After reviewing the prices, if the People's Committees of provinces and central affiliated cities request the declaring establishment in writing to report about the declared prices which are conformable with the changes of pricing elements, such establishment must also send 01 report to the Ministry of Health.

71. Clause 1, Article 132 is amended as follows:

"1. Within the license period of the drug, the regulatory agency shall apply the principles specified in Article 134 to review the submitted declarations and re-declarations of drug prices. Review the date on which the declared/re-declared prices are applied, detect the inaccurate declaration, request the declaring establishment in writing to report about the declared prices which are conformable with the pricing elements or the re-declared prices which are conformable with the changes of such pricing elements, in order to stabilize the prices, carry out state management and inspect such prices according to the laws."

72. Clause 2b, Article 132 is amended as follows:

"b. Failure to adjust drug prices and to send a written notification at the request of a drug pricing authority; failure to report about the pricing elements."

73. Clause 2, clause 3, clause 4, Article 133 are amended as follows:

"2. A pharmacy business establishment may sell a drug from the date on which its price is declared or re-declared by the manufacturer, outsourcing entity or importer.

3. A pharmacy business establishment must not sell a drug wholesale or retail at a price higher than the price declared or re-declared by the manufacturer, outsourcing entity or importer.

4. In cases where the competent authority requests a pharmacy business establishment to report about a declared or re-declared price of drug, within 60 days from the date on which the request is issued, the applicant must send a written report about such declared price which is conformable with the pricing elements or adjust such declared price as requested by the competent authority. If no respond is made by the aforesaid deadline, the application will be invalidated."

74. Clause 1, Article 134 is amended as follows:

"1. Declared/re-declared drug prices shall be reviewed on the following basis:

a. Such prices must not be higher than those of ASEAN countries.

b. The costs constituting drug prices, which are declared by the importer, manufacturer or outsourcing entity, must be accurate.

c. Changes in costs constituting drug prices, such as cost of materials, fuel, exchange rates, salaries and other relevant costs, must be conformable with the price increase."

75. Clause 5 and 6, Article 134 are amended as follows:

"5. Drug pricing authorities shall establish a Drug Pricing Department to review the accuracy of the declared and re-declared drug prices.

6. The Minister of Health shall establish a Drug Pricing Council, which consists of representatives of the Ministry of Health, Ministry of Finance, Social Security Administration of Vietnam and relevant organizations and units, in order to give counsel to the Minister of Health on review of the declared and re-declared drug prices in the following cases:

a. The concentrations/contents of the drug are different from those of other drugs posted on the website of the Ministry of Health.

b. The dosage form of the drug is different from that of other drugs posted on the website of the Ministry of Health.

c. The drug is a new drug.

d. The drug is on the list of drugs undergoing price negotiation, the drug is a proprietary drug, a drug manufactured according to EU-GMP or PIC/S-GMP standards by a manufacturer in a member state of the ICH or Australia, a drug manufactured according to WHO-GMP standards certified by the Ministry of Health of Vietnam and granted the certificate of free sale in a member state of the ICH or Australia with the following increase rates:

- Over 10% if the drug price is exceeding 5.000 VND but not exceeding 100,000 VND per smallest pack.

- Over 7% if the drug price is exceeding 100.000 VND but not exceeding 1.000.000 VND per smallest pack.

- Over 5% if the drug price is exceeding 1.000.000 VND."

76. Clause 2, Article 136 is amended as follows:

The drug retailer within the premises of a health facility may only buy drugs from suppliers that are awarded contracts for supplying drugs to such health facility and drugs selected at the health facilities in provinces and central-affiliated cities within 12 months; drugs selected and procured in localities and nationwide within the term of the contract or the centralized procurement framework before the procurement. The buying prices are specified below:

a. The buying price for a drug on the list of drugs supplied by successful bidders of the health facility must not exceed the successful bid at the same time.

b. The buying price of a drug that is not included in the list of drugs supplied by successful bidders of the health facility must not exceed the successful bids at the health facilities in provinces and central-affiliated cities within 12 months; the successful bids of centralized procurements in localities and nationwide within the term of the contract or according to the centralized procurement framework before the procurement.

This regulation is not applicable to drugs which are licensed for import according to Articles 67 and 68 of the Decree No. 54/2017/ND-CP; narcotic drugs, psychotropic drugs, precursor drugs and new drugs according to clause 14, Article 2 of the Law on Pharmacy. Such drugs are not supplied by successful bidders of the health facilities."

77. Clause 2, Article 140 is amended as follows:

“2. Deadline for the person in charge of drug quality assurance of manufacturers to obtain the pharmacy practice certificate is on January 01, 2021.

78. Article 143 is amended as follows:

a. Clause 3 is amended as follows:

“3. Licenses to export or import drugs/medicinal ingredients, orders for exported or imported drugs/ medicinal ingredients and relevant administration procedures shall be issued and carried out according to the Law on Pharmacy No. 34/2005/QH11 and its instructional documents shall remain effective until their expiration dates.

Drugs and medicinal ingredients mentioned in this Clause are imported or exported and granted customs clearance documents if they satisfy the requirements of the Law on Pharmacy No. 34/2005/QH11 and related instructional documents or according to this Decree, from the date on which this Decree takes effect.”

b. Clause 5a is amended as follows:

“a. An establishment trading controlled drugs specified in Clause 26a and 26b, Article 2 of the Law on Pharmacy may keep operating until the end of June 30, 2019. After this day, it shall obtain the Certificate of Eligibility for Pharmacy Business that permits trading in controlled drugs in accordance with Section 4, Chapter III of this Decree.”

c. Clause 7 is amended as follows:

“7. From January 01, 2021, the certificate of registration or declaration of applied standards shall be obtained in accordance with Clause 1 and Clause 2, Article 93 hereof before herbal ingredients are sold in Vietnam."

d. Clause 11, Article 143 is amended as follows:

"11. A foreign enterprise whose license to trade in drugs and medicinal ingredients in Vietnam or license to trade in vaccines, biologicals and ingredients thereof in Vietnam is granted before the Decree No. 54/2017/ND-CP takes effect and is used until its expiry date."

79. Change the phrase "Department of Health of the province where the applicant's head quarters are located" with the phrase "Department of Health of the province where the applicant's business place is located" in Clause 1b, Article 33, Clause 1b, Article 34, Clause 1b, Article 50, Clause 1b, Article 51, Clause 2b, Article 55.

80. Amend form No. 06, 07, 19 of Appendix I hereto.

81. Amend Form No. 19 in Appendix II hereto.

82. Amend Appendix III:

a. Amend forms No. 03, 04, 05, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 30, 33, 34, 35, 36, 37, 38, 41, 43, 46, 47, 48, 49, 50.

b. Amend forms No. 03, 24, 25, 26, 38, 46.

83. Amend Appendix V: Add the phrase "Narcotic drugs and finished products from narcotic drugs."

84. Amend form No. 06 in Appendix VI hereto.

85. Add form No. 07 to Appendix VI.

86. Amend forms No. 01, 02, 03, 04 in Appendix VII hereto.

Chapter III

DONATION, REMOVAL OR TRANSPLANTATION OF HUMAN TISSUES AND ORGANS AND DONATION AND RECOVERY OF CADAVERS

Article 6. Annulment of some Articles of the Government's Decree No. 118/2016/ND-CP dated July 22, 2016 on amendments to some Articles of the Government's Decree No. 56/2008/ND-CP dated April 29, 2008 on organization and operation of the tissue banks and the National Coordinating Center for Human Organ Transplantation

1. Subpoint 4 in Clause 2b of Article 3a.

2. Sub-point 4 in Clause 2c of Article 3a.

3. Subpoint 2 in Clause 1d of Article 4.

Article 7. Amendments to some Articles of the Government's Decree No. 118/2016/ND-CP dated July 22, 2016 on amendments to some Articles of the Government's Decree No. 56/2008/ND-CP dated April 29, 2008 on organization and operation of the tissue banks and the National Coordinating Center for Human Organ Transplantation

1. Article 3a is amended as follows:

"Article 3a. Requirements for operation and issuance of operating license to tissue banks

1. Operation requirements for tissue banks: the tissue banks shall only operate after receiving the Operating License issued by the Ministry of Health.

2. Requirements for issuance of operating license to tissue banks:

a. If the applicant is a state tissue bank, it must receive an Establishment Approval as mentioned in the competent authority's document specifying the organizational structure of health facilities. If the applicant is a private tissue bank, it must receive an Enterprise Registration Certificate.

b. Appropriate facilities must include:

- Technical room for receiving, treating, storing and providing tissues.

- Laboratory. If the tissue bank is under the management of the health facility, the testing can be conducted in the testing department of the health facility.

- Administrative area which is used for collecting and managing documents, as well as providing counseling.

c. Minimum quantity of personnel:

- The specialized manager of the tissue bank must satisfy the requirements specified in clause 4, Article 35 of the Law on Donation, Removal, Transplantation of Human Tissues and Organs and Donation and Recovery of Cadavers.

- 01 general doctor who has a laboratory practice certificate (Bio-chemistry or Hematology or Microorganism) or 01 laboratory technician who has a bachelor degree and a medical laboratory practice certificate.

- 01 medical technician or 01 nurse who has a medical intermediate degree and a medical practicing certificate.

If the applicant is a tissue bank under the management of the health facility, its personnel can hold several positions, however, a medical technician or a nurse must perform special tasks.

d. Equipment must be sufficiently provided according to the List specified in Appendix I hereto. If the applicant is a tissue bank under the management of the health facility, it may share the same equipment with such facility.

- If the tissue bank performs tasks related to the cornea, it must satisfy the requirements in Clause 3 of this Article.

- Administrative management procedures.

- Technical procedures for removing, storing and distributing each type of tissue registered by the bank.

3. Requirements for issuance of the operating license for the cornea bank (if the tissue bank performs tasks related to the cornea):

a. Facilities must be sufficiently provided according to Clause 2b of this Article.

b. Equipment must be sufficiently provided according to the regulations in Appendix I hereto.

c. Personnel:

- There must be sufficient personnel according to Clause 2b of this Article.

- The technician removing the cornea must have a high school diploma and must be trained in removing, storing and transporting the cornea."

2. Article 4 is amended as follows:

“Article 4. Application and procedures for issuance of the Operating License to tissue banks

1. Application for the Operating License shall contain:

a. An application form for the Operating License, using the form in Appendix II hereto.

b. A copy of the Establishment Approval of the tissue bank or a copy of such Approval enclosed with an original copy, or the Enterprise Business Certificate if the applicant is a private tissue bank.

c. A declaration of the medical facilities and equipment to prove the applicant’s eligibility according to Article 3a hereof.

d. If the applicant is an independent tissue bank, it shall submit a declaration of its personnel to prove its eligibility according to Article 3a hereof. The specialized manager must provide a certified true copy of his/her qualification or certificate.

If the applicant is a tissue bank under the management of the health facility, it shall provide the practicing certificate.

2. Application and procedures for issuance of the Operating License to tissue banks:

a. Agencies, organizations or individuals shall send 01 set of application to request for the Operating License specified in Clause 1 of this Article to the Ministry of Health, in administrative form or in person.

b. Within 03 working days, after receiving the application, the Ministry of Health shall consider the validity of such application. If the application is deemed unsatisfactory, the Ministry of Health shall send a written notification to guide the agencies, organizations or individuals through completing the application.

c. Within 05 working days from the date on which the complete application is received, the Ministry of Health shall establish an Appraisal Council to issue the Operating License to tissue banks. Such Council shall comprise at least 05 members who are the representatives of related units of the Ministry of Health, and who are the medical and legal experts.

d. Within 17 working days from the date on which the Establishment Approval is received, the Appraisal Council shall perform their tasks at the tissue bank, write a report on the appraisal result and send it to the Minister of Health, in order for him to use it as a basis for issuing the Operating License to the tissue bank, using the form in Appendix III hereto.

Time limit for resolution: Within 30 days from the date on which the valid application is received until the date on which the Certificate is issued by the Ministry of Health."

Chapter IV

INSECTICIDAL AND GERMICIDAL CHEMICALS AND PREPARATIONS FOR HOUSEHOLD AND MEDICAL USE

Article 8. Annulments of the following articles of the Government's Decree No. 91/2016/ND-CP dated July 01, 2016 on management of insecticidal and germicidal chemicals for household and medical use

1. Clause 1, Article 4.

2. Clause 1c and Clause 2, Article 5.

3. Clause 1c, 1e, 1g and Clause 2c, Article 7.

4. There must be documents proving that the technical standards for safety distance of the Ministry of Industry and Trade are satisfied according to Clause 1d, Article 7.

5. Clause 1, Article 10.

6. Clause 2b; Clause 3b, 3d, 3dd and 3e of Article 14.

7. Clause 5, Article 15.

8. Clause 1b, Article 40.

9. Clause 1 and Clause 3, Article 41.

10. Clause 3, Article 42.

Article 9. Amendments to some Articles of the government's Decree No. 91/2016/ND-CP dated July 01, 2016 on management of insecticidal and germicidal chemicals and preparations for household and medical use

1. Clause 1, Article 6 is amended as follows:

"Satisfy the requirements in Section 1, Chapter II, of the Government's Decree No. 113/2017/ND-CP dated October 09, 2017 providing guidelines on some Articles of the Law on Chemical."

2. Clause 2d, Article 7 is amended as follows:

"d. The documents specified in Clause 1d and 1dd must be confirmed by the manufacturer."

3. Clause 4, Article 8 is amended as follows:

"4. Within 03 working days from the date on which the application is received, the Ministry of Health shall publish the name, address and phone number of the manufacturer on its website."

4. Clause 5a, Article 8 is amended as follows:

“a. Changes of its personnel: The written request for change of information relating to the declaration of eligibility to produce preparations shall be submitted, enclosed with the documents mentioned in Clause 1b, Article 7 hereof.” <0}

5. Clause 2, Article 10 is amended as follows:

“2. Testing establishments must meet requirements defined in ISO 17025:2005 or its editions certified by the certification organization which has registered for the Certificate of Eligibility to Conduct Evaluation Business according to the law."

6. Article 12 is amended as follows:

“Article 12. Declaration of eligibility to conduct testing

1. Before conducting the first testing, the testing establishment shall send the application documents specified in Article 11 hereof to the Ministry of Health. If the Ministry of Health adopts the methods of online declaration, the aforesaid application shall be submitted online.

2. Within 03 working days from the date on which the application is received, the Ministry of Health shall post the name, address and phone number of the testing establishment on its website, as well as a list of chemicals tested by the establishment.

3. If the testing establishment changes their testing conditions compared to the information declared in the application sent to the Ministry of Health, within 05 working days from the date on which the changes are made, such establishment shall send a written notification enclosed with the documents mentioned in Article 11 hereof to the Ministry of Health.

4. If the additional documents are not satisfactory and the testing establishment cannot develop any remedies within the time limit required by the Ministry of Health, such Ministry shall stop posting information related to the aforesaid establishment and send it a written notification about such termination. The testing establishment shall not conduct the testing from the date on which the aforesaid notification is received, due to the establishment's inability to satisfy the testing requirements.

7. Clause 2a, Article 14 is amended as follows:

“a. The person in charge of managing the experiment division must have at least 03 years of experience in the experiment on preparations.”

8. Clause 2a, Article 14 is amended as follows:

“a. Have a laboratory which is managed and operated under ISO 17025:2005 or ISO 15189:2012 or their editions. If the testing is conducted, it must be registered in accordance with the law on requirements for provision of conformity assessment services.”

9. Article 16 is amended as follows:

“Article 16. Declaration of eligibility to conduct experiment activities

1. Before conducting the first experiment, the experiment establishment shall send the documents specified in Article 15 hereof to the Ministry of Health. If the Ministry of Health adopts the methods of online declaration, the aforesaid application shall be submitted online.

2. Within 03 working days from the date on which the application is received, the Ministry of Health shall post the name, address and phone number of the experiment establishment on its website, as well as a list of experiment procedures carried out by the eligible experiment establishment.

3. If the experiment establishment changes their experiment conditions compared to the information declared in the application sent to the Ministry of Health, within 15 working days from the date on which the changes are made, such establishment shall send a written notification enclosed with the documents mentioned in Article 15 hereof to the Ministry of Health.

4. Within 03 working days from the date on which the application is received according to Clause 3 of this Article, the Ministry of Health shall update the information on its website.

5. If the additional documents are not satisfactory and the experiment establishment cannot develop any remedies within the time limit required by the Ministry of Health, such Ministry shall stop posting

information related to the aforesaid establishment and send it a written notification about the termination. The testing establishment shall not conduct the experiment from the date on which the aforesaid notification is received, due to the establishment's inability to satisfy the experiment requirements.

10. Clause 4d, Article 26 is amended as follows:

"d. The original or valid copy of the written notice of testing results for ingredients and the content of active ingredients in preparations. Such written notice of testing results must be made by an entity that is qualified to conduct testing as referred to in Article 10 hereof. If the testing establishments in Vietnam cannot conduct the testing, the applicant can use the testing results from the manufacturer or an independent laboratory which satisfies ISO 17025:2005 or ISO 15189:2012 or their editions. Also, such manufacturer or laboratory must take responsibility before the law for the legality of their testing results."

11. Clause 3, Article 40 is amended as follows:

"3. Traders in common insecticidal and germicidal preparations, consisting of: mosquito coil; mosquito repellent tablets for household and medical use; insecticidal sprays; insect poisons; insect repelling cream, patch and band for human use; liquid mosquito repellents and killers; mosquito nets with mosquito repellents and killers; and germicidal preparations for household use are not required to satisfy the requirements in Clause 1 and Clause 2c of this Article."

12. Clause 2, Article 41 is amended as follows:

"2. The person directly performing insecticidal and germicidal works must have the following knowledge as confirmed by the provider:

a. Be able to read the information specified on the label of the preparation.

b. Be able to perform insecticidal and germicidal works with skills that are suitable to the provided service.

c. Can use and dispose insecticidal and germicidal preparations."

13. Clause 2, Article 42 is amended as follows:

"2. A declaration of personnel which is confirmed by the provider."

14. Clause 1a is added to Clause 1, Article 63 as follows:

"1a. Provide trainings for the person directly performing insecticidal and germicidal works. If no training is provided, the provider must assign such person to receive trainings at the training units specified in Clause 2, Article 41 hereof."

15. Amend forms No. 01, 03, 04, 05, 06 and 08 in Appendix I; Appendix VI; Appendix VII and Appendix IX hereto.

Chapter V

MEDICAL EXAMINATION AND TREATMENT

Article 10. Annulment of the following regulations of the Government's Decree No. 109/2016/ND-CP dated July 01, 2016 on issuance of practice certificates to healthcare practitioners and operating licenses to the health facilities

1. Clause 1dd, Article 7.

2. Clause 17, 18 and 19 of Article 22.

3. Clause 3a, Article 23.

4. Clause 5b, 5c and 5k of Article 23.

5. Clause 2b and 2c, Article 24.

6. Clause 3, clause 5, Article 24.

7. Clause 2a, 2c and 2d, Article 25.

8. Clause 3a, Article 25.

9. Clause 4b, Clause 5, Article 25.

10. Clause 1a, 1d, 1dd and 1e of Article 26.

11. Sub-point 9, Clause 1c, Article 26.

12. Clause 2a, Article 26.

13. Clause 1a, 1d and 1dd, Article 27.

14. Second subpoint of Clause 2a, Clause 3a, Article 27.

15. Subpoints 10 and 11 of Clause 1a, Clause 1b and Clause 1c of Article 28.

16. Clause 3a and subpoint 3 of Clause 3b, Article 28.

17. Clause 1b and 1c of Article 29.

18. Clause 2, Article 29.

19. Clause 3a and 3b, Article 29.

20. Clause 1a, 1d and 1dd, Article 30.

21. Clause 2a, Article 30.

22. Clause 3a, Article 30.

23. Subpoints 2 and 3 of Clause 3b, Article 30.

24. Clause 4a, Article 31.

25. Clause 5, Article 31.

26. Clause 2b, Clause 3b and Clause 4a, Article 32.

27. Article 33, 34, 35, 36, 37 and 38.

28. Clause 1b and 1c, Clause 2a, Article 39.

Article 11. Amendments to some Articles of the Government's Decree No. 109/2016/ND-CP dated July 01, 2016 on issuance of healthcare certificates to healthcare practitioners and operating licenses to health facilities

1. Clause 1b, Article 4 is amended as follows:

"b. Issuance of a modified practice certificate in case of change in contents of an issued practice certificate, including:

- Supplement the practice scope specified on the practice certificate when the practitioner applies for supplementation of a practice scope of a speciality different from the one specified in the practice certificate.

If the technical skills of one speciality are different from those of the speciality specified in the practice certificate, the practitioners may only practice these skills after receiving the certificate of training in practicing such technical skills. This certificate must be issued by a legal training institution. Also, these skills must be approved in writing by the chief physician of the health facility without the need to supplement the practice scope specified on the practice certificate.

- Supplement the practice scope specified on the practice certificate when the practitioner applies for a change of a speciality different from the one specified on the practice certificate."

2. Article 7 is amended as follows:

"Article 7. Application documents for modification of practice certificates

1. An application for supplementation to the practice scope specified on the practice certificate shall contain:

a. An application form using form No. 05 in Appendix I hereto.

b. A valid copy of the issued practice certificate.

c. A valid of copy of a training qualification or a certificate issued by a legal training institution. The maximum training period is 6 months and must be conformable with the supplemented practice scope.

3. Article 22 is amended as follows:

"Article 22. Forms of organization of health facilities

The health facilities must be established in accordance with the law and must conform to one of the following forms of organization:

1. Hospital, including general hospital and specialized hospital.

2. Infirmaries of People's Public Security Forces.

3. Polyclinic.

4. Specialized clinic, including:

a. General medicine clinic.

b. Specialized clinic for internal medicine: cardiology, respiratory medicine, gastroenterology, pediatrics and other specialities in internal medicine.

c. Clinic providing healthcare consultancy or clinic providing healthcare consultancy by using information technology and telecommunications.

Specialized clinic, including:

dd. Antenatal clinic.

e. Clinic of andrology.

g. Clinic of odonto-stomatology.

h. Clinic of otolaryngology.

Clinic of ophthalmology.

k. Clinic of cosmetology.

l. Clinic of rehabilitation.

m. Clinic of psychiatry.

n. Clinic of oncology.

o. Clinic of dermatology.

p. Clinic of traditional medicine;

q. Clinic of dietetics.

r. Clinic of drug rehabilitation.

s. Clinic of HIV/AIIDS treatment.

t. Laboratory.

u. Image diagnosis clinic, X-ray room.

v. Opioid substitution treatment clinic which implements the regulations specified in the Government's Decree No. 90/2016/ND-CP dated July 01, 2016 on treatment for opioid substitution.

x. Preventive care clinic.

y. Occupational health clinic.

z. Other specialized clinics.

5. Family medicine facilities (or healthcare facilities operated in the principle of family medicine): pilot establishment as prescribed by the Minister of Health.

6. Maternity ward.

7. Medical service providers, including:

a. Injection, dressing change, pulse counting and temperature and blood pressure measurement service provider.

b. Home healthcare service provider.

c. Facilities providing emergency and patient transportation services in Vietnam or abroad.

d. Optical glasses service provider.

dd. Cosmetological service provider.

e. Other healthcare service providers.

8. Commune-level health stations, infirmaries.

9. Medical assessment facility and forensic examination facility providing medical examination and treatment shall be organized as a health facility specified in Clause 3 of this Article. Mental forensics examination facility providing medical examination and treatment shall be organized as a health facility specified in Clause 1 and Clause 3, or Clause 4m of this Article. Such facilities shall satisfy the applicable requirements.

10. Any medical facility affiliated to an agency, unit or organization which conducts healthcare must be operated in a form specified in Clause 3 or Clause 4a of this Article and must comply with the requirements applied to such form of organization.

11. Any medical center having a function of conducting medical examination and treatment shall be issued with a license to operate in form of a general hospital or a polyclinic and shall comply with the requirements applied to such form of organization. If the hospital is granted a license to operate in form of a general hospital, it shall be ranked as level IV, if it is granted a license to operate in form of a polyclinic, its rank shall correspond with its scale.

12. If the health facilities satisfy the requirements for healthcare service providers specified in this Decree, their scale and practice scope shall be supplemented accordingly.

4. Article 23a is added as follows:

"Article 23a. General requirements for issuance of operating licenses for healthcare facilities

1. Facilities:

a. Have a permanent location (unless the health facility provides mobile healthcare).

b. Ensure radiation and fire safety according to the law regulations.

c. Have a separated area for sterilizing reusable medical instruments, unless there are no instruments being reused or there is a contract signed with another health facility for this facility to sterilize such instruments.

2. Medical equipment:

a. Sufficient medical equipment must be provided and be suitable to the practice scope of the health facility.

b. An occupational health service provider must have at least a Biochemistry Laboratory Department.

c. Clinic providing healthcare consultancy or clinic providing healthcare consultancy by using information technology and telecommunications is not required to have the medical equipment specified in points a and b of this Clause. However, it must have sufficient information technology and telecommunications which are suitable to the registered practice scope.

3. Personnel:

a. Each health facility must have a chief physician. The chief physician and the deans of specialized departments of the health facility must:

- Be a doctor with a practicing certificate which is suitable to the practice scope of such facility.

- If the health facility has multiple departments, the chief physician must have a practicing certificate which is suitable to the practice scope of at least one of the registered clinical departments.

- Any chief physician of the following specialized clinics shall satisfy the corresponding conditions as follows:

+ Clinic of rehabilitation: being a doctor with a practice certificate relevant to physical therapy or rehabilitation.

+ Clinic for drug rehabilitation: being a psychiatric doctor or a general practitioner with a certificate of training in psychiatry or a traditional medicine practitioner with a certificate of training in drug rehabilitation using traditional medicine.

+ Clinic of HIV/AIDS treatment: being a doctor of infectious disease speciality or a general practitioner with a certificate of training in HIV/AIDS treatment.

+ Clinic of traditional medicine: Being a traditional medicine practitioner.

+ Traditional medicine facility: Being a herb doctor or a practitioner who is granted a certificate of traditional medicine prescription and treatment.

+ Clinic of dietetics: being a nutrition expert or a general practitioner with a certificate of training in dieting, or a preventive medicine doctor with a certificate of training in dieting or a bachelor in dieting; or a traditional medicine doctor with a certificate of training in dieting or a bachelor in dieting; or a physician with a certificate of training in dieting.

+ Clinic of cosmetic: Being a plastic surgeon or a Cosmetological doctor or a cosmetic surgeon.

+ Clinic of andrology: Being an adrological doctor or a general doctor with a certificate of training in andrology.

+ Clinic of occupational disease: being an occupational medicine doctor with a practice certificate or a general doctor with a practice certificate and a certificate of training in occupational disease.

+ Laboratory: Being a doctor or a physician specialized in testing with a bachelor degree or higher and a practice certificate for testing; or a chemical or biological bachelor, or a pharmacist with a bachelor degree. This requirement is applicable to those who are recruited to work in the laboratory before this Decree takes effect and are physicians who are granted practice certificates for testing.

+ Image diagnosis clinic, X-ray room: Being an image diagnosis doctor or have a bachelor's degree of X-ray therapy or higher, or have a practice certificate.

- Have provided medical examination and treatment for at least 36 months after being granted a practice certificate, or have directly participated in providing medical examination and treatment for at least 54 months. The chief physician of the health facility must be assigned in writing to carry out the tasks.

- He/she must work on a full-time basis at the health facility.

b. Aside from the chief physician, other practitioners working in the health facility must have practice certificates and shall only provide medical examination and treatment within the assigned practice scope. The chief physician of the health facility shall assign the practitioners in writing to undertake the specialized tasks based on the practice scope, qualifications and certificates of training and the potential of such practitioners.

c. A testing physician with a bachelor degree is qualified for reading and signing the testing results. If the health facility does not have any general doctor who conducts the testing or a testing physician who has a bachelor degree, the doctor who recommends the testing must read and sign the testing results.

d. The bachelor who specializes in X-ray therapy is qualified to read and interpret medical images. If the health facility does not have an image diagnosis doctor or a radiologist, the doctor who recommends an imaging test must read and sign the image diagnostic results.

dd. Other entities that participate in the provision of medical examination and treatment but are not required to obtain practice certificates according to the Law on Medical Examination and Treatment must be allowed to perform the tasks assigned by the chief physician (medical physicists, radiation physicians, speech therapists, psychotherapists and other entities). Such entities must be assigned tasks which are suitable to their specialized qualifications.

4. Health facilities must satisfy the following requirements:

a. Be the health facilities which are granted operating licenses according to the law.

b. Have clinical and paraclinical departments, as well as sufficient personnel and equipment used for providing medical examination and detecting the health conditions of patients based on the health standards and medical forms which are enclosed with the documented guidelines on medical examination.

5. Cosmetological service providers are not required to obtain operating licenses but shall have a proof document proving their eligibility for providing Cosmetological services. Such document must be made by using the form specified in Appendix VIII hereto. They shall send this form to the Department of Health where their head office is located, at least 10 days before the operation.

Any Cosmetological service which involves the intervention of drugs, substances and equipment in human bodies (surgery, operation, injection, augmentation, ray emission, wave, firing and other types of intervention) that change the color of skin, shape, weight and shortcomings of human bodies (skin, nose, eyes, lips, face, breasts, belly, buttock and other body parts), or services of doing tattoos and microblading. Anesthetic is injected to the human bodies while providing the aforesaid services and is only used in hospitals having Cosmetological specialists or Cosmetological clinics or healthcare facilities with the practice scope in Cosmetological speciality approved by the competent authorities."

5. Article 23 is amended as follows:

"Article 23. Requirements for issuance of the operating licenses to the hospitals

Aside from the requirements specified in Article 23a hereof, the hospitals must also satisfy the following requirements:

1. Scale of hospitals:

a. A general hospital must have at least 30 patient beds.

b. A specialized or traditional hospital must have at least 20 patient beds. Particularly, an ophthalmologic or a psychiatric hospital must have at least 10 patient beds.

2. Facilities:

Aside from the requirements specified in Article 23a hereof and depends on the scale of the hospital, a specialized or a general hospital must be designed and built in accordance with the following requirements:

a. Departments, rooms and hallways must be arranged conveniently for technique expertise under the interconnected and self-contained complex model within the hospital premises.

b. As for a general and a specialized hospital, there must be a minimum construction floor area of 50 m^2 per patient bed; the hospital façade must be at least 10m.

c. There must be a stand-by generator.

d. Requirements for medical waste treatment must be satisfied according to the regulations on environment.

3. Medical equipment: There must be sufficient emergency vehicles for transporting patients in and out of the hospital. If there are no emergency vehicles providing out-of-hospital treatment, a contract must be signed with a health facility which has been granted an operating license and its practice scope includes the provision of emergency transport services.

4. Organization:

a. Departments:

- There must be at least 02 of 04 departments of internal medicine, surgery, obstetrics and pediatrics, applicable to general hospitals, or an appropriate clinical department, applicable to specialized hospital.

- The medical examination department shall have a place for patient reception, emergency and patient stay rooms, consulting rooms and minor surgery rooms (if any minor surgery is carried out).

- The paraclinical department shall have at least one unit for testing and one unit for image diagnostic. Any ophthalmologic hospital having no image diagnostic unit must have a contract concluded with a healthcare facility having an operating license and with an image diagnostic unit.

- Pharmaceutical department.

- Other specialized departments and sections must be suitable to the scale, functions and tasks of the hospital.

b. There must be departments of general planning, organization and personnel, quality control, convalescence, finance and accounting and other necessary departments.

5. Personnel:

a. The number of full-time (tenured) practitioners in each department must account for at least 50% of the total number of practitioners in such department.

b. The deans of specialized departments of the hospital must have practice certificates which are suitable to such departments and must be the full-time practitioners at the hospital.

c. Deans of other departments who are not granted the practice certificates must have bachelor degrees in the specialities suitable to the assigned tasks. Also, they must be full-time practitioners at the hospital.

"Article 24. Requirements for issuance of operating licenses to infirmaries affiliated to People's Police Force

Aside from the requirements specified in Article 23a hereof, the infirmaries affiliated to People's Police Force must also satisfy the following requirements:

1. Scale:

a. Have at least 10 patient beds.

b. Have at least 02 departments specialized in internal medicine and surgery, including emergency rooms; patient rooms; and a paraclinical department.

2. Facilities: Have consulting rooms, emergency rooms, patient rooms and laboratories with an area sufficient for the use of means and instruments serving the medical examination and treatment."

7. Article 25 is amended as follows:

"Article 25. Requirements for issuance of the operating license to polyclinics

Aside from the requirements specified in Article 23a hereof, the polyclinics must also satisfy the following requirements:

1. Scale of a polyclinic:

a. Have 02 of 04 specialized departments of internal medicine, surgery, obstetrics and pediatrics.

b. Have a paraclinical department (units of testing and image diagnostic).

2. Facilities: Have emergency rooms, patient rooms, specialized consulting rooms and minor surgery rooms (if any minor surgery is carried out). The area of the rooms within the polyclinic must be sufficient for performing specialized techniques.

3. Have anti-shock first aid kits and sufficient specialized emergency drugs.

4. Personnel:

The number of full-time doctors must account for at least 50% of the total number of doctors of the polyclinic. The persons in charge of the specialized consulting rooms and the paraclinical department (units of testing and image diagnostic) which are affiliated to the polyclinic, must work on a full-time basis.

8. Article 26 is amended as follows:

"Article 26. Requirements for issuance of operating licenses to specialized clinics

Aside from the requirements specified in Article 23a hereof and except those applied to the chief physicians, the specialized clinics must also satisfy the following requirements:

1. Facilities:

a. If any operation is conducted, including implanting operation, acupuncture, massage or acupressure, the operation room must be located in a separate area. The area of the operation room must be sufficient for performing specialized techniques.

b. If the specialized clinic conducts both upper and lower gastro-endoscopic techniques, it must have 02 separate rooms.

c. There must be a biochemistry department for diagnosing and treating occupational diseases.

2. Medical equipment: Have anti-shock first aid kits and sufficient specialized emergency drugs."

9. Article 30 is amended as follows:

"Article 30. Requirements for issuance of operating licenses to maternity wards

1. Aside from the requirements specified in Article 23a hereof, the maternity wards shall satisfy the following requirements:

a. Facilities:

- Functional rooms must be interconnected and convenient for emergency and medical examination and treatment.

- There must be rooms for pre-natal and gynecological checkup and for lying-in women. These rooms must have sufficient area for performing specialized techniques.

b. Medical equipment:

- Have sufficient vehicles for internal and external emergency transportation. Maternity wards having no vehicles for external emergency transportation must have transportation contracts signed with healthcare facilities which have operating licenses and are permitted to provide emergency transportation services.

- Have anti-shock first aid kits and sufficient specialized emergency drugs.

2. The chief physician of the maternity ward must:

a. Be a gynecological doctor or a midwife who has a bachelor degree and a practice certificate.

- Have conducted examination and treatment in gynecology for at least 36 months after being granted a practice certificate, or have participated directly in providing medical examination and treatment for at least 54 months. Such chief physician of the maternity ward must be assigned in writing to carry out the aforesaid tasks.

3. Any maternity ward eligible for providing pediatric healthcare services according to the regulations in Article 27 hereof or providing vaccines according to the law on immunization, may add such specialities to its practice scope."

10. Article 33a is added as follows:

"Article 33. Requirements for issuance of operating licenses for healthcare service providers

1. Facilities must satisfy the requirements specified in Clause 1a, Article 23a hereof.

- If the healthcare service provider also provides optical glasses service, its area must be at least 15 m^2.

- A room for injection or dressing change must have an area of at least 10 m^2.

2. Medical equipment:

Aside from the requirements specified in Clause 2a, Article 23a hereof, if the healthcare service provider also provides:

a. Injection, dressing change, pulse counting and temperature and blood pressure measurement, then it must have anti-shock first aid-kits.

b. Emergency transportation, then it must have ambulances, anti-shock first aid kits and sufficient specialized emergency drugs. In case of registration for patient transportation abroad, such provider must have emergency transportation contracts signed with an aviation service company.

3. Personnel:

Aside from the requirements specified in Article 23a hereof and those applicable to the chief physician, if the healthcare service provider also provides:

a. Emergency transportation, the chief physician must satisfy the following requirements:

- Be a doctor with a practice certificate.

- Have specialized qualifications or certificates of recuperation and first aid.

b. Injection, dressing change, pulse counting, temperature and blood pressure measurement; and home nursing services, then the chief physician must have an intermediate or higher degree in medicine and a practice certificate. Also, he/she must have provided the aforesaid services for at least 45 months.

c. Optical glasses services, then the chief physician must have an intermediate or higher degree in medicine, a practice certificate and a certificate of training in ophthalmology or refractive eye defect.

d. Cosmetological services, then the person doing tattoos or embroidering pictures on the surface of the skin without use of anesthetics in injection form at a Cosmetological service provider, shall possess a certificate of study in the corresponding speciality lawfully issued by a training institution or a vocational training facility.

dd. If the home healthcare service providers also provide services including dressing change, suture removal, physical therapy, rehabilitation, mother and baby care, collection of blood samples for testing, result provision, care of patients with cancer and other home nursing services, then the chief physician must have an intermediate or higher degree in medicine and a practice certificate. Also, he/she must have provided medical examination and treatment for at least 45 months."

11. Article 45b is added as follows:

“Article 45b. Issuance, re-issuance and revocation of the certificates of traditional medicine prescription and treatment

1. Application documents for issuance or re-issuance of the Certificate of Traditional Medicine Prescription and Treatment (hereinafter referred to as “Certificate”):

a. Application for the new Certificate shall contain:

- An application form for the Certificate using form No. 01 in Appendix XV hereto.

- A written interpretation of the traditional medicine prescription and treatment, using form No. 02 in Appendix XV hereto.

- A medical certificate which is made within 06 months before the date of submission, using the set form.

- 2 color photos of 2 x 6 cm, with a white background. Such photos must be taken within 06 months before the date of submission.

b. Application documents

- An application form for re-issuance of the Certificate, using form No. 04 in Appendix XV hereto.

- A medical certificate which is made within 06 months, before the date of submission.

- 2 color photos of 2 x 6 cm, with a white background. Such photos must be taken within 06 months before the date of submission.

2. Procedures for issuance of the Certificate of Traditional Medicine Prescription and Treatment:

a. The applicant shall send 01 application dossier to the Department of Health of the same province. After receiving the application, the Department of Health shall issue the written confirmation to the applicant, using form No. 05 in Appendix XV hereto.

b. If the application is deemed unsatisfactory, within 05 working days from the date on which the application is received, the Department of Health shall send a written notification to the applicant to request for additional documents.

Within 60 days from the date on which the written notification is received, if the applicant does not provide additional documents, the application will be invalidated. If needed, the applicant shall submit a new application for issuance of the new Certificate.

c. If the application is deemed satisfactory, within 10 working days from the date on which the application is received, the Department of Health shall send such application to the Oriental Medicine Association of the same province or the same central-affiliated city for advices.

c. Within 30 days from the date on which the application from the Department of Health is received, the Oriental Medicine Association shall respond in writing, using form No. 03 in Appendix XV hereto.

d. After the written advice from the Oriental Medicine Association is received, the Department of Health shall organize a council meeting to appraise such application.

dd. Within 10 working days from the date on which the meeting minute of the Appraisal Council is received, the Department of Health shall issue the Certificate, using form No. 06 in Appendix XV hereto, or reject the application and provide explanations in writing.

3. The Director of the Department of Health shall issue, re–issue or revoke the Certificate.

4. Cases where the Certificate is revoked:

a. The Certificate is issued ultra vires.

b. The contents of the Certificate violate the law regulations.

c. The Appraisal Council established by the Department of Health concludes that the applicant makes serious mistakes that cause negative effects to the health and lives of patients.

d. The applicant who is granted the Certificate falls into the cases mentioned in clause 4, Article 18 of the Law on Medical Examination and Treatment."

12. Clause 5 is added to Article 50 as follows:

"The polyclinics within the areas where inpatients stay and are established and operated before this Decree takes effect shall implement the regulations hereof. This requirement also applies to those within the mountainous areas and remote and isolated areas and is approved in writing by the People's Committees of provinces and Departments of Health.

Chapter VI

COSMETIC PRODUCTS

Article 12. Annulment of some documents and regulations on cosmetic products

1. Annul the following regulations of the Government's Decree No. 93/2016/ND-CP dated July 01, 2016 on requirements for the manufacture of cosmetic products:

a. Clause 1, Article 3.

b. Clause 3c and 3e, Article 4.

c. Clause 1d, Article 7.

d. Clause 2b, Article 7.

2. Annul the following Articles of the Circular No. 06/2011/TT-BYT dated January 25, 2011 of the Ministry of Health on management of cosmetic products:

a. Clause 2, Article 4.

b. Clause 1b, 1d and 1g of Article 34.

c. Clause 1, Article 35.

Article 13. Amendments to clause 3a, Article 4 of the Government's Decree No. 93/2016/ND-CP dated July 01, 2016 on requirements for the manufacture of cosmetic products

"a. Raw materials, auxiliary materials and semi-finished products which are used to manufacture cosmetic products must satisfy the quality standards adopted by the manufacturer."

Chapter VII

PREVENTION AND CONTROL OF COMMUNICABLE DISEASES

Article 14. Annulment to some Articles on prevention and control of communicable diseases

1. Annul the following Articles of the Government's Decree No. 103/2016/ND-CP dated July 01, 2016 on biosafety in laboratories:

a. Article 2.

b. Clause 1d, Article 4.

c. Clause 1a, 1c, 1d, 1dd and 1e of Article 5.s

d. Clause 2b and 2c, Article 5.

dd. Clause 3b and 3d, Article 5.

e. Clause 4b, 4c, 4dd, 4e and 4g, Article 5.

g. Clause 2c, Article 6.

h. Clause 4b, Article 6.

Clause 1dd, Article 7.

k. Clause 2c, Article 7.

l. Article 8.

m. Clause 1d, 1e, 1h, Article 11.

n. Clause 4b, Article 11.

2. Annul the following Articles of the Government's Decree No. 104/2016/ND-CP dated July 01, 2016 on vaccination:

a. Clause 1c, Article 8.

b. Clause 1b, 1c, 1d, 1dd and 1e, Article 9.

c. Clause 2b and 2d, Article 9.

d. Clause 1b, Article 10.

3. Annul Circular No. 43/2011/TT-BYT dated December 05, 2011 of the Ministry of Health on management of infectious specimens.

Article 15. Amendments to some Articles on prevention and control of communicable diseases

1. Amendments to some Articles of the Government's Decree No. 103/2016/ND-CP dated July 01, 2016 on biosafety in laboratories:

Clause 1d, Article 4 is amended as follows:

"d. If the testing facilities specified in points a, b, c of this Clause have the equipment for storing the specimens and satisfy the regulations on standard practice, they are allowed to store, retain, use, research, exchange and dispose blood specimens, serum specimens, urine samples, fecal samples, secretion specimens and other specimens from human bodies which may or may not spread communicable diseases, as well as other micro-organisms specimens which may cause communicable diseases for people."

b. Clause 1b, Article 5 is amended as follows:

"b. Emergency eye wash kits and first aid kits."

c. Clause 1, Article 9 is amended as follows:

"1. Level I, level II and level III biosafety-testing facilities must comply with the requirements for facilities, equipment, employees and practices; restoration, maintenance and calibration of testing equipment and supervision of practices in the laboratory."

d. Clause 1, Article 10 is amended as follows:

"1. The Minister of Health shall conduct inspections, issue, re-issue or revoke the Certificates of Satisfaction of Biosafety Standards for level III biosafety-testing facilities (hereinafter referred to as "Certificate of Biosafety"), excluding testing facilities under the management of the Ministry of National Defense.

dd. Clause 1b, Article 11 is amended as follows:

“b. A list of employees, using form No. 03 in Appendix hereto.”

e. Clause 2c and 2dd, Article 11 are amended as follows:

“c. A report on changes in employees (if any)."

“dd. A report on changes to facilities.”

g. Clause 1, Article 17 is amended as follows:

“1. The Ministry of Health shall conduct regular or irregular inspections of testing facilities which have obtained the Certificate of biosafety of level III and the testing facilities which have declared themselves that they satisfy the biosafety standards of level I or level II nationwide.”

h. Clause 2, Article 19 is amended as follows:

“2. Annually, the level III biosafety laboratories must organize rehearsal of prevention and remedy for biosafety incidents according to the regulations of the Minister of Health.”

Clause 4, Article 20 is amended as follows:

“4. If an incident happening in a biosafety laboratory of level II and level III is spread widely, seriously influence the population communities or national security, the handling and remedy for such incident must comply with the provisions in section 2, Chapter IV of the Law on Prevention and Control of Communicable Diseases."

2. Amend Article 36 of the Government's Decree No. 89/2018/ND-CP dated June 25, 2018 providing guidelines for implementation of the Law on Prevention and Control of Communicable Diseases regarding border health quarantine, as follows:

“1. The health quarantine officer shall collect:

a. The Declaration of biological products, tissues and human body organs which are imported for the purpose of prevention, research, diagnosis and treatment of diseases.

b. The Ministry of Health’s declaration and license for import of blood specimens, serum specimens, urine samples, fecal samples, secretion specimens and other specimens from human bodies which may or may not spread communicable diseases, as well as other micro-organisms specimens which may cause communicable diseases for people. These specimens and samples are imported for the purpose of prevention, research, diagnosis and treatment of diseases.

2. The application for import shall contain:

a. An application form for the import license, using form No. 25 in Appendix hereto.

b. A copy of the written approval from a competent agency which allows the execution of the research project or topic. Such approval must still be effective. Or a copy of the approved outline or approved document of the project, or a copy of an effective agreement, or related documents on the import of specimens between domestic and foreign facilities.

c. A copy of the self-declaration about the ability to satisfy the biosafety standards. Such declaration is made by the biosafety laboratory level I and II. Or a copy of the Certificate of Biosafety-Testing Facility from the biosafety laboratory level III.

3. Procedures for issuance of the import license:

a. The applicant shall send 01 application in person or by post to the Ministry of Health.

b. If the application is deemed satisfactory, the Ministry of Health shall issue the import license within 15 working days from the date on which the application is received.

c. If the application is deemed unsatisfactory, within 10 days from the date on which the application is received, the Ministry of Health shall send a written notification to the applicant to request for additional documents.

d. Within 30 days from the date on which the written notification from the Ministry of Health is received, the applicant shall provide additional documents as required. If the aforesaid period ends and the applicant does not provide additional documents, it shall re-apply for the import license.

dd. If the additional documents are deemed unsatisfactory, the Ministry of Health shall send a written notification to the applicant as specified in point c of this clause. If the additional documents are deemed satisfactory, the Ministry of Health shall issue the import license according to point b of this clause."

3. Amend some articles of the Government's Decree No. 104/2016/ND-CP dated July 01, 2016 on vaccination:

a. Clause 1d, Article 8 is amended as follows:

"d. There must be equipment for monitoring temperature of vaccines throughout the transport, storage and handling of products. Temperatures shall be recorded during transport and delivery. Storage temperatures shall be checked and recorded at least twice a day."

b. Clause 1a, Article 9 is amended as follows:

"a. The vaccination area must be protected from rain and sunlight. Also, it must be airtight and airy and be arranged according to a flow pattern, including: welcoming patients, providing them guidance and counsel, performing screening tests, giving vaccination, monitoring and handling responses of post-vaccination."

c. Clause 3b, Article 9 is amended as follows:

"b. Health workers participating in vaccination must be trained in vaccination. Health workers performing screening tests, providing counsel, monitoring and handling responses of post-vaccination must have medical office assistant's degrees or higher; health workers giving vaccination must have associate degrees in medicine or nursing (midwife) or higher."

d. Clause 1c, Article 10 is amended as follows:

"c. It has adequate insulated containers and anti-shock kits according to the regulations of the Minister of Health."

dd. Clause 2b, Article 10 is amended as follows:

"b. Facilities must be arranged according to a flow pattern, including: welcoming patients, providing them guidance and counsel, performing screening tests, giving vaccination, monitoring and handling responses of post-vaccination."

e. Clause 2c, Article 10 is amended as follows:

"c. Equipment: Have insulated containers and anti-shock kits according to the regulations of the Minister of Health."

g. Clause 2d, Article 10 is amended as follows:

"d. Personnel: Have at least 02 health workers who satisfy the requirements specified in Clause 3b, Article 9 hereof."

h. Clause 2, Article 11 is amended as follows:

"2. Within 03 working days from the date on which the declaration is received, the Department of Health shall post the information about the name, address and head of the clinic on its website (the declaration date is determined according to the date stamp)."

Chapter VIII

PREVENTION AND CONTROL OF HIV/AIDS

Article 16. Annulment of some Articles on prevention and control of HIV/AIDS

1. Annul the following regulations of the Government's Decree No. 75/2016/ND-CP dated July 01, 2016 on conditions for HIV testing:

a. Article 3.

b. Clause 1b, Article 5.

c. Clause 2b, Article 5.

2. Annul the following regulations of the Government's Decree No. 90/2016/ND-CP dated July 01, 2016 on treatment for opioid substitution:

a. Clause 1b, 1c and 1d of Article 12.

b. Subpoints 6 and 7, Clause 2a, Article 12.

c. The sentence "The quantity of full-time employees must reach 75% or above of the total quantity of employees within the establishment" specified in Clause 3h, Article 12.

d. Clause 1b, Article 13.

3. Annul Circular No. 15/2013/TT-BYT dated May 24, 2013 on quality assurance and HIV testing techniques.

Article 17. Amendments to some Articles of the Government's Decree No. 75/2016/ND-CP dated July 01, 2016 on conditions for HIV testing

1. Article 4 is amended as follows:

"1. HIV screening tests conducted by the laboratories:

Personnel:

There must be testers who:

- Have specialized high school diplomas or higher in one of the following majors: Medicine, Pharmacy, Biology or Chemistry.

- Are trained in HIV testing.

b. The laboratory must have equipment used for testing and storing biologicals and specimens and is suitable to HIV testing techniques adopted by such laboratory.

c. Facilities: There must be a permanent location.

2. HIV screening tests in the community:

a. The testers must have knowledge about counseling and HIV tests and shall conduct HIV tests in accordance with the instructions of the manufacturer.

b. There must be equipment used for testing and storing biologicals and is suitable to the HIV biological being used."

2. Clause 1a, Article 5 is amended as follows:

"1a. The chief technician must have at least a bachelor's degree in medicine, pharmacy, biology or chemistry, as well as having experience in HIV testing for 06 months or above."

3. Clause 3, Article 5 is amended as follows:

"3. The facilities must satisfy the following requirements:

a. The materials in the testing area must be waterproof and resistant to high temperature and corrosive chemicals. The testing area must be sufficiently lighted, well-aired, clean, protected from dirt and humidity and must have clean water supply.

b. Testing tables must be easily cleaned with common detergents, placed at sufficiently lighted and windless positions.

c. Hand washing stations must be available.

d. There must be equipment or methods for treating wastes before they are moved to the common garbage dump."

4. Clause 4c, Article 5 is amended as follows:

"c. Receive accurate testing results of reference samples from an HIV testing laboratory recognized by the Ministry of Health."

Chapter IX

REPRODUCTIVE HEALTH

Article 18. Annulment of some Articles on reproductive health

1. Annul Article 7 of the Government's Decree No. 88/2008/ND-CP dated August 05, 2008 on sex reassignment.

2. Annul Clause 1, Article 1 of the Government's Decree No. 98/2016/ND-CP dated July 01, 2016 on amendments to some Articles of the Government's Decree No. 10/2015/ND-CP dated January 28, 2015 on giving birth through in vitro fertilization and conditions for altruistic gestational surrogacy.

3. Annul Circular No. 29/2010/TT-BYT dated May 24, 2010 on guiding some Articles of the Government's Decree No. 88/2008/ND-CP dated August 05, 2008 on sex reassignment.

Article 19. Amendments to some Articles on reproductive health

1. Amendments to the Government's Decree No. 88/2008/ND-CP dated August 05, 2008 as follows:

a. Article 8 is amended as follows:

"Article 8. Requirements for health facilities to be licensed to conduct medical intervention for sex reassignment

A health facility will be licensed to conduct medical intervention for sex reassignment if it satisfies the following requirements:

1. Be a public general or specialized hospital which has departments of surgery, obstetrics and pediatrics and is located in a province or a central-affiliated city, or a private hospital which has departments of surgery, obstetrics and pediatrics.

2. Its practice scope of medical intervention for sex reassignment is approved a competent authority."

b. Article 10 is amended as follows:

"Health facilities which have conducted medical interventions for sex reassignment shall issue the medical certificates for persons who have received medical interventions."

2. Amend the Government's Decree No. 10/2015/ND-CP dated January 28, 2015 on giving birth through in vitro fertilization and conditions for altruistic gestational surrogacy

a. Clause 2, Article 7 is amended as follows:

"2. Medical facilities, equipment and personnel performing in vitro fertilization shall include:

a. Facilities:

- Have an intensive care unit.

- Conduct reproductive endocrinology tests.

- Have a unit performing in vitro fertilization and include the following sections: oocyte retrieval; sperm collection; vitro culture; sperm testing and washing; such sections must satisfy the standards established by WHO.

b. Medical equipment:

Have at least 02 CO-2 incubators; 02 ovens for heat sterilizing; 01 sperm tank; 01 centrifuge; 01 embryo cryopreservation tank; 01 vagina ultrasound machine; 01 inverted microscope; 02 stereo zoom microscopes; 01 laminar flow cabinet.

c. Personnel:

The technicians directly perform in vitro fertilization shall satisfy the following requirements:

- There must be 02 doctors who are trained in performing in vitro fertilization and 02 employees who have bachelor's degrees in medicine, pharmacy or biology and are trained in clinical embryology.

- 02 clinical doctors must have practice certificates according to the Law on Medical Examination and Treatment.

- Employees must have qualifications or certificates of training in in vitro fertilization. Such certificates or qualifications must be granted by a domestic or foreign training institution.

- The employees must be confirmed in writing that they have provided fertility treatment by using in vitro fertilization technology for at least 20 periods. Such written confirmation must be issued by the Ministry of Health.

b. Amend form No. 02 (Appraisal Document) of the laboratory eligible for performing in vitro fertilization and storing sperm and eggs. Such form is enclosed with the Government's Decree No. 10/2015/ND-CP dated January 28, 2015.

Chapter X

IMPLEMENTATION

Article 20. Entry into force

This Decree shall take effect from the date of signing.

Article 21. Transitional provisions

1. Transitional provisions for Decree No. 89/2018/ND-CP:

a. The units granted the import and export licenses before this Decree takes effect shall continue to import specimens according to the contents specified in such licenses.

b. If the units applying for the import and export licenses submit their applications before this Decree takes effect but are not granted the licenses, they shall import the specimens according to the regulations specified in this Decree.

2. Transitional provisions for Decree No. 103/2016/ND-CP:

a. The testing facilities which are granted the certificates shall continue maintaining the required conditions within the effective period of such Certificates and shall submit self-declarations or apply for the re-issuance of the certificates before the expiration date as specified in the Decree No. 103/2016/ND-CP and this Decree.

b. The testing facilities which have submitted self-declarations about their ability to satisfy the biosafety standards shall continue maintaining the required conditions mentioned in the Decree No. 103/2016/ND-CP and this Decree.

c. The testing facilities that are newly built or upgraded after this Decree takes effect shall satisfy the biosafety requirements suitable to each level, according to the regulations in the Decree No. 103/2016/ND-CP and this Decree.

3. Transitional provisions for the Decree No. 104/2016/ND-CP:

a. The vaccination clinics which are granted the Certificates of Eligibility for Vaccination shall continue maintaining the required conditions within the effective period of such Certificates and make a self-declaration about their eligibility before the expiration date of the Certificates, according to the regulations specified in the Decree No. 104/2016/ND-CP and this Decree.

b. The vaccination clinics which have submitted the declarations about their eligibility for vaccination shall continue maintaining the conditions mentioned in the Decree No. 104/2016/ND-CP and this Decree.

c. The vaccination clinics, which operate after this Decree takes effect, shall satisfy the requirements specified in the Decree No. 104/2016/ND-CP and this Decree.

4. Transitional provisions for the Decree No. 54/2017/ND-CP:

a. If the applications for the practice certificates or the Certificates of Eligibility for Pharmacy Business or the import and export licenses which are specified in the Decree No. 54/2017/ND-CP are submitted before this Decree takes effect, they shall be appraised according to the regulations in the aforesaid Decree.

b. The medicinal ingredients, which are used for producing drugs and are licensed before this Decree takes effect, shall continue to be imported until the expiration date of the license.

c. The drugs which are procured by the retailers in the health facilities before this Decree takes effect shall comply with the regulations in the Decree No. 54/2017/ND-CP.

5. Transitional provisions for the Decree No. 109/2016/ND-CP:

The applications submitted to request for the practice certificates or the operating licenses before this Decree takes effect shall comply with the regulations in the Government's Decree No. 109/2016/ND-CP dated July 01, 2016.

Article 22. Implementation responsibilities

The Ministers and Heads of ministerial agencies, Heads of governmental agencies, Chairpersons of the People's Committees of provinces and central-affiliated cities shall implement this Decree./.

PP. THE GOVERNMENT
PRIME MINISTER

Nguyen Xuan Phuc

MINISTRY OF HEALTH ---	SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness ---
No.: 01/2018/TT-BYT	*Hanoi, January 18, 2018*

CIRCULAR

ON LABELING AND PACKAGE INSERTS OF DRUGS AND MEDICINAL INGREDIENTS

Pursuant to the Law on Pharmacy No. 105/2016/QH13 dated April 06, 2016;

Pursuant to the Government's Decree No. 54/2017/ND-CP dated May 08, 2017 on guidelines for implementation of the Law on Pharmacy;

Pursuant to the Government's Decree No. 43/2017/ND-CP dated April 14, 2017 on good labeling;

Pursuant to the Government's Decree No. 75/2017/ND-CP dated June 20, 2017 defining Functions, Tasks, Powers and Organizational Structure of Ministry of Health;

At the request of the Director of the Drug Administration of Vietnam;

Minister of Health promulgates a Circular on labeling of drugs, medicinal ingredients and package inserts.

Chapter I

GENERAL PROVISIONS

Article 1. Scope

1. This Circular provides for information on labels, methods for labeling and package inserts of drugs and medicinal ingredients sold on the market; change of expiry dates of labeled drugs because of national defense and security, epidemic control or disaster recovery need.

2. This Circular does not apply to labels of:

a) Drugs and medicinal ingredients which are used for export but not yet registered in Vietnam;

b) Drugs imported for non-commercial purposes as regulated in Clause 1 Article 75 of the Government's Decree No. 54/2017/ND-CP dated May 08, 2017 on guidelines for implementation of the Law on Pharmacy (hereinafter referred to as "Decree No. 54/2017/ND-CP");

c) Drugs imported to meet urgent need of national defense and security, epidemic control or disaster recovery as regulated in Clause 1 Article 67 of the Decree No. 54/2017/ND-CP.

Article 2. Interpretation of terms

For the purpose of this Circular, the terms below are construed as follows:

1. "commercial package of a drug" means the package that envelops the drugs and the package insert and is sold together with drugs. Commercial packages of drugs include primary package, secondary package, and probably intermediate package.

2. "intermediate package" means the package which is used to wrap one or some units of drugs that already have primary packages and contained in the secondary package.

3. "batch number" means a series of numbers or letters or both that helps recognize the batch of drug or medicinal ingredient and permits the trace of history of a batch of drugs or medicinal ingredients, including all production stages, quality inspections and sale of that batch of drugs or medicinal ingredients.

4. "original label" means the label that is first affixed by the manufacturer on the commercial packages of the drug or medicinal ingredient.

Article 3. Positions of labels of drugs or medicinal ingredients and package inserts

1. Positions of labels of drugs or medicinal ingredients shall follow regulations in Article 4 of the Government's Decree No. 43/2017/ND-CP dated April 14, 2017 on good labeling (hereinafter referred to as "Decree No. 43/2017/ND-CP").

2. Package insert is an integral part of the drug label and contained in the secondary package. If a drug does not have the secondary package, the package insert must be printed or affixed on the primary package.

Article 4. Sizes of labels, sizes of letters and numbers on labels, colors of text, symbols, and pictures on the labels, languages on labels and package inserts

1. Sizes of labels, sizes of letters and numbers on labels, colors of text, symbols, and pictures on the labels of drugs or medicinal ingredients and package inserts shall follow regulations in Article 5 (excluding regulations in Point b Clause 2 Article 5) and Article 6 of the Decree No. 43/2017/ND-CP.

2. Compulsory information on a label of drug or medicinal ingredient and the package insert must be written in Vietnamese language, except for some contents which may be written in other Romance languages as regulated in Clause 4 Article 7 of the Decree No. 43/2017/ND-CP.

Article 5. Affixing secondary labels and addition or replacement of package inserts in Vietnam

1. If the original label of drugs or medicinal ingredients imported into Vietnam does not contain sufficient compulsory information as regulated by the Ministry of Health, the importer must keep the original label unchanged and affix the secondary labels in Vietnamese language in conformity with regulations of the Ministry of Health before such imported drugs or medicinal ingredients are sold on the market.

2. Importers in the following cases shall be granted customs clearance in order to add or replace package inserts in Vietnamese language in Vietnam:

a) Imported drugs which have been granted the Certificate of registration in Vietnam and have the package inserts in Vietnamese language contained in their commercial packages but been not yet updated with compulsory information as regulated the Ministry of Health, except for the cases where package inserts are exempted according to regulations in Points a, b, c and d Clause 1 Article 13 herein;

b) Imported drugs which are not yet granted the Certificate of registration in Vietnam and do not have the package inserts in Vietnamese language contained in their commercial packages, except for the cases where package inserts are exempted according to regulations in Points a, b, c, d and dd Clause 1 Article 13 herein.

3. Principles and locations for affixing secondary labels and adding or replacing package inserts in Vietnam:

After the customs clearance is granted, importers of drugs or medicinal ingredients mentioned in Clause 1 and Clause 2 of this Article must affix the secondary labels, add or replace package inserts in Vietnamese language according to the following principles:

a) Secondary labels shall be affixed in a drug or medicinal ingredient storage facility that has GSP certificate of the importer;

b) Package inserts in Vietnamese language shall be added or replaced by the secondary packaging division of a facility that has GMP certificate in conformity with the scope of the Certificate of eligibility for pharmacy business;

c) Affixing secondary labels or adding or replacing package inserts in Vietnamese language in Vietnam should avoid influencing the quality of drugs or medicinal ingredients.

4. In case of addition or replacement of package inserts in Vietnamese language as regulated in Point b Clause 3 of this Article, the secondary packaging facility must properly comply with GMP guidelines in course of adding or replacing package inserts as regulated in Point b Clause 3 of this Article and also submit reports to the Ministry of Health to serve the fulfillment of pharmacy business management and inspection tasks. To be specific:

a) Reports must be submitted within one (01) month from the completion of the addition or replacement of package inserts in Vietnam;

b) A report must contain the following compulsory contents: Name of importer; name of drug; registration number or import license number; batch number; manufacturing date; expiry date; quantity of drugs of which package inserts have been added or replaced.

5. The entity responsible for labeling shall supervise and cooperate with the facility in charge of affixing secondary labels or adding or replacing package inserts and assume responsibility for quality of drugs or medicinal ingredients during the affixing of secondary labels or addition or replacement of package inserts.

Article 6. Responsibility for labeling of drugs and medicinal ingredients and package inserts

1. Entities responsible for labeling of drugs or medicinal ingredients, including secondary labels and package inserts, must ensure that the information on labels must be truthful, clear and accurate, and reflect the nature of drugs or medicinal ingredients.

2. With regard to drugs or medicinal ingredients manufactured in Vietnam:

a) The manufacturer and/or registrant are responsible for labeling and package inserts of drugs or medicinal ingredients manufactured and/or registered;

b) Health facilities that are allowed to prepare traditional drugs in accordance with regulations in Clause 1 and Clause 2 Article 70 of the Law on Pharmacy and health facilities that are allowed to produce and prepare drugs in accordance with regulations in Clause 2 and Clause 3 Article 85 of the Law on Pharmacy are responsible for labeling of their drugs prepared or produced;

c) Drugstores that prepare prescription drugs and sell them in accordance with regulations in Point b Clause 1 Article 47 of the Law on Pharmacy are responsible for labeling of their prescription drugs prepared.

3. With regard to imported drugs or medicinal ingredients:

a) The importer and/or registrant of drugs are responsible for labeling and package inserts of drugs having registration numbers;

b) The importer and/or registrant of medicinal ingredients are responsible for labeling of imported medicinal ingredients;

c) The importer is responsible for labeling and package inserts of imported drugs without registration numbers.

4. With regard to medicinal ingredients divided into smaller package units in course of wholesale or retail: Pharmacy business establishments that divide drugs into smaller package units are responsible for affixing secondary labels in conformity with regulations in Clause 2 and Clause 3 Article 7 herein.

Chapter II

INFORMATION ON DRUG LABELS AND PACKAGE INSERTS

Section 1. COMPULSORY INFORMATION ON LABELS

Article 7. Secondary package labels of drugs and medicinal ingredients

1. The secondary package label of drugs must contain the compulsory information below:

a) The drug name;

b) Dosage form;

c) The composition of the drugs, contents, weights or concentrations of active ingredients or herbal ingredients;

d) Package contents;

dd) Indications, usage instructions and contraindications;

e) Registration number or import license number (if any);

g) Batch number, manufacturing date, expiry date, quality standards and storage conditions;

h) Precautions and recommendations;

i) Name and address of manufacturer;

k) Name and address of importer (for imported drugs);

l) Drug origin.

2. The secondary package label of medicinal ingredients (including herbal ingredients, traditional ingredients, semi-finished drugs and semi-finished herbal medicines) must contain the compulsory information below:

a) Name of medicinal ingredients;

b) Weight or volume of medicinal ingredients contained in a smallest package unit;

c) Quality standards of medicinal ingredients;

d) Registration number or import license number (if any);

dd) Batch number, manufacturing date, expiry date and storage conditions;

e) Name and address of manufacturer of medicinal ingredients;

g) Name and address of importer (for imported medicinal ingredients);

h) Origin of medicinal ingredients.

3. Labels of controlled medicinal ingredients (including controlled semi-finished drugs):

In addition to compulsory information specified in Clause 2 of this Article, the following texts must be specified on secondary labels of medicinal ingredients which are active ingredients, herbal ingredients or semi-finished drugs containing active ingredients or herbal ingredients on the Lists of narcotic active ingredients, psychotropic ingredients, drug precursors, toxic medicinal ingredients, toxic herbal ingredients and radioactive medicinal ingredients: “Nguyên liệu gây nghiện” (“Narcotic active ingredients”), “Nguyên liệu hướng thần” (“Psychotropic ingredients”), “Nguyên liệu tiền chất làm thuốc” (“Drug precursors"), “Nguyên liệu độc” (“Toxic medicinal ingredients”), “Dược liệu độc” (“Toxic herbal ingredients”) or “Nguyên liệu phóng xạ” (“Radioactive medicinal ingredients”).

The text “Nguyên liệu gây nghiện”, “Nguyên liệu hướng thần”, “Nguyên liệu tiền chất làm thuốc”, “Nguyên liệu độc”, “Dược liệu độc”, “Nguyên liệu phóng xạ” must be printed bold type in box and on the main side of the label on which the name of medicinal ingredients is specified.

4. If the secondary package label cannot contain all compulsory information prescribed in Clause 1 of this Article, the information specified in Point dd Clause 1 of this Article may be briefly summarized by the following text: “Chỉ định, cách dùng, chống chỉ định và các thông tin khác: xem trong tờ hướng dẫn sử dụng thuốc kèm theo” (“Please refer to the package insert for indications, usage instructions, contraindications and other information”).

Article 8. Intermediate package labels

1. The intermediate package label of drugs must contain the compulsory information below:

a) The drug name;

b) Batch number;

c) Expiry date.

2. If the intermediate package is made of transparent materials through which information on the primary package label may be revealed, it is not required to have the information specified in Clause 1 of this Article.

Article 9. Primary package labels of drugs and medicinal ingredients

1. The primary package label of drugs must contain the compulsory information below:

a) The drug name;

b) The composition of the drugs, contents, weights or concentrations of active ingredients or herbal ingredients;

c) Batch number;

d) Expiry date;

dd) Name of manufacturer.

2. Primary package labels of medicinal ingredients:

If the secondary package label of medicinal ingredients contains sufficient compulsory information as regulated in Clause 2 and Clause 3 Article 7 herein, the primary package label may be exempted provided that the medicinal ingredients are not divided for retail.

3. If there is no secondary package, primary package labels of drugs and medicinal ingredients must contain sufficient information of secondary package labels as regulated in Article 7 herein.

Article 10. Secondary labels

1. The secondary label shall contain every compulsory information which is not written on the original label in Vietnamese language as prescribed in Article 7 of this Circular.

2. If the secondary label is so small that it cannot contain compulsory information as specified in Clause 1 of this Article 7, certain compulsory information may be written as follows:

a) Indications, usage instructions, contraindications and other information: Please refer to the package insert;

b) The way to find out the information about manufacturing date, expiry date and batch number printed on the original label must be available;

c) Registration number or import license number may not be specified but the information about registration number or import license number (if any) must be specified before drugs are sold on the market.

Article 11. Drug labels in other cases

1. Traditional drugs prepared according to regulations in Clause 1 and Clause 2 Article 70 of the Law on Pharmacy and drugs produced and prepared according to regulations in Clause 2 and Clause 3 Article 85 of the Law on Pharmacy must have labels containing the following compulsory information, except for the cases mentioned in Clause 3 of this Article:

a) The secondary package label of traditional drugs and prepared drugs must contain the following information:

- The information prescribed in Points a, b, c, d, dd, g and h Clause 1 Article 7 herein;

- Name and address of health facility producing or preparing drugs.

b) The primary package label of traditional drugs must contain the compulsory information below:

- The information prescribed in Points a, b, c and d Clause 1 Article 9 herein;

- Name of health facility producing or preparing drugs.

c) If there is no secondary package, the primary package label of traditional drugs and prepared drugs must contain sufficient compulsory information of the secondary package label as prescribed in Point a Clause 1 of this Article.

2. Drugs prepared according to prescriptions and sold at drugstores in accordance with regulations in Point b Clause 1 Article 47 of the Law on Pharmacy must have secondary package labels or primary package labels containing the compulsory information below:

a) Drug name, dosage form;

b) Active ingredients and concentrations or contents thereof;

c) Preparation date, expiry date, storage conditions;

d) Name and address of drugstore preparing drugs;

dd) Name of patient presenting the prescription;

e) Precautions for controlled drugs.

3. Traditional drugs prepared according to prescriptions in accordance with regulations in Clause 1 Article 70 of the Law on Pharmacy are exempted from labeling as prescribed in this Circular but must have the secondary package on which full name and age of patient are specified to avoid mistake while delivering drugs.

4. Drugs which have been not yet granted the Certificate of registration in Vietnam but are imported to serve the purpose of bioequivalence study, bioavailability assessment, use as specimens for registration, testing or scientific research, or display at a fair or exhibition shall be exempted from labeling with compulsory information prescribed in Article 7 and Article 8 herein but must have their original labels unchanged and affixed with secondary labels as follows:

a) The secondary label of drugs used for bioequivalence study, bioavailability assessment or as specimens for testing or scientific research must have the text "Thuốc dùng cho mục đích nghiên cứu" ("Drugs used for research purpose");

b) The secondary label of drugs used as specimens for registration must have the text "Thuốc làm mẫu đăng ký" ("Drugs used as registration specimens");

c) The secondary label of drugs used for display at a fair or exhibition must have the text "Thuốc làm mẫu trưng bày" ("Drugs for display").

5. Medicinal ingredients which are active ingredients and have been not yet granted the Certificate of registration in Vietnam but are imported to use as specimens for registration, testing or research, or for display at a fair or exhibition in accordance with regulations in Clause 3 Article 60 of the Law on Pharmacy shall be exempted from labeling with compulsory information prescribed in Article 7 and Article 8 herein but must have their original labels unchanged.

6. Medicinal ingredients which are active ingredients, excipients or semi-finished drugs and have been not yet granted the Certificate of registration in Vietnam but are imported to produce drugs according to registration documents of drugs granted the Certificate of registration in Vietnam must have secondary labels containing compulsory information prescribed in Clause 2 and Clause 3 Article 7 herein (except for name and address of importer). The secondary label may be exempted if the original label contains all this compulsory information in other Romance languages.

7. Drugs imported in accordance with regulations in Point b Clause 1 Article 68 of the Decree No. 54/2017/ND-CP shall be exempted from labeling in Vietnamese language as regulated herein provided that their original labels must be kept unchanged.

Section 2. INFORMATION ON PACKAGE INSERTS

Article 12. Information on package inserts

The package insert of drugs must contain the compulsory information below:

1. The drug name.

2. Precautions and recommendations.

3. Composition of the drug.

4. Dosage form.

5. Indications.

6. Usage instructions and dose.

7. Contraindications.

8. Warnings and cautions.

9. Warnings for the use of drugs during pregnancy and breastfeeding.

10. Influence of the drug on ability to drive or operate machinery.

11. Drug interactions and incompatibilities.

12. Adverse drug reactions.

13. Overdose and treatment.

14. Information about pharmacodynamics (not applicable to OTC drugs, herbal drugs and traditional drugs).

15. Information about pharmacokinetics (not applicable to OTC drugs, herbal drugs and traditional drugs).

16. Package contents.

17. Storage conditions, expiry date and quality standards.

18. Name and address of manufacturer.

Article 13. Requirements of a package insert

1. Every drug sold on the market, or produced or prepared by a health facility as regulated in Clause 1 Article 11 herein, must have a package insert written in Vietnamese language, except for the following cases:

a) Drugs produced or prepared according to traditional remedies or prescriptions as regulated in Clause 1 Article 70 and Clause 2 Article 85 of the Law on Pharmacy for use or retail according to prescriptions at health facilities;

b) Drugs prepared and retailed at drugstores in accordance with regulations in Point b Clause 1 Article 47 of the Law on Pharmacy;

c) Drugs which have been not yet granted the Certificate of registration in Vietnam but are imported to serve the purpose of bioequivalence study, bioavailability assessment, use as specimens for registration, testing or scientific research, or display at a fair or exhibition;

d) Drugs imported in accordance with regulations in Point b Clause 1 Article 68 of the Decree No. 54/2017/ND-CP;

dd) OTC drugs having labels containing all compulsory information of the package insert as prescribed in Article 12 herein.

2. Package inserts in foreign languages of the drugs mentioned in Point d Clause 1 of this Article must be kept unchanged.

3. If multiple drugs share the same name, active ingredients, herbal ingredients, dosage form, administration route, indications and manufacturer but the volume, contents, concentrations, weights or package contents are different and all of them are permitted for free sale, they may be written on the same package insert.

If there are differences in concentrations or contents, it is required to specify the concentrations, contents, volumes or package contents.

4. At least one package insert in Vietnamese language must be contained in the secondary package of drugs. If there is no secondary package, at least one package insert must be contained in the primary package of drugs.

Chapter III

PRESENTATION OF INFORMATION ON DRUG LABELS AND PACKAGE INSERTS

Article 14. Names of drugs and medicinal ingredients

1. The name of drug or medicinal ingredient must be easily recognizable and of a size bigger than that of other compulsory information on the label or package insert.

2. The name of drug or medicinal ingredient must be written in a Romance language and may contain digits, Roman numbers or other symbols written in Greek alphabet (e.g. alpha, beta).

3. The drug name shall be its trade name or international nonproprietary name. Names of traditional drugs on the List of traditional drugs recognized by the Ministry of Health shall be trade names or names of traditional remedies approved by the Ministry of Health, except traditional ingredients. The trade name of drug should not:

a) Provide any advertising information;

b) Provide any misleading information about the composition or origin of the drug. If the drug contains multiple active ingredients or herbal ingredients, the name of any ingredient is not used as the drug name;

c) Cause misinterpretation or provide exaggerated description of effects or indications of the drug;

d) Show any disrespect to Vietnamese traditional values and customs;

dd) Cause conflicts with protected products of other intellectual property rights holders;

e) Be identical or similar to the name of drugs granted certificate of registration of another facility;

g) Use the same name for drugs containing different active ingredients;

h) Use different names for the drugs that have same active ingredients or herbal ingredients, dosage form, administration route, concentrations or contents and manufacturer. This provision shall not apply to processed drugs which shall be governed by specific regulations on domestic processing of drugs announced by the Minister of Health;

i) If multiple drugs share the same name, manufacturer, dosage form and active ingredients but the concentrations or contents are different, corresponding concentrations or contents may be written next to the drug name in a recognizable way.

4. The name of medicinal ingredients (excluding herbal ingredients and semi-finished drugs) shall be written in accordance with regulations in Clause 2 Article 16 herein.

5. The name of traditional ingredients shall be the name of herbal ingredients which are written in accordance with regulations in Clause 3 Article 16 herein and have the phrase “vị thuốc cổ truyền” (“traditional ingredients”) added before the Vietnamese name of herbal ingredients.

6. The name of herbal ingredients shall be written in accordance with regulations in Clause 3 Article 16 herein.

7. The name of semi-finished herbal medicines shall be written in accordance with regulations in Clause 4 and Clause 5 Article 16 herein.

8. The name of semi-finished drugs (excluding semi-finished herbal medicines) shall be written in accordance with regulations in Clause 6 Article 16 herein.

Article 15. Precautions and recommendations

1. The following precautions and recommendations must be written on labels and package inserts of drugs:

a) The text ““Để xa tầm tay trẻ em” ("Keep away from children") and “Đọc kỹ hướng dẫn sử dụng trước khi dùng” ("Read instructions carefully before use");

b) For prescription drugs:

- On the label of the secondary package: On the upper left corner of the drug name must have the symbol "Rx" and the text “Thuốc kê đơn" (“Prescription drugs”);

- On the package insert: On the upper left corner of the drug name must have the symbol "Rx" and the text “Thuốc này chỉ dùng theo đơn thuốc” (“This drug is taken with prescription only").

c) For controlled drugs or other drugs:

- Radioactive drugs must have the text “**THUỐC PHÓNG XẠ**” (“**RADIOACTIVE DRUG**”) written in a bold and uppercase type;

- Drugs on the list of toxic drugs announced by the Ministry of Health must have the text "**THUỐC ĐỘC**" ("**TOXIC DRUG**") written in a bold and uppercase type;

- Drugs used to serve a health program of the State must have the text "Thuốc chương trình, không được bán" ("For a health program, not for sale");

- Drugs used as emergency aid or humanitarian aid must have the text "Thuốc viện trợ, không được bán" ("As emergency aid or humanitarian aid, not for sale");

- The label of drugs used for clinical testing purpose must have the text "Thuốc dùng cho thử lâm sàng. Cấm dùng cho mục đích khác" ("Do not use for any purposes other than the clinical testing");

- Biosimilars must have both name of the biosimilar and name of the reference biologic.

d) Other precautions and recommendations for each type of drug:

- The administration route of injectable drug must be written briefly or in full on the label, including: "tiêm bắp" ("intramuscular injection"), "tiêm dưới da" ("subcutaneous injection"), "tiêm tĩnh mạch" ("intravenous injection"), "tiêm truyền tĩnh mạch" ("intravenous infusion"), etc.

- The text "Thuốc nhỏ mắt" and "Thuốc tra mắt" shall be written on labels of eye drops and eye ointment respectively; "Thuốc nhỏ mũi" on labels of nose drops; "Thuốc nhỏ tai" on labels of ear drops;

- The text "Thuốc dùng ngoài" shall be written on labels of topical drugs; "Không được tiêm" ("No injection") on bottles of oral drugs;

- Drugs that must be shaken well before use (E.g.: multi-dose packages of drugs in the form of blends, powder and granule that must be reconstituted before use or easily deposited or separated into layers after being dissolved) must have the text "Lắc kỹ trước khi dùng" ("Shake well before use").

2. Format of precautions and recommendations:

a) The text and symbols must be clearly printed on secondary packages or secondary labels and package inserts. Contents must be clear enough to be read in normal conditions;

b) On package inserts: Precautions and recommendations prescribed in Points a, b and c Clause 1 of this Article, except for the symbol "Rx", must be written right below the drug name;

c) All the precautions of the drug must be written.

Article 16. Composition of drugs and semi-finished drugs

1. General provisions:

a) Secondary package labels of drugs and semi-finished drugs:

- The names of active ingredients or herbal ingredients and concentrations or contents thereof in a smallest dose or package of drugs or semi-finished drugs shall be specified;

- For vaccine: Active ingredients in a dose unit shall be specified;

- For biologics: Contents of the biologic shall be expressed according to the weight unit, the unit of biologic activity or the international unit of each biologic;

- For traditional drugs, herbal drugs, semi-finished traditional rugs and semi-finished herbal drugs: Names of herbal ingredients shall be Vietnamese names. Their scientific names are not required on the labels;

- Composition, contents, weights, volumes or concentration of excipients is not required on the labels;

- Labels of traditional drugs on the list of State secrets and labels of family remedies as recognized by the Ministry of Health are allowed to omit certain herbal ingredients and contents or weights thereof. In such case, secondary package labels must have the text "Công thức sản xuất thuốc là bí mật nhà nước" ("The formula is state secret") or "Công thức sản xuất thuốc là bí mật gia truyền" ("The formula is family secret").

b) Primary package labels of drugs and semi-finished drugs:

- If the drug or semi-finished drug contains from one to three active ingredients or herbal ingredients, all active ingredients or herbal ingredients shall be specified in accordance with regulations in Point a of this Clause;

- If the drug or semi-finished drug contains more than three active ingredients or herbal ingredients, names of active ingredients or herbal ingredients are not required on primary package labels. Active ingredients or herbal ingredients and contents thereof may be also specified on labels in accordance with regulations in Point a of this Clause;

- If drug is in a liquid form, the drug labels must have the volume in a smallest package unit.

c) Package inserts:

- The names of active ingredients or herbal ingredients and concentrations, weights or contents thereof in a smallest dose or smallest package unit must be specified on package inserts. The text “Thành phần dược chất:” or “Thành phần hoạt chất:” (“Active ingredients:”) must be specified before names of active ingredients or herbal ingredients;

- All excipients in the drug formula must be specified and the text “Thành phần tá dược:” (“Excipients:”) must be also specified before names of excipients. The excipients that evaporate or disappear during the manufacturing process may be omitted. The weights, volumes, contents or concentrations of excipients are not required;

- The package insert of vaccines must have all active ingredients in a dose unit;

- For biologics: Contents of the biologic shall be expressed according to the weight unit, the unit of biologic activity or the international unit of each biologic;

- For traditional drugs and herbal drugs: Both Vietnamese name and scientific name of each herbal ingredient shall be specified. The scientific name of herbal ingredient shall be italicized in the brackets right after its Vietnamese name;

- Package inserts of traditional drugs on the list of State secrets and labels of family remedies as recognized by the Ministry of Health are allowed to omit certain herbal ingredients and contents or weights thereof. In such case, package inserts must have the text “Công thức sản xuất thuốc là bí mật nhà nước” or “Công thức sản xuất thuốc là bí mật gia truyền”.

2. Expression of active ingredients and excipients:

a) Name of an active ingredient or excipient shall be its international nonproprietary name or scientific name;

b) It is not required to translate names of active ingredients and excipients into Vietnamese language.

3. Expression of herbal ingredients and traditional ingredients:

a) Vietnamese name:

- Names of herbal ingredients and traditional ingredients shall be conventional names in Vietnamese language as specified in the Pharmacopoeia of Vietnam or in the lists of drugs and medicinal ingredients announced by the Minister of Health;

- If Vietnamese names of herbal ingredients are not available in the Pharmacopoeia of Vietnam or the lists of drugs and medicinal ingredients announced by the Minister of Health, Vietnamese names of these herbal ingredients as specified in the book “Những cây thuốc và vị thuốc Việt Nam" (“Traditional plants and ingredients of Vietnam”) of Mr. Do Tat Loi, or the book “1000 Cây thuốc và động vật làm thuốc" (“1000 medicinal plants and animals”) of the National Institute of Medicinal Materials. In such cases, names of herbal ingredients shall be decided by the Minister of Health according to the counseling of the Advisory Council for drug registration certification affiliated to the Ministry of Health.

- If the names of imported herbal ingredients cannot be translated into Vietnamese language, the names in the exporting country (or the country of origin) and their scientific names shall be written;

- If more than one part of the plant is used as herbal ingredients of traditional ingredients, the parts must be specified. Example: Tam sen, Hoa hoe, Kim ngan hoa.

b) Scientific names (Latin names):

- Scientific names of herbal ingredients or traditional ingredients shall be their scientific names in italics in the Pharmacopoeia of Vietnam or in the lists of herbal ingredients and traditional ingredients announced by the Minister of Health;

- If scientific names of herbal ingredients and traditional ingredients are not available in the Pharmacopoeia of Vietnam or in the Minister of Health's lists of herbal ingredients and traditional ingredients, their scientific names in foreign pharmacopoeias shall be written.

4. Expression of bone glue, type and formula of bone glue:

a) Expression of the bone glue:

- Name of the bone glue, type and composition of the bone glue, concentrations, contents or weights of herbal ingredients in the bone glue must be specified;

- If the bone glue has a trade name, this trade name and names of herbal ingredients in the bone glue shall be specified in accordance with regulations in Clause 3 of this Article;

- In case there is no trade name, the word "cao" ("bone glue") shall be specified right before the name of herbal ingredient (if the bone glue contains the only ingredient) or the phrase "cao hỗn hợp dược liệu" ("bone glue mixture") shall be specified right before names of herbal ingredients (if the bone glue contains multiple ingredients).

b) Expression of type of the bone glue:

- Type of the bone glue must be clearly specified. There are three types of the bone glue, liquid, solid and dried glue according to Vietnam's pharmacopoeia;

- If the type of the bone glue is not identified, the moisture content limit and name of the bone glue or the ratio of bone glue and initial herbal ingredients must be specified.

c) Expression of formula of the bone glue:

- If the treatise of Vietnam's pharmacopoeia or a foreign pharmacopoeia recognized by the Ministry of Health provides criteria for quantifying contents of active ingredients or compounds, name of the bone glue must be written together with the contents (%) of active ingredients or compounds quantified in each herbal ingredient;

- If the treatise of Vietnam's pharmacopoeia or foreign pharmacopoeias recognized by the Ministry of Health does not provide criteria for quantifying contents of active ingredients or compounds, name of the bone glue must be written together with the weight of corresponding initial herbal ingredients or the ratio of the bone glue and the initial herbal ingredients (initial herbal ingredients are herbal ingredients qualified for medicinal use);

- If the solvent used for extracting herbal ingredients to manufacture bone glue is not ethanol, water or a mixture of ethanol and water, the name of the bone glue must be written together with that of the solvent.

5. Expression of name of semi-finished herbal medicines (excluding bone glue):

a) The name of semi-finished herbal medicine and the composition, concentrations, contents or quantities of herbal ingredients contained in the semi-finished herbal medicine must be fully specified;

b) Expression of the name of semi-finished herbal medicine:

- If the semi-finished herbal medicine has a trade name, this trade name shall be written together with the name of every herbal ingredient contained in the semi-finished herbal medicine in accordance with regulations in Clause 3 of this Article;

- If there is no trade name, the name of herbal ingredient shall be written according to regulations in Clause 3 of this Article (if the semi-finished herbal medicine contains the one herbal ingredient) or the text "hỗn hợp dược

liệu" ("mixture of herbal ingredients") shall be written (if the semi-finished herbal medicine contains multiple herbal ingredients). The form of the semi-finished herbal medicine (such as powder or granule) must be also written right before the name of herbal ingredient or the text " hỗn hợp dược liệu".

c) Expression of formula of the semi-finished herbal medicine:

- If the treatise of Vietnam's pharmacopoeia or a foreign pharmacopoeia recognized by the Ministry of Health provides criteria for quantifying contents of active ingredients or compounds, name of the semi-finished herbal medicine shall be written together with the contents (%) of active ingredients or compounds quantified in each herbal ingredient;

- If the treatise of Vietnam's pharmacopoeia or foreign pharmacopoeias recognized by the Ministry of Health does not provide criteria for quantifying contents of active ingredients or compounds, name of the semi-finished herbal medicine must be written together with the weights of corresponding initial herbal ingredients or the ratio of the semi-finished herbal medicine and the initial herbal ingredients (initial herbal ingredients are herbal ingredients qualified for medicinal use).

6. Expression of name of semi-finished drugs (excluding semi-finished herbal medicines):

a) The name of semi-finished drug and the composition, contents, concentrations or weights of active ingredients contained in the semi-finished drug must be sufficiently specified; b) Expression of the name of semi-finished drug:

- If the semi-finished drug has a trade name, this trade name shall be written together with the name of every active ingredient contained in the semi-finished drug in accordance with regulations in Clause 2 of this Article;

- If there is no trade name, the name of active ingredient shall be written according to regulations in Clause 2 of this Article (if the semi-finished drug contains the one active ingredient) or the text "hỗn hợp dược chất" ("mixture of active ingredients") shall be written (if the semi-finished drug contains multiple active ingredients). The form of the semi-finished drug (such as powder or granule) must be also written right before the name of active ingredient or the text " hỗn hợp dược chất".

c) Expression of formula of the semi-finished drug: Regulations on semi-finished drugs in Clause 1 of this Article shall be applied.

7. Measurement units:

Contents, concentrations, weights and volumes are expressed as weight units, volume units, activity units or other common measurement units. To be specific:

a) Weight units: gram (g), milligram (mg), microgram (μg or mcg), or kilogram (kg). The weight below 1 mg shall be expressed as a decimal fraction (e.g. 0.25 mg);

b) Volume units: Mililiter (ml), microliter (μl or mcl), or liter (l or L). The volume below 1 ml shall be expressed as a decimal fraction (e.g. 0.5 ml);

c) Other measurement units:

- International activity units may be used for special active ingredients;

- If internationalized medical measurement units such as IU and other conventional units of activity of certain special active ingredients may cause misinterpretation if translated into Vietnamese language, they may be kept unchanged.

d) Where the form of an active ingredient is different from the form used for dose determination, the secondary package label and package insert must have the conversion of the concentration, content or weight of that active ingredient to the form used for dose determination. The form of an active ingredient is either base, salt, hydrate or another form.

Article 17. Dosage form

1. The dosage form must be clearly specified and might be: tablets, hard capsules, solution for injection, powder for solution for injection, suppositories (specify inserting positions), powders, granules and other types of drugs according to the Pharmacopoeia of Vietnam or common International Pharmacopoeias.

2. In addition to the information specified in Clause 1 of this Article, package inserts must have the additional information below:

a) External features such as color, size, form, shape or other external signs (if any);

b) Whether scored tablets should be split in half or not;

c) Information about pH and osmotic concentration (if any).

Article 18. Indications

Indications of a drug must be conformable with its dosage form and administration route. The indications must be clear, particular, and must specify:

1. Purposes of the drug: whether the drug is used for curative, supportive care, preventive or symptom relief purpose.

2. Drug users (if any): specify the drug indications applied to each type of drug users; drug users may be sorted by age or group of age.

3. Additional conditions for safe and effective use of drugs (if any), e.g. the drug must be combined with other drugs or methods to improve the effectiveness or reduce side effects during the course of treatment.

Article 19. Dose and usage instructions

1. Dose:

a) Specify the recommended dose for each administration route or/and each indication or method for drug use.

- Specify the interval between drug uses in a day, method to achieve best result (e.g. drink a lot of water or take before eating);

- Specify the recommended minimum and maximum total dose; specify the limited use duration of drugs (if any).

b) Specify the doses and directions applied to adults and children (if any). Doses for children must be sorted by age group or body weight;

c) Specify the doses for special users such as children, elderly people, patients suffering from renal failure, liver failure, etc.

2. Usage instructions:

a) Specify the administration route, administration time, and directions in order to achieve best results:

- If the drug is injectable, the preparation or reconstitution for injection and injection method must be specified e.g. intramuscular injection, intravenous injection, infusion, subcutaneous injection, deep subcutaneous injection, deep intramuscular injection, or other method; injection or infusion rate shall be specified if required;

- Directions for drug use in special cases of precautions or recommendations as mentioned in Point d Clause 1 Article 15 herein must be specified;

- Herbal drugs: specify the usage instructions (water, tools, method, temperature, and time), contraindications and cautions.

b) For prescription drugs:

In addition to directions in Point a Clause 2 of this Article, directions for children or special drug users and recommendations (if any) must be specified as follows:

- Doses shall be specified by group of age. A dose is calculated according to body weight or body surface area (mg/kg or mg/m2) or divided into intervals. If a drug is used for children with similar indications as those applied to adults, the dose and usage applied to children must be specified;

- If there is no indication for one or all age group of children, the dose and usage must be specified in either of the following manners:

+ The safety and effectiveness of drugs for children at certain ages (expressed as months or years) or group of patients (e.g. by gender, body weight) is not proven;

+ The drug is not recommended for children at certain ages (express as months or years) or group of patients (e.g. by gender, body weight) due to its safety and effectiveness;

+ The drug should not be used for infant patients (from age x to y), (or other groups of patients e.g. by gender, body weight) with regard to certain indications.

- Recommendations with regard to dose and usage (if any):

+ When to stop using drugs? What to do when forgetting to take a dose? What foods and drinks to use with drugs? When to reuse drugs after a course of treatment?;

+ Adjustment of dose when combining with other drugs; adjustment of dose to the patient's conditions (depending on the clinical symptoms and signs and/or kidney or liver function test results);

+ Preventive measures for some specific adverse reactions (e.g. taking antiemetics before using antineoplastic drugs); mild adverse reactions that are common when taking the first dose;

+ Recommendations about drug administration for health officials or patients (if any); information about other routes of administration, especially through gastric sonde (if information is available). If the administration route is other than the gastrointestinal tract, the injection or infusion rate must be specified.

3. Special notes for treatment of drugs before and after use:

Instructions for treatment of drugs before and after use must be specified as follows:

a) Treatment of drugs before use (if any):

- Specify the preparation of drugs before use (reconstitution or dilution);

- Specify measures for protecting drug preparer;

- Specify external features of drug before being reconstituted or diluted, and features of reconstituted drug.

b) Treatment of drugs after use (if any):

- Specify precautions for discarding drugs after use in certain cases such as cytotoxic drugs, preparations that contain live bacteria and other cases where specific regulations apply;

- If there is no usage instruction or special treatment precaution for health officials, the text "Không có yêu cầu đặc biệt về xử lý thuốc sau khi sử dụng" ("No precaution for treatment for drugs after use") shall be written.

Article 20. Contraindications

1. If there are contraindications, the cases in which drugs must not be used must be specified.

2. If the contraindications involve children, the ages of children (expressed as months or years) or other group of patients (e.g. by gender or body weight) must be specified.

Article 21. Warnings and cautions

1. Specify the cautions when using drugs and recommendations about use of drugs for children and chronic disease patients (if any).

2. Conditions that need cautions:

a) The test results or conditions of the patients that need assessing before using drugs; necessary measures for minimizing the risk of adverse reactions while using drugs;

b) Serious adverse reactions that need to be reported to health officials;

c) The preventive measures and early detections of symptoms of serious adverse reactions;

d) The risks related to the beginning or suspension of treatment;

dd) The subjects likely to have adverse reactions to the group of drugs (usually serious or common);

e) The clinical symptoms, signs, or test results that need monitoring during the course of treatment. The tests affected by drug use;

g) The warnings and cautions for infant patients related to safety of long-term drug administration (such as influence on the child's growth, mental development, sexual development, etc.);

h) Warnings related to excipients or drug residues that cause adverse drug reactions or influences as proven. Warnings related o these excipients must be specified in this part or in the part of warnings and cautions when using drugs;

i) Warnings related to ethanol in the drugs;

k) The risks related to inaccurate administration route.

3. For biosimilars:

Specify warnings about risks related to replacement or conversion between reference preparations and biosimilars during the treatment.

Article 22. Using drugs during pregnancy and breastfeeding

1. Using drugs during pregnancy:

a) Provide information about the influence of drugs on pregnant women. If such information is not available, the text "Không có dữ liệu về sử dụng thuốc trên phụ nữ có thai, chỉ nên dùng thuốc nếu lợi ích vượt trội so với nguy cơ" ("There is no controlled data in human pregnancy. The drug is only recommended for use during pregnancy when benefit outweighs risk") must be specified;

b) The recommendations for pregnant women must include recommendations about the use of drugs by women suspected of pregnancy, women practicing birth control, and the use of drugs in various stages of pregnancy;

c) Provide additional information about the influence of drugs on the fetus, including information about possible influence of drugs on the fetus. The unavailability of information about toxicity of drugs upon the fetus must be specified;

d) Provide recommendations about monitoring of the fetus and newborn babies whose mother uses drugs during pregnancy (if information is available).

2. Using drugs during breastfeeding:

Recommendations for breastfeeding must specify whether the breastfeeding must be stopped or may be carried on, whether the treatment must be stopped or may be carried on (if sufficient information is available).

Article 23. Influence of the drug on ability to drive or operate machinery

1. The level of influence must be specified: no influence or inconsiderable influence, mild influence, medium influence, or serious influence.

The text "Chưa có bằng chứng về ảnh hưởng của thuốc lên khả năng lái xe, vận hành máy móc" ("There is no proven influence of the drug on ability to drive or operate machinery") must be written.

2. Additional important information (if any) must be specified such as the time the effects decreases and the effectiveness of drugs when resuming the drug use.

Article 24. Drug interactions and incompatibilities

1. Drug interactions:

a) Specify the reactions of the drug with other drugs and other reactions (e.g. with alcohol, foods, etc.) that may affect the effectiveness of the drug. To be specific:

- Specify information about drug interactions with clinical significance based on their pharmacodynamic properties and pharmacokinetic studies;

- Specify consequences of drug interactions such as: clinical signs (if any), influence of drug interactions on drug concentration in blood, pharmacokinetic data of drugs or active metabolites of drugs; influence of drug interactions on test results. Treatment for minimizing consequences of drug interactions must be also specified;

- Specify the mechanism of interaction if the mechanism is clear. The unavailability of drug interaction studies must be specified;

- Other serious drug interactions such as the adsorption of the drug onto its package or syringe.

b) The contraindications of herbal drugs or traditional drugs must be specified (if any). E.g.: if the drug tends to cause damp-heat, raw, cold and frozen foods should be abstained; if the drug tends to cause damp-cold, hot and spicy foods should be abstained.

2. Drug incompatibilities:

a) Specify information about chemical and physical incompatibilities with other drugs when they are mixed or used simultaneously, especially drugs reconstituted or diluted before use for intravenous infusion;

b) If the information about drug incompatibilities is unavailable, the text ““Do không có các nghiên cứu về tính tương kỵ của thuốc, không trộn lẫn thuốc này với các thuốc khác” (“There is no study on drug incompatibilities. Do not mix this drug with other drugs") shall be specified.

Article 25. Adverse drug reactions

1. Specify the cases in which drug use must be suspended, the cases in which adverse drug reactions must be reported to the physician or pharmacist, or reported to the National Center of Drug Information & Adverse Drug Reactions.

2. Apart from the information specified in Clause 1 of this Article, information about adverse drug reactions according to the summary (if any) must be added as follows:

a) Adverse reactions shall be sorted by frequency: very common (ADR $\geq$ 1/10), common (1/100 $\leq$ ADR < 1/10), not common (1/1000 $\leq$ ADR < 1/100), rare (1/1000 $\leq$ ADR < 1/10000) and very rare (ADR < 1/10000);

Classification of adverse reactions of herbal drugs or traditional drugs by frequency is not required.

b) If the users are children, it is required to describe the children’s ages and seriousness of adverse reactions (if any); clinical differences in drug safety between adults and children (or between certain age groups). If such information is already mentioned in another part of the package insert, it must be referred to;

c) Every clinical difference in frequency, seriousness of reactions, ability to recover, and the cases that need monitoring in special users (e.g. elderly people, patients suffering from liver failure, renal failure, and other diseases) must be specified.

3. If there is no record or evidence about drug adverse reactions, the text "Chưa ghi nhận được báo cáo về phản ứng có hại của thuốc" (“There is no reported case of adverse drug reactions”) and “Thông báo ngay cho bác sỹ hoặc dược sỹ những phản ứng có hại gặp phải khi sử dụng thuốc” (“Any adverse drug reactions should be immediately reported to the physician or pharmacist”) shall be specified.

Article 26. Overdose and treatment

1. Overdose:

a) Specify the symptoms and signs of overdose: Symptoms and signs of acute poisoning and possibility to cause permanent injuries (if any);

b) If the information about drug overdose is unavailable, the text “Không có dữ liệu về sử dụng thuốc quá liều, không dùng quá liều chỉ định của thuốc” (“There is no record of drug overdose. Do not use this medicine in larger mounts than recommended”) shall be specified.

2. Treatment for overdose:

a) Specify the measures or treatment for overdose, including monitoring and using adrenergic agonists, antagonists, antidotes, or enhanced drug excretion. If such information is not available or not sufficient, there must be the text “Tích cực theo dõi để có biện pháp xử trí kịp thời” ("Keep monitoring to respond in time");

b) Provide information for special users such as: elderly people, pregnant and breastfeeding women, children, patients having kidney failure, liver failure, or other diseases (if any).

Article 27. Pharmacological and clinical effects

1. Pharmacodynamics: The following information about pharmacodynamics must be specified:

a) Pharmacological group and ATC number (if any);

b) Description of the reaction mechanism corresponding to the approved indications;

2. Pharmacokinetics: The following information about pharmacokinetics must be specified:

a) Pharmacokinetic properties of drugs (absorption, distribution, metabolism, elimination, and other properties) corresponding to the recommended dose, concentration, and dosage form;

b) Description of the differences between the factors (such as ages, genders, body weights, smokers and non-smokers, patients suffering from kidney failure or liver failure) that influence the pharmacokinetics. If such influences are clinical, they must be quantified;

c) The relationship between the dose, concentration, pharmacodynamics (including primary and secondary criteria, and side effects) and characteristics of the test subjects;

d) With regard to infant patients: summarize results of pharmacokinetics study on children at various ages and comparison to adults (if any). Specify the dosage form used for pharmacokinetics study on children, the uncertainties due to limited use of drugs on children.

3. Results of clinical and non-clinical tests (if any):

a) Summary of primary results of major clinical tests that support the approved indications (if any), including:

- Description of primary characteristics of the sample;

- Primary criteria;

- Secondary criteria (if any);

- Study results related to primary criteria.

b) Provide basic information concerning non-clinical studies (if any).

Article 28. Smallest package unit and package contents

1. Common smallest package units are as follows:

a) Drugs in the form of tablets: The smallest package unit shall be tablet. With regard to drugs in the form of Chinese tablets, the smallest package unit shall be pack, jar, bottle or bag;

b) Drugs in liquid form: The smallest package unit shall be jar, bottle, vial, pack, prefilled syringe or injection device;

c) Drugs in form of powder that have to be reconstituted before use: The smallest package unit shall be jar, bottle, vial, pack, prefilled syringe or injection device;

d) Drugs in the form of powder or granule: The smallest package unit shall be jack, bottle, jar or pack;

dd) Drugs in the form of cream, ointment or gel for external use: The smallest package unit shall be tube, jar or pack;

e) Drugs in the form of transdermal patches: The smallest package unit shall be patch;

g) Drugs in the form of spray or aerosol: The smallest package unit shall be spray bottle, metered dose inhaler or drug jar of aerosol nebulizer;

h) Drugs in the form of kits: The smallest package unit shall be the kit;

i) Herbal drugs: The smallest package unit shall be pack, bag or box;

k) Medicinal ingredients: The smallest package unit shall be bag, pack, box, bottle, jar, or vial.

2. Expression of package contents:

a) The package contents of a drug must be expressed as natural numbers of the quantity, net weight, or true volume of drugs contained in a commercial package;

b) If a commercial package contains multiple package units, the content of each package and quantity of packages must be specified;

c) Every equipment accompanied to the drug such as injection needle, syringe, measuring spoon, measuring cup, aerosol device and other supportive tools contained in the commercial package (if any) must be specified.

3. If the drug is on the list of controlled drugs which are narcotic drugs, psychotropic drugs, or drug precursors, the secondary package shall not contain more than 100 smallest package units.

Article 29. Batch number, manufacturing date and expiry date

1. Batch number:

Batch number shall be expressed fully as “Số lô sản xuất” or briefly as “Số lô SX”, “Lô SX”, “LSX” or “SLSX” and information about the batch number. The information and composition of the batch number is decided by the manufacturer.

2. Manufacturing date and expiry date:

a) The manufacturing date and expiry date shall be written fully as “Ngày sản xuất”, “Hạn dùng” or “Hạn sử dụng”, or briefly as “NSX”, “HD” or "HSD" before information about the manufacturing date and expiry date;

b) The manufacturing date and expiry date shall be expressed in any of the following format: [dd/mm/yy], [dd. mm. yy], [dd-mm-yy], [dd mm yy], or [ddmmyy];c) Where the secondary package contains diluent vials or reconstitution kit:

- If the drug and its component parts share the same manufacturing date and expiry date, that manufacturing date and expiry date shall be specified on the label of the secondary package;

- If the expiry dates of the drug and its component parts are different, the shortest expiry date or the expiry date of every component part shall be specified.

3. Expression of manufacturing date, expiry date and batch number:

a) Where the manufacturing date, expiry date and batch number are written on in a foreign language:

- If the manufacturing date, expiry date and batch number on the original label are written in a foreign language, the secondary label must contain the text: “ngày sản xuất (NSX), hạn dùng (HD/HSD), số lô sản xuất (LSX/SLSX) xem thông tin ghi ngày sản xuất, hạn dùng, số lô sản xuất bằng tiếng nước ngoài được in trên nhãn gốc sản phẩm”.

E.g.: NSX, HD, SLSX: see “Mfg Date”, “Exp Date”, “Lot.No.” on the original label.

- If the expiry date on the primary package label is expressed as “mm/yy” and the expiry date on the secondary package label is fully expressed as “dd/mm/yy”, the expiry date expressed on the secondary package label shall apply;

- If the expiry date on both the primary package label and secondary package label is expressed as “mm/yy” but:

+ the manufacturing date on the original label is fully expressed as “dd/mm/yy”, the expiry date on the secondary label shall be calculated and expressed according to the manufacturing date on the original label;

+ the manufacturing date on the original label is expressed as “mm/yy”, the expiry date shall be the last day of the expiry month and the secondary label must have the text ““hạn dùng là ngày cuối cùng của tháng hết hạn” (“expiry date is the last day of the expiry month”).b) If the primary package label is so small that the batch number or expiry date has to be written in series of numbers instead of with the text “Số lô SX” and “HD” as prescribed in Clause 1, Clause 2 of this Article, such information must be fully written on the secondary package as prescribed;

c) The package insert must contain the following information:

- Expiry date of the drug as a period from the manufacturing date;

- The useful life after opening the primary package for the first time for drugs without divided dose such as eye drops, nose drops, ear drops, ointment, gel and orally administered multi-dose liquid drugs or tablets bottled in large quantities (if any);

- The useful life after preparation for drugs in the form of powder, granule that must be reconstituted before use (e.g. injection or oral administration).

Article 30. Change of expiry dates of labeled drugs because of national defense and security, epidemic control or disaster recovery need

Because of national defense and security, epidemic control or disaster recovery need, Minister of Health may decide to change the expiry dates of labeled drugs and stipulate the way to express the expiry date in each specific case on the basis of drug quality, comparison between benefits and risks or lack of domestic supply of drugs.

Article 31. Storage conditions and quality standards

1. The label of drugs or medicinal ingredients and package inserts must:

Specify the storage conditions in terms of temperature (expressed as ^{0}C), humidity, and lighting or other special storage conditions in order to avoid affecting the drug quality during storage and transport (if any).

2. The package insert must specify storage requirements with regard to the cases mentioned in Paragraph 2 and 3 Point c Clause 3 Article 29 herein.

3. Expression of quality standards:

The secondary package label and package insert must have quality standard of the drug or medicinal ingredient. To be specific:

a) If the drug or medicinal ingredient follows quality standards of the Pharmacopoeia of Vietnam or a foreign pharmacopoeia recognized by the Ministry of Health, the quality standard shall be specified according to the full name in Vietnamese language of the pharmacopoeia or the abbreviated name in Vietnamese language of the Pharmacopoeia of Vietnam or the abbreviated name in English of the foreign pharmacopoeia. The version or publishing year is not required;

b) If the drug or medicinal ingredient follows a basic standard, the text “Tiêu chuẩn cơ sở” or “TCCS” shall be specified.

Article 32. Registration number and import license number

1. Registration number in Vietnam:

Specify “Số giấy đăng ký lưu hành:” (“Registration number:”) or “SĐK:” without information specified when applying for the registration number. Before selling drugs on the market, the registration number issued by the Ministry of Health to the drug or medicinal ingredient granted the Certificate of registration must be added.
2. Import license number:

Specify “Số giấy phép nhập khẩu:” ("Import license number") or “GPNK:” without information specified when submitting the application for license to import drugs. Before selling drugs on the market, the import license number issued by the Ministry of Health to the drug or medicinal ingredient without the Certificate of registration must be added.

Article 33. Names and addresses of manufacturer, preparation and processing factory, importer and relevant entities (if any)

1. General provisions on name and address of manufacturer and importer on the drug label and package insert:

a) Secondary package labels of drugs and medicinal ingredients:

- If drugs are manufactured in Vietnam: write the role, name and address of the drug manufacturer;

- If medicinal ingredients manufactured in Vietnam or imported: write the name and address of manufacturer of medicinal ingredients;

- If drugs are imported: write the role, name and address of the drug manufacturer; the name and address of the drug importer.

b) Primary package labels: Full name or business name of the manufacturer shall be specified as long as the manufacturer is identified.

If a drug has more than one manufacturer:

- Specify every manufacturer of the commercial drug; or

- Specify the name of the manufacturer responsible for the release of the batch.

c) With regard to traditional drugs prescribed in Clause 1 and Clause 2 Article 70 of the Law on Pharmacy and drugs produced or prepared within health facilities as prescribed in Clause 2 and Clause 3 Article 85 of the Law on Pharmacy:

- On the secondary package label: write the name and address of the health facility that prepare or produce drugs;

- On the primary package label: write the full name or business name of the health facility. d) Labels of drugs prepared according to prescriptions for sale at drugstores in accordance with regulations in Point b Clause 1 Article 47 of the Law on Pharmacy must have the name and address of the drugstore;

dd) Package inserts: write the role, name and address of manufacturers. If drugs are imported, the name of manufacturing country must be translated into Vietnamese unless Vietnamese name is not available;

e) Apart from the name and address of the manufacturer and importer, the drug label and package insert may contain the roles, names and addresses of relevant entities such as the registrant, distributor, brand owner, drug owner or relevant entities.

2. Expression of role of entities responsible for the drug:

a) Manufacturer:

- If a drug has the one manufacturer: the role shall specified by the text “Cơ sở sản xuất:”
- If a drug has more than one manufacturer: the role of each manufacturer must be specified either as “Cơ sở sản xuất bán thành phẩm” (“Manufacturer of semi-finished drugs”), “Cơ sở đóng gói cấp 1” ("Primary packaging facility”) or “Cơ sở chịu trách nhiệm xuất xưởng lô” (“The entity responsible for release of the batch”);

- The name of manufacturer shall be the name specified in the Certificate of eligibility for pharmacy business issued by a regulatory authority.

b) Importer: write the role as “Doanh nghiệp nhập khẩu” (“Importer”);

c) Other entities: specify the role as “Cơ sở phân phối” (“Distributor”), “Chủ sở hữu sản phẩm” (“Drug owner”), “Chủ sở hữu nhãn hiệu hàng hóa” (“Brand owner") or other entities (if any).

3. Expression of name and address of manufacturer:

a) If a drug has more than one manufacturer, names and addresses of all manufacturers must be written. Their names must be of the same size and on the same plane;

b) If drugs are processed by another entity, the label shall have the text “Sản xuất tại ... theo hợp đồng với ... “ ("Manufactured by [processor's name and address] under contract with [hirer's name and address]”). The processor's name and address must be on the same plane of the label and have the same size as the hirer's;

c) Labels of drugs manufactured under technology transfer must have the text “Sản xuất tại … được chuyển giao công nghệ từ …” (“Manufactured by [transferee’s name and address] by adopting the technology transferred from [transferor’s name and address]”). The transferor's name and address must be on the same plane of the label and have the same size as the transferee’s.

4. Expression of name and address of importer: a) Fully specify the text là “Doanh nghiệp nhập khẩu: tên, địa chỉ của cơ sở nhập khẩu thuốc, nguyên liệu làm thuốc” (“Importer: name and address”) on the label; or

b) Briefly specify “DNNK: tên, địa chỉ đầy đủ cơ sở nhập khẩu” (“Importer: name and address”).

Specify “Doanh nghiệp nhập khẩu:” or “DNNK:” without the importer's name. The importer's name and address must be added before selling drugs on the market.

5. Other provisions on expression of name and address:

a) Expression of names of relevant establishments:

- Name of a domestic establishment: write the name specified in the Certificate of eligibility for pharmacy business, the certificate of enterprise registration or the investment certificate issued by a regulatory authority;

Names of health facilities shall be the names specified in the license to provide healthcare services in accordance with regulations of the Law on medical examination and treatment.
- Name of a foreign establishment: write the name specified in the drug certificate or GMP certificate, or relevant legal document issued by the competent authority in the home country.

Particularly, name of a foreign manufacturer shall be the same as the name specified in the drug certificate or GMP certificate issued by the competent authority in the home country.

b) Expression of addresses of relevant establishments:

- Address of a domestic manufacturer: specify the address which is the business location specified in the Certificate of eligibility for pharmacy business. The address of the enterprise’s head office may be also specified;

- Address of a manufacturer must include the house number, name of the street or neighborhood, commune or ward, district, province or centrally-affiliated city;

Particularly, the address of a health facility shall be the address of its manufacturing factory as specified in the License to provide healthcare services in accordance with regulations of the Law on medical examination and treatment.

- For imported drugs:

The address of the manufacturer shall be the address of its manufacturing factory as specified in the drug certificate or GMP certificate issued by the competent authority in the home country.

c) The names, addresses, logos of relevant entities specified in the label or package insert as regulated in this Clause must not be larger in size than those of the manufacturer, unless it is the drug owner as proven;

d) If the label contains the name, address, and/or logo of the distributor, the distributor's name, address, and logo must not be larger in size than the manufacturer's;

dd) If the manufacturer is a member or dependent unit of an organization such as a company, general company, corporation, association, or another organization, its name, address, brand, trademark, and other contents may be written on the label if permitted by such organization as long as the address of the factory where drugs are manufactured is specified.

E.g.: Drugs are manufactured at factory A of company B, the label may have the text "Công ty B, Chi nhánh công ty, sản xuất tại địa chỉ A" ("Company B, branch, manufactured at A").

Article 34. Origins of drugs and medicinal ingredients

1. Determination of origins of drugs and medicinal ingredients:

a) Origins of drugs and medicinal ingredients shall be determined in accordance with the Law on Commerce, legislative documents on guidelines for the Law on Commerce with regard to goods origins and relevant legislative documents;

b) The entities responsible for labeling as prescribed in Article 6 herein shall determine and specify origins of their drugs and medicinal ingredients in honest and genuine manner and in conformity with the law regulations on good origins or international treaties to which Vietnam is a signatory.

2. Expression of origins of imported drugs and medicinal ingredients:

Origins of drugs or medicinal ingredients shall be written on secondary packages as follows:

a) The phrase "xuất xứ:" ("origin:") or "sản xuất tại:" ("manufactured in:") or "sản xuất bởi:" ("manufactured by:") and the name of the country or territory in which the drug or medicinal ingredient is manufactured;

The name of the country or territory in which the drug or medicinal ingredient is manufactured must be the full name.

b) If the drug or medicinal ingredient origin is the same as the country or territory in which it is manufactured, only the country's name in Vietnamese (or English if Vietnamese name is not available) is required;

c) If the drug or medicinal ingredient origin is different from the country or territory in which it is manufactured, full information about drug or medicinal ingredient origin as set out in Point a Clause 2 of this Article must be written.

3. For drugs or medicinal ingredients manufactured in Vietnam for domestic sale, if the manufacturer's address is already written, the drug or medicinal ingredient origin may be omitted.

Article 35. Other contents on labels

1. In addition to the compulsory information prescribed in this Circular, other information may be written on the label and package insert included in the application for registration or license to import the drug without registration number or the drug label in the case prescribed in Clause 1 or Clause 2 Article 11 herein provided it must satisfy regulations in Clause 3 of this Article.

2. In addition to the compulsory information prescribed in this Circular and before selling drugs on the market, the responsible entity may write other information on the drug label and/or package insert which has been approved by a regulatory authority without giving a notification and obtaining the approval from a regulatory authority provided that it must satisfy the requirements in Clause 3 of this Article. In such case, the responsible entity shall ensure the accuracy of additional information. To be specific:

a) Affix or alter anti-fraud stamps as well as other security warnings and anti-counterfeit contents on drug labels to help fight against counterfeit products or recognize their products;

b) Change the form or color of the package insert; the size of the secondary package label or the primary package label;

c) Add or alter the telephone number, zip code, web address or email address of any relevant entity responsible for the drug or of the brand owner;

d) Add or alter the symbol ® behind the drug name or behind the company's name or logo; change logo of any relevant entity responsible for the drug;

dd) Change the position of the registration number or import license number, the position of the secondary label, or the position of batch number, expiry date or manufacturing date on the label;

e) Add information in another language which is translated from the information in Vietnamese language as approved by the Ministry of Health according to the application for drug registration or the application for the license to import drugs without registration number.

3. Provisions on additional information on the label:

a) Additional information must be lawful, truthful, and accurate, and reflect the true nature and effects of drugs, must not be advertising information and must not block or falsify compulsory information on the label, and ensure that the compulsory information is conformable with the label approved by a functional unit of the Ministry of Health;

b) Additional information must not be:

- Information or images prohibited in advertising as regulated in Article 8 of the Law on Advertising;

- Information prescribed in Clauses 2, 3, 4, 5, 6, 10, 11, 12, 13, 14, 15 and 16 Article 126 of the Decree No. 54/2017/ND-CP;

- Information and images prescribed in Clause 2 Article 18 of the Decree No. 43/2017/ND-CP;

- Information or images about the bioequivalence or clinical equivalence between biosimilars and reference biologics.

c) The information in another language as prescribed in Point e Clause 2 of this Article must be conformable with the information in Vietnamese language. The text or numbers in another language must not block or be larger in size than those in Vietnamese language;

d) The label and package insert of drugs or medicinal ingredients manufactured in Vietnam and exported may have the information written in the language of the importer's country as requested under the sale contract provided that it shall not falsify the information and the nature of drugs or medicinal ingredients.

Chapter IV

IMPLEMENTATION

Article 36. Effect

1. This Circular comes into force from June 01, 2018.

2. The Circular No. 06/2016/TT-BYT dated March 08, 2016 of the Minister of Health on drug labeling is annulled from the effective date of this Circular, except for regulations on labeling of in vitro diagnostic reagents, which shall remain effective until superseding documents are promulgated.

Article 37. Transition

1. With regard to drugs or medicinal ingredients granted registration numbers or import licenses before this Circular comes into force:

a) They may be sold with the labels and package inserts approved by the Ministry of Health until the expiry dates of batches of drugs or medicinal ingredients manufactured or imported within the validity of the registration certificates or the import licenses granted before this Circular comes into force, except for the case prescribed in Point b Clause 1 of this Article.

b) With regard to drugs and medicinal ingredients on the List of toxic drugs and toxic medicinal ingredients enclosed with the Circular No. 06/2017/TT-BYT dated May 03, 2017 of the Minister of Health on promulgation of the List of toxic drugs and toxic medicinal ingredients; drugs which are on the List of OTC drugs enclosed with the Circular No. 23/2014/TT-BYT dated June 30, 2014 of the Minister of Health on promulgation of the List of OTC drugs but not on the List of OTC drugs enclosed with the Circular No. 07/2017/TT-BYT dated May 03, 2017 of the Minister of Health on promulgation of the List of OTC drugs (hereinafter referred to as the "Circular No. 07/2017/TT-BYT"), registrants or importers must classify, update and supplement relevant information as follows:

- Drugs or medicinal ingredients manufactured before this Circular comes into force: comply with regulations in Point a Clause 1 of this Article;

- Drugs or medicinal ingredients manufactured from the date of entry into force of this Circular: Update information concerning the classification of drugs or medicinal ingredients on labels and package inserts in accordance with regulations in this Circular before selling drugs or medicinal ingredients on the market within 12 months as from the date of entry into force of this Circular without giving any notification to the Ministry of Health, unless an application is submitted for modification of the certificate of registration related to the package insert of drugs granted registration number as regulated in the Ministry of Health's Circular on registration of drugs and medicinal ingredients.

2. Applications for certificate of free sale or permission for import of drug without registration numbers submitted to units affiliated to the Ministry of Health and have not been granted before the effective date of this Circular, excluding drugs and medicinal ingredients mentioned in Clause 3 of this Article, shall be considered as follows:

a) The registrant or importer may submit additional documents about the label and package insert of the drug in accordance with this Circular in order to be considered and granted the registration number or license for import of drugs without registration number;

b) If no additional documents are submitted as prescribed in Point a of this Clause, the label and package insert may be considered under Circular No. 06/2016/TT-BYT, excluding the case prescribed in Point b Clause 1 of this Article;

Within 06 months from the day on which the certificate of free sale is issued, the facility responsible for drug labeling shall update the label and package inserts in accordance with this Circular in the form of registration of changes according to the Ministry of Health's Circular on registration of drugs and medicinal ingredients, excluding the case prescribed in Point b Clause 3 Article 6 of the Circular No. 07/2017/TT-BYT.

3. With regard to applications for registration of drugs or medicinal ingredients in the form of registration of changes of certificate of free sale with regard to changes in label and package insert, which have been submitted to units affiliated to the Ministry of Health and have not been granted, the registrant or importer must supplement samples of label and package insert in accordance with regulations of this Circular before this Circular comes into force.

Article 38. Announcing information on package inserts

1. The Drug Administration of Vietnam shall review, update and announce information on package inserts of drugs, which are on the List of proprietary drugs and reference biologics announced by the Ministry of Health and have been granted registration numbers, on its website so that manufacturers and registrants may refer to when preparing applications for registration of generic drugs or biosimilars.

2. Any information added to package inserts of drugs on the proprietary drugs and reference biologics during the sale of drugs must be announced and published on the website of the Drug Administration of Vietnam within 45 days from the date on which such additional information is given approval.

3. Registrants and manufacturers shall update and supplement information on package inserts of generic drugs or biosimilars in conformity with corresponding guidelines on use of drugs on the List of proprietary drugs and reference biologics published on the website of Drug Administration of Vietnam as follows:

a) Package inserts of generic drugs or biosimilars must be conformable with package inserts of drugs on the List of proprietary drugs and reference biologics in terms of concentrations, contents, active ingredients, dosage form, and administration routes, excluding information about expiry dates, composition, quality standard, bioavailability, pharmacokinetics, adverse effects and clinical test results. The package insert of generic drugs or biosimilars must have more adverse effects than those of corresponding proprietary drugs and reference biologics, except adverse effects of proprietary drugs or reference biologics related to excipients which are not contained in such generic drugs or biosimilars;

b) Within 12 months from the date on which Drug Administration of Vietnam announced and published package inserts of proprietary drugs and reference biologics on its website as regulated in Clause 1, Clause 2 of this Article, registrants and manufacturers of generic drugs and biosimilars must update information on labels and package inserts of their products in conformity with package inserts of proprietary drugs and reference biologics in terms of the information mentioned in Clause 2 of this Article without giving notification to the Ministry of Health, unless otherwise requested by the Ministry of Health.

Article 39. Terms of reference

In case the legislative documents and regulations cited in this Circular are changed or replaced, the newer ones shall apply.

Article 40. Responsibility for implementation

The Drug Administration of Vietnam, the Traditional Medicine Administration and units affiliated to the Ministry of Health, Departments of Health of provinces or central-affiliated cities, Vinapharm, Vietnamese and foreign drug registrants and drug manufacturers, importers, exporters of drugs and medicinal ingredients, health facilities and facilities preparing drugs according to prescriptions are responsible for the implementation of this Circular.

Difficulties that arise during the implementation of this Circular should be promptly reported to the Ministry of Health (via the Drug Administration of Vietnam or the Traditional Medicine Administration) for consideration./.

PP. MINISTER
DEPUTY MINISTER

Truong Quoc Cuong

MINISTRY OF HEALTH --------	SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness ----------
No: 11/2018/TT-BYT	*Hanoi, May 4, 2018*

CIRCULAR

ON DRUG/DRUG INGREDIENT QUALITY

Pursuant to the Law No. 34/2005/QH11 dated June 14, 2005 on Pharmacy;

Pursuant to the Government's Decree No. 54/2017/ND-CP on detailing a number of articles of, and providing measures for implementing, the Law on Pharmacy dated May 8, 2017;

Pursuant to the Government's Decree No. 75/2017/ND-CP dated June 20, 2017 defining Functions, Tasks, Powers and Organizational Structure of Ministry of Health;

At the quest of the Director General of the Drug Administration,

The Ministry of Health promulgates the Circular on Drug/Drug Ingredient Quality.

Chapter I

GENERAL PROVISIONS

Article 1. Scope

This Circular provides for application of quality standards of drugs (modern drugs, herbal drugs, vaccines and biological) and drug ingredients (except herbal ones); drug/drug ingredient tests and procedures for recall and handling of unconformable drugs.

Article 2. Definitions

For the purpose of this Circular, the terms below shall be construed as follows:

1. *Drug/drug ingredient quality standards* are documents regulating technical characteristics of drugs and drug ingredients, including quality criteria, quality levels, test methods and other administrative requirements.

2. *GLP* stands for Good Laboratory Practice.

3. *WHO* stands for World Health Organization.

4. *ICH* stands for International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Chapter II

APPLICATION OF DRUG/DRUG INGREDIENT QUALITY STANDARDS

Article 3. General provisions

1. Pharmacy business establishments and drug preparing facilities shall apply drug/drug ingredient quality standards by way of pharmacopeia or internal standards for drugs and drug ingredients produced and prepared by those facilities.

2. Pharmacy business establishments and drug preparing facilities must carry out evaluations of test methods stated in drug/drug ingredient quality standards published and applied by the drug manufacturers. Assessment and evaluation of test methods are carried out in accordance with guidelines for assessment of analytic processes by ASEAN or ICH, specified in the Circular on Registration of Drugs and Drug Ingredients promulgated by the Minister of Health.

3. The Ministry of Health organizes document assessment and approval of drug/drug ingredient quality standards, in accordance with regulations on drug/drug ingredient registration, issuing permits for drugs /drug ingredients which do not have prior registrations for circulation.

Article 4. Application of pharmacopeia

1. Application of Vietnam's pharmacopeia and reference pharmacopeias:

a) Pharmacy business establishments and drug preparing facilities can apply Vietnam's pharmacopeia or one of the following reference pharmacopeias: European, British, United States, International, and Japanese;

b) The application of standards of the pharmacopeias specified in Point a of this Clause must include all regulations on quality criteria, quality levels and test methods specified in the respective drug/drug ingredient's treatise in the chosen pharmacopeia; also including regulations on quality criteria, quality levels and test methods specified in the appendix of that pharmacopeia;

c) If the manufacturer announces its application of one of the pharmacopeias specified in Point a of this Clause, but adopt test methods different from the ones specified in the drug/drug ingredient's treatise in the chosen pharmacopeia, the manufacturer must prove their chosen methods' equivalence to the pharmacopeia's methods. The test results from the methods stated in the pharmacopeia are the basis for evaluation of drug quality;

d) For herbal drugs, pharmacy business establishments and drug preparing facilities can apply the pharmacopeias specified in Point a of this Clause or the pharmacopeia of the drug's country of origin.

2. Application of pharmacopeias other than the ones specified in Point a of this Clause:

If the pharmacy business establishment or drug preparing facility decides to apply a pharmacopeia other than ones specified in Point a of this Clause, the applied quality standards must at least:

a) Meet the requirements of quality criteria and levels specified in the respective quality criteria's treatises in Vietnam's pharmacopeia or one of the aforementioned reference pharmacopeias;

b) The applied common test methods must be appropriate for the equivalent common test methods stated in Vietnam's pharmacopeia or one of the reference pharmacopeias specified in Point a of this Clause.

Article 5. Application of internal standards

1. The internal drug/drug ingredient standards must conform to the regulations specified in Point b, Clause 2, Article 102 of the Law on Pharmacy, as follows:

a) Meet the requirements of quality criteria and levels specified in the respective treatises in Vietnam's pharmacopeia and quality criteria, quality levels and common test methods specified in the appendix of Vietnam's pharmacopeia;

b) If Vietnam's pharmacopeia or the reference pharmacopeias specified in Point a, Clause 1, Article 4 of this Circular do not have any treatise for the required drug/drug ingredient, the facility shall form the standard using the scientific research results (also including the product development research results) or the regulations in other foreign pharmacopeias as the basis.

2. The internal standards of drugs prepared in medical facilities are formed and evaluated for appropriateness by the facility, and promulgated by the facility's head.

Article 6. Update of quality standards and application of updated pharmacopeia

1. When applying for circulation (or circulation extension) of a drug/drug ingredient: The quality standards of that drug/drug ingredient must conform to one of the following pharmacopeias at the time of application:

a) The pharmacopeia's latest edition;

b) The pharmacopeia's previous editions which did not come more than two years before the current edition.

2. In the case of drugs or drug ingredients that have already been allowed for circulation: For a maximum of two years from the effective date of the pharmacopeia's latest edition, the applier or manufacturer have the responsibility to update the standards of drugs/drug ingredients as regulated by that edition.

3. During drug/drug ingredient circulation, if the applier or manufacturer finds any factor that severely affect drug safety, quality or efficacy or is requested by the Ministry of Health (Drug Administration), the manufacturer must the update the drug/drug ingredient standards' criteria in order to bring that factor under control.

Chapter III

DRUG/DRUG INGREDIENT TESTS

Article 7. Drug/drug ingredient tests

1. The test must be carried out in accordance with the approved and updated drug/drug ingredient quality standards.

If the drug/drug ingredient quality standard is not updated, the testing facility shall use the equivalent pharmacopeia specified in Clauses 1 and 2, Article 6 of this Circular, based on the production date of the drug/drug ingredient being tested.

If the drug is prepared in a medical facility, the test is carried out in accordance with the drug quality standards formed and promulgated by the facility.

2. The collection of drug/drug ingredient samples for testing is carried out in accordance with Appendix I and the sample collection form in Template No. 1 of Appendix III issued together with this Circular.

3. Presenting drug/drug ingredient test/analysis results:

a) The drug/drug ingredient test and analysis results are shown on the test/analysis report based on Samples No. 2 and No. 3 shown in Appendix III issued together with this Circular;

b) The testing facility must present the test/analysis results of the drug sample, which was collected by the quality inspection authority, in no more than 15 days after receiving the drug sample, in the following cases:

- There is information on severely adverse effects of the drug;

- The drug comes from a facility committing serious violations against good practice;

- Additional samples of the drug are collected in the cases mentioned in Point b, Clause 1 and Point b, Clause 2 of this Circular's Article 14.

b) The testing facility must present the test/analysis results of the drug sample in no more than 20 days after receiving it in the following cases:

- The drug requires testing before circulation, as specified in Clause 1, Article 8 of this Circular;

- The drug does not fit any of the cases mentioned in Points b and d of this Clause.

d) The testing facility must present the test/analysis results of the drug/drug ingredient sample in no more than 30 days after receiving it in the following cases:

- The drug/drug ingredient has test methods that require long testing time;

- The drug/drug ingredient requires re-testing or reevaluation of results.

- The drug/drug ingredient has dubious contents or quality, which require test methods other than the ones stated in the registered quality criteria;

- The drug/drug ingredient requires test methods that the testing facility is incapable of conducting (e.g. lack of equipment, chemical, reagents, reference material).

dd) If the deadlines mentioned in Points b, c and d of this Clause are not met, the testing facility has to explain the reason for lateness in a document attached to the test/analysis report;

e) In 24 hours from the time the test/analysis report is issued, the testing facility must send the form to the quality inspection authority, the facilities producing or importing the drug/drug ingredient being tested on and the facility where the sample was taken from.

If the drug/drug ingredient sample does not meet the quality standards, in 24 hours from the time the test/analysis report is issued, the testing facility must notify the Ministry of Health (Drug Administration) of that sample in writing with the test/analysis report attached, both physical and electronic copies (the latter, which is scanned, can be sent to the email address quanlychatluongthuoc.qld@moh.gov.vn or via messaging to the Drug Administration's phone number, with both methods of correspondence using the testing facility's official email address and phone number). A similar notification must also be sent to the Department of Health whose jurisdiction is where the tested drug/drug ingredient comes from.

g) In the case of the drug/drug ingredient sample is sent by a pharmacy business establishment, a facility using it, an organization or an individual for analysis, testing or drug/drug ingredient quality standard assessment, the time of result presentation shall be agreed upon by the parties.

4. Filing and handling of complaints about test results:

a) If there is disagreement with the sample's test results, in five days from the date the test results are received, the pharmacy business establishment has the right to request the quality inspection authority to assign another testing facility to carry out drug/drug ingredient quality tests/analyses;

b) Re-testing of challenged quality criteria is carried out at the testing facility designated by the Ministry of Health, as specified in Clause 2, Article 105 of the Law on Pharmacy.

5. Retention of samples:

a) The drug/drug ingredient sample must be retained after testing and quality conclusion. The retained sample must be sealed up and preserved as specified in the conditions on the label.

b) Sample retention period:

- In the case of drug/drug ingredient production and importers: the finished product's sample must be retained for a minimum of 12 months after product's expiry date; the active ingredient's sample must be retained for a minimum of 12 months after the expiry date of the finished product prepared from that ingredient.

- In the case of drug testing facilities: the sample retention period is at least 12 months after the drug's expiry date, or 24 months after the sample collection date for drug samples collected for quality inspection; or after the date of receipt for additional collected samples specified in Point b, Clause 1 and Point b, Clause 2, Article 14 of this Circular.

6. Archiving records and documents:

a) The records and documents on drug/drug ingredient quality inspection must be archived as specified in the Law on Archives and relevant guiding documents;

b) The records and documents on narcotic, psychiatric, precursor and radioactive drugs/drug ingredients must be archived for a minimum of two years from the expiry dates.

c) After the end of their archive periods, the records and documents shall be handled in accordance with present regulations.

Article 8. Pre-circulation test for drugs specified in Clause 4, Article 103 of the Law on Pharmacy

1. Drugs that belong to one of the following categories must undergo testing carried out by a testing facility designated by the Ministry of Health (Drug Administration) before circulation:

a) The drugs specified in Points a and b, Clause 4, Article 103 of the Law on Pharmacy;

b) Biologicals which are derivatives of human blood and plasma;

c) Imported drugs specified in the Government's Decree No. 54/2017/ND-CP on detailing a number of articles of, and providing measures for implementing, the Law on Pharmacy dated May 8, 2017;

d) Drugs produced by foreign manufacturers on the list of manufacturers with drugs that do not conform to quality standards, published by the Ministry of Health (Drug Administration).

2. Regulations on drug quality tests:

a) Drug sample collection

- The samples of the drugs specified in Points a, b, c, Clause 1 of this Article shall be collected by manufacturers (in case of domestic drugs) or importers (in case of imported drugs);

- The facilities importing he drugs specified in Point d of this Article shall request the state's quality inspection or testing authority for to collect samples of those drugs.

b) The importer shall send the drug sample alongside a copy of the producer's test report to the testing facility specified in Clause 3 of this Article for drug quality inspection in accordance with the approved drug quality standards;

c) Facilities producing or importing vaccines, biologicals which are antisera, derivatives of human blood and plasma mentioned in Points a and b, Clause 1 of this Article shall send the sample as specified in Articles 10 and 11 of this Circular;

d) The testing facility must present the received sample's test results within the time limit specified in Point c, Clause 3, Article 7 of this Circular.

3. The Ministry of Health (Drug Administration) shall designate a testing facility which is granted certificates of eligibility for pharmacy business including drug testing, or testing facilities specified in Clause 1, Article 35 of the Law of Medicine meeting GLP requirements, to carry out drug tests specified in Clause 1 of this Article.

If the testing facility does not have sufficient capacity for carrying out one or multiple test methods, the testing facility must notify the production/importer and cooperate with the latter in sending samples to other GLP-compliant testing facilities or laboratories compliant to ISO/IEC 17025 which have capacity for carrying out those test methods.

4. The designated testing facility report testing activities to the Ministry of Health (Drug Administration) on a monthly basis, following Template No. 7 of Appendix III issued together with this Circular.

5. The Ministry of Health (Drug Administration) publishes and updates the list of designated testing facilities mentioned in Clause 3 of this Article on the Drug Administration's website.

6. The production/importer has the responsibility to:

a) Pay its expenses for drug quality tests;

b) Provide reference materials (including those of impurities) to the testing facility if the National Institute of Drug Quality Control, the Institute of Drug Quality Control Ho Chi Minh City, the National Institute for Control of Vaccines and Biologicals or other testing facilities fail to establish;

c) Circulate and distribute the drugs only after their test results show conformity to quality standards.

7. Tests on vaccines, biologicals which are antisera, derivatives of human blood and plasma are carried out in accordance with Articles 10 and 11 of this Circular.

Article 9. The testing periods for facilities on the list of manufacturers with drugs that do not conform to quality standards and withdrawal from that list

1. The testing period starts from the first drug batch's import date after the Ministry of Health (Drug Administration) publishes the list of manufacturers with drugs that do not conform to quality standards and lasts:

a) 6 months for the manufacturer having one drug batch with third-degree violation;

b) 12 months for the manufacturer having one drug batch with second-degree violation or two or more drug batches with third-degree violations;

c) 24 months for the manufacturer having one drug batch with first-degree violation or two or more drug batches with second-degree violations;

d) If the manufacturer continues having uncomformable drugs, the total testing period shall be the sum of individual drugs' periods.

2. A manufacturer will be withdrawn from the list of manufacturers with drugs that do not conform to quality standards after meeting the following requirements:

a) The manufacturer completes all drug tests before circulation within the time limit specified in Clause 1 of this Article;

The drug manufacturer/registrant files reports which follow Template No. 7 of Appendix III issued together with this Circular, with proof of test on all imported drug batches carried out during the implementation of Clause 1 of this Article;

c) The manufacturer has no drug quality violation (including voluntary drug recall due to quality) during the implementation of Clause 1 of this Article.

3. On a monthly basis, the Ministry of Health (Drug Administration) publishes and updates the list of manufacturers with drugs that do not conform to quality standards, drops the names of facilities complying with the regulations this Article's Clause 2 from the list based on reports from testing facilities that participate in testing activities, drug manufacturers and registrants.

Article 10. Test on vaccines, biologicals which are antisera, derivatives of human blood and plasma

1. The production/importer must send the samples and production records of vaccines, biologicals which are antisera, derivatives of human blood and plasma to the National Institute for Control of Vaccines and Biologicals for testing and evaluation before circulation. The sample sending documents are specified in Article 11 of this Circular.

The production/importer must only circulate vaccines, biologicals which are antisera, derivatives of human blood and plasma after the National Institute for Control of Vaccines and Biologicals confirms the vaccine/biological batches' quality, safety and efficacy and issues quality certificates.

2. Within the time limit specified in Clause 3, Article 7 of this Circular, from the date all samples and documents specified in Article 11 of this Circular are received, National Institute for Control of Vaccines and Biologicals shall:

a) Review the records and conduct tests on the vaccine/biological samples received;

b) Issue quality certificates which follow Template No. 8 of Appendix III issued under this Circular, in which the requirements that are met and which requirements are not, alongside conclusions on the vaccine/biological batch's quality, safety and efficacy;

c) Notify the Ministry of Health (Drug Administration) of the test results.

Article 11. Test samples and records for evaluation of quality, safety and efficacy of vaccines, biologicals which are antisera, derivatives of human blood and plasma

1. For local vaccines, biologicals which are antisera, derivatives of human blood and plasma: The manufacturer shall send the production records and samples from the product batches (either finished semi-finished products) to the National Institute for Control of Vaccines and Biologicals, including:

a) The sample sending form;

b) The vaccine/biological samples to be test on (the number of samples for each kind of vaccine/biological is specified in the Guidelines for testing finished vaccines, biologicals which are antisera, derivatives of human blood and plasma);

c) The records summarizing the vaccine/biological batch's production and quality tests (copies certified by the manufacturer);

d) The manufacturer's batch test report.

2. For imported vaccines, biologicals which are antisera, derivatives of human blood and plasma: The importer shall send the production records and samples from the product batches to the National Institute for Control of Vaccines and Biologicals, including:

a) The sample sending form;

b) The vaccine/biological samples to be test on (the number of samples for each kind of vaccine/biological is specified in the Guidelines for testing finished vaccines, biologicals which are antisera, derivatives of human blood and plasma);

c) The records summarizing the imported vaccine/biological batch's production and quality tests (copies certified by the manufacturer or importer)

d) The quality certificate issued by the country of origin's authorities for each batch of imported vaccine/biological (copies certified by the importer);

dd) The table of data on preservation conditions (cold storage) during the imported batch's transport (certified by the importer) from automatic temperature recorders, freeze indicators (if any).

3. The manufacturer and importer must be responsible for their documents' legality.

Chapter IV

REGULATIONS ON RECALL AND HANDLING OF NONCONFORMABLE DRUGS

Article 12. Compulsory drug recall procedure

1. Receiving information on unconformable drugs:

The Ministry of Health (Drug Administration) receives information on unconformable drugs as follows:

a) Information on drugs that do not guarantee effective treatment or is unsafe from the drug registration advisory board or post-vaccination complication handling advisory board;

b) Information on drug quality criteria that are not met from drug testing facilities;

c) Information on discovered unconformable drugs from the Drug Administration, Health/Pharmaceutical inspection authority;

d) Unconformable foreign drug notices from manufacturers, pharmaceutical and drug quality inspection authorities;

dd) Information on unconformable drugs from public security, customs and market surveillance;

e) Drug information from pharmacy business establishments requesting voluntary drug recall.

2. Identification of the violation’s seriousness:

a) In 24 hours from the time the information on unconformable drugs mentioned in Points a, c, d, dd and e, Clause 1 of this Article, the Ministry of Health (Drug Administration) shall identify the violation’s seriousness and draw conclusions on drug recall, based on evaluation of consumer health's risks.

If the drug registration advisory board's opinion is requested for identification of the violation’s seriousness, as specified in Section IV, Appendix II issued together with this Circular, the time limit of identification of violation's seriousness will be 7 days.

b) The seriousness of a drug’s violation is specified in Appendix II issued together with this Circular;

c) For information on unconformable drugs mentioned in Point b, Clause 1 of this Article, the handling shall be carried out in accordance with Article 14 of this Circular.

3. Issuance of drug recall decision:

a) In 24 hours from the time the conclusion on drug recall is drawn, the Ministry of Health (Drug Administration) shall issue the drug recall decision in accordance with Clause 1, Article 65 of the Law on Pharmacy;

b) The drug recall decision must include the following information: drug name, circulation registration number or import permit number, name of active ingredient, concentration, content, form of preparation, batch number, expiry date, manufacturer, importer, recall level, the facility responsible for drug recall.

4. Notification of drug recall decision:

a) The drug recall decision of the Ministry of Health (Drug Administration) is announced by post, fax, email, telephone or the mass media. The scope of drug recall announcement is specified in Clause 3, Article 63 of the Law on Pharmacy;

b) Immediately after making the recall decision, the Ministry of Health (Drug Administration) announces the drug recall decision on websites of the Ministry of Health and the Drug Administration, and the Ministry of Health's national pharmaceutical database;

Departments of Health announce drug recall decisions on their websites immediately after receiving those decisions.

Domestic drug manufacturers and importers must notify the information about recalled drugs to drug traders/users which purchased those drugs.

c) For recalling drugs with first-degree violations, besides carrying out the actions specified in Point b of this Clause, the Ministry of Health must announce the drug recall decision on Vietnam Television and Voice of Vietnam.

5. Recalling drugs:

a) The drug trader/user must discontinue provision and use of the recalled drugs; place inventory drugs in quarantine; make a list of drug traders/users and individuals (if any) that purchased those drugs, contact them and receive the returned drugs; return the drugs to the providers;

b) The manufacturer (of domestic drugs) and importer cooperate with the import entrustor or distribution hub (of imported drugs) in recalling unconformable drugs. The recall form follows Template No. 4 of Appendix III issued together with this Circular.

The drug trader/provider that fails to recall drugs or receiving returned drugs shall be notified by facilities and individuals purchasing those drugs to the local Department of Health and face actions.

c) Drug recall has to be completed within one of the time limits specified in Clause 3, Article 63 of the Law on Pharmacy.

6. Drug recall report, evaluation and additional measures:

a) In one day (for first-degree recalls) or three days (for second- and third-degree recalls) from the recall's date of completion, the facility in charge of recalling must report the results to the Ministry of Health (Drug Administration) and the local Department of Health in writing. The report consists of the following documents:

- Summary drug recall report, which follows Template No. 5 of Appendix III issued together with this Circular.

- List of drug traders/users (including those receiving drugs from the facility in charge of recalling unconformable drugs, or from distributors) with their addresses, phone numbers, email addresses (if any), amount of drugs received, amount of drugs recalled;

- Delivery reports, receipts of return or other evidence of drug recall;

- Drug recall self-evaluation form;

- Investigation results, evaluation of causes, evaluation of risks in the unconformable drug's other batches and/or other drugs coming from the same production line.

b) The Ministry of Health (Drug Administration) consider the report mentioned in Point a of this Clause, evaluate it or send it to the Department of Health for evaluation. If the drug recall is evaluated to be insufficient and the product can still be circulated and used, posing a risk to the consumers' health, the Drug Administration cooperates with the Department of Health and other related authorities in coercive drug recall.

Article 13. Voluntary drug recall procedure

1. The pharmacy business establishment that carries out voluntary drug recall shall evaluate and identify the seriousness of the drug's violation and report on the unconformable drug, seriousness of violation, reason for recall and handling measure proposal to the Ministry of Health (Drug Administration) in writing, as specified in Clauses 3 and 4, Article 15 of this Circular.

2. In three days from the date the pharmacy business establishments' report is received, the Ministry of Health (Drug Administration) consider the report and identify the seriousness of the drug's violation as specified in Appendix II issued together with this Circular.

a) If an agreement with the pharmacy business establishment's proposal concerning the drug with third-degree violation is reached, the Ministry of Health (Drug Administration) shall send an document allowing the facility to voluntarily recall the drug.

b) In the case of drugs with first- or second-degree violations, the Ministry of Health (Drug Administration) shall follow the drug recall procedures mentioned in Clauses 3, 4, 5 and 6, Article 12 of this Circular;

c) If additional information or clarification of information in the pharmacy business establishment's report is needed, the Ministry of Health (Drug Administration) shall request the establishment to provide additional information and explanations in writing. In five days from the day the Ministry of Health's request is received, the establishment must provide additional information and explanations in writing.

3. In 24 hours from the time the Ministry of Health (Drug Administration) issues the document allowing voluntary drug recall, the establishment can issue the drug recall decision, notify it to traders/users and carry out drug recall as specified in Clauses 5 and 6, Article 12 of this Circular.

Article 14. Handling of drugs not meeting quality standards by place of collection

1. In the case of unconformable drug samples collected from retailers, level-III and level-IV medical facilities:

a) In 24 hours from the time the testing facility's test/analysis report is received, the Department of Health shall seal the unconformable drug at the sample's facility of origin.

b) In 48 hours from the time the testing facility's test/analysis report is received, the Ministry of Health (Drug Administration) shall request the responsible drug registrant/manufacturer/importer to:

- Report its drug distribution to the Ministry of Health (Drug Administration);

- Request the quality inspection authorities to collect additional samples from domestic drug manufacturers or importers, and from at least two wholesalers, with one of them already supplied drugs to the facility where the samples are collected from;

- Send samples to central testing facilities in order to have the unfulfilled criteria tested.

c) If at least one of the additional sample does not meet the quality standards, the Ministry of Health (Drug Administration) shall identify the violation's seriousness and draw the conclusion on recalling the unconformable drug as specified in Appendix II issued together with this Circular, and issue the drug recall decision as specified in Clause 3, Article 12 of this Circular. The recall's scope and time limit is specified in Clause 3, Article 63 of the Law on Pharmacy;

d) If all of the additional samples meet the quality standards, the Ministry of Health (Drug Administration) shall only carry out the steps of identifying the violation's seriousness, drawing the conclusion on recalling the unconformable drug, issuing the drug recall decision and drug handling to the drugs of the facility providing the initial samples.

2. In the case of unconformable drug samples collected from wholesalers, level-II or above medical facilities:

a) In 24 hours from the time the testing facility's test/analysis report is received, the Department of Health shall seal the unconformable drug at the facility of origin.

b) In 48 hours from the time the testing facility's test/analysis report is received, the Ministry of Health (Drug Administration) shall issue the drug recall decision applying to the province the facility of origin is based on and traders/users receiving the drug from that facility, as specified in Clause 3, Article 12 of this Article, and request the responsible trader/user/importer to:

- Report its drug distribution to the Ministry of Health (Drug Administration);

- Request the quality inspection authorities to collect at least two additional samples from other wholesale establishments, with one of them already supplied drugs to the facility where the samples are collected from;

- Send samples to central testing facilities in order to have the unfulfilled criteria tested.

c) If at least one of the additional sample does not meet the quality standards, the Ministry of Health (Drug Administration) shall identify the violation's seriousness and draw the conclusion on recalling the unconformable drug as specified in Appendix II issued together with this Circular, and issue the drug recall decision as specified in Clause 3, Article 12 of this Circular. The recall's scope and time limit is specified in Clause 3, Article 63 of the Law on Pharmacy;

d) If all of the additional samples meet the quality standards, the Ministry of Health (Drug Administration) shall only carry out the process specified in Point b of this Clause.

3. If the sample is collected from manufacturers, importers and preservation service providers, or the sample's quality violation is identified to be caused by the production process, the Ministry of Health (Drug Administration) shall identify the violation's seriousness and draw the conclusion on recalling the unconformable drug as specified in Appendix II issued together with this Circular, and issue the drug recall decision as specified in Clause 3, Article 12 of this Circular. The recall's scope and time limit is specified in Clause 3, Article 63 of the Law on Pharmacy.

Article 15. Handling of recalled drugs

1. The recalled drug can either be rectified or re-exported if it has third-degree violation and does not fall into the type of drug mentioned in Point b, Clause 2 of this Article.

2. The recalled drug must be destroyed if it has:

First- or second-degree violation;

b) Third-degree violation, considered by the Ministry of Health (Drug Administration) to be neither rectifiable nor re-exportable, as specified by Clauses 3 and 4 of this Article;

c) Third-degree violation, considered by the Ministry of Health (Drug Administration) to be rectifiable or re-exportable, but the facility fails to rectify or re-export that drug.

3. Procedure for proposing rectification of recalled drugs:

a) The facility that has recalled drugs shall send the Ministry of Health (Drug Administration) a document stating the rectification process, drug quality and stability risk assessment, the program for monitoring and surveillance of the drug's quality, safety and efficacy during circulation.

b) In 60 days from the date the facility's rectification proposal is received, the Ministry of Health (Drug Administration) must consider the proposal and reply their agreement or disagreement in writing The reason for disagreement must be specified;

c) If additional information or clarification of the rectification's information is required, in 60 days from the date the Ministry of Health's (Drug Administration) document is received, the facility must provide documents additional information and explanations. Failure to do so within the aforementioned time limit will result in invalidation of the rectification proposal.

4. Procedure for proposing re-export of recalled drugs:

a) The facility that has recalled drugs shall send the Ministry of Health (Drug Administration) a document with the re-export plan, stating the time and re-export country;

b) In 15 days from the date the facility's proposal is received, the Ministry of Health (Drug Administration) shall reply their agreement or disagreement on the re-export in writing; the reason for disagreement must be specified.

5. The rectification and re-export of recalled drug shall only be carried out after the written agreement of the Ministry of Health (Drug Administration) is issued.

6. Drug destruction:

a) The head of the facility that has drugs to be destroyed shall decide to form the drug destruction council. The council shall have at least three persons, with one representative having professional responsibility;

b) Drug destruction must be safe for both humans and animals, does not pollute the environment in accordance with the rules of law in environmental protection;

c) Drug destruction that requires special control must be carried out as specified in Article 48 of Decree No. 54/2017/ND-CP ;

d) The facility carrying out drug destruction must notify the Department of Health, and send the Department a drug destruction form that follows Template No. 6 in Appendix III issued together with this Circular.

7. The recalled drug handling period shall not exceed 12 months from the recall's date of completion, as specified in Points a, b and c, Clause 3, Article 63 of the Law on Pharmacy.

Article 16. Responsibilities for drug recall

1. Responsibilities of pharmacy business establishments, medical facilities and drug users:

a) Comply with the regulations in Clauses 1, 2 and 3, Article 64 of the Law on Pharmacy;

b) Regularly review and update information on drug recall from websites of the Ministry of Health, the Drug Administration, and Departments of Health.

2. Responsibilities of the Drug Administration:

a) Receive information, identify seriousness of drug's violations and issue drug recall decisions;

b) Announce drug recall decisions as specified in Point a, Clause 4, Article 12 of this Circular, publish information about recalled drugs on websites of the Ministry of Health and the Drug Administration after those decisions are issued. Cooperate with Vietnam Television and Voice of Vietnam in announcing recall of drugs with first-degree violations;

c) Consider the evaluation reports and reply to the pharmacy business establishments' proposals for voluntary drug recall, rectification or re-export of recalled drugs;

d) Cooperate with related units (Ministerial Inspector, Department of Health, health divisions of other agencies) in inspection of organization and execution of drug recall; take actions against violating facilities in accordance with the regulations of law;

dd) Produce documents providing detailed guidelines for the processes of drug recall and handling, evaluation of drug recall in drug manufacturers and pharmacy business establishments.

3. Responsibilities of Departments of Health:

a) Publish drug recall decisions on websites of the Departments of Health;

b) Organize announcement and dissemination of drug recall information to local drug manufacturers, pharmacy business establishments and medical facilities;

c) Cooperate with facilities having drugs with quality violations in collecting additional drug samples as specified in Point b, Clause 1 or Point b, Clause 2, Article 14 of this Circular, or direct the testing facilities to do so;

d) Organize surveillance of drug recall in the Departments' jurisdictions; take actions against and penalize facilities violating drug recall regulations within their competence;

dd) Participate in or carry out evaluations of pharmacy business establishments' drug recall in the Departments' jurisdictions, under the Ministry of Health's (Drug Administration's) direction. Report any drug manufacturer, importer, wholesalers which are distribution hubs that fail to, or insufficiently, recall drugs to the Ministry of Health (Drug Administration)

e) Organize and participate in coercive drug recall.

Chapter V

IMPLEMENTATION PROVISIONS

Article 17. Effect

1. This Circular is in effect from June 20, 2018.

2. The following documents shall be annulled on the date this Circular comes into effect:

a) The Minister of Health's Circular No. 09/2010/TT-BYT dated April 28, 2010 providing guidance on drug quality management;

b) The Minister of Health's Circular No. 04/2010/TT-BYT dated February 12, 2010 providing guidance on sample collection for quality identification.

Article 18. Implementation

1. The Drug Administration has the responsibility to:

a) Preside over and cooperate with related units in organizing propagation, dissemination and implementation of this Circular;

b) Preside over and cooperate with the National Institute of Drug Quality Control, the Institute of Drug Quality Control Ho Chi Minh City, the National Institute for Control of Vaccines and Biologicals in formulating plans to collect drug samples for quality inspection and present those plans to the Ministry of Health for consideration, approval and allocate budget for plan implementation within the Ministry's competence.

Collect drug samples for quality inspection and update the Ministry of Health's drug quality inspection database with information on collected drug/drug ingredient samples (including: name of drug/drug ingredient, concentration, content, type of preparation, batch number, expiry date, circulation registration number or import

permit number, manufacturer, importer, sample collector) and the drug/drug ingredient's quality inspection results;

c) Provide scientific and technical information on ensuring drug/drug ingredient quality.

Provide the National Institute of Drug Quality Control and the Institute of Drug Quality Control Ho Chi Minh City with label templates and the quality standard of the drug/drug ingredient that is issued circulation registration certificate or import permit (the updated standard if any changes occur). In the case of vaccines and biological, the label template and quality standard shall be sent to the National Institute for Control of Vaccines and Biologicals;

d) Organize quality inspections on drug/drug ingredients manufactured, prepared, circulated and used nationwide. Direct and survey the drug testing system nationwide. Draw conclusions on drug quality, based on the test results from state-owned drug testing facilities' and relevant records;

dd) Preside over or participate in carrying out state inspections, inspect and take action against violations against the law in drug quality within the Administration's competence.

2. Departments of Health have the responsibility to:

a) Organize drug quality inspections within their jurisdictions and take actions against violations in accordance with the law;

b) Formulate plans to collect drug samples for quality inspection and present those plans to the provincial People's Committees for consideration, approval and allocate budget for plan implementation within the Committees' competence;

c) Update the Ministry of Health's drug quality inspection database with information on collected drug/drug ingredient samples (including: name of drug/drug ingredient, concentration, content, type of preparation, batch number, expiry date, circulation registration number or import permit number, manufacturer, importer, sample collector) and the drug/drug ingredient's quality inspection results.

3. Responsibilities of the drug testing system:

a) Central drug testing facilities (National Institute of Drug Quality Control, Institute of Drug Quality Control Ho Chi Minh City, National Institute for Control of Vaccines and Biologicals):

- Analyze and test samples to identify the quality of manufactured, circulated and used drugs/drug ingredients; report the test results to the Ministry of Health (Drug Administration) and the local Department of Health;

- Research, establish and publish on websites of the institute and the Drug Administration the list of reference materials (including those of impurities) for analyses and tests on manufactured, imported, circulated and used in Vietnam;

- The National Institute of Drug Quality Control and the Institute of Drug Quality Control Ho Chi Minh City have the responsibility to provide drug testing centers in assigned provinces with physical and electronic copies of drug/drug ingredient quality standards;

- The National Institute for Control of Vaccines and Biologicals, on an annual basis, review and evaluate vaccine/biological quality trends and present the evaluation to the Ministry of Health for consideration, and formation of guidelines for testing finished vaccines, biologicals which are antisera, derivatives of human blood and plasma (including reviewing vaccine/biological batch quality certificate's test criteria).

Update information about quality certificate issuance for vaccines, biologicals which are antisera, derivatives of human blood and plasma on websites of the institute and the Drug Administration.

b) Provincial testing facilities:

- Analyze and test samples to identify the quality of manufactured, circulated and used drugs/drug ingredients;

- Report the test results to the Department of Health and the Ministry of Health (Drug Administration).

4. Traders have the responsibility to:

a) Organize researches and carry out implementation of the regulations of law on drug/drug ingredient quality promulgated by this Circular;

b) Implement regulations on inspection, control of drugs/drug ingredients' source and quality. Carry out quality control in order to ensure drug/drug ingredient quality throughout the facility's operation;

c) Establish a system of records and documents in order to monitor circulation of drugs/drug ingredients. Carry out monitoring and surveillance of the quality of drugs/drug ingredients produced by the facility; timely discover and handle unconformable drugs, report those drugs to the pharmaceutical and drug quality inspection authorities.

5. When the drug quality inspection force has not yet been established at all levels, the Ministry of Health shall assign:

a) The National Institute of Drug Quality Control, the Institute of Drug Quality Control Ho Chi Minh City, the National Institute for Control of Vaccines and Biologicals, by their functions, tasks and jurisdictions, to:

- Formulate plans to collect drug samples for testing and surveillance of drug/drug ingredient quality; reserve, receive and use the annual budget for sample collection and tests on drug/drug ingredient samples;

- Collect drug/drug ingredient samples in accordance with the approved plans at establishments doing pharmacy business and using drugs;

- Update the Ministry of Health's drug quality inspection database with information on drug/drug ingredient samples collected for quality inspection and those samples' test results;

- Report the test results to the Ministry of Health (Drug Administration) and the local Department of Health if the drug/drug ingredient samples do not meet the quality standards as specified in Clause 3, Article 7 of this Circular.

- The National Institute of Drug Quality Control shall the drug quality inspection database for the Ministry of Health;

b) Provincial testing facilities:

- Formulate plans to collect drug samples for testing and surveillance of drug/drug ingredient quality; reserve, receive and use the annual budget for sample collection and tests on drug/drug ingredient samples;

- Collect drug/drug ingredient samples for quality inspection in accordance with the approved plans at establishments doing pharmacy business and using drugs;

- Update the Ministry of Health's drug quality inspection database with information on drug/drug ingredient samples collected for quality inspection and those samples' test results;

- Report the test results to the Ministry of Health (Drug Administration) and the Department of Health if the drug/drug ingredient samples do not meet the quality standards as specified in Clause 3, Article 7 of this Circular.

Article 19. Implementation responsibilities

The Director General of the Drug Administration, Chief of the Ministry Office, Chief Ministerial Inspector, heads of units affiliated with the Ministry of Health, provincial Departments of Health, pharmacy business establishments, other related authorities, organizations and individuals have the responsibility to implement this Circular.

If any complication arises during implementation, the authorities, organizations and individuals are advised to notify the Ministry of Health (Drug Administration) for consideration and solution.

ON BEHALF OF THE MINISTER
DEPUTY MINISTER

Truong Quoc Cuong

MINISTRY OF HEALTH ------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
Number: 29/2018/TT-BYT	*Hanoi, January 29 00 2018*

CIRCULARS

PROVISIONS ON TRIAL MEDICINE ON CLINICAL

Pursuant to Law No. 105/2016/QH 1 of April 6, 2016 on pharmacy;

Pursuant to the Government's Decree No. 75/2017/ND-CP of June 20, 2017 defining the functions, tasks, powers and organizational structure of the Ministry of Health;

At the request of the Director of Department of Science, Technology and Training, Ministry of Health; The Minister of Health promulgates a Circular on clinical trials.

Chapter I

GENERAL RULES

Article 1. Scope

1. This Circular provides for the promulgation and application of good clinical trial practice; assess the compliance with Clinical Trials Good Practice and clinical trial records and procedures.

2. Clinical trial activities related to medical examination and treatment, apart from complying with the provisions of this Circular, must also comply with the provisions of law on medical examination and treatment.

Article 2. Subjects of application

This Circular applies to:

1. Clinical drug-testing establishments, including:

a) Establishments providing clinical trial services are those granted certificates of eligibility for pharmacy business with clinical scope .

b) Establishments providing drug bioequivalence testing services are facilities that are granted certificates of eligibility for pharmacy business and have drug bioequivalence testing scope .

c) Establishments that are not required to be issued with certificates of eligibility for pharmacy business specified in Clause 1, Article 35 of the Law on Pharmacy are medical examination and treatment establishments and scientific research establishments conducting drug testing. clinically, receiving drug bioequivalence and other establishments conducting clinical trial and non-commercial bioequivalence testing.

2. Agencies, organizations and individuals involved in clinical trial activities.

Article 3. Interpretation of terms

1. *Clinical drug trial* is a scientific activity of drug research on volunteers who probe or determine the safety and efficacy of drugs; identify and detect adverse reactions due to the effects of the drug; drug absorption, distribution, metabolism , elimination.

2. *Good Clinical Practice (GCP)* is a set of principles and standards for designing, organizing, implementing, monitoring, testing, recording, analyzing and analyzing. report on clinical trials to

ensure the reliability and accuracy of data and report on research results, protect the rights, safety and confidentiality of research subjects.

3. *The international clinical trial regulations recognized by the Ministry of Health* as Guidelines for Good Clinical Trial Practice are provided in the General Guidelines of the International Conference on Harmonization. International Conference on I lamonization of Technical R e quiments for Registration of Pharmaceuticals for Human use (ICH), Guidelines for Good Practice on Clinical Trials of the Health Organization The World (World Health Organization - WHO) and the clinical trial guidelines of reference management agencies specified in Clause 5 of this Article.

4. *The product profile for researchers* (Investigator's Brochure - I B) is a document containing information and data on preclinical research and clinical trials of research drugs.

5. *Reference management agencies* specified in this Circular include: European Pharmaceutical Regulatory Agency (EMA), USA, Japan, France, Germany, Sweden, United Kingdom, Switzerland, Australia, Canada, Belgium, Austria, Ireland , Denmark and the Netherlands.

6. *A Research* Report Form (CRF) is a paper or electronic tool designed to collect research data from clinical trial participants. sieve.

chapter II

ISSUANCE AND APPLICATION OF GOOD PRACTICE TRIAL MEDICINE ON CLINICAL

Article 4. Principles and standards Good clinical practice for drug trials

1. To promulgate principles and standards of Good Clinical Trial Practice in Appendix I to this Circular and updated documents specified in Clause 2 of this Article based on the guidance of ICH, WHO and reference management agencies specified in Clause 5, Article 3 of this Circular.

2. Where ICH and WHO amend and supplement GCP principles and standards (updated documents), the Department of Science, Technology and Training will update and publish updated documents on the Electronic Information Portal of Ministry of Health and the website of the Department of Science, Technology and Training for related subjects to look up, update and apply.

Article 5. - Subjects of application of good clinical trial principles and standards

1. Clinical drug testing establishments apply and meet GCP specified in Appendix I issued with this Circular and updated documents.

2. In cases where establishments providing drug bioequivalence testing services and establishments conducting non-commercial bioequivalence testing activities fail to meet GCP for the research period. on a clinical basis , a contract or written agreement with a clinical drug-testing establishment that satisfies the GCP is specified in Appendix I issued with this Circular and updated documents for the implementation of the research phase. Clinical studies.

3. Clinical drug testing establishments shall apply updated GCP documents according to the provisions of Clause 2, Article 4 of this Circular within 12 months, for cases where there is a request to change facilities for testing. or 06 months for other updates, counting from the time the updated material is published by the Department of Science, Technology and Training on the Ministry of Health's website and the Department's website Technology learning and Training.

Chapter III

GENERAL PROVISIONS ON ASSESSMENT OF MEETING GOOD PRACTICE TRIAL TESTS

Article 6. Cases of evaluation, inspection and examination of the satisfaction of clinical trial good practice

1. The initial evaluation of pharmaceuticals shall be conducted together with the granting of certificates of satisfaction of pharmaceutical business conditions to clinical trial drug service providers and drug bioequivalence testing service providers. c (hereinafter referred to as drug testing service provider). For clinical trial establishments specified at Point c, Clause 1, Article 2 of this Circular, the first evaluation is conducted when they conduct clinical trial activities.

2. Periodic assessment of the maintenance of GCP response is conducted every 3 years from the date of signing of the evaluation record of the previous audit (excluding unexpected audits, inspections and inspections of Ministry of Health, Department of Health).

3. Irregular assessments of GCP's meeting comply with Clause 1, Article 15 of this Circular.

4. The inspection and examination of the maintenance of GCP response by clinical drug-testing establishments shall comply with the provisions of law on inspection and examination.

Article 7. Degree of compliance Good clinical practice

Clinical evaluation of GCP compliance of drug testing establishments is based on the following three levels:

1. Level 1: Clinical drug testing establishment meets GCP in case there is no content that needs correction and correction .

2. Level 2: Clinical trial establishments still have issues that must be corrected and corrected to meet GCP in case the content needs to be repaired and corrected. research quality and safety and health of participants in the trial.

3. Level 3: Clinically tested establishments do not meet GCP in the following cases:

a) There is a content that deviates from the GCP standard, which may affect the quality of research and / or health and safety of participants in drug testing ;

b) Fraud, forgery, correction of data, data and documents.

Chapter IV

FIRST ASSESSMENT MEETING GOOD PRACTICE TRIALS ON CLINICAL TRIAL

Article 8. Dossiers of application for first-time evaluation of the satisfaction of good clinical trial practice

1. Dossiers used as a basis for assessment of GCP satisfaction for drug testing service-providing establishments are dossiers of application for certificates of eligibility for pharmaceutical business (to be submitted when applying for certificates of eligibility. conditions for pharmaceutical business, drug testing service providers are not required to submit this additional file) in accordance with Article 38 of the Law on Pharmacy and Article 32 of Decree No. 54/2017 / ND-CP dated May 8, The Government details 2017 a number of articles and measures to implement the Pharmacy Law (hereinafter referred to as Decree No. 54/2017 / ND-CP). Where business establishments providing drug testing services are subject to special control, the provisions of Article 38 of the Pharmacy Law and Article 49 of Decree No. 54/2017 / ND-CP shall apply ;

Technical documents on drug testing service providers prescribed in Article 38 of the Law on Pharmacy and Article 32 of Decree No. 54/2017 / ND-CP are presented according to the instructions on the overall regulatory documents. in Appendix II issued with this Circular or the

dossier may be updated in case of supplementing the scope of operation, stamped by the drug testing service provider.

If a drug testing service provider requests a GCP certificate together with a certificate of eligibility for pharmacy business, a drug testing service provider must clearly state this content in the application. grant certificates of eligibility for pharmaceutical business.

2. A dossier to serve as a basis for assessing GCP response to a clinical drug establishment specified at Point c, Clause 1, Article 2 of this Circular includes:

a) An application form for assessment of GCP response using Form No. 01 provided in Appendix III to this Circular. If the establishment applies for a GCP certificate, this content must be clearly stated in the application;

b) Technical documents on premises are presented according to the instructions on the general dossier specified in Appendix II attached to this Circular, stamped by the establishment.

Article 9.- Order of receiving dossiers of evaluation for meeting Good Clinical Practice Practices

1. Receiving records:

a) Establishments providing clinical trial services and establishments conducting clinical trial activities not for commercial purposes shall submit 1 set of dossiers as prescribed in Article 8 of this Circular together with evaluation fees. according to the regulations of the Minister of Finance on charges of evaluation of criteria and conditions for clinical trial to the Department of Science, Technology and Training and the Ministry of Health ;

b) Establishments providing drug bioequivalence testing services and establishments conducting bioequivalence testing activities of non-commercial drugs shall submit 01 set of dossiers as prescribed in Article 8 of this Circular. together with the evaluation charge prescribed by the Minister of Finance on the evaluation charge of standards and conditions for bioequivalence testing of drugs to the Drug Administration of Vietnam or the Ministry of Health. The Drug Administration of Vietnam is responsible for receiving the records and coordinating with the Department of Science, Technology and Training to organize the assessment of clinical trial good practice compliance .

2. The order of receipt and appraisal of dossiers complies with the following provisions:

a) Clauses 2, 3, 4, 5 and 6 Article 50 of Decree No. 54/2017 / ND-CP for clinical trial facilities of addictive drugs, psychotropic drugs, collection of precursor snails , raw materials for making drug means addictive substance, psychotropic drug substance, pre-substance used as medicine, radioactive drug; generic drugs containing narcotic active ingredients, opioid drugs containing psychotropic substances, combined medicines containing precursors;

b) Clauses 2, 3, 4 and 5 of Article 51 of Decree No. 54/2017 / ND-CP for clinical trial facilities of toxic drugs and toxic medicinal ingredients; drugs and pharmaceutical substances on the list of drugs and pharmaceutical substances on the list of substances banned from use in a number of branches and domains;

c) Clauses 2, 4 and 5, Article 33 of Decree No. 54/2017 / ND-CP for establishments other than those specified at Points a and b of this Clause.

3. Within 5 working days after receiving a complete dossier, the Department of Science, Technology and Training or the Drug Administration of Vietnam (hereinafter referred to as the dossier-receiving agency) establishes a meeting to assess the response. GCP applicants

(hereinafter referred to as the audit Team), notify in writing the clinical trial facility of the assessment team and the estimated actual time for the actual evaluation at the establishment.

Within 15 days from the date of the written notice, the assessment team conducts physical assessment at the establishment as prescribed in Article 10 of this Circular.

Article 10. Procedures for evaluating the satisfaction of clinical trial good practice

1. Evaluation process:

a) Step 1. The audit team announces the decision to set up the audit team; purpose, content and plan for assessment at the clinical trial facility;

b) Step 2. Clinical trial facility presents a brief summary of the organization, personnel, implementation, GCP application or other issues according to the content of the assessment;

c) Step 3. The evaluation team conducts the actual evaluation of the application of GCP at the clinical trial basis for each specific evaluation content;

d) Step 4. The evaluation team meets with the clinical trial facility to notify the level of GCP response of the clinical trial facility as prescribed in Article 7 of this Circular, the contents has not yet met, corrected and corrected detected during the evaluation process (if any); discuss with the clinical trial facility in case it does not agree with the evaluation of the delegation for each content.

dd) Step 5. Prepare and sign the evaluation record:

The assessment record is signed for certification by the clinical establishment leader of the school in the evaluation team; The minutes must show the composition of the audit team, location, time, scope of the assessment, the inconsistency (if any), between the audit team and clinical trial facilities related to the assessment. price meets GCP. The record is made into 03 copies: 01 copy is kept at the clinical trial facility, 02 copies are kept at the dossier-receiving agency.

2. GCP meeting evaluation report

a) Immediately after the end of the physical assessment at the clinical trial facility, the assessment team is responsible for making a report on assessment of GCP response according to Form No. 02 provided in Appendix III. attached to this Circular, to list and analyze in detail the unmet contents that clinical trial establishments need to overcome and correct (if any) in comparison with the prescribed provisions. corresponding legal documents, assessment of the level of GCP compliance of clinical drug testing facilities as prescribed in Article 7 of this Circular;

b) If the clinical trial establishment has disagreement with the content of the assessment, within 30 days from the date of signing the assessment record, the clinical trial facility shall send a written explanation. send to the dossier-receiving agency accompanied with evidence (documents, photos, videos, certificates) proving related to the evaluation content;

c) Within 10 days from the receipt of the written explanation of the clinical trial facility, the receiving authority shall review the GCP evaluation report and explanation of the clinical trial facility. , consult experts in the relevant field (if necessary) and reply in writing to the clinical trial facility. The written response must clearly state the approval and disapproval of the explanation of the clinical trial facility . This time is not included in the evaluation term.

Article 11. Handling results of assessment of Good Clinical Trial Good Practice

1. In case the report on assessment of GCP meeting concludes that the clinical trial of drug meets GCP as prescribed in Clause 1, Article 7 of this Circular:

Within 10 working days after signing the assessment record, the dossier-receiving agency shall submit to the Minister of Health the certificate of eligibility for pharmaceutical business and grant a certificate of satisfaction. GCP is made according to Form No. 03 provided in Appendix III to this Circular if the establishment has made a request in the application for a certificate of eligibility for pharmaceutical business. If the establishment does not apply for a GCP certificate, the GCP meeting evaluation report concludes that the clinical trial facility that meets the GCP has a valid certificate that the clinical trial facility meets GCP and be used as a basis for submission to the Minister of Health for issuance of a certificate of eligibility for pharmacy business or as a basis for conducting clinical trial activities of a clinical trial establishment specified at Point c, Clause 1, Article 2 of this Circular.

If the clinical trial establishment conducts drug testing and drug trading, it must be under special control within 20 days from the end of the physical assessment at the clinical trial facility and sign the evaluation sheet, if the establishment requests in the application, the receiving agency shall issue the certificate of GCP according to Form No. 03 specified in Appendix III issued with this Circular. (concurrently with the certification of pharmacy business conditions).

2. In case the report on assessment of GCP's meeting, conclusions on clinical trial establishments need to be overcome and amended according to the provisions of Clause 2, Article 7 of this Circular:

a) Within 05 working days from the end of the physical assessment at the clinical trial facility and signing the assessment record, the receiving authority shall send a report on evaluation of GCP response. enclosed with the written notice of the contents that need to be corrected and modified for clinical trial establishments.

If the clinical trial establishment conducts drug testing and drug trading, it must be under special control within 15 days from the end of the physical assessment at the clinical trial facility and signing the evaluation sheet , the receiving authority shall send a report on evaluation of GCP response, together with a written notice of the need to repair and correct the problem to the clinical trial facility. .

b) After completing the correction and modification , the clinical trial facility must have a written report enclosed with the certificate (documents, photos, videos, certificates).) proof that the correction, corrections and contents of the evaluation report have been completed;

c) Within 20 days from the date on which the clinical trial facility's correction and correction report is received , the receiving authority shall review the corrective report of the testing facility and conclude comment on the GCP response status of clinical trial facilities:

- If the correction or modification of a clinical trial establishment has met the requirements: The receiving authority shall comply with Clause 1 of this Article.

- If the clinical trial establishment has not yet met the requirements: The receiving authority shall send a written request for continued remediation, modification and supplementation of the clinical trial establishment. until satisfactory.

d) Within 06 months from the day on which the receiving authority sends a written request for correction and repair, the clinical trial facility must submit a request for correction and repair as required. bridge. After the above time-limit, the clinical trial establishment fails to rectify or repair or after 12 months from the date of submission of the first-time submission dossier but the dossier of correction or repair does not meet the requirements , The submitted file is no longer valid.

3. In case the report on assessment of GCP meeting concludes that the clinical trial of drug does not meet GCP as prescribed in Clause 3, Article 7 of this Circular:

Within 05 working days, since the end of the actual assessment at the clinical trial facility and signing the assessment record, the receiving authority shall issue a written notice of do not meet the GCP attached to the GCP Evaluation Report to the clinical trial facility and do not issue a GCP certification.

4. Within 05 working days from the date of issuance of the certificate of eligibility for pharmacy business or the certificate of establishment meeting GCP, the receiving authority shall publish the information published on the Ministry of Health's electronic information portal. The website and the website of the Agency receiving the following information:

a) Name and address of the testing facility on the GCP-ready ready;

b) The full name of the person in charge of the profession, the number of the practice certificate;

c) Number of the certificate of eligibility for business and the number of certificate of obtaining GCP (if any);

d) The expiry date of the GCP meeting assessment and the next periodic review date;

d) Scope of operation of clinical trial facilities.

Chapter V

EVALUATION OF MAINTENANCE TO MEET GOOD PRACTICE TRIALS ON CLINICAL

Article 12. Periodic assessment of the maintenance of good clinical practice trial

1. In November of each year, the receiving agency shall publish the announcement on the website of the receiving authority on the plan for periodic assessment of GCP maintenance of clinical trial facilities. in the following year and send this plan to clinical testing facilities listed in the plan.

2. Based on the periodic evaluation plan announced by the dossier-receiving agency, the clinical trial establishment shall submit a dossier of request for periodic evaluation according to the provisions of Clause 6 of this Article together with the evaluation charge according to the Minister of Finance's regulations on the dossier-receiving agency for at least 30 days, before the time of evaluation according to the plan already announced by the dossier-receiving agency .

3. If the clinical trial establishment fails to submit the application for periodic evaluation within the time limit specified in Clause 2 of this Article within 15 days from the date the establishment has to submit the dossier, the receiving agency shall receive the document in writing requesting the establishment to submit the dossier as prescribed.

4. Within 45 days after the dossier-receiving agency makes a written request, a clinical trial establishment must submit a dossier together with explanations for the reason for late submission of dossier as prescribed.

5. After submitting the dossier of request for periodic assessment of maintenance of GCP meeting within the prescribed time, clinical trial establishments may continue clinical trial activities within the scope prescribed in the certificate of eligibility for pharmacy business or the certificate of obtaining GCP for clinical drug testing facilities specified at Point c, Clause 1, Article 2 of this Circular, from the date of submission of dossiers till the time when the results of the assessment are recurring prices.

6. A dossier of request for periodic evaluation of maintenance of GCP meeting comprises:

a) An application for periodic assessment of maintenance of GCP meeting according to Form No. 04 prescribed in Appendix III enclosed herewith;

b) Summary report on clinical trial activities of the clinical trial facility within the latest 03 years from the time of the preceding assessment (excluding unexpected audits, audits) examination and inspection by the Ministry of Health and Health in the date of request for periodic evaluation;

c) Updated technical documents on facilities, specifications, and personnel of the clinical trial facility (if any);

7. The process and handling of results of assessment to maintain GCP compliance comply with Articles 9, 10 and 13 of this Circular.

Article 13. Handling of results of periodic assessment of maintenance of Good clinical practice trial

1. If the GCP evaluation report concludes that the clinical trial establishment satisfies the GCP as prescribed in Clause 1, Article 7 of this Circular:

Within 10 days after the end of the practical assessment at a clinical trial facility and signing the assessment record, the receiving agency shall issue the certificate of GCP according to the Form. u No. 03 provided in Appendix III to this Circular if the establishment so requests in the application; If the establishment does not apply for a GCP certification, the GCP meeting assessment report concludes that the clinical trial establishment that meets the GCP is valid to certify that the clinical trial facility meets GCP and is used. used as a basis for establishments to conduct clinical trial activities to continue conducting clinical trial activities.

2. In case the GCP evaluation report concludes that the clinical trial establishment needs to overcome and correct the provisions of Clause 2, Article 7 of this Circular:

a) Within 05 working days from the end of the physical assessment at the clinical trial facility and sign the evaluation record, the dossier-receiving authority shall request the testing facility in writing. clinically carry out corrections and corrections , send the corrective report to the dossier-receiving agency;

b) Within 45 days from the day on which the receiving authority sends a written request, the clinical trial facility must complete the remediation, repair, and enclose a written report. According to the evidences (documents, photos, videos, certificates) that have been completed, the existing corrections and corrections have been recorded in the assessment report;

c) Within 20 days from the day on which the corrective or corrective report is received, enclosed with proof (documents, photos, videos, certificates), the receiving authority a dossier of evaluation of the clinical trial establishment's remedy results and conclusions on the clinical trial drug's GCP satisfaction status as follows:

- In case the compliance of a clinical trial establishment has met the requirements: The receiving agency shall issue the certificate of GCP according to Form No. 03 specified in Appendix III issued together with this Circular;

- If the clinical trial's compliance has not yet met the requirements: The dossier-receiving agency has a written request for contents to be further remedied, repaired and submitted a supplementary report. figs. The time limit for extension to continue correcting, correcting and reporting is 45 days from the date of the written request.

d) Within 90 days from the end of the practical assessment, the clinical trial establishment does not have a report on remedial or after remedying as prescribed at Point c of this Clause, the remedy results Continuing to be unsatisfactory, the dossier-receiving agency issues a written notice of non-compliance with the GCP and, depending on the nature and seriousness of the

violation, the dossier-receiving agency makes one or the other. Measures prescribed at Points a and b, Clause 3 of this Article.

3. If the GCP evaluation report concludes that the clinical trial establishment does not meet the GCP as prescribed in Clause 3, Article 7 of this Circular:

Within 05 working days from the end of the assessment at the clinical trial facility and signing the assessment record, on the basis of the detected exist risk assessment for research quality and health health and safety of subjects participating in the drug trial, the dossier-receiving agency issues a written notice of non-compliance with the GCP and, depending on the nature and seriousness of the violation, the dossier-receiving agency makes a or the following measures:

a) To sanction according to its competence (if any) or propose competent agencies to sanction administrative violations according to the provisions of law on handling of administrative violations;

b) Submit to the Minister of Health to issue a decision to revoke the certificate of eligibility for pharmacy business and / or revoke the certificate of GCP (if any) in accordance with Article 40 of the Law on Pharmacy..

4. Within 05 working days from the date of conclusion that the clinical trial facility is assessed to maintain GCP satisfaction or from the date of issuing the Decision to revoke the certificate of satisfaction of pharmaceutical business conditions, issued by a drug testing service provider that does not maintain GCP, the receiving authority shall update the website on the website of the receiving authority about the GCP satisfaction status according to the content specified in Clause 4, Article 11 of this Circular, for clinical trial establishments that satisfy GCP or information on revocation of certificates of eligibility for pharmaceutical business or certificates of GCP (if any) issued to business of drug testing services does not maintain GCP.

Article 14. Control of change

1. During the period between periodic assessments, clinical trial establishments must carry out the procedures for application for certificates of eligibility for pharmaceutical business according to the provisions at Point b, Clause 1, Article 36 of the Law. Pharmacy or a dossier of request for assessment of GCP response or a report on changes made according to Form No. 05 provided in Appendix III to this Circular (if any of the following cases):

a) Changes in one of the cases specified at Point b, Clause 1, Article 36 of the Pharmacy Law ;

b) Change of drug testing locations for clinical trial facilities specified at Point c, Clause 1, Article 2 of this Circular;

c) Change position of one of the technical rooms serving clinical trials (clinic, treatment, emergency room, laboratory, phase 1 clinical trial area) at the same business location joint / drug testing;

d) Add one of the technical rooms serving clinical trials (clinics, treatment rooms, emergency rooms, laboratories, clinical trial areas in phase 1) at a new location at same business place / drug test;

d) Expand one of the technical rooms serving clinical trials (clinics, treatment rooms, emergency rooms, laboratories, clinical trial areas of phase 1) on the basis of room structure had;

e) Repair , major structural changes, arranged in one of the technical rooms for clinical trials (clinics, treatment rooms, emergency rooms, laboratories, drug testing areas Clinically stage 1).

2. In case of change of an establishment providing drug testing services under the provisions of Point a, Clause 1 of this Article, a medicine testing service-providing establishment must send a dossier of application for a certificate of eligibility for pharmaceutical business. according to the provisions of Clauses 2 and 4, Article 38 of the Pharmacy Law .

The order of evaluation of GCP compliance, classification of results and handling of results of assessment of GCP compliance comply with Articles 9, 10 and 11 of this Circular.

3. In cases where a clinical trial establishment specified at Point c, Clause 1, Article 2 of this Circular changes according to the provisions at Point b, Clause 1 of this Article, the establishment must send a dossier of request for evaluation to meet GCP. According to the provisions of Clause 2, Article 8 of this Circular.

Procedures for assessing GCP compliance, classification of results, and handling of results of assessment of GCP compliance comply with Articles 9, 10 and 11 of this Circular.

4. If the clinical trial establishment has changes in one of the cases specified at Points c and d, Clause 1 of this Article, the clinical trial establishment must submit a change report together with the Technical data corresponds to a change in the Receiving Authority.

a) The receiving authority conducts a physical assessment at a clinical trial facility . If the clinical trial facility satisfies the requirements, the receiving authority shall give a written consent to the change of the clinical trial facility;

b) The order of assessment, classification of results and handling of assessment results for clinical trial establishments with changes as prescribed at Point c, Clause 1 of this Article shall comply with the provisions of Article 9. , 10 and 13 of this Circular;

c) The order of assessment, classification of results and handling of assessment results for clinical trial establishments with changes as prescribed at Point d, Clause 1 of this Article shall comply with the provisions of 9, 10 and 11 T this quarter.

5. If a clinical trial establishment changes in one of the cases specified at Points e and f, Clause 1 of this Article, the clinical trial establishment must submit a change report together with documents. Technical corresponds to a change in the Recipient Authority. The receiving authority will assess the change of clinical trial facility.

a) Within 10 days after receiving the written notice, the dossier-receiving agency shall issue a written notice of consent to the changed contents in case the change meets the requirements;

b) Within 10 days after receiving the written notice, the dossier-receiving agency shall issue a written notice of the content to be repaired or repaired in case it has not yet met the requirements;

c) Within 45 days from the day on which the receiving authority receives the written notification, the clinical trial facility must complete the remediation and correction and send a written notice enclosed with the proof (documents, photos, videos, certificates) that have completed corrections, corrections existing in the notice;

d) Within 10 days from the receipt of the corrective report with evidence (documents, images, videos, certificates), the receiving authority shall assess the result. of the clinical trial establishment and conclude the GCP response status of the clinical trial establishment:

- Where the remedy has satisfied the requirements: The receiving agency shall issue a written notice of its approval to the changed content;

- If the remedy does not meet the requirements: The dossier-receiving agency shall conduct unexpected assessment and handle the evaluation results according to Article 15 of this Circular.

Article 15.- Irregular assessment of maintenance of clinical trial good medicine response

1. At the request of the Ministry of Health and the Department of Health, based on the level of risk of the effect of the test drug on the health of participants in the trial, the degree of GCP compliance prescribed in Article 7. This Circular, the dossier-receiving agency shall conduct an irregular assessment of the maintenance of GCP response at clinical trial establishments in one of the following cases:

a) The clinical trial facility fails to meet requirements as prescribed in Point d Clause 5 Article 14 of this Circular;

b) Clinical drug testing establishments complying with GCP at level 2 specified in Clause 2, Article 7 of this Circular must be irregularly evaluated at least 01 time within 03 years from the end of the campaign. last period prices;

c) Clinical drug testing establishments that have inspection and examination results of functional agencies conclude that there are serious violations of GCP principles and standards;

d) There is information reflecting and proposing that clinical trial facilities seriously violate GCP principles and standards;

dd) Clinical drug testing facilities do not submit documents on assessment of maintenance of GCP as prescribed in Clause 4 Article 12 of this Circular.

2. The composition of the Evaluation Team is decided by the Director of the Receiving Agency according to the scope and purpose of the assessment.

3. Dossiers, order and procedures for irregular evaluation at clinical drug-testing establishments comply with Clauses 6 and 7, Article 12 of this Circular.

Chapter VI

THE ASSESSMENT ASSESSED THE GOOD PRACTICE FOR TRIAL MEDICINE ON Clinical Use

Article 16. Composition and criteria of audit team members

1. The Minister of Health decides to set up an Assessment Team to meet GCP, the composition of the delegation includes:

a) Representative of 01 Leaders of the Agency receiving the profile of being a Union leader ;

b) 01 Specialist of the Agency receiving the dossier acts as a Union Secretary;

c) Representatives of units of the Ministry of Health (each unit of no more than 01 member), including: Department of Medical Examination and Treatment Administration; Legal services; Ethics Council in National Biomedical Research; Drug Administration; Department of Science, Technology and Training; Department of Management of Traditional Medicine Long, in case of establishments providing services of trial of traditional medicines and traditional medicines;

d) 01 member is the representative of the provincial Department of Health (hereinafter referred to as the Department of Health) where the clinical trial establishment is headquartered in case: facilities directly under the Department of Health ;

d) Members of relevant agencies and units in case of necessity.

2. Cadres participating in the evaluation team must meet the following criteria:

a) Have university or higher degree;

b) Has been trained in GCP, GCP evaluation;

c) Be honest, objective and strictly abide by the rules and regulations of the law during the evaluation process, there is no conflict of interest with the drug testing service provider assessed under Clause 3 of Article this;

d) The school must have university or higher degree in pharmacy and have experience in clinical trial management for 5 years or more.

3. Principles of conflict of interest assessment: A member of an evaluation team is considered to have a conflict of interest with a clinical trial facility to be assessed in one of the following cases:

a) Having worked in the last 05 years for a clinical trial facility to be evaluated;

b) Has participated in consultancy activities within the last 05 years for establishments in clinical trial to be evaluated;

c) Having financial interests with the assessed clinical trial facility;

d) Having a spouse, child, father or mother, siblings of the father or mother or the spouse or child working at an assessed clinical trial facility .

Article 17. Responsibilities and powers of the Evaluation Team

1. Responsibilities of the Evaluation Team:

a) Evaluate all activities of the clinical trial facility according to GCP equivalent in Article 4 of this Circular, documents updating GCP (if any) and relevant technical and professional regulations ; record in detail the evaluation contents, findings at the discovery, make records and evaluation reports;

b) Prepare or explain the GCP evaluation result report in case the clinical trial establishment has disagreement with the content of the Report;

c) Keep all relevant information about the assessment and all clinical trial activities of clinical trial facilities confidential; except with the consent of the establishment or at the request of a competent state agency in service of inspection, examination and investigation.

2. Powers of the Evaluation Team:

a) Examining the entire area related to clinical trials of clinical trial facilities;

b) Request to provide documents related to clinical trial activities of clinical trial facilities;

c) Collecting evidence-based documents (photocopying documents, taking photos, videos) proving the existence detected during the evaluation process;

d) Make a record and request the clinical trial facility to suspend clinical trial operation if during the evaluation process, the establishment found that clinical trial has violated seriously affecting safety and health of participants in clinical trials or the accuracy and truthfulness of research data and report to competent persons for handling according to regulations.

Chapter VII

DOSSIERS AND PROCEDURES FOR DRUG TESTING ON CLINICAL

Article 18. Clinical trial process

Clinical trials include stages and procedures specified in Articles 86 and 95 of the Law on Pharmacy and are specified as follows:

1. Sign up for clinical trial study;

2. Approval of clinical trial studies includes first approval and approval of changes in the course of clinical trial when the clinical trial establishment changes the trial research outline clinical drugs or copies of research information and volunteering papers for participants in clinical trials;

3. Organizing clinical trials of drugs;

4. Approving clinical trial results.

Article 19. Clinical trial dossier

Clinical trial dossier include the clinical trial study registration file; a dossier of approval for clinical trial study; a dossier of application for approval of a change in clinical trial of the drug; Dossiers of application for approval of clinical trial results are specified as follows:

1. A dossier of registration for clinical trial of drug trials comprises:

a) An application form for clinical trial study using the form No. 06 prescribed in Appendix III enclosed herewith;

b) Dossier of information about researched products (general information about clinical reagents: name, composition, indications, physical, chemical, preparation and other relevant information); preclinical research materials; clinical trial study documents from previous periods) in Vietnamese or in English with a Vietnamese summary.

2. Dossiers of application for approval of clinical trial study include:

a) An application form for approval for clinical trial study, using the Form No. 07 in Appendix III enclosed herewith;

b) Information about clinical trial drug includes:

- Drug research documents: ingredients, manufacturing process, quality standards, drug testing slips (for pharmaco-chemical drugs, herbal medicines, traditional medicines: testing cards of testing establishments state-of-the-art drugs that meet the GLP or GLP drug-testing service-providing establishments suitable to the scope of activities or manufacturers meeting good manufacturing practice (GMP) standards ; for vaccines: quality control slips of the national testing agency or factory release certificates for batch of vaccines and biologicals);

-Professional clinical research documents of the drug to be tested: research reports on pharmacological effects, toxicity, safety, recommendations on dosage, route of administration, usage;

- Documents about clinical trial of the previous stages (if the clinical trial is proposed for the next stage and the drug is not subject to testing in the previous stages).

c) Legal documents of clinical reagents include:

- A copy of the written approval of clinical trial drug registration by the Department of Science, Technology and Training, Ministry of Health.

- Certified copy or copy with seal of the establishment that produce the original for comparison with the request for clinical trial of stage 4 of the pharmacy authority. clinical stage 4;

- A package insert issued with a marketing authorization for the drugs requested for phase 4 clinical trial;

- Certified copy or copy with seal of the establishment showing the original for comparison with the certificate of eligibility for pharmaceutical business of the drug testing service provider;

- A document certifying the participation of research organizations for multicenter research in Vietnam;

- Certified copy or copy with seal of the establishment that produce the original for comparison of the study consent document of the People's Committee of province or city directly under the Central Government for field studies geography;

- Co-operation contract for clinical trial study between agencies, organizations and individuals that have reagents and clinics providing clinical trial services; cooperation contracts between organizations and individuals having reagents and research support organizations (if any).

d) Clinical trial research outline and explanation include:

- Explanatory statement on clinical trial study according to Form No. 08 prescribed in Appendix III enclosed herewith;

- Research information form or Case Report Form (CRF);

d) Scientific records and copies of certificates of completion of Good Clinical Good Practice Practice courses of key researchers, issued by the Ministry of Health or by establishments with GCP training functions;

e) A copy of the research information and a volunteer's participation in the clinical trial of the drug using Form No. 09 of the Appendix specified in Appendix III enclosed herewith;

g) Written record of scientific and ethical evaluation in the ethics biomedical research committee at the grassroots level;

h) Study drug labels according to the Minister of Health's Circular No. 01/2018 / TT-BYT dated January 18, 2018, specifying drug labels, medicinal ingredients and drug use instruction sheets.

3. A dossier of application for approval of a change in clinical trial of a drug comprises:

a) An application for approval of a change in clinical trial of drug according to Form No. 10 specified in Appendix III issued with this Circular;

b) The updated version of the corresponding documents specified in Clause 2 of this Article has been changed;

c) The minutes of evaluation of the Ethics Council in grassroots biomedical research for clinical trial changes that have significant effects on the health and benefits of the participants in the trial or photo. affect design, processes, and research procedures.

4. Dossiers of application for approval of clinical trial results include:

a) An application form for approval of clinical trial results, using Form No. 11 in Appendix III enclosed herewith;

b) A copy of the approved research proposal;

c) A copy of the Decision approving the approved research proposal;

d) Minutes of evaluation of clinical trial results of the ethics council in grassroots biomedical research;

dd) A full report on clinical trial results according to Form No. 12 provided in Appendix III to this Circular.

Article 20. Requirements for language, form and legality of the file

1. Language of the application:

Clinical trial records must be in Vietnamese or English. In case it is not presented in Vietnamese or English, a notarized translation of that document must be added into Vietnamese or English (including contents of consular certification and legalization).

2. Application form:

Clinical drug testing records must be prepared in A4 size paper, tightly bound, with catalogs, documents arranged in the order of the table of contents, separated and instructed between the The item, the delimiters, must be numbered for easy reference.

3. The legality of the file:

a) The application for registration and content of the registration application must be registered and stamped by the legal representative or the lawful authorized representative of the registration organization;

b) For papers issued by foreign management agencies, they must be consularly legalized according to the provisions of law on consular legalization, except for cases where they are permitted by law.

Article 21.- Procedures and order for registration of clinical trial drug research

1. Organizations and individuals that have clinical reagents shall send them directly or by post 01 set of clinical trial drug registration dossiers to the Department of Science, Technology and Training, the Ministry of Health.

2. The Department of Science, Technology and Training and the Ministry of Health check the validity of the dossiers within 5 working days after receiving the dossiers. In case of invalid dossier, there must be a written notice and specific guidance for additional organizations and individuals until the dossier is valid.

3. Organizations and individuals with clinical reagents shall have to coordinate with the Department of Science, Technology and Training and the Ministry of Health in completing the dossiers within 60 days after receiving them. notice. Past this time limit, the submitted documents are no longer valid.

4. Within 5 working days after receiving a complete and valid dossier, the Director of the Department of Science, Technology and Training shall issue a written approval to research on clinical trial of drug according to Form No. 13 specified in Appendix III issued with this Circular. In case of disapproval, you must reply in writing and clearly state the reasons.

Article 22: Procedures and order for approval of clinical trial of drug

1. Clinical drug trial establishments send directly or by post 01 set of dossier of application for approval of clinical trial study to the Department of Science, Technology and Training, Ministry of Health.

2. The Department of Science, Technology and Training and the Ministry of Health examine the validity of dossiers within 5 working days after receiving them. In case the dossier is invalid, there must be a written notice and specific guidance for the establishment to supplement the dossier until the dossier is valid.

Clinical drug-testing establishments shall have to coordinate with the Department of Science, Technology and Training and the Ministry of Health in completing dossiers within 60 days after

receiving written notices. Beyond this deadline, the procedure for approving a study must be repeated from the beginning.

3. Within 25 days after receiving a complete and valid dossier, the Health Ministry shall organize a meeting of the Ethics Council in the national biomedical research (hereinafter referred to as the National Ethics Council) and there are minutes of evaluation of clinical research protocol .

4. Within 05 working days from the day on which the appraisal record of the National Ethics Council is issued, the Department of Science, Technology and Training will summarize and complete the dossier and submit it to the Minister of Health for approval. approve the clinical trial study protocol if the clinical trial study proposal is satisfactory. If the research proposal is not approved or needs repair, the Department of Science, Technology and Training shall send a written notice to the establishment and clearly state the reason.

5. If the clinical trial study outline needs revision , the clinical trial facility is responsible for coordinating with the Department of Science, Technology and Training and the Ministry of Health to complete the dossier. Maximum time limit is 90 days from the date of receiving written notice. Beyond this deadline, the procedure for approving the research proposal must be repeated from the beginning.

6. Within 05 working days from the date of receipt of the completed research proposal in accordance with the notification, the Department of Science, Technology and Training and the Ministry of Health summarize and complete the dossier and submit it. The Minister of Health has decided to approve the clinical trial protocol.

Article 23: Procedures and order for approval of changing clinical trial of drug trials

1. Clinical drug trial establishments send directly or by post 01 set of dossier of application for approval of changes of clinical trial study outline to the Department of Science, Technology and Training, Ministry of Medicine International.

2. The Department of Science, Technology and Training and the Ministry of Health examine the validity of dossiers within 5 working days after receiving them. In case the dossier is invalid, there must be a written notice and specific guidance for the establishment to supplement the dossier until the dossier is valid.

Clinical drug testing establishments shall coordinate with the Department of Public Science and Training and the Ministry of Health to complete dossiers within 60 days after receiving the written notice. Past this time-limit, the research approval procedure must be repeated from the start .

3. Within 25 days after receiving a complete and valid dossier, the Ministry of Health shall organize a meeting of the National Ethics Council and make a written record of evaluation of changes in the clinical trial drug trial outline. .

4. Within 05 working days from the day on which the appraisal record of the National Ethics Council is issued, the Department of Science, Technology and Training will summarize and complete the dossier and submit it to the Minister of Health for approval. approve amendments and supplements to the clinical trial study outline if the clinical trial study proposal satisfies. In case the research proposal is not approved or needs amendment , the Department of Science, Technology and Training shall notify the establishment in writing and clearly state the reason.

5. In case the clinical trial study outline needs repair, the clinical trial facility shall coordinate with the Department of Science, Technology and Training and the Ministry of Health in completing the dossier within the maximum time limit. up to 90 days after receiving the written notice. Beyond this deadline, the procedure for approving the research proposal must be repeated from the beginning.

6. Within 5 working days after receiving the research proposal, which has been completed in accordance with the written notice, the Department of Science, Technology and Training and the Ministry of Health summarize and complete the dossier. and submit to the Minister of Health for approval of amendments and supplements to the clinical trial study protocol.

Article 24. Organization of clinical trial implementation

Clinical testing facilities organize clinical trials according to the approved research protocol and GCP guidelines.

Article 25. Procedures and order for approval of clinical trial results

1. Clinical drug testing establishments send directly or by post 01 set of dossier of application for approval of clinical trial results in Vietnamese to the Department of Science, Technology and Training, Ministry of Health.

2. The Department of Science, Technology and Training and the Ministry of Health examine the validity of dossiers within 5 working days after receiving them. In case the dossier is invalid, there must be a written notice and specific guidance for the establishment to supplement the dossier until the dossier is valid.

Clinical drug testing establishments shall coordinate with the Department of Science, Technology and Training and the Ministry of Health to complete dossiers within 60 days after receiving written notices. Beyond this time limit, procedures for approving clinical trial results must be repeated from the beginning .

3. Within 25 days after receiving a complete and valid dossier, the Ministry of Health shall organize a meeting of the National Ethics Council and make a record on clinical trial acceptance, in which there must be: satisfactory conclusion; pass but need corrections , additions or unsatisfactory.

4. Within 5 working days after receiving a written record on acceptance of safety and efficiency requirements of the National Ethics Council, the Director of the Department of Science, Technology and Training shall decide to approve the clinical test results according to Form No. 14 provided in Appendix III to this Circular. In case the acceptance record is satisfactory but it is necessary to repair, supplement or fail to meet safety and efficiency requirements, the Department of Science, Technology and Training shall notify in writing the establishment and clearly state the reasons therefor. .

5. In case the acceptance record is accepted but needs to be repaired and supplemented, the establishment shall have to coordinate with the Department of Science, Technology and Training and the Ministry of Health in completing the dossier within a maximum of 90 days as follows. from the date of the written notice. Beyond this time limit, procedures for approving clinical trial results must be repeated from the beginning.

6. Within 05 working days from the date of receipt of the completed application in accordance with the written notice, the Director of Department of Science, Technology and Training decides to approve the clinical trial results. .

Chapter VIII

TERMS ENFORCEMENT

Article 26. Effect

1. This Circular takes effect from January 1, 2019.

2. To annul Article 2, Article 3, Article 4, Chapter III, Chapter IV , Chapter V, Chapter VI , Chapter VII, Chapter VIII, Article 39 and Article 40 of Circular No. 03/2012 / TT-BYT dated 02/2012 February 2012 of the Minister of Health providing guidance on clinical trials and Decision No. 799 / QD-BYT dated March 7, 2008 of the Minister of Health on promulgating "Guidelines for Good Practice clinical medicine "from the effective date of this Circular.

Article 27. Terms of reference

If the documents referred to in this Circular are replaced or amended, the replaced or amended documents shall apply.

Article 28. Transitional provisions

Clinical trials dossiers submitted before the effective date of this Circular shall be reviewed and verified according to the Minister of Health's Circular No. 03/2012 / TT-BYT of February 2, 2012. clinical trial or as prescribed by this Circular in case the establishment requests it.

Article 29. Organization of implementation

1. Department of Science, Technology and Training, Ministry of Health are responsible for:

a) Be the focal point for organizing the evaluation of the clinical trial service provider's compliance with Clinical Traceability Practice and the establishments conducting clinical trials. for commercial purposes;

b) Take charge and cooperate with relevant agencies in organizing the dissemination and guidance of the contents of this Circular;

c) Be the focal point and coordinate with the relevant units to guide the implementation of Department of Health, Department of Health and clinical trial facilities within the scope of their assigned functions and tasks;

d) Summarize and publish on the website of Department of Science, Technology and Training the list of clinical trial service providers and establishments conducting drug testing activities in forestry ready for non-commercial purposes nationwide have been granted certificates of eligibility for pharmaceutical business, certificates of obtaining GCP, updating status of certificates of eligibility for pharmacy business, certificates of obtaining GCP, status GCP satisfaction status and other information as prescribed in Clause 4, Article 11 of this Circular, according to the scope of their assigned functions and tasks;

dd) Publish the GCP update document on the Ministry of Health's website and the Department of Science, Technology and Training's website;

e) Invest or coordinate with the Inspectorate of the Ministry of Health and relevant units of the Ministry of Health to inspect and inspect the compliance with GCP and handle violations according to its competence;

g) Receive and check clinical trial documents, instruct organizations and individuals that have clinical trial drugs and clinical trial facilities to comply with this Circular and other regulations of relevant laws;

h) To assist the Ministry of Health to organize meetings of the National Council of Council for evaluation of clinical trial research protocols , evaluation of changes in trial research proposals. clinical medicine, clinical trial acceptance ; carry out the approval of clinical trial results;

i) Organize periodic or irregular monitoring and examination of clinical trial.

2. The Drug Administration of Vietnam, Ministry of Health shall:

a) Be the focal point for organizing the evaluation of the satisfaction of Practice on clinical trial results of establishments providing bioequivalence testing services and facilities conducting equivalent testing activities. biology of the drug for non-commercial purposes;

b) Coordinate with relevant units in organizing the dissemination of content and guide the implementation of this Circular;

c) Summarize and publish on the website of the Drug Administration of Vietnam a list of establishments providing drug bioequivalence testing services and establishments conducting drug bioequivalence testing activities c for non-commercial purposes nationwide have been granted certificates of eligibility for pharmaceutical business, certificates of obtaining GCP, updating status of certificates of eligibility for pharmaceutical business, certificates of attainment GCP, GCP fulfillment status and other information as prescribed in Clause 4, Article 11 of this Circular, according to the scope of their assigned functions and tasks;

d) Acting as a focal point and coordinating with relevant units of the Ministry of Health to inspect and inspect the compliance with GCP of bioequivalence testing service providers and drugs whether the department has received bioequivalence testing of drugs for commercial purposes and handled violations according to its competence.

3. Department of Health is responsible for:

a) Coordinate with relevant units to organize the dissemination of this Circular and guide implementation for units in the area;

b) Join an inspection team to assess GCP's responsiveness; supervise and handle violations within its competence of GCP compliance to clinical trial establishments under its management.

4. Clinical drug-testing establishments shall:

a) Organize the implementation of this Circular in accordance with the reality of the establishment;

b) Ensure that GCP principles and standards are met throughout the operation of the establishment;

c) Conduct clinical trial activities within the licensed scope on the basis of compliance with the provisions of law;

d) Comply with the regulations on time limit, dossiers, and procedures for evaluating the GCP's compliance with the provisions of this Circular;

d) Subject to unexpected inspection, examination and evaluation of GCP's maintenance of GCP compliance as prescribed by law.

Article 30. Implementation responsibilities

Directors of Department of Science, Technology and Training, Directors of Departments of Drug Administration, Directors of Ministry Offices, Chief Inspectors of Ministries, Directors, Departments of Administration , Directors of Departments, Departments and General Departments under the Ministry of Health, heads of units attached to the Ministry of Health, concerned organizations and individuals shall implement this Circular.

In the course of implementation, if there are any difficulties or difficulties , agencies, organizations and individuals shall promptly report them to the Ministry of Health (the Department of Science, Technology and Training) for consideration. , to handle./.

KT. MINISTER
DEPUTY

Recipients:

- Committee of social affairs of the National Assembly (for reporting);
- Government Office (Official Gazette, Shareholder TTTCP);
- Minister (for reporting);
- Deputy Ministers of Health;
- Ministries, ministerial-level agencies, agencies under the Government;
- Ministry of Justice (Legal Document Verification Department);
- Department of Health of prefectures , cities directly under the Central Government;
- Health ministries, branches;
- Units belonging to, under the Ministry of Health;
- Vietnam Pharmaceutical Corporation - Joint Stock Company;
- Pharmaceutical business associations Vietnam;
- Vietnam Pharmaceutical Association;
- Web portal of the Ministry of Health;
- Website of Department of Science, Technology and Investment;
- Archive: VT, PC , K2ĐT (05).

Truong Quoc Cuong

APPENDIX I

GOOD PRACTICE TRIAL MEDICINE ON CLINICAL

(Issued together with Circular No. 2/2018 / TT-BYT dated October 2 , 2018 of the Minister of Health providing regulations on clinical trials)

Chapter I

TERMS AND PRINCIPLES IN GOOD PRACTICE TRIAL ON CLINIC

Article 1. Terminology

1. *Organizations and individuals having clinical trial drugs* are organizations and individuals that own research drugs, have a clinical trial demand and have a commitment to provide financial support for clinical trial.

2. *Researchers* are responsible for carrying out research at research sites.

3. *Principal investigator* is a directed researcher who is directly responsible for completing the research and directly reporting the research process and results to the donor.

4. *Standard Operating Procedure (SOP)* is a detailed instruction document to achieve consistency in carrying out a specific job or task in clinical drug trial.

5. *Research monitoring and research* is the process of examining and monitoring the research progress, the researchers' compliance with the approved outline and the provisions of law on research. assist.

6. *Examination of the Ethics Council or examination of organizations and individuals having clinical reagents (audit)* means the systematic and independent examination of research-related activities and documents clinical trial to determine whether the activities related to the evaluated clinical trial are conducted, the data are recorded, analyzed and reported exactly according to the outline, SOPs of donors, GCP and the provisions of law.

7. *Inspection by a competent authority (inspection)* means the operation of a management agency conducting an official evaluation of documents, facilities, records and other resources related to research. Clinical trial study. Inspection by a regulatory authority may be carried out at a trial site, an establishment of an organization, an individual with a clinical trial or a research support organization, or at other facilities considered by a regulatory authority. fit.

8. An *adverse event (AE)* is an incident or medical condition that includes any negative signs, symptoms , illness, or test results. During the clinical trial period, the clinical trial participants affected the clinical trial participants, whether or not they were related to clinical trials.

9. A *serious adverse event (SAE)* is an *adverse event* that can lead to one of the following situations in a clinical trial participant:

a) Death;

b) Threatening ;

c) Be hospitalized or extend the hospital stay;

d) Being disabled, permanently or seriously disabled;

d) Congenital malformations or fetal deformities of the drug test participant ;

e) Situations where appropriate medical interventions are required to prevent or prevent one of the situations specified at Points a, b, c, d, dd of this Clause or other circumstances of significant significance. medicine according to the current researcher at the research site.

10. *Unexpected adverse events in drug clinical trial (unexpected SAE)* are adverse events occurring in clinical trial of drug g , which The substance or severity or specificity or consequences for the patient of the variable are not the same as described or have not been detailed in advance in the outline or related research documents. .

Article 2. Principles of Good clinical practice of drug trials

1. Principle 1 :

Clinical trials must be conducted according to the basic principles of biomedical research ethics in the Helsinki Declaration adopted for the first time by the World Medical Association (WMA) in 1964 in Helsinki (Finland) and updated periodically.

2. Principle 2:

The benefits and risks or inconveniences to clinical trial participants, to society or to the community need to be considered, fully considered before starting a clinical trial of clinical trials on the basis of ensuring the safety, health and benefits of participants in clinical trials.

3. Principle 3:

Clinical trials will only begin if the clinical and social trial participants' benefits are outweighed by possible risks. The social and scientific benefits need to be considered, adequately and appropriately considered on the basis of ensuring the safety, health and rights of participants in clinical trials. .

4. Principle 4:

Clinical trials must be conducted on the basis of strict adherence to the guidelines and research processes approved by the Ethics Committee and Scientific Council and approved by competent management agencies. Any changes in research protocols and procedures must be reported in a timely manner and fully approved by competent agencies and organizations.

5. Principle 5:

The approval of clinical trial studies should be reviewed in a comprehensive, comprehensive and comprehensive manner, based on adequate pre-clinical, clinical, and other research findings. Other previous studies related to reagents (if any).

6. Principle 6:

Participants in clinical trials of drugs shall have the following rights: to provide all relevant information according to Form No. 09 in Appendix III to this Circular (not printed herein); request clarification and clarification of information related to research when necessary; respect individual cultural and cultural characteristics of individuals, regions and ethnic groups and decide whether or not to participate in clinical trial drug trials; provide appropriately free medical services; Research participants who are underage years of age, restricted civil act capacity or lost civil act capacity must obtain the consent of their representatives according to the provisions of law on participation in the trial collection. Clinical status.

7. Principle 7:

Clinical drug-accepting establishments are responsible for arranging physicians with appropriate expertise to carry out medical care and making medical decisions for clinical trial participants in necessary cases and the provisions of law.

8. Principle 8:

Every individual who is involved in conducting clinical trials needs to meet professional qualifications, training, and experience to carry out the respective task. in their clinical trial.

9. Principle 9:

All information about clinical trials must be properly recorded, processed, managed and maintained in order to have accurate reports, explanations and monitoring to check the accuracy and reliability of the information. Information and data on clinical trials.

10. Principle 10:

The records used to identify the participants of clinical trials must be protected and preserved to ensure the right to privacy in accordance with the law.

11. Principle 11:

Reagents must be manufactured, managed according to regulations, stored in accordance with the corresponding good practice guidelines and used only for research in accordance with the approved research protocol.

12. Principle 12:

The quality assurance system and methods for quality assurance in clinical trials must be fully and accurately implemented in accordance with the quality assurance regulations in this manual and the regulations. legislation on ensuring quality of drugs used in research.

13. Principle 13:

Respect the culture, identity, traditions and practices of the communities where clinical trial trials are conducted.

chapter II

RIGHTS AND RESPONSIBILITIES OF ORGANIZATIONS AND INDIVIDUALS IN CLINICAL TRIAL STUDY

Article 3. Rights and responsibilities of organizations and individuals having clinical reagents

Rights and responsibilities of individuals and organizations having clinical trials comply with Article 92 of the Law on Pharmacy No. 105/2016 / QH13.

Article 4. Rights and responsibilities of establishments accepting clinical trials

The rights and responsibilities of clinical trial facilities comply with Article 93 of the Law on Pharmacy No. 105/2016 / QH13.

Article 5. Rights and responsibilities of researchers

1. Researchers have the following rights:

a) Receive financial benefits in accordance with the agreement with the organization or individual who has clinical reagents;

b) Sign a research contract with the principal investigator or clinical trial facility to coordinate the implementation of a number of specific clinical trial contents on the basis of compliance with the research protocol. clinical clinical trial approved;

c) Proposing to the principal researcher to change the clinical trial study outline if necessary;

d) Proposing to the principal investigator to stop or end the clinical trial soon if detecting adverse events that seriously affect the safety and health of participants in the trial or the community.

2. Researchers have the following responsibilities:

a) Contribute suggestions on clinical trial study outline, the provision of research information and volunteer participation sheets for clinical trial participants, and relevant documents;

b) Cooperate with clinical trial facilities and organizations and individuals with clinical reagents to develop and complete documents for approval for clinical drug research;

c) Carry out tasks assigned by the researcher in connection with the research deployment; select participants to try the drug; record and retain source documents and essential documents; regular and irregular reports as prescribed; monitor and supervise the implementation of research according to the approved research protocol and current regulations;

d) Comply with the approved research protocol and protocol, except for cases where immediate changes are needed to ensure safety for participants in drug testing ;

d) Proposal for the main researcher to change the research proposal if necessary. The implementation of the change outline shall be conducted only after it is approved by a competent agency or organization;

e) Pay compensation for drug test participants when adverse events cause serious damage to the safety and health of participants of the trial because the researcher violates the research proposal assist;

g) Cooperate with organizations and individuals that have clinical reagents to complete the application for approval of clinical trial results to submit to competent authorities for appraisal and approval.

Article 6. Rights and responsibilities of principal researchers

1. Principal researchers have the following rights:

a) Enjoy financial benefits according to the agreement with the organization or individual that has clinical reagents;

b) Proposing the coordinating unit and the list of researchers with organizations and individuals that have clinical reagents and management agencies;

c) Proposing a laboratory with a system of quality assurance suitable for clinical trial study with organizations and individuals having clinical reagents and management agencies;

d) Signing research contracts with agencies, organizations and individuals for coordinating the implementation of a number of specific contents of clinical trial on the basis of compliance with approved research protocols;

d) Proposing organizations and individuals that have clinical reagents to change research protocols in necessary cases;

e) Stop or end research early if detecting adverse events that seriously affect the safety and health of the participants in the trial or the community;

g) Publish research results in accordance with agreements with organizations and individuals having clinical reagents.

2. Principal researchers have the following responsibilities:

a) Take highest responsibility for the safety and health of the participants in the clinical trial facility;

b) Designing or commenting on the research proposal, research information sheets and volunteer research papers with relevant research documents;

c) Cooperate with clinical trial facilities and organizations and individuals with clinical trial to develop and complete the application for approval of clinical trial research;

d) Organization of research implementation; select participants to try the drug; record and retain source documents and essential documents; regular and irregular reports as prescribed; monitor and supervise the implementation of research according to the approved research protocol and current regulations;

d) Comply with the approved research protocol and protocol, unless it is necessary to immediately change it to ensure safety for participants in the trial;

e) Pay the participants in the trial according to the content of the research information provision and the approved study participation form;

g) Proposing organizations and individuals that have clinical reagents to change research protocols if necessary. The implementation of the outline of changes will only be conducted after it has been approved by a competent agency or organization;

h) Provide clinical trial-related documents and documents to competent agencies and organizations when there is a request for examination, supervision and research inspection;

i) Pay compensation for drug test participants when adverse events cause serious damage to the safety and health of participants of the trial because the principal researcher violates the research proposal. assist;

k) Cooperate with organizations and individuals that have clinical reagents to complete the application for approval of clinical trial results and submit them to competent authorities for appraisal and approval.

Article 7.- Rights and obligations of participants in clinical trial

The rights and obligations of participants in clinical trials comply with Article 91 of the Law on Pharmacy No. 105/2016 / QH13.

Chapter III

SUBJECT TO RESEARCH TRIAL MEDICINE ON Clinical

Article 8. Clinical trial research outline

1. Organizations and individuals that have clinical reagents in coordination with key researchers are responsible for formulating clinical trial drug research outlines.

2. The clinical trial protocol must be approved by the Ethics Council in biomedical research at the grassroots level, the Ethics council in national biomedical research and competent agencies before it is approved. conduct research.

3. Change of clinical trial study outline:

a) For administrative changes: Clinical trial-receiving establishments shall send a written report to the Ethics Council of all levels and competent management agencies.

b) For changes that do not affect the health , rights of participants in the testing of drugs, designs , research procedures and procedures: it is necessary to be ethical council in biomedical research grassroots level, the Ethics Council in national biomedical research evaluation and approval. Dossier and appraisal process are implemented in accordance with the Circular No. 45/2017 / TT-BYT dated November 16, 2017 of the Minister of Health stipulating the establishment, functions, tasks, powers of the Ethics Council in biomedical research.

c) For changes that affect the health and benefits of participants in the trial or affect the research design , process and procedures: must be managed by the regulatory authority. authorized to approve. Dossiers of application for approval of changes and procedures and order for approval of changes in clinical trial drug trials comply with Articles 19 and 23 of this Circular.

Article 9.- Clinical trial study designs

Clinical trial drug design should ensure the scientificity, feasibility and suitability for each study period as well as the characteristics of the reagents, specifically as follows:

1. Phase 1 clinical trials are performed on healthy volunteers or patients. The selection of the group of participants for the trial must be reasonably explained based on the consideration of the risks and benefits of the study drug.

2. Clinical trials of stages 2, 3 and 4 are conducted on patients (for studies assessing the therapeutic effect) or participants in the trial who are at high risk of disease (for research studies). price backup effect). In case of necessity for the participation of other groups of subjects, there must be appropriate explanations.

3. The selection of control and comparison groups in clinical trials of drugs should be considered and rationally explained in a number of the following methods:

a) Comparative control with placebo;

b) Comparison of controls with the untreated group with research drugs;

c) Control comparisons between different dose levels;

d) Compare the control with another active ingredient;

đ) Comparison of evidence with historical data.

4. Phase 3 clinical trial trials for drug registration purposes must be designed in a randomized, double-blind, controlled manner. In cases where randomized, double-blind, or control groups are not feasible, an appropriate explanation is required.

5. For studies that confirm safety and efficacy in phase 3 clinical trials, the following principles can be applied in the study design to minimize deviations:

a) Blindness in the phase 3 study is required for cases where the main variables of the study are subjective or difficult to measure accurately (for example: pain level, level of response of tumors on magnetic resonance imaging in ...) but not required for studies where the main variable can be measured objectively and accurately. Where it is impossible to blind, there must be a reasonable explanation for the methods of control and reduction of errors used in the study.

b) Random allocation is an important requirement for phase 3 clinical studies to ensure objectivity in grouping. Where it is not possible to randomize groups, there must be a rational explanation.

6. For medicines from materia medica, traditional medicines, depending on their experience, knowledge and persuasiveness of the evidence on the safety and efficacy of medicinal ingredients, designed in each stage. The research section will be reviewed based on each specific record and outline.

7. Phase 4 clinical trial study is the one after the drug is licensed for circulation. Phase 4 studies may be designed as a non-intervention observational study; safety surveillance studies based on medical data facilities or existing safety monitoring reporting systems or designed as closely as Phase 3 clinical trials to confirm Safety or efficacy of the drug in actual use conditions.

Article 10. Sample size of research

1. The sample size needs to be calculated and explained appropriately to achieve the research goal. The assumptions for calculating the sample size of the research sample need to specify the reference source, the sensitivity analysis of the sample size should be performed according to the variation of the assumed parameters.

2. In the course of research, if assumptions are found to be included in the calculation of sample sizes, which are significantly different from the actual ones, the sample sizes must be recalculated and reported to competent agencies. approved.

3. The sample size in the Phase 1 study needs careful consideration based on the results of preclinical studies. The recommended sample size is 10-30 subjects (including intervention and control groups, if any). In the case of fewer sizes the account must be reasoned with.

4. Sample size in phase 2 study is recommended for at least 50 subjects (including both intervention and control groups, if any). For medicines from materia medica, traditional medicines, the minimum sample size is recommended at least 30 subjects. In case the sample size is less than that, it must be justified.

5. The sample size in the Phase 3 study must be fully calculated and justified . The size of the Phase 3 study sample must be large enough to allow for scientifically valid and safe verification of the study drug. The recommended sample size is at least 100 subjects (including intervention and control groups, if any). For medicines from materia medica, traditional medicines, the minimum sample size is recommended at least 50 subjects. In the case of smaller sample sizes, a reasonable explanation is required.

6. The sample size in Phase 4 studies must be done at the request of the governing body or must be fully calculated and justified . The sample must be large enough to permit further scientific,

effective and safe verification of the study drug. The recommended sample size is at least 200 subjects (including intervention and control groups, if any). In the case of fewer sizes the account must be reasoned with.

Chapter IV

DEPLOYMENT OF MEDICAL TRIAL RESEARCH ON Clinical

Article 11. Conducting clinical trial research

a) Clinical drug trials are only permitted to be conducted when approved by a competent authority;

b) The research deployment on participants in the trial is only started after the research information is fully informed to the testing participants and trial participants or their legal representatives. Signing the Board for providing research information and Volunteer for research participation;

c) The research team and clinical trial facility are responsible for organizing and conducting the study in accordance with the approved research outline and research process;

d) Essential documents before conducting, during the implementation process and after finishing clinical trial of the drug according to the Form No. 01, 02 and 03 issued with this Appendix;

d) The Ministry of Health encourages researches to register and publish research activities on reputable databases at home and abroad.

Article 12.- Technical standards of facilities serving clinical trials

1. Clinical areas of establishments receiving clinical trials (or under contracts / documents associated with medical examination and treatment establishments in cases where establishments receiving vaccine tests do not have clinical areas) must meet The following technical standards:

a) The reception area must have enough seats for at least 30 people to take part in the test, ensuring that rain, sun and ventilation are covered;

b) The counseling area ensures the privacy of drug testing participants who are eligible for temperature, light and ventilation;

c) Clinical clinics, treatment rooms to ensure privacy for participants in drug trials;

d) The injection room, the procedure room, the treatment room must be air-tight, well-ventilated and warm enough for the subject;

d) The emergency room has sufficient area for emergency services as prescribed by the Minister of Health;

e) The room for participants to test drugs to monitor adverse changes after using research drugs (for vaccine studies) must meet the temperature, light and ventilation conditions; enough area to take advantage of the object;

g) Separate sanitary facilities for men and women;

h) Ensuring hygienic and safe conditions for fire prevention and fighting and comply with the collection, management and disposal of medical wastes according to the provisions of law;

i) Phase 1 clinical trials or bioequivalence study areas should be arranged in a closed and controlled manner with at least 12 beds for inpatient treatment; 24-hour central physiological

monitoring room; drug preparation room; entertainment and dining rooms; personal locker for drug test participants.

2. The laboratory of the establishments receiving clinical trials of drugs (or under contracts / documents associated with professional establishments in cases where the establishments receiving vaccine tests do not have laboratories) must answer Meet the following criteria:

a) Enough area to arrange specialized equipment, documents and working space for employees suitable to the scale of clinical trial activities;

b) Having an appropriate laboratory quality assurance system.

3. Area where biological samples are stored and research drugs; areas for archives of clinical trial drug-receiving establishments must research the following criteria:

a) The area for drug storage is separate, limited access, and ensures that conditions on temperature, humidity, light, area and volume meet drug storage requirements ;

b) The place of sampling, processing and preserving the samples ensures aseptic, meeting the requirements of sample handling and preservation as prescribed;

c) Areas where records and documents are kept confidential, restrictions on access, fire and explosion prevention; avoid the adverse effects of light, temperature, humidity, the penetration of insects and other animals.

4. The clinical medicine trial management unit, which is responsible for monitoring, managing and coordinating the units in clinical trial facilities, must meet the following criteria:

- Having a working room, meeting room eligible for area, working tables and chairs;

- Sufficient office equipment, computers are connected to the internet, security and access restrictions.

5. The office of the Ethics Council in grassroots biomedical research of a clinical trial facility must meet the following criteria:

- Having a working room, meeting room eligible for area, working tables and chairs;

- Enough office equipment, computers connected to the Internet, confidential and restricted access.

6. Equipment for clinical trial must meet the following criteria:

a) There are sufficient basic equipment for assessing and monitoring the health of the study participants;

b) Having sufficient specialized equipment for clinical trials of specialized fields;

c) Having sufficient emergency service equipment as prescribed by the Ministry of Health;

d) Having testing equipment meeting the list of tests registered for clinical trial;

d) Having sufficient equipment to store and monitor the storage conditions of research drugs in accordance with the preservation requirements inscribed on the labels;

e) Having injection equipment, tools, chemicals for disinfecting, tools containing medical waste and necessary materials as prescribed by the Ministry of Health;

g) Having adequate equipment to meet the requirements of preservation of biological samples;

h) Having a device to monitor the temperature at the storage place and during transporting the research drug;

i) Equipment for testing, preserving research drugs and biological samples must be arranged, appraised, used and maintained in accordance with the purpose of use, and be calibrated. Check and periodically check using the appropriate method;

k) Having an emergency power backup system, ensuring uninterrupted power supply for important research stages; alarming and monitoring systems suitable for research drug storage devices, biological samples, and testing equipment;

l) For phase 1 clinical trial: a bedside physiological monitoring system is needed; surveillance camera system to support safety supervision and appropriate drug preparation equipment;

m) Having equipment to preserve records and documents to avoid adverse effects of light, temperature, humidity; the entry of insects and other animals and ensure fire prevention and fighting safety.

Article 13.- Technical documents and quality management for clinical trial service

1. Technical professional documents must meet the following criteria:

a) There are sufficient standards, guidelines and standard practice procedures for activities performed in clinical trials;

b) There is a document showing the scope of professional activities relevant to the field of clinical trial registration;

c) Having sufficient legal documents, instructions on clinical trial of drugs;

d) Having documents on management and handling of conflicts of interest in clinical trials;

d) Having personnel and training records of researchers updated at least once a year;

e) Having records and electronic database managing clinical trial studies;

g) There are sufficient source and essential documents of clinical trials.

2. The quality management system applied in clinical trials meeting ISO 9001 standards or equivalent or higher.

Article 14. Professional criteria for personnel

1. Professional criteria of researchers

a) Having diplomas and certificates granted or recognized in Vietnam suitable to the job positions;

b) Possessing a valid practice certificate suitable to the assigned work (for jobs requiring performers to have a practice certificate);

c) Having a certificate of completion of GCP course issued by the Ministry of Health or an establishment with GCP training function, updated every 3 years;

d) Possessing a certificate of completion of a course on safety reporting in clinical trial according to the GCP issued by the Ministry of Health or an establishment with training in safety reporting in clinical trials. once every 3 years;

d) The contingent of researchers has a sufficient quantity and components suitable to the assigned work and has sufficient time for research.

2. Criteria of principal researcher:

a) Having diplomas and certificates granted or recognized in Vietnam suitable to the job positions;

b) Possessing a valid practice certificate suitable to the assigned work (for jobs requiring performers to have a practice certificate);

c) Having a certificate of completion of GCP course issued by the Ministry of Health or an establishment with GCP training function, updated every 3 years;

d) Possessing a certificate of completion of a safety report in the clinical trial of drugs according to the GCP issued by the Ministry of Health or an establishment with training in safety reporting in clinical trials., updated every 3 years;

d) Having adequate professional knowledge, clinical experience, practical capacity to ensure GCP principles, grasping the clinical trial drug regulations, being capable of implementing the project.outline research fully and on schedule;

e) At the same time, each major researcher shall not lead more than 03 clinical trials of clinical trials.

3. Members of the clinical management and trial drug department members:

a) Having university or higher degree in the health sector;

b) Having a certificate of completion of GCP course issued by the Ministry of Health or an establishment with GCP training function, updated every 3 years.

4. The Ethics Council in biomedical research at grassroots level shall comply with the provisions of the Minister of Health's Circular No.45/2017/TT-BYT of November 16, 2017, establishing, functions, duties and powers of the Ethics Council in biomedical research.

Article 15. Recording, reporting and statistical analysis

a) Take notes and report:

Principal investigators are responsible for ensuring the accuracy, honesty, confidentiality, integrity and veracity of research data. The correction of data must comply with regulations: do not delete the original data, the researcher is assigned to sign, sign for confirmation and specify the date of repair. The principal investigator must submit an encrypted list of participants to the trial after the clinical trial has ended. The retention and submission of the list of participants for the trial after decoding must be kept. secret.

b) Statistical analysis:

- Planning and performing statistical analysis should be carried out and verified by an experienced and competent statistician;

- The statistical analysis plan must fully and fully describe the descriptive statistics or the inference statistics of the variables to be performed in the study according to the approved outline.; measures should be described to ensure the blindness of the data in the case of a study using a design in which the statistical analyst is partially blinded;

- Statistical analysis should follow analytical plan. In case of statistical analysis changes compared to the plan, it is required to have detailed explanations and explanation. The mid-term analysis (if applicable) must be clearly defined in the statistical analysis plan and plan;

- The results of statistical analysis must conform to the research objectives and answer the research questions.

Article 16.- Monitoring and examination of clinical trial and drug trials

1. Supervision:

a) Purpose: protect the rights and health of participants in the trial; ensure the accuracy, completeness and truthfulness of research data; Ensure the conduct of testing of drugs comply with research protocols, GCP and relevant legal regulations.

b) Supervision authority:

- Organizations and individuals having clinical reagents shall appoint supervisors to supervise the study. Supervisors are appointed by organizations and individuals with clinical reagents and comply with the provisions of Circular No. 08/2014 / TT-BYT dated February 26, 2014 of the Minister of Health. support for clinical trial research in Vietnam. In the course of supervision, if detecting serious violations that cause harm to the safety of subjects or the accuracy and truthfulness of data, organizations and individuals having clinical reagents may stop researching. research and send notices to the Ethics Council at all levels and management agencies and notify clinicians of clinical trial and principal researchers.

- Ethics Council supervises unexpectedly or periodically.

c) Monitoring process:

- The organization or individual having a clinical trial or the Ethics Council shall send the notice of the monitoring to the clinical trial facility at least 05 days before the monitoring time.

- The monitoring record or report should be completed and sent to the clinical trial establishment and the principal investigator no later than 20 days after the end of the monitoring.

d) Scope and frequency of supervision:

Based on the objectives, objectives, design, complexity, blinding techniques, scale, results of research, organizations and individuals with clinical reagents and the Ethics Council decide on the scale. and frequency of monitoring before, during, after clinical trials.

d) Content of supervision:

- Resources of establishments receiving clinical trials before conducting clinical trials;

- You provide research information and Volunteering papers to participate in the research, the process of obtaining volunteer votes to participate in research;

- Files, source documents, essential documents of the research;

- Research drugs (expiry date, storage conditions, management, dispensing for participants in the trial);

- The research institution's compliance with the research proposal (including the changed proposal);

- Record, report adverse events in clinical trials;

- Other contents related to the research.

2. Inspection of organizations and individuals having clinical reagents or ethics councils:

a) Purpose: to assess the appropriateness of clinical trial implementation with the research quality system, with the study SOPs, research protocol, GCP and relevant legal requirements. Testing is

part of a quality assurance activity, so it is important to be systematic and can check the quality of the monitoring.

b) Competence:

- Organizations and individuals that have clinical reagents and testers who conduct periodic examination. Inspectors are designated by organizations and individuals with clinical reagents and comply with the provisions of Circular No. 08/2014 / TT-BYT dated February 26, 2014 of the Minister of Health. support for clinical trial research in Vietnam. In the course of examination, if detecting serious breaches of the protocol, harming the safety of subjects or the accuracy and truthfulness of data, organizations and individuals having clinical reagents may stop researching and send notices to ethics councils at all levels and management agencies and notify clinical trial establishments and principal researchers.

- The Ethics Council unexpectedly inspects or periodically researches.

c) Process:

- Organizations and individuals that have clinical trial drugs or the Council of memory send notice of the examination to the clinically accepting establishments and principal researchers at least 5 days before the time of examination.

- An inspection record or report must be completed and sent to the clinical trial establishment and the principal investigator no later than 20 days after the end of the examination.

d) Scale and frequency:

Based on the objectives, objectives, design, complexity, blinding techniques, scale and points of research, organizations and individuals with clinical reagents and the Ethics Council decide on the scale and frequency of checking before, during, after testing drugs on screening.

dd) Content of inspection:

The contents are similar to those of the ones specified in Clause 1, Point d of this Article

3. Inspection by competent management agencies:

a) Purpose: to ensure the rights and health of participants in the trial, to ensure the quality and integrity of the research data, to ensure the responsibility of the stakeholders in the study. comply with regulations, promptly detect violations of research proposals.

b) Authority: Department of Science, Technology and Training - Ministry of Health presides over

clinical drug testing in Vietnam.

c) Process:

- The Ministry of Health shall send notice of the examination to organizations and individuals that have clinical reagents and establishments that receive clinical trials at least 05 days before the examination time.

- The minutes of examination need to be completed and sent to organizations and individuals having clinical reagents and establishments receiving clinical trials within 20 days after the end of the examination.

d) Scale and frequency: Based on objectives, objectives, designs, complexity, blinding techniques, scale, and results of the study, the Ministry of Health decides the scale and frequency of testing. investigate before, during and after clinical trial.

d) Content:

- For clinical trial facilities: resources for research; A copy of the research information sheet and the Volunteer Form to participate in the study, the process of obtaining consent for research participation ; collect research data; document and store source and essential documents; contents related to research drugs (management, storage, inventory, use ...).

- For organizations and individuals having clinical reagents: resources for research, supervision and examination activities of organizations and individuals that have reagents; comply with the SOP; keep records and research materials; manage research data and other relevant information.

- Activities of coordinating establishments related to clinical trials of drugs;

- The supervision and inspection activities of the Ethics Council and organizations and individuals with clinical reagents.

Article 17. Management of adverse events (AE) in clinical trial drug research in Vietnam

1. In case of occurrence of an AE which is dangerous, life-threatening or fatal for a participant in a clinical trial, the principal investigator and clinical trial establishment must stop the trial immediately. medicine on that subject, emergency, overcoming and resolving consequences, making a record in case of death, and immediately reporting by phone and email to the Ethics Council in medical research grassroots biology, Ethics committee in national biomedical research, Department of Science, Technology and Training - Ministry of Health and National Center for Drug Information, monitoring adverse drug reactions and Make a written report according to Article 18 of this Appendix.

2. In case of occurrence of AE leading to health injury to participants in clinical trial, the principal or assigned researcher must treat and monitor the health progress of until that person is stable, record and report events as prescribed in Article 18 of this Appendix.

Article 18. AE report in clinical trial of drug research in Vietnam

1. The content of AE reporting activities in clinical drug research in Vietnam includes:

a) Monitoring, detecting and reporting information related to AEs in clinical trials conducted in Vietnam or multinational trials in which Vietnam participates;

b) Collect and process information about reported AEs; benefit assessment, risk and risk management related to clinical trial of AE drug reported;

c) Publish the conclusions of the competent authority on issues related to the follow-up of AE reports of clinical trials.

2. Scope of report:

a) All SAEs that occur at research sites in Vietnam, especially those that are fatal, life-threatening or unexpected. These SAEs include situations where the treatment regimen is ineffective, fatal, life-threatening for participants who try drugs or request medical interventions to prevent these outcomes, except those SAEs that have been approved by the competent authority in the research protocol are not required to report;

b) SAEs occurred at research sites outside the Vietnamese territory of multinational studies involving Vietnam that led to suspending, suspending research, withdrawing subjects from the study or change research outline;

c) All other AEs in clinical trial study at research sites in Vietnam.

3. Provisions on reporting

a) For SAE cases occurring at research sites in Vietnam:

- All SAEs occurring at research sites in Vietnam in clinical trial trials must be reported according to Form No. 04 attached to this Appendix to the Ethics Council in Medical Research. National Biology, Department of Science, Technology and Training - Ministry of Health and National Center for Drug Information and Monitoring adverse drug reactions;

- Deadline for reporting: Deaths or life-threatening SAEs must be reported urgently within 07 working days from the date of receiving information about SAE. Other SAEs must be reported within 15 business days of receipt of information about the SAE. Information about SAE progress must be kept up to date in additional reports until the participant has recovered or stabilized;

b) For SAE cases occurring at research sites outside of Vietnam:

- All SAEs occurred at research sites outside of Vietnam of multinational studies involving Vietnam that led to discontinuation, suspension of study, withdrawal of participants from drug trials. Research or change of research proposal must be reported to the Department of Science, Technology and Training - Ministry of Health, Ethics Council in National Biomedical Research and National Center for Drug Information and Monitor adverse drug reactions ;

- The time limit for reporting does not exceed 10 working days from the date of issuance of the decision to stop or suspend the study, withdraw participants from the trial or change the research proposal;

c) Non-serious AEs occurring in Vietnam must be recorded, summarized and summarized in the periodic and full text reports of clinical trial results to the Department of Science. Technology and Training - Ministry of Health and Ethics Council in national biomedical research.

4. Responsibilities of the parties in reporting AE in clinical trial drug research in Vietnam:

a) Principal researchers and researchers at research sites: detect and manage AE in time, ensuring safety for participants in drug testing; track and record all the information; SAE reports and periodic updates of AE and SAE information to organizations and individuals with clinical reagents, Ethics Council in biomedical research at grassroots level, Ethics council in biomedical research National Institute of Science, Technology and Training - Ministry of Health and National Center for Drug Information and Monitoring adverse drug reactions within a prescribed time limit. In the event that the degree and frequency of AE and SAE exceed the permissible limits, the researcher may propose to organizations and individuals having clinical reagents, ethics councils and competent authorities. clinical trial;

b) Establishments receiving clinical trials: manage and supervise the detection, management and monitoring of AE and SAE reports at research sites to ensure safety for participants in drug trials.

c) Grassroots ethics council: reviewing and giving professional opinions on AEs and SAEs occurring at the study site, ensuring absolute safety for participants in the trial;

d) Organizations and individuals that have clinical trial drugs and authorized research support organizations :

- Coordinate with the principal researcher to report the AEs, SAEs occurring at research sites in Vietnam on the Ethics Council in grassroots biomedical research of clinical trial facilities, the Council ethics in national biomedical research, Department of Science, Technology and Training - Ministry of Health, National Center for Drug Information and Monitoring of adverse drug reactions;

- Report on SAEs that occurred at research sites outside of Vietnam that led to stopping, suspending the study, withdrawing participants from the trial or changing the research protocol of the studies. multinational countries in which Vietnam is a party;

- Summary of data of AE and SAE;

- Report findings from clinical trial studies, epidemiological studies, animal studies, in vitro studies, information in the literature and from other sources of information that may lead to a serious risk associated with the study drug;

d) Ethics council in national biomedical research:

- Review, evaluate, in case of necessity, respond to individual SAE reports and SAE information in annual progress reports and full report on results of drug testing on n clinical;

- Organize supervision and examination of research points in case of necessity;

- Advise the regulatory agency to timely guide the facility to receive clinical trials, organizations and individuals with clinical reagents to ensure absolute safety for participants in the trial;

e) National Center for Drug Information and Monitoring of adverse drug reactions receiving SAE reports in clinical trials; coordinate with the Ethics Council in national biomedical research to review and evaluate SAE reports; statistic and data analysis of SAE reports in clinical trials of clinical trials; report, advise and propose competent management agencies on contents of assurance of safety for drug test participants.

Article 19. Finance and payment for participants in drug trial in clinical trial study

1. Finance for clinical trial drug research:

a) Funding for clinical trial testing includes hiring professional experts, consumable supplies, assisting participants in drug trial, insurance ... provided by the principal researcher and the testing facility. clinical drugs in collaboration with organizations and individuals having clinical trials to discuss, formulate and sign contracts;

b) Funds for management and supervision of clinical trial drug trials for the following activities: survey, evaluation of research sites ; research sessions, conferences and seminars; training for research team; supervision, examination, inspection ... by the principal investigator, clinical trial facility in collaboration with organizations and individuals having clinical reagents discuss, formulate and sign under the contract;

c) Organizations and individuals that have clinical trial drugs are responsible for paying clinical trial drug research costs.

2. The payment and compensation for damages (if any) to clinical trial participants must be clearly stated in the research information supply form and volunteer participation report of the test participants. clinically and in research protocol.

Article 20. Ending clinical trial of drug

1. At the end of a study, the principal researcher must inventory the research drug, pay the funding and coordinate with the organization and individual that has the clinical reagents to formulate and complete the research dossier and materials. according to the List of necessary documents after finishing the study in Form 03 attached to this Appendix.

2. Research dossiers and documents must be archived and preserved under contracts between organizations and individuals that have clinical reagents and clinical trial-receiving

establishments. For new product development research, records should be kept for at least 10 years.

3. Organizations and individuals that have clinical trial drugs shall save samples of research drugs after finishing clinical trials according to current regulations.

4. Organizations and individuals that have clinical trial drugs shall coordinate with clinical trial drug establishments in recalling and destroying residual medicines strictly according to current regulations.

Article 21.- Reporting and announcing research results

1. For clinical trials for the purpose of drug circulation registration in Vietnam, within 1 year from the date the last participant of the drug trial ended the last visit, the testing facility on the clinical floor, it is responsible for coordinating with organizations and individuals having clinical reagents to complete the dossier of application for approval of clinical trial results and submit them to the competent management agency for approval.

2. The full report on clinical trial results should be presented under Form 12 in Appendix III to this Circular (not printed herein). For multinational studies, in addition to analyzing joint research results, separate analyzes of key safety and efficacy variables for the Asian or Vietnamese research populations for drugs that need to be conducted are required. Ethnic factors are considered to have effects on efficacy and safety.

3. The publication of research results must be made within 03 years from the date of the competent authorities' decision on approval of clinical trial results and compliance with regulations on Copyright in publishing research results.

4. Encouraging key researchers to publish research results in prestigious domestic and international journals.

Sample 01 - List of essential documents before conducting clinical trials

No.	file name	Purpose	Requirements for		D r e r e
			Main investigator / institution in clinical trials	Organizations and individuals that have clinical reagents	
1.1	Application for clinical trial study	Provide summary information about the product proposed for trial and the principal researcher / clinical trial proposal		□	Form No. 05 Appendix III (promulgated with this Circular)
1.2	Profile information about products (IB)	To prove that scientific information related to clinical trials has been provided to the Principal Investigator.	□	□	
1.3	An application for approval for clinical trial study		□		Form No. 06 Appendix III

1.4	Explanatory notes on clinical trial research protocol and research sample (CRF)	Detailed research protocol, standard practice procedures, monitoring , monitoring, evaluation ... and research sample.	□	□	Form 07 Appendix III
1.5	Contract for clinical trial of drugs between organizations and individuals having clinical reagents and principal researchers / establishments receiving clinical trials.	In order to prove a financial agreement between the principal researcher / institution to receive clinical and institutional drug collection, the individual has a clinical trial for clinical trial.	□	□	
1.6	Confirmation of research participation is signed between the parties concerned, for example:	To confirm your consent to participate in the research in accordance with applicable regulations.	□	□	
	- Principal investigator - Principal investigator and organization or individual with clinical trial drug .		□	(where required)	
	- Principal investigator / facility receiving clinical trials and local competent authorities at the study site (if required).		□		
1.7	Information provided to clinical trial participants:				Form No. 08 Appendix III
	- A copy of the research information sheet and the Voluntary Participation Form (including all relevant information to be provided to the subject).	- To confirm volunteering to participate in research.	□	□	
	- Any other information in writing.	- To prove that participants in the trial will be provided with appropriate information in the form of a text (content and interpretation) as well as sufficient support for the decision to sign a Voluntary Voucher. participate in research.	□	□	

	Notice of recruitment of subjects participating in the trial (if used).	To prove that the selected measures are appropriate and non-coercive, ensure ethical research.	□		
1.8	Insurance contract	To prove that participants in the trial are compensated if they are injured during the clinical trial.	□	□	
1.9	Certificate of approval from the Ethics Council in Biomedical Research at all levels	Prove the approval of the Council of Ethics in biomedical research at all levels.			
1.10	The date the document was approved / approved by the Ethics Council at all levels for the following: - Research proposal (including all amendments); - Case report - Voluntary vote to try the drug - Other information in writing provided by the participant in the trial - Notification of recruitment of participants (if used) - Compensation for participants (if any) - Any other documents showing approval / approval	To confirm that clinical trials have been appraised and approved by the Ethics Council at all levels . To confirm the version number and approval date of the document (documents)	□	□	Certificate of approval of Ethics Council at all levels
1.11	The decision to establish an ethics council in grassroots and national biological research	To demonstrate that the Ethics Committee in Biomedical Research is established in accordance with the requirements of the GCP and the relevant current regulations.	□	□ (where required)	Decision to establish the Council
1.12	Approval of the competent authority for the research proposal.	To confirm the approval of the competent authority before starting clinical trials according to current regulations.	□	□	Decision on approving the outline of the

					Minister of Health
1.13	Scientific curriculum vitae and GCP certificate granted by the Ministry of Health of Principal Investigators and researchers (including managers of the Research Materials, Pharmacists, Nurses, Laboratory technicians ...)	Demonstrate capacity and uniformity, suitable for conducting clinical trials and medical monitoring and supervision of participants in drug trials.	□	□	
1.14	GCP-led clinical drug testing facility (Clinical area , record keeping area, monitoring, surveillance, meeting room, office equipment ...) and appropriate quality standards (standard laboratories, standard technical procedures ...) or Ministry of Health approval for clinical drug testing facilities.	To demonstrate the capacity of the drug testing facility, the equipment meets the conduct of subclinical tests for the pilot study.	□	□	
1.15	A sample of a test drug is included with the clinical reagent ingredient.	To demonstrate compliance with the relevant label model regulations and the reasonableness of instructions provided to the test participants.		□	
1.16	Instructions for the management of clinical reagents and materials related to drug testing (if not included in the outline or product profile)	To demonstrate the necessary instructions for the storage, packaging, reconstitution, destruction of clinical reagents and materials related to drug testing according to the current regulations.	□	□	
1.17	Documentation of transport of clinical trial products and other data relating to drug testing	To prove the shipping date, lot number and method of transportation of clinical trials and materials related to drug testing. Allows batch tracking , verification of shipping conditions and accountability.	□	□	
1.18	Acknowledge the analysis of the tested product	To prove the type, purity and strength of the product will be clinically tested.		□	
1.19	The procedure of re-coding the code for blind clinical trials	To prove in case of emergency. Blind testing products can be disclosed without breaking the principle of blindness for the	□	□	

		remaining subjects being treated.		
1.20	Standard operating procedures (SOPs) for the techniques used in the study	Prove and ensure the uniformity, science , objectivity and accuracy of the techniques used in the research.		
1.21	Random process or list	To demonstrate the random selection method of the subjects participating in the test.		

Sample 02 - List of essential documents used during clinical trial study

No.	Name the document	Purpose	Requirements for		D r e r e
			Principal investigator / Facility receiving clinical trials	Organizations and individuals that have clinical reagents	
2.1	Updates on product records	To prove that researchers are promptly informed of information related to research drugs.			
2.2	Any changes to: - Research outline - Volunteer votes to participate in the study - Any other written information provided to participants of the test - Notify the selection of participants for drug testing (if any).	To prove that changes in clinical trial related documents are effective during the trial.			
2.3	Approval decision / certificate of approval of the governing body / Ethics Council according to the following: - Change research outline - Change about: + Volunteer votes to participate in the study	To demonstrate that the changes have been approved / approved by the governing body / Ethics Council . To determine the version number and date of the record			

	+ Any other information provided in writing to the participants + Notify the selection of participants (if any) + Any other documents giving consent + T annual estimate			
2.4	Curriculum vitae, GCP certificate issued by the Ministry of Health of a researcher or supervisor.	Demonstrate capacity and appropriateness to conduct clinical trials and medical surveillance at the study site.	□	□
2.5	Update values which are considered normal in medicine / tests / technical procedures / tests mentioned in the research proposal.	To prove that values / ranges considered normal have been adjusted during the test.	□	□
2.6	Medical facilities / testing rooms / technical procedures / tests - Certificate - Quality control has been established and / or assessed for external quality - Other assessments	To demonstrate that testing has been maintained appropriately throughout the test period.	□	□
2.7	Documentation of the transport of test products and the related test materials		□	□
2.8	Test certificates for new batches of test products			□
2.9	Report on the monitoring	To demonstrate the supervision and the results of the monitoring missions.		□
2.10	Other forms of contact other than field supervision, through: - The correspondence - Notes from the meeting - Memories of phone calls	To record any important agreements or discussions about trial management , recommended violations , drug testing, AE / SAE reporting.	□	□

2.11	The signed version of the research report and the Volunteer to participate in the study	To prove that the Volunteer Card is compliant with the GCP and outline, it must be signed before the subject participates in the trial. Document the approval directly.	□	
2.12	The source document	To prove the existence of the study subjects, together with the data collected through the trial. This document includes all the original information related to the trial, the medical treatment and history of the study subjects.		
2.13	The medical record is signed, signed and completed	To prove that the researcher or authorized members of the Principal Investigators recorded it to confirm the observations.	□ (copy)	□ (original)
2.14	Document on correction of medical records	To demonstrate all changes i / additions or corrections of the medical record after the beginning of data collection have been recorded.	□ (copy)	□ (original)
2.15	Report SAE to the sponsor	SAE report of the principal researcher for organizations and individuals with clinical trials.	□	□
2.16	Report SAE to the Ethics Council	SAE report of organizations and individuals having clinical trials and key researchers for Ethics Council	□	□
2.17	Notification of organizations and individuals having clinical reagents for researchers about safety information	Notice of organizations and individuals having clinical reagents to researchers for safety information about reagents and concurrent drugs .	□	□ (where required)
2.18	Periodical or annual reports to the Governing Body and governing body.	Mid-term or annual report to the Board of Education and the governing body.	□	□ (where required)
2.19	List of object identifiers	To prove that the principal investigator / clinical trial establishment has kept a confidential list of the test participants' names	□	

		associated with the testing numbers and identification of the participants.			
2.20	The log records which number of participants	To demonstrate chronological participation of subjects with test number	□		
2.21	Explanation of research products at the testing site	To prove the research product has been used according to the outline.	□	□	
2.22	List of signatures	To confirm the signatures and initials of those authorized to participate and / or revise the medical records .	□	□	
2.23	Records of tissue samples / biological fluids stored (if needed)	To confirm the storage and identification of stored samples if experiments need to be repeated.	□	□	

Sample 03 - List of essential documents after the end of clinical trial

After completing or stopping the test, all documents identified in paragraphs 1 and 2 should be documented with the following sections:

			Requirements for		
No.	**file name**	**Purpose**	**Principal / Mechanical researcher in the research**	**Organizations and individuals that have clinical reagents**	**D r e r e**
3.1	Explanation of research products at the testing site	To prove that the clinical reagents used in accordance with the research protocol, received at the study site, have been distributed to subjects, returned by the subjects , have been paid back to organizations and individuals with clinical reagents.	□	□	
3.2	Documents about the cancellation of clinical reagents	To confirm the cancellation of non-clinical reagents is to be carried out by organizations or individuals having reagents clinically or at the research site according to the current regulations.	□ (if doing so at the research site)	□	
3.3	List of identification numbers of subjects completing the research	To allow all subjects involved in drug trials to be identified in case of follow-up. This list must be kept confidential for the agreed period.	□		

3.4	Monitoring report on drug trials	To prove that all activities required for the end of the trial have been completed, and copies of necessary documents have been stored in the appropriate files.		□	
3.5	Regular and irregular monitoring reports	Demonstrate compliance of the drug test with the research protocol, GCP and relevant legal regulations.	□	□	
3.6	Documentation of treatment groups and blind decoding in case of necessity	In order for organizations and individuals with clinical reagents to know and carry out the right grouping, as well as know how to decode for appropriate interventions when serious adverse events occur .		□	
3.7	Written report and proposal for approval of clinical trial results of the principal researcher to the Ethics Council and governing body	To confirm the completion of clinical trial study.	□		
3.8	Full text report on clinical trial results	To confirm clinical trial results and interpretation .	□	□	Form 12 Appendix III
3.9	Database of Vietnamese patients (if required)	To check the accuracy and truthfulness of the research results.	□	□	

Sample 04 - Report serious adverse events in a clinical trial of drug testing

Report number of the unit: .....

SAMPLE REPORT OF MAJOR FACILITY (SAE) INCREASED IN CLINICAL TRIAL STUDY

1. I T O T R T E T T I T L T O T O T O T A

Report Type: □ First report □ Additional reports

Classification by the seriousness of the event:

□ Death

□ Life threatening

□ Hospitalized / extended hospital stay

□ Permanent disability / serious disability

□ Birth defects / fetal deformities

□ Request medical intervention to prevent one of the above situations or be evaluated with medical significance by a researcher or principal investigator.

Research name ....

....

research design	□ Open label	□ Single blind	□ Double blindness
If this is a blind study, will SAE lead to blindness?	□ Yes	□ No	□ No information available

Donors .....

Principal researcher name .....

The study site recorded SAE .....

When did you receive information about SAE? .....

When did SAE occur? ....

The end of SAE (or check the *"Ongoing" box* if SAE is in progress) ..... □ Ongoing

SAE name (diagnose SAE or main symptoms of SAE) .....
.....

Abbreviation of clinical trial participants .....

Clinical participant identification number .....

2. DESCRIPTION OF DESCRIPTION AND HANDLING OF SAE

Provide information on clinical signs, symptoms, clinical laboratory tests related to SAE, and measures to treat SAE if any (including dose / dose reduction), clinical trials / research protocols), developments after the implementation of such management measures and other necessary information, along with specific timelines (if any).

……

……

……

……

……

Results after handling SAE:

□ Recovery without leaving g □ In recovery □ Death (date of death: .....)

□ Recovered but left a sequelae □ Not restored □ No information available

3. TRIAL PARTICIPANTS C ON L READY

Date of birth .....

Year old .....

Sex □ Male □ Female For women: □ Pregnant (week...)

Weight (Kg) .....

Medical history related to SAE .....
.....

4. CANDIDATE TRIAL TRIAL / STUDY RESEARCH

TT	Clinical reagents or rescue regimens [a]	Dosage form, content	Road used	Dosage	Date of use (*day / month / year*)	
					Get started	End
I						
II						
III						
IV						
V						
BECAUSE						

[a] Clearly state the clinical trial drug / research protocol used by the clinical trial participants. For blind studies and SAE that do not lead to blind / unknown determination of clinical trial drugs / research protocols used by clinical trial participants , record regimen. is applied in the study and arm (arm) of clinical trial participants (described in section 2) (if available).

5. INTERVENTION FOR CLINICAL TRIAL / CARE METHOD AFTER RESEARCH AFTER HAPPENING

S TT [b]	Has the clinical trial drug / study regimen been discontinued / decreased in clinical trial participants meeting with SAE?		If stopping / reducing the dose of clinical trial drug / study protocol (or blindness), does the severity of SAE improve?			If the clinical trial / treatment regimen is reused , will the event occur again?			
	Have	Is not	Have	Is not	No information	Have	Is not	No information	Do not reuse
I	□	□	□	□	□	□	□	□	□
II	□	□	□	□	□	□	□	□	□
III	□	□	□	□	□	□	□	□	□
IV	□	□	□	□	□	□	□	□	□
V	□	□	□	□	□	□	□	□	□
BECAUSE	□	□	□	□	□	□	□	□	□

[b] Order No. (STT) corresponding to item 4.

6. TIME- EFFICIENCY DRUGS / TREATMENT MAY BE RELATED TO THE FINDINGS OF THE STUDY ASSISTANCE (not including drugs used to treat SAE)

S TT	Simultaneous use of drugs / preparations (original name and trade name)	Dosage form, content	Road used	Dosage	Date of use (*day / month / year*)	
					Begin	End

first

2

3

4

5

6

7. ASSESSMENTS OF RESEARCHERS / MAIN RESEARCHERS I FINDING ITS RELATIONSHIP BETWEEN THE STARS AND THE CONCENTRATION OF LAMINOLOGY / MULTI- STUDY

S TT (b)	Assess the causal relationship between SAE and clinical trials / research protocols			If relevant, is this the expected reaction or expected outcome of the clinical trial drug / study protocol? (c)	
	May be related	Irrelevant	No conclusions have been made	Already know / expected	Out of expectation
i	☐	☐	☐	☐	☐
ii	☐	☐	☐	☐	☐
iii	☐	☐	☐	☐	☐
iv	☐	☐	☐	☐	☐
v	☐	☐	☐	☐	☐
Because	☐	☐	☐	☐	☐

(b) Ordinal numbers (STTs) corresponding to item 4.

(c) The fact that the SAE is *"intended"* or *"unintended"* should be evaluated based on clinical reagents / protocol documents as the most up to date research protocol. if the clinical trial drug has not been licensed for circulation, or the latest version of the Instruction Manual is available if the clinical trial drug has been licensed for circulation.

- Explain the reason for SAE's evaluation of causality and expected nature:

.....

.....

.....

- How many SAE or similar AEs have occurred in this study as of the time of reporting:

+ At the research site , SAE / AE was mentioned in this report: .....

+ At other research locations: ....

8. COMMENTS OF THE COUNCIL REPRESENTATIVE OF THE SC / COUNCIL OF THE DEPARTMENT OF RECEIVING CANDIDY C ON LAM (if any)

Recommendations for participants in clinical trials *(not applicable in case of clinical trial deaths)* :

□ Continue to participate in research □ Temporarily stop participating in research □ Withdraw from the study

Proposals for the study:

□ Continue to conduct research □ Temporarily stop conducting research □ Stop conducting research

Other suggestions (if any):

.....

.....

.....

9. REPORTER (principal researcher or authorized researcher)

Signature: .....

Date of signing (*date / month / year*): .....

Full name: .....

Position, department / department: .....

Phone number: .....

Email address: .....

BOARD OF REPRESENTATIVES C / SCIENCE COUNCIL SUPPORT AC DEPARTMENT
GET CARD TRIAL ON CLOSE
(k, specify full name) (d)

IS LEADER BASIS
TEST CARD FOR CLINICAL TRAVELING
(please, specify full name and stamp)

(d) Only apply if comments in section 8.

APPENDIX II

OVERALL PROFILE ON MEDICINE TRIAL BASIS IN CLINICAL READY
(Issued together with Circular No. 9/9/2018 / TT-BYT dated October 29, 2018 of the Minister of Health)

I. Overview of the overall record of clinical trials

II. Content of overall records:

1. General information about the establishment (administrative, legal and related information);

2. The dossier of technical standards of a material establishment in service of clinical trial;

3. Document of technical expertise, standard operating procedures (SOPs) for clinical trial;

4. Document of personnel serving clinical trials;

5. Quality management system applied in clinical trials;

6. Internal monitoring.

I. BASIC OVERVIEW OF BASIS OF THE BASIS

The general record of the testing facility is a document prepared by the clinical trial facility and includes specific and clear information about technical and professional standards for clinical trial operation., quality control and quality control policies for drug testing activities are conducted on-site to serve the management, planning , testing and evaluation of GCP responsiveness. effective.

The overall profile must include sufficient information, but it is best not to exceed 25 - 30 pages including the attached appendix. Emphasis should be placed on the overview information, overall drawings and the layout of the establishment rather than verbal descriptions .

The overall profile of the clinical trial facility is part of the documentation system of the facility's quality management system and must be updated regularly. Corporate records must be reviewed periodically to ensure updated and representative information for the establishment's current operations, which must be clearly noted the version number , effective date, and The date was reviewed. Each addendum may have its own effective date for the independent updating of the appendix.

The update and modification history of the Master File is considered as a part of the Master File, which summarizes the changes of the content of the Master File and its appendices, time of change, and reason for change. due to change.

II. CONTENTS OF THE OCCUPATIONALITY

1. General information about clinical trial establishments

1.1. Contact information of drug testing facility

- Name and official address of the establishment;

- Name and detailed address of the facility that clinically tests the drug;

- Contact information of the establishment, including 24-hour phone call of the person in charge of ensuring safety and health for participants in the drug trial;

- Other positioning information (if any): GPS coordinates, postal area code ...

1.2. Licensed operation of the establishment

- Copy of operation license, business registration certificate (if any), legal documents on the establishment and functions and tasks of clinical trial facilities for non-commercial purposes, certificates receive pharmaceutical business conditions (if any) granted by competent agencies;

- Brief description of drug testing activities and other activities permitted by the competent authority (if any), including activities assessed by foreign management agencies, information information about the scope not yet specified in the certificate of eligibility for pharmaceutical business;

- List of GCP inspection and assessment conducted at the establishment within the last 05 years, including information on the date and name of the agency competent to carry out the inspection. Copy of current GCP certificate (if any).

1.3. Other related activities are carried out at the facility

- Description of clinical trial activities of non- local products (if any).

2. Files on technical standards of facilities serving clinical trial

- Brief description of facilities: List, address, area of areas, rooms / office / department;

- Simple description of the clinical area, laboratory, biological sample storage area, research drugs, storage area, research documents, and research and testing administration department Clinically, the Office of Ethics Council, Phase 1 clinical trial area or bioequivalence testing (if any);

- Design drawing, layout of clinical area, laboratory, storage area for biological samples / research drugs, document storage area, clinical trial management department ready, the Ethics Council office in grassroots biomedical research and stage 1 clinical trial area (if any);

- Description of laboratory quality assurance system;

- Listing of major equipment for clinical trials;

- Other relevant information in case of necessity as prescribed in Article 12, Annex I of this Circular.

3. Dossiers of technical and professional documents, procedures for standardization of clinical practice in drug testing

- Brief description of the system of on-site documents and documents (for example, electronic documents system, hard copy documents);

- List of regulations, dossiers, documents related to the medicine activities as prescribed in Article 13, Annex I of this Circular;

- List of standard practice procedures for clinical trial activities;

- For documents and records that are preserved or stored outside the premises: List of documents / records, name and address of information storage facilities , calculation of time period needed to retrieve information from those external documents.

4. Records of clinical trial service personnel

- Preliminary description of the number of personnel involved in the management process , clinical trial implementation;

- List of personnel of the facility as prescribed in Article 14, Annex I of this Circular: name, title, title / degree (if any) , diploma, professional certificate, certificate of completion GCP course, certifying completion of the course of safety reporting in clinical trials, the task assigned in clinical trials and other relevant information;

- Documents about the Ethics Council in biomedical research at grassroots level as prescribed in the Minister of Health's Circular No. 45/2017 / TT-BYT dated November 16, 2017 .

5. Quality management system applied in clinical trials

5.1. Quality management system of the establishment

- Brief description of the establishment's quality management system and applicable standards;

- Responsibilities related to maintaining the quality system, including senior management;

- Information on activities that have been assessed for certification, including the date and content of certification, the name of the certification body;

- The personnel chart should show the personnel arrangement in the quality management system, the main responsible positions, including senior management and trained / authorized personnel (managerial positions). quality control, quality inspection, ...).

5.2. Management of associated contract facilities (in case of co-operation with other facilities)

- Summary of associated facilities and external assessment program (if any);

- Summary of evaluation system of associated contracts;

- Summary of the sharing of responsibilities between the contractor and the contract recipient in compliance with quality assurance regulations.

5.3. Manage quality risk

- A brief description of the quality risk management (QRM) method used at the facility: the purpose, the activities ...

6. Internal monitoring

Briefly describe the establishment's monitoring system, self-monitoring results, and self-assessment of the establishment's GCP response, focusing on the areas that are monitored according to the plan, regulations, and activities. follow-up monitoring.

Appendix I:	Copies of operating licenses, business registration certificates, legal documents on the establishment and functions and tasks of non-commercial clinical drug-testing establishments, certificates of satisfaction of conditions business conditions (if any), Copy of current GCP certificate (if any).
Appendix II:	Map of facilities serving drug testing.
Appendix III:	List of main equipment for drug testing.
Appendix IV:	List of SOPs for related activities in drug testing.
Appendix V:	Organizational chart, personnel, serving drug testing, copies of diploma, related certificates and certificates.
Appendix VI:	List of associated contract facilities (address, contact information, field of professional contracting ...).

APPENDIX III

TEXT FORM

(Attached to the Minister of Health's Circular No. 9/2018 / TT-BYT dated October 29 , 2018)

Form No. 01	Request for evaluation to meet GCP
Form No. 02	The sample report evaluates the response to Good Clinical Trial Practice
Form No. 03	GCP certificate
Form No. 04	A proposal for periodic review of maintenance of GCP
Form No. 05	Report changes
Form No. 06	Application for clinical trial study
Form No. 07	Request for approval of clinical trial study
Form No. 08	Explanatory note for clinical trial study

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Form No. 11 It is recommended to approve clinical trial results

Form No. 12 Full report on clinical trial results

Form No. 13 A written approval of clinical trial study

Form No. 14 The decision approving the clinical trial result

Form No. 01 - Request for evaluation meeting GCP

NAME OF MANAGER UNIT **BASE NAME** ------	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** ----------
Number: ...../	....., *date* ... *month* ... *year 20* ...

APPLICATION FOR ASSESSMENT OF RESPONSE FOR CONDUCTING MEDICINE TESTING ON LAM

To: Science, Technology and Training Department / Drug Administration - Ministry of Health

Establishment's name: ....

Address: ....

Telephone / fax / email: ....

Contact person: ..... Title: ....

Telephone / fax / email: ....

Implementing the Ministry of Health's Circular No. 2018 / TT-BYT dated ... month ... 2018 on clinical trials, after conducting GCP self-assessment ..... year ...., please request the Ministry of Health (Department of Science, Technology and Training / Drug Administration) to be assessed for GCP compliance and to be granted a GCP certificate for the scope of regulation on Our mission functions.

[Establishment name] encloses this application with the following documents:

1. Legal documents on the establishment and functions and duties of the unit;

2. General file of clinical trial establishment.

The head of the premises
(Sign, write full name, stamp)

Form No. 02 -Sampling Assessment of the satisfaction of clinical trial good practice

MINISTRY OF HEALTH **DEPARTMENT OF SCIENCE AND TECHNOLOGY AND TRAINING /** **DRUG ADMINISTRATION** ------	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** ----------

..... , date ... month ... year 20 ....

EVALUATION REPORT

"GOOD PRACTICE TO TRIAL C ON LAM"

I. GENERAL INFORMATION OF THE HOUSING

- Name of the establishment: ...
- Address of the inspected establishment: ...
- Phone:....
- Establishment decision number: ...
- Legal representative: ...
- Person in charge of the profession: ...

II. GENERAL INFORMATION OF THE ASIA REVIEW

- Evaluation time: ....
- Time of the latest previous assessment: ...
- Evaluation form: ...
- Scope of evaluation: ...

III. INFORMATION ABOUT THE ASSESSMENT

- Decision No. .... , dated .... of the Director of Science, Technology and Training Department / Drug Administration, Ministry of Health on establishing the GCP Response Evaluation Team, at ...
- The composition of the evaluation team includes: ...

IV. REAL ASSESSMENT

1.11 The decision to establish an ethics council in grassroots and national biological research	To demonstrate that the Ethics Committee in Biomedical Research is established in accordance with the requirements of the GCP and the relevant current regulations.	□	□ (where required)	Decision to establish the Council
1.12 Approval of the competent authority for the research proposal.	To confirm the approval of the competent authority before starting clinical trials according to current regulations.	□	□	Decision on approving the outline of the Minister of Health
1.13 Scientific curriculum vitae and GCP certificate granted by the Ministry of Health of Principal Investigators and researchers (including managers of the Research Materials,	Demonstrate capacity and uniformity, suitable for conducting clinical trials and medical monitoring and supervision of participants in drug trials.	□	□	

	Pharmacists, Nurses, Laboratory technicians ...)			
1.14	GCP-led clinical drug testing facility (Clinical area , record keeping area, monitoring, surveillance, meeting room, office equipment ...) and appropriate quality standards (standard laboratories, standard technical procedures ...) or Ministry of Health approval for clinical drug testing facilities.	To demonstrate the capacity of the drug testing facility, the equipment meets the conduct of subclinical tests for the pilot study.	□	□
1.15	A sample of a test drug is included with the clinical reagent ingredient.	To demonstrate compliance with the relevant label model regulations and the reasonableness of instructions provided to the test participants.		□
1.16	Instructions for the management of clinical reagents and materials related to drug testing (if not included in the outline or product profile)	To demonstrate the necessary instructions for the storage, packaging, reconstitution, destruction of clinical reagents and materials related to drug testing according to the current regulations.	□	□
1.17	Documentation of transport of clinical trial products and other data relating to drug testing	To prove the shipping date, lot number and method of transportation of clinical trials and materials related to drug testing. Allows batch tracking , verification of shipping conditions and accountability.	□	□
1.18	Acknowledge the analysis of the tested product	To prove the type, purity and strength of the product will be clinically tested.		□
1.19	The procedure of re-coding the code for blind clinical trials	To prove in case of emergency. Blind testing products can be disclosed without breaking the principle of blindness for the remaining subjects being treated.	□	□
1.20	Standard operating procedures (SOPs) for the techniques used in the study	Prove and ensure the uniformity, science , objectivity and accuracy of the techniques used in the research.		

1.21	Random process or list	To demonstrate the random selection method of the subjects participating in the test.	□	

Sample 02 - List of essential documents used during clinical trial study

No.	Name the document	Purpose	Requirements for		D r e r e
			Principal investigator / Facility receiving clinical trials	Organizations and individuals that have clinical reagents	
2.1	Updates on product records	To prove that researchers are promptly informed of information related to research drugs.	□	□	
2.2	Any changes to: - Research outline - Volunteer votes to participate in the study - Any other written information provided to participants of the test - Notify the selection of participants for drug testing (if any).	To prove that changes in clinical trial related documents are effective during the trial.	□	□	
2.3	Approval decision / certificate of approval of the governing body / Ethics Council according to the following: - Change research outline - Change about: + Volunteer votes to participate in the study + Any other information provided in writing to the participants + Notify the selection of participants (if any) + Any other documents giving consent	To demonstrate that the changes have been approved / approved by the governing body / Ethics Council . To determine the version number and date of the record	□	□	

	+ T annual estimate			
2.4	Curriculum vitae, GCP certificate issued by the Ministry of Health of a researcher or supervisor.	Demonstrate capacity and appropriateness to conduct clinical trials and medical surveillance at the study site.	□	□
2.5	Update values which are considered normal in medicine / tests / technical procedures / tests mentioned in the research proposal.	To prove that values / ranges considered normal have been adjusted during the test.	□	□
2.6	Medical facilities / testing rooms / technical procedures / tests - Certificate - Quality control has been established and / or assessed for external quality - Other assessments	To demonstrate that testing has been maintained appropriately throughout the test period.	□	□
2.7	Documentation of the transport of test products and the related test materials		□	□
2.8	Test certificates for new batches of test products			□
2.9	Report on the monitoring	To demonstrate the supervision and the results of the monitoring missions.		□
2.10	Other forms of contact other than field supervision, through: - The correspondence - Notes from the meeting - Memories of phone calls	To record any important agreements or discussions about trial management , recommended violations , drug testing, AE / SAE reporting.	□	□
2.11	The signed version of the research report and the Volunteer to participate in the study	To prove that the Volunteer Card is compliant with the GCP and outline, it must be signed before the subject participates in the trial. Document the approval directly.	□	
2.12	The source document	To prove the existence of the study subjects, together with the data collected		

		through the trial. This document includes all the original information related to the trial, the medical treatment and history of the study subjects.		
2.13	The medical record is signed, signed and completed	To prove that the researcher or authorized members of the Principal Investigators recorded it to confirm the observations.	□ (copy)	□ (original)
2.14	Document on correction of medical records	To demonstrate all changes i / additions or corrections of the medical record after the beginning of data collection have been recorded.	□ (copy)	□ (original)
2.15	Report SAE to the sponsor	SAE report of the principal researcher for organizations and individuals with clinical trials.	□	□
2.16	Report SAE to the Ethics Council	SAE report of organizations and individuals having clinical trials and key researchers for Ethics Council	□	□
2.17	Notification of organizations and individuals having clinical reagents for researchers about safety information	Notice of organizations and individuals having clinical reagents to researchers for safety information about reagents and concurrent drugs .	□	□ (where required)
2.18	Periodical or annual reports to the Governing Body and governing body.	Mid-term or annual report to the Board of Education and the governing body.	□	□ (where required)
2.19	List of object identifiers	To prove that the principal investigator / clinical trial establishment has kept a confidential list of the test participants' names associated with the testing numbers and identification of the participants.	□	
2.20	The log records which number of participants	To demonstrate chronological participation of subjects with test number	□	
2.21	Explanation of research products at the testing site	To prove the research product has been used according to the outline.	□	□

2.22	List of signatures	To confirm the signatures and initials of those authorized to participate and / or revise the medical records .	□	□
2.23	Records of tissue samples / biological fluids stored (if needed)	To confirm the storage and identification of stored samples if experiments need to be repeated.	□	□

Sample 03 - List of essential documents after the end of clinical trial

After completing or stopping the test, all documents identified in paragraphs 1 and 2 should be documented with the following sections:

No.	file name	Purpose	Requirements for Principal / Mechanical researcher in the research	Organizations and individuals that have clinical reagents	D r e r e
3.1	Explanation of research products at the testing site	To prove that the clinical reagents used in accordance with the research protocol, received at the study site, have been distributed to subjects, returned by the subjects , have been paid back to organizations and individuals with clinical reagents.	□	□	
3.2	Documents about the cancellation of clinical reagents	To confirm the cancellation of non-clinical reagents is to be carried out by organizations or individuals having reagents clinically or at the research site according to the current regulations.	□ (if doing so at the research site)	□	
3.3	List of identification numbers of subjects completing the research	To allow all subjects involved in drug trials to be identified in case of follow-up. This list must be kept confidential for the agreed period.	□		
3.4	Monitoring report on drug trials	To prove that all activities required for the end of the trial have been completed, and copies of necessary documents have been stored in the appropriate files.		□	
3.5	Regular and irregular monitoring reports	Demonstrate compliance of the drug test with the research protocol, GCP and relevant legal regulations.	□	□	
3.6	Documentation of treatment groups	In order for organizations and individuals with clinical reagents to		□	

	and blind decoding in case of necessity	know and carry out the right grouping, as well as know how to decode for appropriate interventions when serious adverse events occur .			
3.7	Written report and proposal for approval of clinical trial results of the principal researcher to the Ethics Council and governing body	To confirm the completion of clinical trial study.	□		
3.8	Full text report on clinical trial results	To confirm clinical trial results and interpretation .	□	□	Form 12 Appendix III
3.9	Database of Vietnamese patients (if required)	To check the accuracy and truthfulness of the research results.	□	□	

Sample 04 - Report serious adverse events in a clinical trial of drug testing

Report number of the unit: .....

SAMPLE REPORT OF MAJOR FACILITY (SAE) INCREASED IN CLINICAL TRIAL STUDY

1. I T O T R T E T T I T L T O T O T O T A

Report Type: □ First report □ Additional reports

Classification by the seriousness of the event:

□ Death	□ Life threatening
□ Hospitalized / extended hospital stay	□ Permanent disability / serious disability
□ Birth defects / fetal deformities	□ Request medical intervention to prevent one of the above situations or be evaluated with medical significance by a researcher or principal investigator.

Research name	....		
	....		
research design	□ Open label	□ Single blind	□ Double blindness
If this is a blind study, will SAE lead to blindness?	□ Yes	□ No	□ No information available
Donors	.....		
Principal researcher name	.....		
The study site recorded SAE	.....		
When did you receive information about SAE?	.....		
When did SAE occur?			

The end of SAE (or check the "*Ongoing*" *box* if SAE is in progress) .... □ Ongoing

SAE name (diagnose SAE or main symptoms of SAE) ....

Abbreviation of clinical trial participants .....

Clinical participant identification number .....

2. DESCRIPTION OF DESCRIPTION AND HANDLING OF SAE

Provide information on clinical signs, symptoms, clinical laboratory tests related to SAE, and measures to treat SAE if any (including dose / dose reduction), clinical trials / research protocols), developments after the implementation of such management measures and other necessary information, along with specific timelines (if any).

……

……

……

……

……

Results after handling SAE:

□ Recovery without leaving g □ In recovery □ Death (date of death: .....)

□ Recovered but left a sequelae □ Not restored □ No information available

3. TRIAL PARTICIPANTS C ON L READY

Date of birth .....

Year old .....

Sex □ Male □ Female For women: □ Pregnant (week...)

Weight (Kg) .....

Medical history related to SAE ....

4. CANDIDATE TRIAL TRIAL / STUDY RESEARCH

TT	Clinical reagents or rescue regimens (a)	Dosage form, content	Road used	Dosage	Date of use (*day / month / year*)	
					Get started	End
I						
II						
III						

IV

V

BECAUSE

(a) Clearly state the clinical trial drug / research protocol used by the clinical trial participants. For blind studies and SAE that do not lead to blind / unknown determination of clinical trial drugs / research protocols used by clinical trial participants , record regimen. is applied in the study and arm (arm) of clinical trial participants (described in section 2) (if available).

5. INTERVENTION FOR CLINICAL TRIAL / CARE METHOD AFTER RESEARCH AFTER HAPPENING

S TT (b)	Has the clinical trial drug / study regimen been discontinued / decreased in clinical trial participants meeting with SAE?		If stopping / reducing the dose of clinical trial drug / study protocol (or blindness), does the severity of SAE improve?			If the clinical trial / treatment regimen is reused , will the event occur again?			
	Have	Is not	Have	Is not	No information	Have	Is not	No information	Do not reuse
I	□	□	□	□	□	□	□	□	□
II	□	□	□	□	□	□	□	□	□
III	□	□	□	□	□	□	□	□	□
IV	□	□	□	□	□	□	□	□	□
V	□	□	□	□	□	□	□	□	□
BECAUSE	□	□	□	□	□	□	□	□	□

(b) Order No. (STT) corresponding to item 4.

6. TIME- EFFICIENCY DRUGS / TREATMENT MAY BE RELATED TO THE FINDINGS OF THE STUDY ASSISTANCE (not including drugs used to treat SAE)

S TT	Simultaneous use of drugs / preparations (original name and trade name)	Dosage form, content	Road used	Dosage	Date of use (*day / month / year*)	
					Begin	End
first						
2						
3						
4						
5						
6						

7. ASSESSMENTS OF RESEARCHERS / MAIN RESEARCHERS I FINDING ITS RELATIONSHIP BETWEEN THE STARS AND THE CONCENTRATION OF LAMINOLOGY / MULTI- STUDY

STT [b]	Assess the causal relationship between SAE and clinical trials / research protocols			If relevant, is this the expected reaction or expected outcome of the clinical trial drug / study protocol? [c]	
	May be related	Irrelevant	No conclusions have been made	Already know / expected	Out of expectation
i	☐	☐	☐	☐	☐
ii	☐	☐	☐	☐	☐
iii	☐	☐	☐	☐	☐
iv	☐	☐	☐	☐	☐
v	☐	☐	☐	☐	☐
Because	☐	☐	☐	☐	☐

[b] Ordinal numbers (STTs) corresponding to item 4.

[c] The fact that the SAE is *"intended"* or *"unintended"* should be evaluated based on clinical reagents / protocol documents as the most up to date research protocol. if the clinical trial drug has not been licensed for circulation, or the latest version of the Instruction Manual is available if the clinical trial drug has been licensed for circulation.

- Explain the reason for SAE's evaluation of causality and expected nature:

.....

.....

.....

- How many SAE or similar AEs have occurred in this study as of the time of reporting:

+ At the research site , SAE / AE was mentioned in this report: .....

+ At other research locations: .....

8. COMMENTS OF THE COUNCIL REPRESENTATIVE OF THE SC / COUNCIL OF THE DEPARTMENT OF RECEIVING CANDIDY C ON LAM (if any)

Recommendations for participants in clinical trials *(not applicable in case of clinical trial deaths)* :

☐ Continue to participate in research ☐ Temporarily stop participating in research ☐ Withdraw from the study

Proposals for the study:

☐ Continue to conduct research ☐ Temporarily stop conducting research ☐ Stop conducting research

Other suggestions (if any):

.....

.....

.....

9. REPORTER (principal researcher or authorized researcher)

Signature: .....

Date of signing *(date / month / year)*: .....

Full name: .....

Position, department / department: .....

Phone number: .....

Email address: .....

BOARD OF REPRESENTATIVES C / SCIENCE COUNCIL SUPPORT AC DEPARTMENT
GET CARD TRIAL ON CLOSE
(k , specify full name) (d)

IS LEADER BASIS
TEST CARD FOR CLINICAL TRAVELING
(please , specify full name and stamp)

(d) Only apply if comments in section 8.

APPENDIX II

OVERALL PROFILE ON MEDICINE TRIAL BASIS IN CLINICAL READY
(Issued together with Circular No. 9/9/2018 / TT-BYT dated October 29 , 2018 of the Minister of Health)

I. Overview of the overall record of clinical trials

II. Content of overall records:

1. General information about the establishment (administrative, legal and related information);

2. The dossier of technical standards of a material establishment in service of clinical trial;

3. Document of technical expertise, standard operating procedures (SOPs) for clinical trial;

4. Document of personnel serving clinical trials;

5. Quality management system applied in clinical trials;

6. Internal monitoring.

I. BASIC OVERVIEW OF BASIS OF THE BASIS

The general record of the testing facility is a document prepared by the clinical trial facility and includes specific and clear information about technical and professional standards for clinical trial operation., quality control and quality control policies for drug testing activities are conducted on-site to serve the management, planning , testing and evaluation of GCP responsiveness. effective.

The overall profile must include sufficient information, but it is best not to exceed 25 - 30 pages including the attached appendix. Emphasis should be placed on the overview information, overall drawings and the layout of the establishment rather than verbal descriptions .

The overall profile of the clinical trial facility is part of the documentation system of the facility's quality management system and must be updated regularly. Corporate records must be reviewed periodically to ensure updated and representative information for the establishment's current operations, which must be clearly noted the version number , effective date, and The date was reviewed. Each addendum may have its own effective date for the independent updating of the appendix.

The update and modification history of the Master File is considered as a part of the Master File, which summarizes the changes of the content of the Master File and its appendices, time of change, and reason for change. due to change.

II. CONTENTS OF THE OCCUPATIONALITY

1. General information about clinical trial establishments

1.1. Contact information of drug testing facility

- Name and official address of the establishment;

- Name and detailed address of the facility that clinically tests the drug;

- Contact information of the establishment, including 24-hour phone call of the person in charge of ensuring safety and health for participants in the drug trial;

- Other positioning information (if any): GPS coordinates, postal area code ...

1.2. Licensed operation of the establishment

- Copy of operation license, business registration certificate (if any), legal documents on the establishment and functions and tasks of clinical trial facilities for non-commercial purposes, certificates receive pharmaceutical business conditions (if any) granted by competent agencies;

- Brief description of drug testing activities and other activities permitted by the competent authority (if any), including activities assessed by foreign management agencies, information information about the scope not yet specified in the certificate of eligibility for pharmaceutical business;

- List of GCP inspection and assessment conducted at the establishment within the last 05 years, including information on the date and name of the agency competent to carry out the inspection. Copy of current GCP certificate (if any).

1.3. Other related activities are carried out at the facility

- Description of clinical trial activities of non- local products (if any).

2. Files on technical standards of facilities serving clinical trial

- Brief description of facilities: List, address, area of areas, rooms / office / department;

- Simple description of the clinical area, laboratory, biological sample storage area, research drugs, storage area, research documents, and research and testing administration department Clinically, the Office of Ethics Council, Phase 1 clinical trial area or bioequivalence testing (if any);

- Design drawing, layout of clinical area, laboratory, storage area for biological samples / research drugs, document storage area, clinical trial management department ready, the Ethics Council office in grassroots biomedical research and stage 1 clinical trial area (if any);

- Description of laboratory quality assurance system;

- Listing of major equipment for clinical trials;

- Other relevant information in case of necessity as prescribed in Article 12, Annex I of this Circular.

3. Dossiers of technical and professional documents, procedures for standardization of clinical practice in drug testing

- Brief description of the system of on-site documents and documents (for example, electronic documents system, hard copy documents);

- List of regulations, dossiers, documents related to the medicine activities as prescribed in Article 13, Annex I of this Circular;

- List of standard practice procedures for clinical trial activities;

- For documents and records that are preserved or stored outside the premises: List of documents / records, name and address of information storage facilities , calculation of time period needed to retrieve information from those external documents.

4. Records of clinical trial service personnel

- Preliminary description of the number of personnel involved in the management process , clinical trial implementation;

- List of personnel of the facility as prescribed in Article 14, Annex I of this Circular: name, title, title / degree (if any) , diploma, professional certificate, certificate of completion GCP course, certifying completion of the course of safety reporting in clinical trials, the task assigned in clinical trials and other relevant information;

- Documents about the Ethics Council in biomedical research at grassroots level as prescribed in the Minister of Health's Circular No. 45/2017 / TT-BYT dated November 16, 2017 .

5. Quality management system applied in clinical trials

5.1. Quality management system of the establishment

- Brief description of the establishment's quality management system and applicable standards;

- Responsibilities related to maintaining the quality system, including senior management;

- Information on activities that have been assessed for certification, including the date and content of certification, the name of the certification body;

- The personnel chart should show the personnel arrangement in the quality management system, the main responsible positions, including senior management and trained / authorized personnel (managerial positions). quality control, quality inspection, ...).

5.2. Management of associated contract facilities (in case of co-operation with other facilities)

- Summary of associated facilities and external assessment program (if any);

- Summary of evaluation system of associated contracts;

- Summary of the sharing of responsibilities between the contractor and the contract recipient in compliance with quality assurance regulations.

5.3. Manage quality risk

- A brief description of the quality risk management (QRM) method used at the facility: the purpose, the activities ...

6. Internal monitoring

Briefly describe the establishment's monitoring system, self-monitoring results, and self-assessment of the establishment's GCP response, focusing on the areas that are monitored according to the plan, regulations, and activities. follow-up monitoring.

Appendix I:	Copies of operating licenses, business registration certificates, legal documents on the establishment and functions and tasks of non-commercial clinical drug-testing establishments, certificates of satisfaction of conditions business conditions (if any), Copy of current GCP certificate (if any).
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APPENDIX III

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Form No. 01 - Request for evaluation meeting GCP

NAME OF MANAGER UNIT
BASE NAME

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Number: ..... / ...., *date ... month ... year 20 ...*

APPLICATION FOR ASSESSMENT OF RESPONSE FOR CONDUCTING MEDICINE TESTING ON LAM

To: Science, Technology and Training Department / Drug Administration - Ministry of Health

Establishment's name: ....

Address: ....

Telephone / fax / email: ....

Contact person: ..... Title: ....

Telephone / fax / email: ....

Implementing the Ministry of Health's Circular No. 2018 / TT-BYT dated ... month ... 2018 on clinical trials, after conducting GCP self-assessment ..... year ..., please request the Ministry of Health (Department of Science, Technology and Training / Drug Administration) to be assessed for GCP compliance and to be granted a GCP certificate for the scope of regulation on Our mission functions.

[Establishment name] encloses this application with the following documents:

1. Legal documents on the establishment and functions and duties of the unit;

2. General file of clinical trial establishment.

The head of the premises
(Sign, write full name, stamp)

Form No. 02 - Sampling Assessment of the satisfaction of clinical trial good practice

MINISTRY OF HEALTH
DEPARTMENT OF SCIENCE AND TECHNOLOGY AND TRAINING /
DRUG ADMINISTRATION

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

..... *, date ... month ... year 20 ....*

EVALUATION REPORT

"GOOD PRACTICE TO TRIAL C ON LAM"

I. GENERAL INFORMATION OF THE HOUSING

- Name of the establishment: ...

- Address of the inspected establishment: ...

- Phone:...

- Establishment decision number: ...

- Legal representative: ...

- Person in charge of the profession: ...

II. GENERAL INFORMATION OF THE ASIA REVIEW

- Evaluation time: ....

- Time of the latest previous assessment: ...

- Evaluation form: ...

- Scope of evaluation: ...

III. INFORMATION ABOUT THE ASSESSMENT

- Decision No. .... , dated .... of the Director of Science, Technology and Training Department / Drug Administration, Ministry of Health on establishing the GCP Response Evaluation Team, at ...

- The composition of the evaluation team includes: ...

IV. REAL ASSESSMENT

Classify:

- Pharmaceutical chemicals:

- Medicinal herbs:

- Traditional medicine:

- Vaccines:

- Biological analogues:

- Medical bio-products used for treatment:

Proposal for clinical trials:

or suggest clinical trials from: stage to:

The drug has completed research at:

Proposal to principal researcher:

Proposal of establishments providing clinical trial services:

Attached documents include:

...

Representatives of organizations and individuals with clinical reagents
(sign and seal)

Form No. 07 - Application for approval for clinical trial study

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

..... , date ... month ... year ...

APPLICATION FOR APPROVING THE APPROVAL OF STUDYING THE MEDICINE ON LAM

***To :* Ministry of Health (Department of Science, Technology and Training)**

Full name of principal researcher:

Clinical trial facilities:

Work address:

Phone: Fax:

Email:

Proposing the Ministry of Health to approve clinical trial of drugs:

- Name of medicine:
- Plot number :
- Concentration :
- Content:
- Dosage forms:
- Route of use:
- Due date:

Classify:

- Pharmaceutical chemicals:
- Medicinal herbs:
- Traditional medicine:
- Vaccines:
- Biological analogues:
- Medical bio-products:

Proposal for clinical trials:

or suggest clinical trials from: to stage:

The drug has completed research at:

Attached documents include:

first.

2.

3.

Principal investigators and clinical trial facilities are fully committed to not have any conflict of interest between participants in clinical trial trials, in compliance with the research protocol approved by the Ministry of Health. Approval and principles of Good Clinical Practice Good Practice .

Principal Investigator	**Facility heads clinical trial**
(sign)	*(sign and seal)*

Form No. 08 - Explanatory note on clinical trial study

Outline of outline

clinical trial studies

I. General information about clinical trial research (TNLS)

1. *Name of research*

....

....

2. *Code number*

.....

.....

3. *Implementation time:*

(From month .... / 20 .... to month .... / 20 ....)

4. Management *grant*

NN Bo / CS

The provincial

5. *Funding*

Total: .....

In which , from SNKH Budget: .....

From another source (specify source): ....

6 Proposal to be studied in life stage study (specify):

Or to refer to life satisfaction research in phases
(specify):

7 *Principal investigators*

Full name: .....

Academic title / degree: ....

Scientific title: .....

Phone: .... (CQ) / .... (NR) .... Fax: .....

Mobile: .....

E-mail: .....

Agency address: .....

Home address: ....

8 *Business establishments dealing with traditional medicines*

Name of organization or organization: ....

Telephone: ..... Fax: ..... E-mail: ....

Address : ....

9 *Agencies or individuals who order clinical trials of drugs (which is the authority to use the product rights to release the TNLS and use the TNLS results so that they can be put into production or preferred to be used in practice , or put into research at the next stage)*

Name of organization: .....

Phone: .... Fax: .... E-mail: .....

Address of agency: ....

Full name (if an individual orders):

Function / function : .....

Scientific position: ....

Phone number: ..... (CQ) / ..... (NR) .... Fax: ....

Mobile: .....

E-mail: .....

Address of institution: .....

Address for home: ....

* ***Note*** :

In the event that the organization or individual needs to present, it is helpful to show certain sections of this Note, which may be presented in a longer format , with the number of pages of the Note. Intelligent unlimited.

II. S&T content of the research

(Describe the items required by the Regulation on Drug Testing on sound sieves with contents according to the testing periods.)

ten ***The goal of the study***

11 ***Research situation at home and abroad***

□ Overview of research products

□ Overview of clinical trial research:

Foreign:

Domestic:

twelfth ***Approach, methodology and content of research and techniques to be used: It is recommended to present arguments supporting the research approach, design, sample selection, sample size, and criteria for selecting research subjects.***
Research, research methods, techniques to be used, standard practice processes (SOPs) for the techniques used in the research - compared to other similar solutions.
, research criteria, technical facilities, equipment to identify research evaluation criteria)

12.1 Study location :

12.2 Study period:

12.3 Method of study : Describe the type of test (random, blind, open), the design of the test (parallel groups, pairing techniques), blinding techniques (double blind, single blind), and the random selection method and process .

12.4 Study subjects: Description of research subjects (criteria for selection and exclusion of potential subjects), standard practice procedures (SOPs) for selection of participants Research: Methods, standards and timing of assigning the subjects to the research groups.

12.5 Sample size: The number of subjects required to achieve the test goal , based on statistical calculations.

12.6 Research drug regimen: Develop standard practice procedures (SOPs): Describe and clearly state the route of administration, dose, distance of use and duration of treatment for research products and products. comparative products. Persons responsible, technical and operating for drug administration. The monitoring criteria evaluation. The dose response relationship should be considered.

12.7 Simultaneous treatment: Any other treatment that may have been identified or permitted for concomitant use.

12.8 Tests used: Development of standardized technical procedures (SOPs): Clinical and laboratory tests, pharmacological analyzes, etc. The tests are performed. Person in charge, sampling , storage and technical procedures. Criteria for evaluation and comparison of results .

12.9 Assessment of adverse reactions: Describes how the response is recorded (describe and evaluate the method and frequency of measurement), monitoring and measurement procedures to determine levels. adherence to treatment among the study subjects.

12.10 Exclusion criteria for the study process: The exclusion criteria for the study subjects and indications on the end of the entire study or part of the study.

12.11 Documentation and reporting of side effects: A method of recording and reporting reactions or incidents, and the terms relating to compliance.

12.12 Blinding and identity protection techniques of research subjects: Procedures to maintain object identification lists, treatment records , random selection lists and / or report forms

cases (CRFs). Records must allow individual or participant identification as well as data review and reconstruction.

12.13 Rules for opening codes: Information on the establishment of the test number, where the list is kept and who, when, how is it unlocked in the event of an emergency.

12.14 Preservation of research products: Measures taken to ensure safe packaging and safety of research products and comparative products if used, and to promote and determine compliance with treatment and other guidelines.

12.15 Method of evaluation of results: Describe the method used to evaluate results , (including statistical methods), and report on patients or patients who have opted out. experiment.

12.16 Methods for dealing with adverse events

12.17 How to provide information to an audience: Information is presented to test subjects, including how they will be informed about the test, and their consent is obtained. Collect when and how.

12.18 Training for the Research Team: Training for a team of researchers to participate in clinical trial research (including: Topic assignment , Topic assignment , Coordinator, Researches) Researchers, Pharmacists , Nurses, and Technicians) include: Basic content of research , information on how to conduct experiments, standard operating procedures (SOPs) for management and drug use.

12.19 Ethical issues: **Ethical** considerations and measures related to testing.

12.20 Post-test medical care : Medical care is provided after the test, post-test treatment.

12.21 Implementation plan

12.22 Plans for monitoring, supervising and inspecting:

- Supervision by Principal researcher and research team
- Sponsor supervision
- Supervision and inspection by the Agency , Ethics Council.

12.23. Standard practice procedures (SOPs) of the study

Ethical issues in biomedical research :

(Including: Information about research, You provide information and volunteer votes to participate in research, The commitment to implement ethical guidelines in research)

13 ***International cooperation***

Cooperative content	**Partner name**

14 ***Implementation schedule***

TT	The content, the work done primarily (**Key assessment milestones**)	Product must reach	Time (TC-KT)	People, implementing agencies
first	*2*	*3*	*4*	*5*

III. Results of the study

15 ***Expected outcome of the study***

I	II	III
□	□	□ Diagram
□	□	□ Data sheets
□	□	□ Analysis report
□	□	□ Forecasting documents
□		□ Treatment process
□		□

IV. Organizations / individuals participating in the study

16 ***Activities of coordinating organizations participating in the research implementation***
(Write down all co-ordinating organizations conducting the study and the content of the work involved in the study)

TT	Organization Name	Address	Activities / contributions to the research
first			
2			
3			

17 ***Research team - Collaborators - Research coordinator***

TT	First and last name	Scientific title - Working agency	Certification of training in GCP
A	Principal Investigator		
B	Staff involved in the study		
first			
2			
3 ...			

V. Research costs and funding sources (for explanation please see the attached appendix)

Unit: million VND

18 ***Funding for research is divided into expenditures***

TT	Funding	Total numbers	In that g				
			Specialized lease	Raw materials, materials and energy	Equipment, machinery	Construction, repair and repair	Other expenses
first	*2*	*3*	*4*	*5*	*6*	*7*	*8*
	Total funding						
	Of which:						
first	SNK budget H						
2	Other sources (specify)						
	-Finance, ordering of organizations and individuals						
	- Other (mobilized capital, own capital ...)						

……, date …… month …… years 20….

The head
Clinical trial facility
(Full name, signature and stamp)

Principal Investigator
(Full name and signature)

……, hey …… month …… year 20 ….

Director
Department of Science Technology and Training

ESTIMATION OF RESEARCH FUNDS

Unit: million dong

TT	**Content of the expenses**	***Total***		***Capital***		
		Expense	***Percentage (%)***	***NSSNKH***	***Sponsor***	***Other***
first.	Specialized lease					
2.	Raw materials, materials and energy					
3.	Specialized equipment and machinery					first
4.	Construction and minor repairs					
5.	Other expenses					
	total					

Explanation of expenses
(Million dong)

Clause 1. Professional contracting

TT	*Content of contracting*	Total funding	Funds		
			NSSNKH	*Sponsor*	*Other*

Addition

Clause 2. Raw materials, energy

TT	*content*	*Unit of measure*	*Amount*	*Unit price*	*into money*	*Capital*		
						NSSNKH	*Sponsor*	*Other*
2.1	*Materials*							
2.2	*Tools and spare parts*							

2.3 *Energy , fuel*

- Coal
- Electricity kW / h
- Petroleum
- Other fuels

2.4 *Country* m^3

2.5 *Buy books, documents, data*

Addition

Clause 3. Specialized equipment and machinery

TT	content	Unit of measure	Amount	Unit price	into money	Capital		
						NSSNKH	Sponsor	Other
3.1	*Buy technology equipment*							
3.2	*Buy testing and measuring equipment*							
3.3	*Equipment depreciation*							
3.4	*Rent equipment*							

3.5	*Shipping for installation*	

\ í mi

Addition

Clause 4. Construction, minor repair

TT	***content***	***Expense***	***Capital***		
			NSSNKH	***Sponsor***	***Other***
4.1	Construction cost of m ² workshops and laboratories				
4.2	Repair cost of ² factories and laboratories				
4.3	Installation costs of electricity and water systems				
4.4	Other costs				

Addition

Clause 5. Other expenses

TT	***content***	***Expected fee***	***Capital***		
			NSSNKH	***Sponsor***	***Other***
5.1	*Business fee*				
5.2	*Basic answer*				
5.3	*Expenses for assessment , inspection and acceptance* - Evaluation cost - Document approval fee				

- Supervision costs
- Expenses for inspection and intermediate acceptance
- Internal acceptance fee
- Official acceptance fee

5.4 Other expenses

- Educate
- Conference
- Printing documents, stationery
- Document translation

.....

5.5 Researcher allowance

Addition

Form No. 09 -

Provide information about research and Volunteers for research of participants in clinical trials (ICF)

Research Name:

Version: I CF Date ..... / ..... / ....

Names of organizations and individuals that have clinical reagents:

Subject code: ....

This document is fully informed to participants, no pages or parts of this document are omitted . The content in this document needs to be explained in a language that is relevant to the study participants.

1. Describe the issues related to the research, the purpose of the study, the scheduled time, the method of conducting (specify what was tested).
2. Criteria for selecting subjects
3. Criteria excluded from study
4. Who will assess personal and medical information to select you / ... to participate in this study?
5. Number of people who will participate in the study
6. Describe any risks or disadvantages
7. Describe benefits to the audience or to others
8. The amounts you paid for in the research
9. Alternative methods or treatments
10. How to keep private records confidential

11 . Specify the objects to be accessed for inspection, examination and supervision of his / her records ...

12. Compensation or care, treatment if any health event occurs

13. Who to contact when you have questions related to the research

Stating that the participation is voluntary, you have the right to refuse to participate or stop participating at any time during the research period while still getting medical care.

Signature of the object of the study

Date of signing the volunteer vote

Volunteer application

I,

_____

Confirm that

- I have read the information provided about the research .... in the research information sheet and the research volunteer, version, date .... / ... / ... ..., ... pages). I was clearly explained by the researchers about the study and the procedures for volunteering to participate in the study.
- I had the opportunity to ask questions about the research and I was satisfied with the answers given.
- I had the time and opportunity to consider participating in this study.
- I understand that I have the right to access to the information described in the research information sheet.
- I understand that I have the right to withdraw from the rescue at any time for any reason
- I agree that the doctors who are treating me (if any) will be notified of my participation in the study.

Check the appropriate boxes :

Have: **Is not**:

I agree to participate in this research.

Signature of participant Day month Year

....

Necessary,

* Signature of witness Day month Year

....

* The name of the witness Day month Year

....

The signature of the person who obtained her provides the research information and volunteer vote to participate in the study Day month Year

.....

.....

The name of the person who took the copy, provided the research information and voluntarily participated in the study

.....

Form No. 10 - Request for approval of a change in clinical trial of the drug

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

..... , date ... month ... year ....

APPROVAL FOR APPROVAL

REPLACING DRIVE I RESEARCH C TESTING ON LAM

***To*: Ministry of Health (Department of Science, Technology and Training)**

Full name of principal researcher:

Clinical trial facilities:

Work address:

Phone: Fax:

Email:

Already permitted by the Ministry of Health to conduct clinical trial drug trials [research name] in Decision No. / QD-BYT dated May

Establishments report the following changes:

Content changes	Interpret the changed content	List of documents related to changes
first.		
2.		
3.		

Attached documents include :

...

After researching the Circular No. 2018 / TT-BYT dated 2018/2018 on clinical trials and related regulations, we are committed to fully comply with the legal documents and regulations. relevant professional mechanism, ethical compliance in research . The Department of Technology, Training and Education is requested to consider and approve the above mentioned changes of the establishment.

Principal Investigator	**Mechanical leader at clinical trial**
(no name)	*(please note name and stamp)*

Form No. 11 - Application for approving clinical trial results

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

……, date … month … year …

APPLICATION FOR APPROVAL OF TESTING THE MEDICINE TESTING ON LAM

To: **Ministry of Health (Department of Science, Technology and Training)**

Principal Investigator:

Clinical trial facilities:

Basis of collaborative research:

Proposing the Ministry of Health to consider and approve clinical trial results:

Research Name:

Name of research drug:

Names of organizations and individuals that have clinical reagents:

Research code:

Research phase:

Study time:

Attached documents include:

……..

Principal Investigator	**Head of clinical trial facility**
sign	*Signed and sealed*

Form No. 12 - Full text report on clinical trial results

Cover page 1

MINISTRY OF HEALTH

REPORT

OVERVIEW OF CULTURE TEST FORESTRY

Research Name:

Principal Investigator:

Clinical trial facilities:

Management level: Ministry of Health

Duration: from month … year … to month … year …

Total expenditure for research implementation …… million dong

In which: SNKH funding ..... million dong

Other sources (if any) ..... million dong

Years 20

Title page

REPORT

RESULTS OF TESTING C TESTING ON LAM

1. Name of research

2. Names of drugs used in the study

3. Research content (if the name of the study is not yet presented, brief description (1-2 sentences) on the design, comparison, dosing time, dose and patient population ..

4. Names of organizations and individuals that have clinical reagents

5. Research code

6. Research phase.

7. Start date of the study

8. End date of the study

9. Name and title of principal researcher

10. Name of supervisor.

11. Commitment to research complies with GCP.

12 Report date

Page 3

SUMMARY OF THE STUDY

Page 4

ABBREVIATIONS

Page 5

TABLE OF CONTENTS

REQUIRED CONTENTS IN THE REPORT

1. Set the problem

2. Research objectives

3. Research plan

3.1. Planning and research design

3.2. Discuss design of research, selection of controls

3.3. Selection of research subjects (populations) (selection criteria, exclusion criteria)

3.4. Study drug

3.5. Description of data quality assurance methods

3.6. The statistical method is stated in the outline and sample size

3.7. Changes in research and analysis according to the research plan.

4. Participants in the study (patients / volunteers)

4.1. Situation of patients participating in the study

4.2. Differences from the outline

5. Assess the effectiveness

5.1. Data analysis

Exactly identify the patients used in the effectiveness analysis, and the exceptions and reasons.

5.2. Anthropological and other basic characteristics Make a summary of the individual anthropological characteristics

5.3. Determine the suitability of the drug

Summarize and analyze any results that assess each patient's suitability for the study dosage regimen as drug concentrations in biological fluid over time.

5.4. Treatment effects and data sheets for each patient

a) Effectiveness analysis

b) Analysis / statistics

c) Make a response sheet for each patient

d) Drug dose, drug concentration and relationship with response

d) Drug - drug, drug - drug interactions

e) Present the data of each patient

g) Conclusion on effectiveness

6. Safety assessment

Analysis of safety-related data is considered at 3 levels:

- Exposure level (dose, duration of medication, number of patients) should be checked to determine the safety level of the study.

- Unfavorable variables , factors affecting the frequency of adverse events.

- Serious adverse events regardless of whether the drug is related to the research drug.

7. Degree of exposure

Exposure to study drugs, control drugs or placebo should be assessed according to the number of patients who have taken the drug, the time taken and the dose used.

8. Unexpected events (AE)

Summary of AE

Presenting the AE

Analysis of the AE

List AE by patient

9. Death and serious adverse events (SAE)

List of deaths and the SAE

Death report, SAE

Analysis and discussion of mortality, the SAE

10. Evaluate the test

List the individual test values (appendix) and abnormal values.

Evaluate each test parameter

11. Life signs, physiological manifestations, and other observations related to safety.

Analysis of vital signs, physiological manifestations and observed changes.

12. Safety rules and regulations

Summary of safety of the drug, with particular attention to changes in dose, AEs leading to discontinuation of the drug, medical intervention or death ...

13. Discussion and Conclusion

Overall assessment of drug efficacy and safety, correlation between benefits and risks.

14. Relevant tables, charts, graphs

15. List of references

16. Ap pe nd ix

List of annexes included in the report.

Form 13 - Written approval for clinical trials of the drug

MINISTRY OF HEALTH **DEPARTMENT OF SCIENCE AND TECHNOLOGY** **V A D O A T** ------	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** ----------
Number: / K2ĐT-TNLS Subject: approving the policy of building clinical trial dossier	*Hanoi, day ... month ... year ...*

To: [name of organization or individual that has reagents on the ground floor]

The Department of Science, Technology and Training (Department of Science, Technology and Education) has received a request from [name of organization or individual having clinical reagents] for the request to conduct clinical trial trial [name of research] assist]. After review, the Department of Science & Technology has the following opinion:

Approve the principle of preparation, formulation of records, clinical trial study protocol [research name]. It is suggested that organizations and individuals with clinical reagents coordinate with the research units proposed in the application and the main researchers to develop research documents in accordance with the provisions of the Circular. No. / 2018 / TT-BYT dated / / 2018 of the Minister of Health Regulations on clinical trials as a basis for submission to the Ministry of Health for review and approval before conducting research.

Please inform the organization and individuals who have clinical reagents known and implemented./.

Department leaders

Recipients:
- As above;
- TT in charge (for reporting);
- School Administration (for reporting);
- Receive the proposed test (for implementation);
- Filing: VT, TNLS (02 copies).

Form 14 - Certificate of clinical trial results

MINISTRY OF HEALTH **DEPARTMENT OF SCIENCE AND TECHNOLOGY** **V A D O A T** ------	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** ----------
Number: / CN-K2ĐT	*Hanoi, day ... month ... year ...*

CERTIFICATE

Research results on clinical trials

Pursuant to Decision No. ... / Q -BYT dated ... / ... / ... of the Ministry of Health on defining the functions, tasks, powers and organizational structure of the Department of Science and Technology and Training under the Ministry of Health;

Pursuant to the Minister of Health 's Decision No. ... / QD-BYT dated ... / ... / ... on approval of clinical trial research outline;

Based on the record No ... / BB-BĐĐD dated ... / ... / ... of the Ethics Council in National Biomedical Research, evaluating and accepting the results of clinical trials of clinical trials;

The Department of Science, Technology and Training certifies the completion and pre-acceptance test of the research:

1. Name of research:

2. Research phase:

3. Principal researcher:

4. Clinical trial establishments:

5. Organizations and individuals that have clinical reagents:

6. Location of deployment:

7. Research subjects:

8. Number of objects:

9. Research time:

10. Product name:

11. Manufacturer:

12. Doses and regimens used in research products: according to the research protocol approved in Decision No. .... / QD-BYT dated ... / ... / ... of the Ministry of Health .

13. Date of meeting of the Acceptance Council:

14. Conclusion on acceptance of research results of the Ethics Council in national biomedical research for ethics in biomedical research of the Ministry of Health:

Date of certification: date ... month ... year ...

Department leaders

Recipients:
- T T in charge (for reporting);
- School Administration (for reporting);
- Relevant Department / Department (for coordination);
- Principal researcher (for implementation);
- Testing organizations (for implementation);
- Organizations and individuals having clinical reagents (for implementation);
- Filing: VT, TNLS (02 copies) ;

English Version

MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom - Happiness

No: 32/2018/TT-BYT
Hanoi, November 12, 2018

CIRCULAR

Regulating the registration of drugs, drug raw materials

Pursuant to Pharmaceutical law of 06 Apr 2016;

Pursuant to Decree no 54/2017/ND-CP of 08 May 2017 of the Government detailing a number of articles and measures for implementing Pharmaceutical law;

Pursuant to Decree No. 75/2017/ND-PC of 20 June 2017 of the Government defining the functions, tasks, powers and organizational structure of the Ministry of Health;

Pursuant to Decree no 155/2018/ND-CP of 12 Nov 2018 of the Government amending, supplementing a number of provisions related to conditions required for Ministry of Health-regulated business investment.

At the request of the Director of Drug Administration,

The Minister of Health hereby promulgates the Circular regulating the registration of drugs, drug raw materials

Chapter I GENERAL PROVISIONS

Article 1. Scope of regulation

1. This Circular provides details on:
a) The dossier, formalities for the issuance, extension, modification, supplementation, withdrawal of marketing registration certificate of drugs (pharmaceuticals, vaccines, biologics, medicinal material drugs) and drug raw materials (pharmaceutical substances, semi-finished medicinal material products, excipients, capsule shells) for human use in Vietnam;
b) The requirements of safety [and] efficacy-supporting clinical data in drug registration dossiers;
c) The criteria for determining cases of drugs to be exempted from clinical trial, exempted from certain clinical trial phases in Vietnam, drugs requiring a phase 4 clinical trial;
d) The organization and operating principles of experts evaluating application dossiers for issuance, extension, modification, supplementation of marketing registration certificate of drugs and drug raw materials;

đ) The organization and operating principles of experts evaluating application dossiers for importation of drugs not yet covered by a marketing registration certificate as stipulated in point a Clause 43 Article 5 of Decree No. 155/2018/ND-CP;

e) The organization and operating principles for the Advisory Council for the issuance of marketing registration certificate of drugs, drug raw;
g) The procedures for evaluating application dossiers for issuance, extension, modification, supplementation of marketing registration certificate of drugs, drug
raw materials; The procedures for evaluating application dossiers for importation of drugs not yet covered by a marketing registration certificate.
2. This Circular shall not apply to the cases specified in Clause 2 Article 54 of Pharmaceutical Law regarding the drug raw materials not requiring registration before marketing in Vietnam,

semi-finished pharmaceutical products produced by the establishments themselves for the manufacture of finished drug products.

Article 2. Interpretation of terms

In this Circular, the following terms are construed as follows:

1. *ASEAN Common Technical Dossier (ACTD)* is a set of documents guiding application dossiers for drug registration in conformance with the common technical requirements of the Association of Southeast Asian Nations (ASEAN) as specified in Appendix I of this Circular.

2. ICH-CTD Common technical document is the common format for drug registration of the International conference on harmonization of technical requirements for pharmaceuticals for human use.

3. *Major variations* are changes cause apparent and direct impacts to the quality, safety and effectiveness of a drug, as defined in Appendix II of this Circular.

4. *Minor variations* are changes that cause no or minimal impact to the effectiveness, quality and safety of a drug, as defined in Appendix II of this Circular.

5. *Registrant of drugs, drug raw materials* is the establishment that acts as applicant on the application dossier for the issuance, extension, modification, supplementation of certificate of marketing registration of drugs, drug raw materials.

6. *Drug manufacturer* is the establishment that performs one, some, or all operations of the entire manufacturing process or conducts the batch release of a drug.

7. *Manufacturer of drug raw material* is the establishment that produces the drug raw materials for the manufacture of finished drug products or the establishment that conducts the batch release of drug raw materials.

8. *Product license holder or product owner with regard to foreign drugs* is the legal entity responsible for the products and have their name recorded on Certificate of pharmaceutical product (CPP).

9. *Reference regulatory authorities* referred to in this Circular include: European medicines agency (EMA), US, Japan, France, Germany, Sweden, the UK, Switzerland, Australia, Canada, Belgium, Austria, Ireland, Denmark and the Netherland ['s regulatory authorities].

10. *The SRA – Stringent Regulatory Authorities* are pharmaceutical regulatory authorities which are classified by World Health Organization (WHO) as belonging to the SRA list, comprising:

a) Member of the ICH before 23 October 2015, comprising: US Food and Drug Administration (FDA), the pharmaceutical regulatory authorities of member countries of European Commission (EC), the UK Medicines and Healthcare products Regulatory Agency (MHRA) Japan Pharmaceuticals and Medical Devices Agency ((PMDA)

b) Observer members of ICH before 23 Oct 2015, comprising pharmaceutical regulatory authorities of European Free Trade Association (EFTA) and Swiss regulatory authority (Swiss medic), and Canada Health Ministry (Health Canada).

c) Regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement before 23 Oct 2015, comprising Australia, Iceland, Liechtenstein and Norway.

11. *Certificate of pharmaceutical product (CPP)* is a certificate stipulated under World Health Organization's (WHO) certification scheme on the quality of pharmaceutical products moving in international commerce.

12. *Semi-finished medicinal materials* are raw materials for the production of drugs of medicinal material source in the form of dry extract, granule, powder, liquid extract, oil essential, resin, gum, algae.

Article 3. Responsibilities of registrants of drugs, drug raw materials

1. Be responsible for revising, supplementing the content of drugs' label, package insert in accordance with the request for updating from Ministry of Health (Drug Administration) while the drugs' marketing registration certificate is still in effect without having to a submit a dossier registering such changes, supplements.

2. Register changes, supplements in accordance with the provisions of clause 4 Article 28 and Article 40 this Circular while the drugs' marketing registration certificate is still in effect.

3. Assure the quality, safety, efficacy of drugs, drug raw materials in accordance with the registration dossiers of such drugs, drug raw materials.

4. Be responsible for the legality and accuracy of all documents submitted in registration dossiers. Coordinate with the manufacturer, the foreign competent authority in responding to written enquiries from Drug Administration seeking to verify the authenticity of legal papers pertinent to drug registration dossiers.

5. Notify Drug Administration in writing within 30 days from the date a decision to revoke the marketing authorization is issued in any country of a drug which is being covered by a still valid marketing registration certificate in Vietnam and provide the reason for such revocation.

6. Work closely with the manufacturer to ensure that either the registrant or the manufacturer conduct studies or provide additional information regarding a registered drug in accordance with the competent authority's request when there is safety and efficacy-related information or evidence surfacing.

7. Coordinate with drug manufacturers, importers, distributors to monitor, supervise, collect, synthetize, evaluate information and send reports to National Centre for Drug information and Drug adverse reactions (DI&ADR National Centre) of post vaccination adverse reaction cases, drug adverse reaction cases in accordance with the provisions of Clause 5 Article 77 of Pharmaceutical Law, Good Pharmacovigilance practices, and national guidance on pharmacovigilance and relevant regulations.

8. Maintain operating conditions of the registrant establishment throughout the validity period of the drug's, drug raw material's certificate of marketing registration. In the case that the eligibility conditions are no longer maintained, the registrant shall be responsible for

registrant changing in accordance with the provisions of clause 4 Article 28 and Article 40 of this Article.

9. Be responsible for intellectual property right-related issues concerning the drugs, the drug raw materials it registers for marketing in Vietnam.

10. Coordinate with the manufacturer to update quality specifications of drugs, drug raw materials in accordance with the provisions of Circular no 11/2018/TT-BYT of 04 May 2018 of the Minister of Health regulating the quality of drugs, drug raw materials (hereafter referred to as Circular 11/2018/TT-BYT) and Circular no 13/2018/TT-BYT of 15 May 2018 of the Minister of Health regulating the quality of medicinal materials, traditional drugs.

11. Implement risk management plans that have been approved as part of application dossiers for issuance, extension of marketing registration certificate for vaccines.

12. Be responsible in accordance with the provision of clause 2 Article 57 of Pharmaceutical law and this Article with regard to the drugs, the drug raw materials it registers from the date Drug Administration signs off the official letter authorizing the change in registrant, including those that were placed in market circulation before the issue date of such authorizing official letter, in accordance with applicable laws.

13. Assume other responsibilities as stipulated in this Circular and applicable legislation.

Article 4. Responsibilities of manufacturers of drugs, drug raw materials

1. Manufacture drugs, drug raw materials at the manufacturing facility that are licensed for the purpose by the competent authority.

2. Request for the withdrawal of certificate of marketing registration of a drug it manufactures when there are issues arising in relation to the drug's quality, safety and efficacy that may impact user's health using Form 01/TT enclosed with this Circular;

3. Coordinate with the registrant to ensure compliance with the provisions of clause 1, 2 and 3 Article 3 of this Circular.

4. Coordinate with the registrant to implement requirements relating to the inspection, assessment of manufacturing facilities upon request of the competent regulatory authority.

5. Ensure the operating conditions of the manufacturing facility throughout the validity period of the drug's, drug raw material's certificate of marketing registration.

6. Undertake formalities for registrant changing with regard to the drugs, the drug raw materials it produces that are covered by a marketing registration certificate within 30 days from the date Drug Administration signs off the official letter notifying that the registrant's operating conditions no longer satisfy the requirements.

7. Update quality specifications of drugs, drug raw materials in accordance with the provisions of Circular 11/2018/TT-BYT.

Article 5. Requirements regarding the safety [and] efficacy surveillance and evaluation reports

1. Pharmaceutical business establishments, medical service establishments shall monitor, supervise, collect, synthetize, evaluate information and send reports to the competent authority of cases of post vaccination adverse reactions, drug adverse reactions in accordance with the provisions of Article 77, Article 78 of Pharmaceutical law, Good Pharmacovigilance Practices, national guidance on pharmacovigilance and applicable regulations.

2. The drug registrant shall report on the safety [and] efficacy evaluation of drugs according to the provision of clause 2 Article 8 of this Circular using Form 2A/TT (for drugs) or Form 2B/TT (for vaccines):

a) To DI&ADR National Centre every 6 months throughout the marketing registration's validity period for synthetizing, evaluation and reporting to Drug Administration;

b) To Drug Administration upon submission of application dossiers for extension of marketing registration certificate;

3) Medical service establishments using drugs shall report on the usage of drugs using Form 2C/TT (for drugs) issued with this Circular every 6 months throughout the marketing registration's validity period with regard to the drugs stipulated in clause 2 Article 8 of this Circular and send the report to DI&ADR National Centre for synthetizing, evaluation and reporting to Drug Administration.

Article 6. Language and format of registration dossier, quantity of dossiers, documents

1. Language of registration dossiers:

The registration dossier for drugs, drug raw materials shall be in Vietnamese or English language. The drug package insert and Summary of product characteristics shall be Vietnamese language.

2. The drug registration dossier shall be prepared on A4 size paper, firmly bound (unless submitted online). The dossier shall come with a cover page (Form 3/TT), the product information sheet (Form 4/TT) and be assembled following the order of the table of contents (Form 5/TT), with separator tabs in between sections. The separated sections must be numbered for ease of reference and certified by the registrant or the manufacturer of the drugs, the drug raw materials, on the first page of each section of the entire dossier (with regard to foreign drugs, the representative office's seal shall be acceptable).

The following documents shall be bound into separate sections and enclosed with 01 product information sheet:

a) Bioequivalence study document;

b) Pre-clinical, clinical documents;

c) GMP-conformance assessment document in accordance with Article 95, 98 of Decree 54/2017/ND-CP dated May 8, 2017 of the Government regarding foreign manufacturers of drugs, drug raw materials registering for marketing in Vietnam

3. Drugs (except vaccines) that share the following elements may be registered using one common dossier: drug name; dosage form; route of administration; drug's quality specification; manufacturer name and address; formulation, of which: the strengths of pharmaceutical substance per smallest dose unit are the same with regard to solid dosage form drugs; the concentrations or strengths of pharmaceutical substance per smallest dosage unit are the same with regard to solid non-dosage form, liquid form or semi solid form drugs; the concentrations or strengths of pharmaceutical substances and primary packaging are the same with regard to infusion, injection form drugs.

4. The quantity required of copies of documentation required in application dossiers for issuance, extension of certificate of marketing registration is as follows:

a) 01 (one) set of dossier comprising all documents required under the provisions of clause 1, 2, 3, 5, 6, 7 Article 28 of this Circular as regard pharmaceutical drugs, vaccines, biologics and the documents specified under clause 1 and 2 Article 31, clause 1, 2 Article 33 of this Circular as regard medicinal material drugs, drug raw materials;

b) 01 (one) duplicate copy of the complete dossier; 02 (two) duplicate copies of registration application, quality specification and test method for the drug, the drug raw material as regard all other cases;

c) 02 (two) sets of label mock-up of the drug, the drug raw material and package insert of the drug intended for marketing, certified by the registrant's seal (representative office' seal is acceptable in the case of foreign drugs) or the manufacturer's seal. The label mock ups of drugs, drug raw materials must be affixed, designed on A4 paper.

5. The quantity of copies of documentation required in dossiers registering changes, supplements to marketing registration certificate:

a) 01 (one) set of dossier comprising all documents required under clause 4 Article 28 of this Circular as regard pharmaceutical drugs, vaccines, biologics and clause 3 Article 31, clause 3 Article 33 as regard medicinal material drugs, drug raw materials.

b) 02 (two) sets of [revised] label and package insert mock up intended for the drug in the case of changes in label, packaging insert, certified by the registrant's seal (representative office's seal is acceptable in the case of foreign drugs) or manufacturer's seal. The mock up labels shall be affixed, designed on A4 paper;

6. Requirements regarding on-line submission of registration dossiers:

a) Dossier quantity, dossier composition: 01 (one) set of complete dossier in accordance with this Circular shall be submitted online and in addition 01 paper based administrative document (excluding the label, the package insert of the drug) shall be sent to Drug Administration;

b) The implementation roadmap for on line submission shall be publicized by the Minister of Health.

Article 7. Registration fees for the registration of drugs, drug raw materials:

Registrants of drugs, drug raw materials shall pay fees associated with the registration of drugs, drug raw materials in accordance with applicable regulations on fees and charges.

Article 8. Validity period of certificate of marketing registration of drugs, drug raw materials and timelines for submission of application dossier for certificate extension

1. The validity period of certificate of marketing registration of drugs, drug raw materials is 05 years from issue date or extension date, except for the cases categorized under clause 2 of this Article.

2. The validity period of the certificate of marketing registration of the following drugs is 03 years from issue date:

a) New drugs, vaccines for the first time issued with certificate of registration for marketing in Vietnam;

b) Drugs having the same pharmaceutical substance, concentration, strength, dosage from with those of a new drug which has not been issued a 5 year-validity certificate of marketing registration;

c) Drugs not of the categories stipulated in point a and point b of this clause but at the point of dossier submission for certificate extension the report on the drug safety, efficacy is not yet available as the drugs have not been marketed or such report is already available but in the opinion of the Advisory council for issuance of marketing registration certificate, the volume of the drugs being consumed, the number of patients they were used on, the usage duration are still limited or of which ongoing monitoring for safety [and] efficacy are recommended by medical service establishments.

d) Drugs for which ongoing monitoring for safety [and] efficacy is recommended by the Advisory council for issuance of marketing registration certificate.

3. Within 12 months before the expiry date of a Certificate of marketing registration, the registrant may apply dossier for certificate extension. Past the Certificate expiry date, the application dossier must be submitted anew under the provisions for certificate issuance.

4. Each Certificate of marketing registration shall have a distinguishing code number to identify whether it is for a domestically produced drug, a domestically produced drug raw material, an imported drug, an imported drug raw material, a vaccine, a biologic, a drug produced under technology transfer arrangement [or] a drug the secondary packaging is performed in Vietnam.

5. While a certificate of marketing registration is still valid, [if] the registrant has the certificate renewed, the old certificate shall remain valid in parallel with the new one for a period of 6 months from the effective date of the new one.

Article 9. Eligibility criteria for brand name drug classification

1. For a drug to be classified as brand name drug (not applicable to biologics) it must be so requested in the registration dossier and must simultaneously satisfy the following criteria:

a) Clinical data on the safety [and] efficacy of the drug is complete in accordance with Article 13 of this Circular;

b) Licensed for marketing by one of the regulatory authorities specified in clause 9, 10 Article 2 of this Circular, except for new drugs produced in Vietnam.

[Drugs that are] brand name drug before undergoing changes in manufacturer or before being the subject of a technology transfer arrangement shall still be recognized as brand name drug.

2. With regard to the drugs that have been publicized by Ministry of Health as brand name drug according to the provision of clause 1 of this Article, which subsequently become the subject of a technology transfer arrangement involving one, some operations, or the entire manufacturing process by a manufacturer in Vietnam, all of the following criteria must be assured for both the brand name drug and the drug produced in Vietnam:

a) The formulations are the same;

b) The manufacturing processes are the same;

c) The quality specifications of the drugs' raw materials are the same;

d) The quality specifications of the finished drug products are the same;

đ) To any variations related to the requirements of point a, b, c, d of this clause, the registrant must provide supporting data demonstrating similarities in quality between the drug produced in Vietnam and the brand name drug being the source drug of the technology transfer.

3. If a drug already publicized as brand name drug undergoes changes in manufacturer, pursuant to the registrant's written request, the drug that is issued with a new marketing registration certificate under the new manufacturer shall also be publicized as brand name drug if satisfying all the following criteria:

a) The drug is licensed for marketing by one of the regulatory authorities stipulated in clause 9, 10 Article 2 of this Circular;

b) The drug simultaneously satisfy all the requirements of point a, b, c, d clause 2 of this Article.

Article 10. Requirements for the registration of drugs produced in Vietnam under technology transfer arrangements; drugs the secondary packaging of which is performed in Vietnam

1. A drug to be registered as produced under technology transfer arrangement must simultaneously satisfy the following:

a) The transfer of drug manufacturing technology may be carried out by way of transferring one, some or all operations of the process of manufacturing finished drug products, not applicable in the cases where only the secondary packaging operation is transferred;

b) The drug registered and the drug being the object of the technology transfer arrangement share all of the following criteria:

- The formulations are the same;

- The manufacturing processes are the same;

- The quality specifications of the drugs' raw materials are the same;

- The quality specifications of the finished drug products are the same;

To any variations related to the afore specified requirements, the registrant must provide supporting data demonstrating similarities in quality between the drug produced in Vietnam and the brand name drug subject of the technology transfer.

c) With regard to generic drugs with systemic action, the drug's bioequivalence must be demonstrated in accordance with applicable regulations before the technology transfer taking place, except for drugs of dosage forms exempted from bioequivalence study under the provisions of Circular no 08/2010/TT-BYT of 26 Apr 2010 of the Minister of Health guiding the reporting of bioavailability/bioequivalence study data in drug registration;

d) Registration dossier shall conform to the provisions of clause 5 Article 28 of this Circular.

2. Drugs with secondary packaging performed in Vietnam

a) Within 05 years from the date the certificate of marketing registration is issued, the registrant, the manufacturer shall have to complete the technology transfer of all manufacturing operations according to the conditions stipulated in point 1 of this Circular. Three (03) years from the date the marketing registration certificate is issued, the registrant shall report the progress of the technology transfer process using Form 6/TT of issued with this Circular;

b) The dossier shall be prepared in conformance with the provision of clause 6 Article 28 of this Circular.

3. The source drug of the technology transfer, of the transfer of secondary packaging operation, shall be allowed continuing marketing in accordance with the validity of its marketing registration certificate.

Article 11. Data exclusivity with regard to drug registration dossiers

Drug registrants having the need for data exclusivity with regard to a drug registration dossier shall proceed according to the provisions of Circular 05/2010/TT-BYT dated 01 Mar 2010 of the Minister of Health guiding the protection of test data in drug registration and must clearly state its request for data exclusivity in the registration application, using Form 6A/TT enclosed with this Circular.

Article 12. Provisions regarding the authenticity verification of information on legal papers

1. Drug Administration shall coordinate with diplomatic missions and relevant national agencies, foreign agencies to verify the authenticity of legal papers submitted in registration dossiers, namely:

a) CPP of all application dossiers for issuance, extension, modification, supplementation of marketing registration certificate;

b) Legal papers issued by foreign competent authorities with regard to foreign registrant for the first time registering drugs in Vietnam.

2. The verification shall be carried out at the same time with the evaluation of drug registration dossiers and within the time limit stipulated in clause 5 Article 56 of Pharmaceutical law.

Chapter II

REQUIREMENTS OF CLINICAL DATA TO ENSURE SAFETY AND EFFICACY AND CRITERIA FOR DETERMINING EXEMPTION OF CLINICAL TRIAL, EXEMPTION OF CERTAIN CLINICAL TRIAL PHASES, REQUIREMENT OF PHASE 4 CLINICAL TRIAL IN VIETNAM

Article 13. Clinical data required as part of registration dossiers of new drugs, vaccines, biologics

1. Requirements of clinical data to ensure safety, efficacy in registration dossiers of new pharmaceutical drugs, vaccines, biologics:
a) The clinical trials on drugs, the clinical data included in clinical documents must be in line with guidelines of ICH, Vietnam Ministry of Health or other organizations recognized by Vietnam (including guidelines of international organizations of which Vietnam is a member, guidelines of the reference regulatory authorities referred to in clause 9 Article 2 of this Circular) except for the cases stipulated in clause 2 of this Article.

b) Clinical data (except for biologics similar to reference biologics and vaccines similar to the vaccines already licensed for marketing in Vietnam) shall cover information adequate for the analysis, the explanation of Asian ethnic factors on the safety and efficacy of the drug to allow extrapolation of the clinical data on Asian population according to the guidelines stipulated in point a clause 1 of this Article or there must be data of bridging studies according to ICH-E5 for the extrapolation of clinical data on Asian population;
c) With regard to the vaccines that have been licensed for marketing meeting the requirements of point g clause 4 Article 23 of this Circular and for which there are complete clinical data on safety [and] efficacy according to the provision of point a, b clause 1 of this Article but not all operations in the manufacture of which are carried out on manufacturing lines of member countries stipulated in clause 10 Article 2 of this Circular, clinical data pertinent to the evaluation of safety and immunogenicity on the target population in Vietnam must be available before a marketing registration certificate can be issued.
d) With regard to the vaccines for which complete clinical data evaluating safety [and] efficacy stipulated in point a, b, clause 1 of this Circular is available but which have not satisfied the requirements of point g clause 4 Article 23 of this Circular, clinical data pertinent to the evaluation of safety and immunogenicity on the target population in Vietnam must be available before a marketing registration certificate can be issued.
2. If clinical trials are conducted before the regulations, guidance on drug development stipulated in point a clause 1 of this Article become available, the data from such trials shall be acceptable for the purpose of dossier evaluation.

Article 14. Clinical data required in registration dossiers to ensure safety and efficacy of drugs produced from new combination of pharmaceutical substances, biosimilars

1. Drugs produced from new combination of pharmaceutical substances must have complete clinical data submitted in line with the guidelines of US FDA, EMA or WHO regarding clinical development of fixed dose combinations in conformance with the provisions of Appendix IV of this Circular.

2. For biosimilars, complete clinical data in line with the guidelines for biosimilar development issued by Vietnam Ministry of Health or WHO's guideline. Guidelines of USFDA, EMA and the guidelines developed based on these shall be acceptable. WHO, US FDA, EMA's guidelines are referenced in Appendix IV of this Circular.

Article 15. Clinical data required in registration dossiers to ensure safety and efficacy of new pharmaceutical drugs other than brand name drugs

1. With regard to the drugs licensed for marketing in the home country being prescription drug (other than those produced in Vietnam) and to which there is at least one similar drug (of the same active ingredient, concentration, strength, dosage form, route of administration) that has been licensed for marketing by one of the regulatory authorities stipulated in clause 10 Article 2 of this Circular, clinical data of one of the following categories shall be required:

a) Clinical data on the very same similar drug which are permitted for use by the owner. The clinical data of the similar drug must satisfy the requirements set out under Article 13 of this Circular;

b) Clinical data compiled from research studies in published medical literature and bioequivalence study data (unless the drug is not required to undergo bioequivalence according the regulations of the home country's regulatory authority).

2. With regard to the drugs that are non-prescription drug according the home country's regulations (other than the drugs produced in Vietnam and the drugs stipulated in clause 3 of this Article) and to which there is at least one similar drug (of the same active ingredient, strength, concentration, dosage from, route of administration) licensed for marketing by at least one country clinical data of one of the following categories shall be required:

a) Clinical data on the very same similar drug which are permitted for use by the owner. The clinical data of the similar drug must satisfy the requirements set out under Article 13 of this Circular;

b) Clinical data compiled from research studies in published medical literature and bioequivalence study data (unless the drug is not required to undergo bioequivalence according the regulations of the home country's regulatory authority).

3. With regard to the drugs that are licensed for marketing and classified as non- prescription drug by at least one of the reference regulatory authorities stipulated in clause 9 Article 2 of this Circular, an explanatory document and evidence demonstrating that the use of pharmaceutical substances in the drug composition (regarding indications, dosage, route of administration, target users) has been indicated in Vietnam national formulary, Vietnam Pharmacopoeia or in documents accepted by one of the reference regulatory authorities stipulated in clause 9 Article 2 of this Circular.

Article 16. Clinical data required in registration dossiers of pharmaceutical drugs having the strength, concentration, route of administration, method of administration, dosage, indication, target patient different from those of the brand name drug which was licensed for marketing in Vietnam

With regard to the pharmaceutical drugs having the strength, concentration, route of administration, method of administration, dosage, indication, target patient different from those of the brand name drug which was licensed for marketing in Vietnam or having new dosage form impacting the drug's bio pharmacology, a clinical document in accordance with the provision of Article 13 of this Circular shall be required.

Article 17. Clinical data required of drugs already licensed for marketing in Vietnam but undergoing clinical data-related changes, supplementation in comparison with the approved registration dossier

With regard to the pharmaceutical drugs, vaccines, biologics, medicinal materials drugs already licensed for marketing in Vietnam but undergoing clinical data-related changes, supplementation in comparison with the approved registration dossier, the registrant shall submit supplementary clinical data in accordance with the provision of Appendix II of this Circular.

Article 18. Qualifying criteria for exemption from one, some, of the clinical trial phases on new pharmaceutical drugs, vaccines, biologics before the issuance of marketing registration certificate

The drugs that have not met the requirements of Article 13 of this Circular shall be reviewed by the Minister of Health for the decision to have one, some ,of the clinical trial phases exempted (including a waiver or reduction in clinical data requirement) on the basis of advice provided by the Advisory council on the issuance of marketing registration certificate if such drugs fall into one of the following categories:

1. Drugs for emergency requirements in national defence, security, prevention and combatting epidemics, mitigating consequences of natural disasters, calamities for which there are no substitutable drugs yet available in the market.

2. Drugs already licensed for marketing by at least two of the reference regulatory authorities stipulated in clause 9 Article 2 of this Circular or licensed for marketing by the US (US FDA) or by EMA on the basis of clinical data requirement being waived or reduced by these authorities;

3. Drugs for the treatment of orphan disease; life threatening diseases.

4. Vaccines, biologics produced in Vietnam under technology transfer arrangement involving one, some or all operations of the finished product's manufacturing process, providing that clinical data meeting the requirements of clause 1 Article 13, Article 14 of this Circular for such vaccines, biologics prior to the technology transfer are available.

Article 19. Clinical data required in registration dossiers of new medicinal material drugs

1. Requirements of clinical data to ensure safety and efficacy in registration dossier of new medicinal material drugs

a) Clinical trials on the drug, clinical data in clinical document shall be in conformance with Guidance for preclinical trials and clinical trials on medicinal material drugs of Ministry of Health or other organizations recognized by Vietnam, comprising: WHO's Research guidelines for evaluating the safety and efficacy of herbal medicines or guidelines from the regulatory authorities stipulated in clause 10 Article 2 of this Circular. Where the trials are conducted before the afore stipulated regulations, guidelines on drug development research, data from such trials shall be acceptable for the purpose of dossier evaluation;

b) Medicinal material drugs of which data are extracted from the following documents shall be accepted as clinical data for the examination of the drugs' safety and efficacy:

- Monographs regarding the drug safety and efficacy featured in Vietnam's or other countries' pharmacopoeias, formularies.

- Publications evaluating the drug safety and efficacy published in journals of the List covered by Science Citation Index (SCI) and clinical data compiled from research studies published in other medical literature;

- Report evaluating the safety and efficacy of [drugs as an outcome of] national level, ministerial level or provincial level scientific and technology research grants which has been assessed as satisfactory.

2. Clinical data stipulated under clause 1 of this Article shall not be required for the medicinal material drugs that meet the following conditions:

a) Medicinal material drugs having the same composition, mass weight of medicinal materials, indications, route of administration with those of another medicinal material drugs already licensed for marketing (including those for which marketing registration certificate has expired) other than the drugs that have been designated as traditional drugs and that have no indications for diseases on the Ministry of Health-issued List of diseases referred to in point b clause 1 Article 89 of Pharmaceutical law;

b) With regard to the drugs having the same composition, mass weight of medicinal material, indication, route of administration with those of a new medicinal material that is

licensed for marketing in Vietnam on the basis of complete clinical data being available in accordance with the provision of point b clause 1 Article 89 of Pharmaceutical law, consideration for the issuance of marketing registration certificate for the drugs shall only be considered after 5 years from the date such other drug is licensed for marketing.

Article 20. Qualifying criteria for exemption of one, some, of the phases of clinical trial on medicinal material drugs before issuance of marketing registration certificate

The medicinal material drugs that have not met the requirements of Article 9 of this Circular shall be reviewed by the Minister of Health for the decision to have one, some, of the clinical trial phases exempted (including a waiver or reduction in clinical data requirement) on the basis of consultancy provided by the Advisory council on the issuance of marketing registration certificate if such drugs fall into one of the following categories:

1. Drugs for emergency requirements in national defense, security, prevention and combatting epidemics, mitigating consequences of natural disasters, calamities for which there are no substitutable drugs yet available in the market.

2. Drugs already licensed for marketing by at least one of the reference regulatory authorities stipulated in clause 9 Article 2 of this Circular on the basis of clinical data requirement being waived or reduced by these authorities;

3. Drugs with indications for diseases on the Minister of Health-issued List of diseases referred to in point b clause 1 Article 89 of Pharmaceutical law but not of the categories exempted from clinical trial stipulated under clause 3 Article 21 of this.

4. Drugs involving a new combination of medicinal materials which have been used for drug manufacture in Vietnam and having no indications for diseases on the Minister of Health- issued List of diseases referred to in point b cause 1 Article 89 of Pharmaceutical law.

Article 21. Qualifying criteria for exemption from clinical trial in Vietnam before marketing licensing

1. Generic drugs having the same pharmaceutical substances, strength, concentration, route of administration, method of use, dosage, indication, target patients, dosage form with those of another drug for which a certificate of marketing registration has been issued.

2. New drugs (except vaccines) which have been licensed for marketing in at least one foreign country and of which there are complete clinical data on safety and efficacy in accordance with the provisions of Article 13, Article 19 of this Circular.

3. Medicinal material drugs for which was licensed for marketing before the effective date of Pharmaceutical law and which has no indications for diseases on the Minister of Health- issued List of diseases.

4. Vaccines which have been licensed for marketing meeting the requirements of point g clause 3 Article 23 of this Circular, of which all manufacturing operations are carried out on manufacturing lines of member countries stipulated in clause 10 Article 2 of this Circular and for which complete safety and efficacy clinical data is available as required under Article 13 of this Circular.

Article 22. Criteria for determining the requirement of a phase IV clinical trial in Vietnam

Drugs that have been licensed for marketing but still require further safety [and] efficacy assessment at the advice of the Advisory council for issuance of marketing registration certificate.

Chapter III

REGISTRATION DOSSIERS FOR DRUGS, DRUG RAW MATERIALS

Section 1

GENERAL PROVISIONS FOR APPLICATION DOSSIER FOR ISSUANCE, EXTENSION, MODIFICATION SUPPLEMENTATION OF MARKETING REGISTRATION CERTIFICATE OF DRUGS, DRUG RAW MATERIALS

Article 23. Requirements of documents submitted in application dossier for issuance, extension, modification, supplementation of marketing registration certificate of drugs, drug raw materials

1. Documents issued by foreign regulatory authorities must be consular legalized in accordance with the laws on consular notarization, except for exemption cases allowed for under applicable laws.

2. License, certification, confirmation paper, registration paper (referred to in general as legal papers) submitted in the dossier must be still valid at the point of the dossier being accepted as recorded in the Dossier receipt and must be in English or Vietnamese language. Where the validity is not stated on CPP the validity period shall be counted as 24 months from issue date.

3. Legal papers shall be submitted in original copy or authenticated duplicate copy:

a) The original copy must bear the signature, name of the signing person and the certifying seal of the competent authority of the issuing country;

b) The authenticated duplicate copy must be authenticated by the competent agency, competent organization of Vietnam in accordance with Vietnam laws on authenticating duplicate from original. Where necessary the original copy must be presented for validation purpose;

c) Where legal papers are issued in electronic form which do not show in full the signature, name of the signing person and the certifying seal of the competent authority of the issuing country, the registrant must make available in writing the link to the website (English language website) of the issuing authority and undertake to take responsibility for the legality of these legal papers.

4. Requirements of CPP:

a) CPP must bear the signature, name of the signing person, issue date and the seal of the CPP issuing authority;

b) CPP must be issued by the national-level competent pharmaceutical regulatory authority.

Where the CPP is issued by a pharmaceutical regulatory authority but not a national- level one: The registrant must provide legal papers proving that this issuing agency is the competent authority for the purpose and that the national-level pharmaceutical regulatory authority of such country does not issue CPP as a matter of law of the country.

c) The signature, the name of the signing person and the seal of the CPP-issuing authority must be authenticated by the competent authority; Where this authenticating verbiage is not in English language, a Vietnamese or English notarized translation must be provided;

d) The content of CPP must cover all the information required in Form 7/TT enclosed with this Circular and the following information:

- Formulation of the drug, of which the name, composition, concentration, strength of each of the active ingredients, medicinal materials, excipients are indicated; with regard to soft capsule, hard capsule dosage forms information about the formulation composition of the capsule shell must also be provided;

- Specifications of finished product, of pharmaceutical substances, of medicinal materials, name, address of manufacturer of pharmaceutical substances, medicinal materials;

- Where a drug the manufacture of which involves several different manufacturing establishments, the name, the address, the role each performs, must be clearly indicated on CPP;

- Where a CPP does not contain information about manufacturer's GMP conformity status, the registrant must submit in addition the GMP certificate of all manufacturing establishments [involved], in conformance with the requirements of clause 1, 2, 3 of this Article;

- Annexes to the CPP (if any) must be certified by the CPP issuing authority.

đ) With regard to generics, medicinal material drugs, probiotic biologics (digestive enzymes), drugs being subject of applications for extension, modification, supplementation of marketing registration certificate: CPP certifying that the drug is licensed for marketing and is marketed in the manufacturing country. Where a drug is not licensed for marketing in the manufacturing country or is licensed but not is actually marketed in the manufacturing country, the registrant must provide CPP containing language certifying that the drug is licensed for marketing and is marketed in one of the countries stipulated in clause 10 Article 2 of this Circular;

e) With regard to new pharmaceutical drugs and imported biologics, other than probiotics (digestive enzymes): CPP issued by the manufacturing country and another CPP issued by one of the regulatory authorities stipulated in clause 10 Article 2 of this Circular containing language certifying that the drug is licensed for marketing and is actually marketed;

g) With regard to imported vaccines: CPP issued by the manufacturing country and another CPP issued by one of the regulatory authorities stipulated in clause 9 Article 2 of this Circular containing language certifying that the vaccine is licensed for marketing and is actually marketed;

h) With regard to generics of which bioequivalence study report is available: CPP issued by one of the regulatory authorities stipulated in clause 10 Article 2 of this Circular containing language certifying that the drug is licensed for marketing and is actually marketed;

Where a CPP meeting these requirements is not available, a report of bioequivalence study on the drug, which is performed at a bioequivalence study service provider in Vietnam or at bioequivalence study facilities recognized by Vietnam according to the Minister of Health's stipulations or according to international agreements to which Vietnam is a signatory.

i) With regard to the drugs being the subject of a request for brand name drug classification, CPP issued by one of the regulatory authorities stipulated in clause 9, 10 Article 2 of this Circular, except for the drugs produced in Vietnam;

k) With regard to the drugs, vaccines, imported biologics for which a CPP meeting the requirements of point đ, e, g, h of this clause cannot be provided, the Minister of Health shall review the case on the basis of advice from the Advisory council for issuance of marketing registration certificate providing that such a drug is licensed for marketing by at least one country's regulatory authority and falls into one of the categories:

- Drugs, vaccines, biologics to meet emergency requirements in national defense, national security; for the prevention, combatting of epidemics, diseases, for the mitigation of consequences of natural disasters, calamities drugs for the service of health programs of the states;

- Vaccines for the use in national expanded immunization programs, for which there are no substitutable vaccines readily available in the market in terms of quantity, quality, safety, efficacy or cost;

- Other specific cases covered by agreements, mutual recognition between State pharmaceutical regulatory authorities regarding the manufacturing conditions, the marketing of drugs, vaccines, biologics.

l) Information recorded on CPP must be consistent with relevant information in registration dossier of the drug.

5. Registration application and other records, materials in the relevant administrative document must be signed directly in person and sealed, or by persons delegated to do so, by any one of the following position holders: Chair of the board of members, Chair of the board of directors, chief executive officer, director, stamped signatures shall not be acceptable.

6. Power of attorney shall be prepared using Form 8/TT enclosed with this Circular and be submitted in one of the following cases:

a) Delegation of authority to act as registrant using Form 8A/TT enclosed with this Circular. The power of attorney delegating the authority to act as registrant for a foreign drug must have the signature authenticated and be consular legalized in accordance with applicable regulations.

Each dossier must be accompanied by the original copy or an authenticated duplicate copy of the Power of attorney.

b) Delegation of authority to sign on registration dossier using Form 8B/TT enclosed with this Circular; if the delegated person in this case is not the Chief representative of the representative office, the power of attorney must bear the certifying seal and signature of the Chief representative of the representative office in Vietnam.

Each dossier must be accompanied by the original copy or a duplicate copy of the Power of attorney certified by the Representative office's seal (in the case of foreign registrants) or certified by the seal of the domestic registrant.

7. Duplicate copy of technology transfer agreement certified by the seal of the registrant or of the manufacturer or of the representative office (in the case of foreign registrant).

8. Certificate of satisfaction of conditions for pharmaceutical business for one of the following business operations: manufacture, wholesale, exportation, importation of drugs, drug raw materials (in the case of registrants of Vietnam).

9. License for establishing Representative office in Vietnam

Where the name, the address of the registrant as recorded on the license for establishing Representative office in Vietnam differ from those recorded on the Legal papers of the

registrant that are issued by the foreign competent authority, supporting evidentiary documents must be provided.

10. Legal papers issued by the foreign competent authorities licensing at a minimum one of the following business operations: manufacture, wholesale, exportation, importation of drugs, drug raw materials (in the case of foreign registrants).

Where the registrant is the same entity with the manufacturer as recorded on CPP the Legal papers stipulated in this clause shall not be required.

In countries where there is no license issued for the manufacture, wholesale, exportation, importation of drugs, drug raw materials, the incorporation license or the business registration certificate covering as business scope at a minimum one of the following operations: manufacture, wholesale, exportation, importation of drugs, drug raw materials, accompanied by a certification from the competent authority to the effect that the registrant meets the conditions required and has been operating in pharmaceuticals or any one of the certificates of good manufacturing practices, good distribution practices, good supplying practices, good storage practices for drugs.

With regard to registrants of drug raw materials, where the home country does not issue a license for pharmaceutical business to businesses operating in drug raw materials, alternative licenses issued by the home country shall be acceptable provided that they contain language ascertaining the registrant operates in any of the following: manufacture, wholesale, exportation, importation of drug raw materials.

11. Where a registrant already has its name listed as registrants of drugs, drug raw materials on Drug Administration's website, the papers stipulated in clause 8, 9, 10 of this Article shall not be required.

12. Legal papers of manufacturers of pharmaceutical substances, excipients, capsule shells, semi-finished medicinal materials and medicinal materials (for the production of medicinal materials) demonstrating conformity with good manufacturing practice (GMP) for drug raw materials may be one of the following types of paper:

a) GMP Certificate;

b) Manufacture license containing language certifying that the establishment is GMP conforming;

c) CPP of pharmaceutical substances containing language certifying GMP conformity;

d) Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP).

13. Sample of the drug's, the drug raw material's label and the drug's package insert as they are marketed in the manufacturing country or in the CPP-issuing country bearing the representative office's or of the registrant's or the manufacturer's certifying seal. Where the drug's package insert in use in the home country is not in English language, a Vietnamese translated version certified by the representative office's or the registrant's or the manufacturer's seal must be provided.

14. Mock-up of the drug's, the drug raw material's label and the drug's package insert intended for marketing in Vietnam shall be presented in compliance with the Minister of Health's regulations on the labelling of drugs, drug raw materials and the following requirements:

a) Mock-up of labels, package inserts intended for marketing must bear the representative office's or the registrant's or the manufacturer's certifying seal;

b) The label of the drug's, the drug's raw material outer packaging must be printed with a bar code or a QR (quick response) code or a Data Matrix Code (DMC) according the implementation roadmap stipulated in point 1 clause 1 Article 50 of this Circular.

15. Where the manufacturer of drugs, drug raw materials already has its name listed as GMP-conforming manufacturer on Drug Administration's website, the dossier for GMP- conformity assessment shall not be required as part of the registration dossier.

16. The quality specification, test method, test certificate and stability study document (applicable for both the dossier sections on pharmaceutical substances and on finished drug product) must be in original copy bearing the certifying signature and seal of the manufacturer; if a duplicate copy is submitted, it must be certified by the registrant's seal (for foreign drugs, the representative office's seal shall be acceptable).

The Test certificate must cover the following information: administrative information (name, address of the manufacturer, test certificate number, name and signature of the person in charge, issue date of the test certificate) and information on the specimen of the drug, specimen of the drug raw material (product name, lot number, shelf life, quality specification applied, quality criteria, quality requirements, test results, conclusion of the quality of the product lot).

17. Requirements regarding test certificate, results of validation of quality specification, method for experimental testing in Vietnam:

Original copy or authenticated duplicate copy of Test certificate, results of validation of quality specification, experimental testing method (in the case of manufacturing establishments not yet GMP conforming according to Ministry of Health's implementation roadmap or cases notified by Drug Administration according to the provisions of Appendix III of this Circular) certified by a GLP-conforming state-owned testing establishment or by a provider of testing services for drugs, drug raw materials, which is covered by a certificate of satisfaction of conditions for pharmaceutical business in the respective business line.

18. Certification that the drug raw material is licensed for manufacture or marketing in the manufacturing country, covering the following mandatory information: name of the drug raw material; name and address of the manufacturer; manufacturing country; signature, seal and full name of the signing person.

Article 24. General provisions for administrative document in application dossier for the issuance, extension, modification, supplementation of marketing registration of drugs, drug raw materials

The administrative document shall comprise:

1. Registration application using Form 6/TT enclosed with this Circular.

2. Power of attorney (if applicable) using Form 8/TT enclosed with this Circular.

3. Certificate of satisfaction of conditions for pharmaceutical business in the case of registrant of Vietnam.

4. Legal papers in the case of foreign registrants.

5. License for establishing representative office in Vietnam in the case of foreign registrants.

6. CPP certificate using Form 7/TT enclosed with this Circular.

7. Mock-up of the drug's, the drug raw material's label and the drug's package insert intended for marketing.

8. Sample of the drug's, the drug raw material's label and the drug's package insert that are actually marketed in the manufacturing country or the CPP-issuing country.

9. Summary of product characteristics in the case of new pharmaceutical drugs, vaccines, biologics using Form 9/TT enclosed with this Circular.

10. Document assessing GMP conformity for the cases stipulated in Article 95 Decree no 54/2017/NĐ-CP regarding foreign manufacturer of drugs, drug raw materials registering for marketing in Vietnam.

11. Legal papers of the manufacturers of pharmaceutical substances, excipients, capsule shells, semi-finished medicinal materials, medicinal materials.

12. Certification that the drug raw material is licensed for manufacture or for marketing in the manufacturing country.

13. GLP certificate of the testing establishment in the cases stipulated in clause 17 Article 23 of this Circular.

14. Risk management plan (for vaccines) using Form 10/TT enclosed with this Circular.

15. Technology transfer agreement in the case of drug produced under technology transfer arrangement.

16. Report on the drug safety, efficacy, usage using Form 2/TT enclosed with this Circular.

17. Report on the marketing of the drug, the drug raw material using Form 11/TT enclosed with this Circular.

18. Certificate, patent, licensing agreement of industrial property rights, papers proving the origin of the raw material (GACP, CEP, medicinal materials of domestic source, medicinal materials of imported sources...) and pertinent documents (if applicable).

19. Duplicate copy of marketing registration certificate of the drug, the drug raw material in Vietnam.

Section 2

APPLICATION DOSSIER FOR THE ISSUANCE, EXTENSION, MODIFICATION, SUPPLEMENTATION OF MARKETING REGISTRATION CERTIFICATE OF PHARMACEUTICAL DRUGS, VACCINES, BIOLOGICS

Article 25. Quality document in application dossiers for the issuance, extension, modification, supplementation of pharmaceutical drugs, vaccines, biologics

The quality document shall be prepared in conformance with the guidelines of Part II- ACTD or Module 3 ICH-CTD and the following provisions:

1. With regard to vaccines, antibody-containing sera, blood derivatives and plasma from human:

a) Batch release certificate issued by the competent authority of the CPP issuing country according to applicable regulations;

b) Test certificate, quality specification and test method certified by the National institute for control of vaccines and biologics;

2. With regard to orphan drugs and drugs for the special therapeutic requirements:

a) Orphan drugs for the treatment of orphan diseases: readily available stability study data conforming to ASEAN or ICH guidelines;

b) With regard to the drugs required for special therapeutic purposes: The Minister of Health shall consider and make decision on the acceptance of ICH-conforming stability study data on the basis of advice of the Advisory council for issuance of certificate of marketing registration in the case that the registrant demonstrate that the drug cannot be stored in conditions of IVb climatic zone according to ASEAN guidelines.

3. Where the manufacturer uses drug raw materials which have been licensed for marketing in Vietnam:

a) Quality document regarding drug raw materials and the documents stipulated in clause 11 Article 24 of this Circular shall not be required as part of registration dossier of the finished product.

b) The registrant shall submit:

- 01 test certificate of drug raw materials from the manufacturer of the finished product that performs the test covering all quality criteria at a quality level equivalent to or higher than those applied by the drug raw material's manufacturer;

- 01 test certificate of drug raw material from the drug raw material's manufacturer that performs the test.

4. With regards to the drug produced under technology transfer arrangement in Vietnam a) The entire quality document part, prepared in conformance with the guidelines in Part II-ACTD in Appendix 1 of with this Circular or Module 3-ICH-CTD, of the drug prior to technology transfer taking place, provided by the transferred party (in the case where the drug subject of the transfer has not been issued a certificate of registration for marketing in Vietnam).

b) A detailed tabular comparison of variations, additions (if any) between the drug subject of the transfer and the drug being registered in conformance with the guidelines of Appendix II of with this Circular;

c) Document on the pharmaceutical substances of the drug being registered, prepared by the transferee party when there are changes in the manufacturers of pharmaceutical substance in relation with those prior to the technology transfer;

d) Document on the finished product of the drug being registered, prepared by the transferee party, covering:

- Manufacturing process for the drug being registered.

- Report on manufacturing process validation (regarding the operations to be performed by the transferee party).

- Report on the suitability of analytical procedures (may be substituted by a document transferring the analytical process, jointly prepared by the technology transferrer party and the transferee party).

- Batch analysis data (Test certificate of finished product).

- Stability study report of the drug being registered. If the source drug of the technology transfer either has been issued a certificate of registration for marketing in Vietnam or for which stability study data conforming to the respective ASEAN guidelines has been available, the stability study data registered as major variation or minor variation (subject to variations between the drug subject of the transfer and the drug being registered) according to ASEAN guidelines for stability study shall be acceptable.

- Bioequivalence study report of the drug being registered (with regard to the drugs seeking publicization as brand name drug, drugs requiring bioequivalence study report according to Circular no. 08/2010/TT-BYT of 26 Apr 2010 of Ministry of Health guiding the reporting of bioavailability study, bioequivalence study in drug registration or drugs not requiring bioequivalence study report per Ministry of Health regulations but the registrant requests for the drug to be classified as bioequivalent-proven drug). If the all of following conditions are met, bioequivalence study report may be substituted with a report on equivalence in dissolution profiles between the drug being registered and the source drug of the technology transfer:

+ The drug was issued a certificate of registration for marketing in Vietnam before being subject to the technology transfer arrangement and has been announced as brand name drug, bioequivalence-proven drug.

+ The drug being registered are similar to the drug subject of the transfer in formulation, drug raw material manufacturer, quality specification and analytical procedures for drug raw materials, manufacturing process, types of equipment used, environment conditions during manufacturing process. Variations with regard to these factors if any must be at a level not requiring post-variation submission of bioequivalence study report according to the US-FDA (SUPACs) guidelines for lot- upsizing and post-approval changes with regard to solid oral dosage forms and documentation pertinent to each variation must be submitted in the registration dossier in accordance with the requirements of these guidelines.

5. With regard to drugs with secondary packaging carried out in Vietnam

The entire quality document part of the drug prior to the secondary packaging being transferred to Vietnam shall be prepared in conformance with the guidelines of Part II-ACTD or Module 3-ICH-CTD in the case where the drug subject of the transfer arrangement has not been issued a certificate of registration for marketing in Vietnam.

6. With regard to the drugs being subject of a request for dossier evaluation under simplified evaluation scheme

a) Document on pharmaceutical substances:

- Name of pharmaceutical substances (using international non-proprietary name);

- Name and address of manufacturer of pharmaceutical substances semi-finished pharmaceutical substances;

- Quality specification and test method for the pharmaceutical substances, semi- finished product containing the pharmaceutical substances. If standards of Vietnam pharmacopoeia or reference pharmacopoeias per Ministry of Health's stipulations are applied for the drug being registered, it shall suffice to indicate the name, edition number, or to state
'current edition' if it is the case, of the applicable pharmacopoeia;

- 01 Test certificate of pharmaceutical substances, semi-finished product from the manufacturer of such substances, semi-finished products and 01 Test certificate of pharmaceutical substances, semi-finished product from the manufacturer of the finished drug product;

- If the pharmaceutical substances are in semi-finished product form, the formulation and manufacturing process of the semi-finished product containing pharmaceutical substances from the semi-finished product's manufacturer must be provided.

b) Document on finished product:

- Description and composition in conformance with guidelines in Part P.1-ACTD;

- Quality specification and test method for the finished drug product. If standards of Vietnam pharmacopoeia or reference pharmacopoeias per Ministry of Health's stipulations are applied, it shall suffice to indicate the name and edition number of the pharmacopeia or to state 'current edition of pharmacopoeia';

- Manufacturing of the finished product, covering: batch formula; manufacturing process and in process control; control of critical operations and intermediate products.

- Test certificate of finished product;

- Container closure system: Description of forms, materials and quality specification of primary packaging components.

- Stability profile of finished drug product.

c) The remainder of quality document shall follow the guidelines of Part II - ACTD or Module 3-ICH-CTD and a copy of which should be retained at the registrant's, the manufacturer's facility.

7. The documents set out under this Article shall be prepared according to the following:

a) Conforming with the provisions of Appendix I of with this Circular, comprising:

- ASEAN Common Technical Dossiers (ACTD);

- Guidelines for the conduct of stability study;

- Guidelines for the validation of manufacturing process;

- Guidelines for the validation of analytical procedures;

- Guidelines for the conduct of bioavailability and bioequivalence studies;

b) The documents that were prepared following ICH-CTD format and ICH relevant technical guidelines shall not have to be converted to the format specified in point a of this clause.

Article 26. Pre-clinical document in application dossiers for the issuance, extension, modification, supplementation of marketing registration certificate of pharmaceutical drugs, vaccines, biologics

The pre-clinical document shall be prepared in conformance with the guidelines of ACTD - Part III or Module 4-ICH-CTD.

Pre-clinical document shall not be required of probiotics (digestive enzymes) with origin, bacterial strain, concentration, strength, indications, dosage similar to a biologic that has been licensed for marketing by one of the regulatory authorities stipulated in clause 9, 10 Article 2 of this Circular.

Article 27. Clinical document in application dossiers for the issuance, extension, modification, supplementation of marketing registration certificate of pharmaceutical drugs, vaccines, biologics

The clinical document shall be prepared in conformance with the guidelines of ACTD - Part IV or Module 5-ICH-CTD.

Clinical document shall not be required of probiotics (digestive enzymes) with origin, bacterial strain, concentration, strength, indications, dosage similar to a biologic that has been licensed for marketing by one of the regulatory authorities stipulated in clause 9, 10 Article 2 of this Circular.

Article 28. Application dossiers for the issuance, extension, modification, supplementation of marketing registration certificate of pharmaceutical drugs, vaccines, biologics

1. Application dossiers for the issuance of marketing registration certificate of new pharmaceutical drugs, vaccines, biologics shall comprise:

a) The administrative documents stipulated in clauses 1, 2, 7, 9, 11, 13, 14, 18 Article 24 of this Circular and the following documents:

- The documents stipulated in clause 3 Article 24 of this Circular in the case of registrants of Vietnam;

- The documents stipulated in clause 4, 5 Article 24 of this Circular in the case of foreign registrants;

- The documents stipulated in clause 6, 8, 10 Article 24 of this Circular in the case of drug registration dossiers of foreign drugs.

b) The quality document stipulated in Article 25 of this Circular; c) Pre-clinical document stipulated in Article 26 of this Circular; d) Clinical document stipulated in Article 27 of this Circular;

đ) Where the registrant does request for brand name drug classification with the submission of application dossier for marketing registration certificate it shall proceed according to the provisions of point a, b, c, d clause 1 of this Article and point 1 Article 9 of this Circular.

2. Application dossiers for the issuance of marketing registration certificate for generics shall comprise:

a) The administrative documents stipulated in clause 1, 2, 7, 11, 13, 18 Article 24 of this Circular and the following documents:

- The documents stipulated in clause 3 Article 24 of this Circular in the case of registrants of Vietnam;

- The documents stipulated in clause 4, 5 Article 24 of this Circular in the case of foreign registrants;

- The documents stipulated in clause 6, 8, 10 Article 24 of this Circular in the case of drug registration dossiers of foreign drugs.

b) Quality document as stipulated in Article 25 of this Circular.

3. Application dossiers for the extension of marketing registration certificate of drugs:

a) The administrative documents stipulated in clause 1, 2, 14, 16, 17, 18, 19 Article 24 of this Circular and the following documents:

- The documents stipulated in clause 3 Article 24 of this Circular in the case of registrants of Vietnam;

- The documents stipulated in clause 4, 5 Article 24 of this Circular in the case of foreign registrants;

- The documents stipulated in clause 6, 10 Article 24 of this Circular in the case of drug registration dossiers of foreign drugs.

b) Relevant documents stipulated in Appendix II of with this Circular in the case where the drugs undergoing changes in administrative document at the point of certificate extension.

If the registrant already submitted the revised administrative document prior to the submission of extension application dossier but the earlier submission has not been approved, the administrative document shall not be required as part of the application dossier for certificate extension.

4. Application dossiers for modification, supplementation of marketing registration certificate of drugs shall comprise:

a) Application for modification, supplementation of marketing registration certificate using Form 6/TT enclosed with this Circular;

b) Documents pertinent to the corresponding major variations, minor variations as stipulated in Appendix II of this Circular. With regard to the vaccines of the same product owner or the same manufacturer or the same holder of marketing license holder, changes in manufacturing site shall be accepted whether it is in the same country or to countries other than that where the vaccine is licensed for marketing.

5. Application dossier for issuance of marketing registration certificate of drugs produced under technology transfer agreement

a) Application dossier for issuance of marketing registration certificate of drugs produced under technology transfer agreement in the case where the source drug of the transfer is already covered by a marketing registration certificate, which is still valid:

- The administrative documents stipulated in clauses 1, 2, 7, 13, 14, 15, 16, 17, 18, 19 Article 24 of this Circular and the following documents:

+ The documents stipulated in clause 3 Article 24 of this Circular in the case of registrants of Vietnam;

+ The documents stipulated in clause 4, 5 Article 24 of this Circular in the case of foreign registrants.

- Quality document in conformance with the provision of clause 4 Article 25 of this Circular.

- Relevant documents stipulated in Appendix II of this Circular in the case where the drugs involve changes in comparison with the source drugs, which has been licensed for marketing, of the transfer.

b) Application dossier for issuance of marketing registration certificate of drugs produced under technology transfer agreement in the case where the source drug of the transfer has not been issued with a marketing registration dossier or has been issued with one but such certificate has expired:

- Documentation on the drug prior to technology transfer shall be prepared in accordance with the provision of clause 1 or clause 2 of this Article and clause 15 Article 24 of this Circular;

- Quality document in conformance with the provision of clause 4 Article 25 of this Circular.

6. Application dossier for the issuance of marketing registration certificate of drugs for which the secondary packaging is carried out in Vietnam

a) Application dossier for the issuance of marketing registration certificate of drugs for which the secondary packaging is carried out in Vietnam in the case where the drug is covered by a still valid marketing registration certificate: the provisions for changes in establishment performing secondary packaging stipulated in Appendix II of this Circular shall apply;

b) Application dossier for the issuance marketing registration certificate of drugs for which the secondary packaging is carried out in Vietnam, which either has not been issued with a marketing registration license or has been issued with one but the certificate has expired:

- Documentation on the drug prior to the secondary packaging: in conformance with the provision of clause 1 or clause 2 of this Article;

- GMP certificate of the establishment performing the secondary packaging in Vietnam;

- Quality document in conformance with the provision of clause 5 Article 25 of this Circular.

7. Application dossier for the issuance of marketing registration certificate under simplified dossier evaluation scheme

a) The administrative documents stipulated in clause 1, 2, 7, 11, 13, 18 Article 24 of this Circular and the following documents:

- The documents stipulated in clause 3 Article 24 of this Circular in the case of registrants of Vietnam;

- The documents stipulated in clause 4, 5 Article 24 of this Circular in the case of foreign registrants;

- The documents stipulated in clause 6, 8 Article 24 of this Circular in the case of registration dossiers of foreign drugs.

b) Quality document in conformance with the provision of point a, b clause 6 Article 25 of this Circular.

Section 3

APPLICATION DOSSIER FOR THE ISSUANCE, EXTENSION, MODIFICATION, SUPPLEMENTATION OF MARKETING REGISTRATION CERTIFICATE OF MEDICINAL MATERIAL DRUGS

Article 29. Quality document in application dossiers for the issuance, extension, modification, supplementation of marketing registration certificate of medicinal material drugs

1. Raw material

a) Manufacturing process (applicable only to raw medicinal materials): Detailed description of the entire preliminary processing and treatment process of the raw medicinal materials. If the raw materials are a semi-finished medicinal material, medicinal extract from raw material a detailed description of manufacturing process of the materials from starting materials shall be required (except for semi-finished medicinal materials, medicinal extract already licensed for marketing).

b) Quality specification and test method

- With regard to medicinal materials that are not in form of semi-finished medicinal material: the provisions of Ministry of Health's Circular no 13/2018/TT-BYT of 15 May 2018 regulating the quality of medicinal materials traditional drugs shall apply.

- With regard to semi-finished medicinal materials: similarly, the provisions on quality specification and test method for medicinal materials that are not in the form of semi-finished medicinal materials of Ministry of Health's Circular no 13/2018/TT-BYT of 15 May 2018 regulating the quality of medicinal materials traditional drugs shall apply.

c) Test certificate of medicinal raw materials

- 01 Test certificate from the finished product's manufacturer.

- 01 Test certificate of semi-finished medicinal materials, medicinal extracts from their manufacturer and 01 Test certificate of the semi-finished medicinal materials, medicinal extract from the manufacturer of the finished drug product.

2. Finished product

a) Manufacturing process

- Formula of the smallest packaging unit: name, strength, concentration, mass percentage, quality specification applied for each component of the formulation; if produced from semi-finished medicinal material products, medicinal extracts the equivalent mass percentage in medicinal materials relative to the starting material volume or the strength (%) of drug substances, compounds that have been quantified per each medicinal material level, must be indicated.

- Batch formula of the finished product: name, weight, mass weight of each component in the formulation must be indicated;

- Manufacturing process flowchart: reflecting all stages in the manufacturing process covering the flow of raw materials and consistent with the description of manufacturing process;

- Manufacturing process description: a full and detailed description of each operation in the manufacturing process covering technical parameters of each operation;

- List of equipment used: name of equipment, parameters, purpose of use;

- Manufacturing in-process control: a full and detailed description of the criteria used for verification, controls in manufacturing operation covering name of criteria, acceptance criteria, control method, control frequency, control sample size.

b) Quality specification and test method

- Formula of the smallest packaging unit: name, strength, concentration, mass percentage, quality specification applied for each component of the formulation. If produced from semi-finished medicinal material products, medicinal extracts the equivalent mass percentage in medicinal materials relative to the starting material volume or the strength (%) of drug substances, compounds that have been quantified per each medicinal material level, must be indicated.

- Specification of finished product: the provisions of Ministry of Health's Circular no 11/2018/TT-BYT of 04 May 2018 regulating the quality of drugs, drug raw materials shall apply.

c) Test certificate of finished product

d) Specification of container closure system: Full and detailed description of quality of packaging materials, quality standards, quality levels and test method.

đ) Stability study report in conformance with the guidelines for stability study in Appendix I of this Circular.

Article 30. Safety and efficacy document in application dossiers for the issuance, extension, modification, supplementation of marketing registration certificate of medicinal material drugs

1. Document on the safety and efficacy of medicinal material drugs shall be prepared in conformance with the provision of Appendix V of this Circular or the provisions of ASEAN (ACTD), ICH-CTD.

2. The documents stipulated in point b clause 1 Article 19 of this Circular (if applicable).

Article 31. Application dossiers for the issuance, extension, modification, supplementation of marketing registration certificate of medicinal material drugs

1. Application dossiers for the issuance of marketing registration certificate for medicinal material drugs shall comprise:

a) The administrative documents as stipulated in clause 1, 2, 7, 11, 13, 18 Article 24 of this Circular and the following documents:

- The documents stipulated in clause 3 Article 24 of this Circular in the case of registrants of Vietnam;

- The documents stipulated in clause 4, 5 Article 24 of this Circular in the case of foreign registrants;

- The documents stipulated in clause 6, 8, 10 Article 24 of this Circular in the case of drug registration dossiers of foreign drugs.

b) The quality document as stipulated in Article 25 of this Circular.

c) The document on safety and efficacy stipulated in Article 30 of this Circular;

2. Application dossiers for the extension of marketing registration certificate of medicinal material drugs:

a) The administrative documents stipulated in clause 1, 2, 16, 17, 18, 19 Article 24 of this Circular and the following documents:

- The documents stipulated in clause 3 Article 24 of this Circular in the case of registrants of Vietnam;

- The documents stipulated in clause 4, 5 Article 24 of this Circular in the case of foreign registrants;

- The documents stipulated in clause 6, 10 Article 24 of this Circular in the case of drug registration dossiers of foreign drugs.

b) Relevant documents stipulated in Section D Appendix II enclosed with this Circular in the case where the drugs undergoing changes in administrative document at the point of certificate extension.

If the registrant already submitted the revised administrative document prior to the submission of extension application dossier but the earlier submission has not been approved, the administrative document shall not be required as part of the application dossier for certificate extension.

3. Application dossiers for modification, supplementation of marketing registration certificate of medicinal material drugs shall comprise:

a) Application for modification, supplementation of marketing registration certificate using Form 6/TT enclosed with this Circular;

b) Documents pertinent to the corresponding major variations, minor variations as stipulated in Section D, Appendix II of this Circular.

Section 4

REGISTRATION DOSSIER OF DRUG RAW MATERIALS

Article 32. Quality document in application dossiers for the issuance extension, modification, supplementation of marketing registration certificate of drug raw materials

1. With regard to pharmaceutical substance raw materials: the document shall be prepared in accordance with ACTD – drug substances. If the pharmaceutical substances registered follow manufacturer's quality specification, the Drug Master file for the pharmaceutical substances must be enclosed.

2. With regard to raw materials in the form of semi-finished products containing pharmaceutical substances: the document shall be prepared following ACTD dossier as in the case of finished product registration, in which the document on finished product is replaced by the document on the semi-finished product registered; the formulation for a dose unit, for the smallest package unit shall be replaced with the manufacturing batch formula.

3. With regard to semi-finished medicinal materials, excipients, capsule shells:

a) Formulation of semi-finished medicinal materials, pre-mixed excipients, capsule shells: composition, mass weight, volume, qualify specification of each component of the formulation. If raw materials of animal source are used, information on adventitious contaminants (viral safety data) must be provided.

b) Manufacturing process

- Process flowchart: reflecting all stages in the manufacturing process covering the flow of raw materials and consistent with the description of manufacturing process;

- Manufacturing process description: a full and detailed description of each operation in the manufacturing process covering technical parameters of each operation;

- List of equipment used: name of equipment, parameters, purpose of use;

- Manufacturing in-process control: a full and detailed description of the criteria used for verification, controls in manufacturing operation covering name of criteria, acceptance criteria, control method, control frequency, control sample size.

c) Quality specification and test method

-With regard to semi-finished medicinal materials: similarly, the provisions on quality specification and test method for medicinal materials that are not in the form of semi-finished medicinal materials of Ministry of Health's Circular no 13/2018/TT-BYT of 15 May 2018 regulating the quality of medicinal materials traditional drugs shall apply.

- With regard to excipients, capsule shells: the provisions of Ministry of Health's Circular no 11/2018/TT-BYT of 04 May 2018 regulating the quality of drugs, drug raw materials shall apply.

d) Test certificate

đ) Specification of container closure system: Full and detailed description of quality of packaging materials, quality standards, quality levels and test method.

e) Stability study report, covering stability study protocol; stability study data; study conclusion and discussion.

Article 33. Application dossiers for the issuance, extension, modification, supplementation of marketing registration certificate of drug raw materials

1. Application dossiers for the issuance of marketing registration certificate for drug raw materials shall comprise:

a) Part 1 Administrative document

-The administrative documents as stipulated in clause1, 2, 7, 11, 13, 18 Article 24 of this Circular and the following documents:

- The documents stipulated in clause 3 Article 24 of this Circular in the case of registrants of Vietnam;

- The documents stipulated in clause 4, 5 Article 24 of this Circular in the case of foreign registrants;

- The documents stipulated in clause 8, 10, 12 Article 24 of this Circular in the case of drug registration dossiers of drug raw materials produced in foreign countries.

b) The quality document stipulated in Article 32 of this Circular;

2. Application dossiers for the extension of marketing registration certificate of drug raw materials

a) The administrative documents as stipulated in clause 1, 2, 11, 17, 18, 19 Article 24 of this Circular and the following documents:

- The documents stipulated in clause 3 Article 24 of this Circular in the case of registrants of Vietnam;

- The documents stipulated in clause 4, 5 Article 24 of this Circular in the case of foreign registrants;
- The documents stipulated in clause 10, 12 Article 24 of this Circular in the case of drug registration dossiers of drug raw materials produced in foreign countries.
b) Relevant documents stipulated in Section B Appendix II enclosed with this Circular in the case where the drugs undergoing changes in administrative document at the point of certificate extension.
If the registrant already submitted the revised administrative document prior to the submission of extension application dossier but the earlier submission has not been approved, the administrative document shall not be required as part of the application dossier for certificate extension.
3. Application dossiers for modification, supplementation of marketing registration certificate of drug raw materials shall comprise:
a) Application for modification, supplementation of marketing registration certificate using Form 6/TT enclosed with this Circular;
b) Documents pertinent to the corresponding major variations, minor variations as stipulated in Part B Appendix II of this Circular.

Chapter IV
FORMALITIES FOR THE ISSUANCE, EXTENSION, MODIFICATION, SUPPLEMENTATION OF MARKETING REGISTRATION CERTIFICATE OF DRUGS, DRUG RAW MATERIALS; PROCEDURES FOR EVALUATING DOSSIER FOR IMPORTATION OF DRUGS NOT YET COVERED BY A MARKETING REGISTRATION CERTIFICATE

Article 34. Cases eligible for dossier evaluation under fast tract evaluation scheme
1. Drugs on the list of orphan drugs issued by the Minister of Health.
2. Drugs to support emergency requirements in national defence, security, prevention and combatting epidemics, mitigating consequences of natural disasters, calamities.
3. Drugs produced domestically on new GMP-conforming manufacturing lines or on upgraded GMP-EU, GMP-PIC/S conforming or equivalent manufacturing lines within 18 months from the GMP certification date;
4. Vaccines that are prequalified by World Health Organization, vaccines used in national expanded immunization programs;
5. Special therapeutic drugs with special dosage form to which there are no more than
02 (two) similar drugs (of the same active ingredients, the same dosage form, the same strength, same concentration) with a certificate of marketing registration still valid at the time of dossier submission, comprising:
a) Drugs for cancer treatment;
b) New generation of antivirals;
c) New generation of antimicrobials;
d) Drugs for the treatment of dengue fever, tuberculosis, malaria.
6. Drugs produced domestically, comprising:
a) Drugs produced under contract manufacturing or technology transfer arrangements being drugs for cancer treatment, vaccines, biologics, new generation of antivirals, new generation of antimicrobials.
b) Medicinal material drugs that are outcomes of satisfactory evaluated national, ministerial-level or provincial-level scientific and technology research grant, that are

manufactured entirely from WHO-GACP domestically cultivated and harvested medicinal material sources.
c) New drugs produced domestically on which a clinical trial in Vietnam has been completed;
7. New drugs (for cancer treatment, new generation antivirals, new generation antimicrobials), biologics;
8. Brand name drugs produced under contract manufacturing or technology transfer arrangements in Vietnam.

Article 35. Cases eligible for dossier evaluation under simplified evaluation scheme
Drug registration dossiers shall be evaluated under simplified evaluation scheme when simultaneously satisfying the following conditions:
1. Drugs manufactured at facilities that are periodically assessed by Drug Administration for GMP conformity.
2. Drugs on the List of non-prescription drugs.
3. Drugs that are not of modified release dosage form
4. Drugs that are not for use directly on the eyes.

Article 36. Competence in the issuance, extension, modification, supplementation of certificate of marketing registration
1. The Minister of Health shall assign to Drug Administration the functions of organizing for dossier evaluation, issuing, renewing marketing registration certificate of drugs, drug raw materials, approving major changes in marketing registration certificate including in indications, dosage, target users and the publicization of brand name drugs, drugs having bioequivalence report on the basis of opinions, advices of the Advisory council for the issuance of marketing registration certificate.
2. The Minister of Health shall assign to Drug Administration the functions of dossier evaluation and approving changes, supplementation of marketing registration dossiers of drugs, drug raw materials, except for cases of major changes stipulated in clause 1 of this Article.

Article 37. General provisions
1. Dossiers shall be submitted online, in person or by post to Drug Administration;
2. After receiving a complete dossier Drug Administration shall issue to the registrant a Dossier receipt using Form no. 12/TT enclosed with this Circular;
3. With regard to dossier for importation of drugs not yet covered by a marketing registration certificate, the acceptance of dossier shall follow the provision of point b clause 1
Article 77 Decree no 54/2017/NĐ-CP.
4. Holding the evaluation of application dossiers for the issuance, extension, modification, supplementation of marketing registration certificate of drugs, drug raw materials and dossier for importations of drugs not yet covered by a marketing registration certificate:
a) Drug Administration shall refer the dossiers to expert evaluators or the units assigned by the Minister of Health (hereafter referred to as evaluation unit) to organize the evaluation drawing from the list of expert evaluators put together and approved by Drug Administration or the evaluation units.
b) On the basis of synthetized evaluating opinions of expert evaluators, the evaluation units referred to in point a of this clause and taking into account relevant information, Drug Administration shall make recommendations as to whether to, or not yet to, or not to issue, renew, modify, supplement a marketing registration certificate of a drug, a drug raw material; whether to, or not yet to, or not to issue an import license for a drug not yet covered by a

marketing registration certificate. The recommendation from Drug Administration shall be reflected on the evaluation minutes.
c) Drug Administration shall present to the Advisory council for the issuance of marketing registration certificate its recommendations referred to in point b of this clause for the latter's appraisal and advice regarding the following recommended decisions:
- Issue, not to issue a marketing registration certificate for a drug, a drug raw material;
- Renew, not to renew the marketing registration certificate for a drug, a drug raw material;
- Approve, not to approve a major change in marketing registration certificate involving indications, dosage, target users;
- Declare, not to declare a drug as brand name drug, a drug as having bioequivalence study report;
- Issue, not to issue an import license for a drug not yet covered by a marketing registration certificate;
- Other cases as recommended by Drug Administration in support of pressing demands in disease prevention and treatment.

Article 38. Formalities for the issuance of marketing registration certificate, procedures for evaluating dossier for importations of drugs not yet covered by a marketing registration certificate

1. Within 12 months from the date of receipt of a complete application dossier for the issuance of marketing registration of a drug (other than the categories stipulated in Article 41 of this Circular), Drug Administration shall issue a marketing registration certificate for the drug. If the certificate is not, or not yet, issued, Drug Administration shall issue a written response and state the reasons accordingly. The timeline for each specific step of the process shall be as follows:

a) Within 03 months from the date of receipt of a compete dossier, Drug Administration shall review, classify and send the dossier to expert evaluators or evaluation units. Within 06 months from the date of receipt of the dossier from Drug Administration, the expert evaluator and evaluation units must complete the evaluation minutes and send it to Drug Administration for the latter to synthetize, give its opinion on the minutes in accordance with the provision of clause 4 Article 37 of this Circular;

b) Within 02 months from the date of receipt of the evaluation minutes, Drug Administration shall issue a written response to cases of which the dossier does not, or not yet, meet the requirements and state the reasons accordingly. With regard to the dossiers of which Drug Administration recommends certificate issuance or recommends seeking the Advisory council's appraisal opinion, advice, Drug Administration shall present them to the Council in the upcoming next meeting;

c) Within 30 days from the Council meeting date, Drug Administration shall issue the decision to issue marketing registration certificate for cases meeting the requirements; Drug Administration shall issue a written response according to the Council's conclusion to cases not, not yet, meeting the requirements and state the reasons accordingly.

2. Within 36 months in the cases requiring follow up submission of pre-clinical document and clinical document, bioequivalence study document, stability study document or within 12 months in the cases requiring follow up submission of other documents, from the date Drug Administration issue the written notice, the registrant must submit the supplementary

documents as requested. Past this timeline, if the registrant does not do so the dossier submitted earlier shall become void.

The registrant shall inform Drug Administration in writing of any update information relating to the safety and efficacy of the drug in relation to the registration dossier submitted pending evaluation.

The time interval from the date Drug Administration's follow up notice becomes available to the date the registrant submits the supplementary documentation shall not be counted against the time limit stipulated in clause 5 Article 56 of Pharmaceutical law.

3. Within 06 months from the date of receipt of a complete supplementary submission, Drug Administration shall issue the decision to issue marketing registration certificate for cases meeting the requirements; Drug Administration shall issue a written response in line with the Council's conclusion to cases not, not yet, meeting the requirements and state the reasons accordingly.

The procedures for examining supplementary documentation shall follow the provision of clause 1 of this Article.

4. Procedures for the evaluation of dossiers for importation of drugs not yet covered by a marketing registration certificate:

a) Within 05 working days from the date of receipt of a complete dossier, Drug Administration shall transfer the dossier to evaluation experts or evaluation units.

The evaluation time shall not exceed 30 days in the cases not requiring clinical data, documents demonstrating bioequivalence with the reference biologics, or not exceeding 60 days in the cases requiring clinical data or documents demonstrating bioequivalence with the reference biologics, from the date Drug Administration transfer the dossier to evaluation experts or evaluation units;

b) Within 20 days from the date of receipt of the minutes which has been evaluated in accordance with evaluation experts' operating protocol:

- Drug Administration shall synthetize the evaluation opinions of evaluation experts or the evaluation units and take into account relevant information in order to make recommendations as to whether to, not yet to or not to, issue an import license for the drug not yet covered by a marketing registration license.

- With regard to dossiers requiring being presented to the Council as referred to in point c clause 4 Article 37 of this Circular, Drug Administration shall present them to the Council in the upcoming next meeting;

- With regard to dossiers for which Drug Administration recommends not to issue a license yet, Drug Administration shall issue a written response and state the reasons accordingly.

c) Within 5 working days from the date of the Council's meeting or the date the concluding opinion of the Council becomes available, Drug Administration shall issue an import license for the cases meeting the requirements; or a written response in line with the Council's conclusion to cases not yet meeting the requirements and state the reasons accordingly.

d) After receiving the revised, supplemented documentation from the importer, Drug Administration shall proceed according to the provisions of point a, b and c of this clause.

With regard to dossiers for which the Advisory council for the issuance of marketing registration certificate requests revision, supplementation and not requiring referral back to the Council again, Drug Administration shall notify the applicant establishment for the latter to revise, supplement the dossier accordingly; if the revised, supplemented dossier is evaluated as satisfactory, Drug Administration shall proceed to issuing the license without further referral to the Council.

Article 39. Procedures for extension of marketing registration certificate of drugs, drug raw materials

1. Within 03 months from the date of receipt of a complete dossier, Drug Administration shall renew the marketing registration certificate of the drug, the drug raw material. If the certificate is not, not yet renewed, Drug Administration shall issue a written response and state the reasons accordingly. The timeline for the steps involved shall be as follows:

a) Within 10 working days from the date of receipt of a complete dossier, Drug Administration shall examine, classify and send the dossier to the evaluation subcommittees. Within 01 month from the date of receipt of the dossier from Drug Administration, the evaluation subcommittees must complete the evaluation minutes and send it to Drug Administration for the latter to synthetize, to conclude the minutes in accordance with the provision of clause 4 Article 37 of this Circular;

b) Within 15 working days from the date of receipt of the evaluation minutes from the evaluation subcommittees, Drug Administration shall issue a written response to cases that are evaluated as not yet or not meeting the requirements and state the reasons accordingly. With regard to cases of which the dossier is evaluated as satisfactory or cases requiring further appraisal opinions, advices from the Advisory council for the issuance of marketing registration certificate, Drug Administration shall present them to the Council in the upcoming next meeting;

c) Within 15 working days from the Council's meeting date, Drug Administration shall issue the decision to renew marketing registration certificate to cases meeting the requirements; Drug Administration shall issue a written response in line with the Council's conclusion to cases of which the dossier is evaluated as not yet or not meeting the requirements and state the reasons accordingly.

2. Within 12 months, with regard to cases requiring follow up dossier supplementation, from the date Drug Administration issues the written notice, the registrant must submit supplementary documentation as requested. Past this timeline, if the registrant fails to do so the dossier submitted earlier shall become void.

The registrant shall inform Drug Administration in writing of any update information related to the safety and efficacy of the drug in relation to the registration dossier submitted pending evaluation.

The time interval from the date Drug Administration's follow up notice becomes available to the date the registrant submits the supplementary documentation shall not be counted against the time limit stipulated in clause 5 Article 56 of Pharmaceutical law.

3. Within 03 months from the date of receipt of a complete supplementary submission, Drug Administration shall issue the decision to renew marketing registration certificate for cases meeting the requirements; Drug Administration shall issue a written response in line with the Council's conclusion to cases not, not yet, meeting the requirements and state the reasons accordingly.

The procedures for examining supplementary documentation shall follow the provision of clause 1 of this Article.

Article 40. Procedures for modification, supplementation of marketing registration certificate of drugs, drug raw materials during the certificate's validity period

1. Modification, supplementation of marketing registration certificate involving major variations in indications, dosage, target users; classification of brand name drug, drug with bioequivalence study report

Within 03 months from the date of receipt of a complete dossier, Drug Administration shall declare the drug as a brand name drug, as a drug with bioequivalence study report, Drug Administration shall approve major variations in indications, dosage, target users. If approval is not or not yet granted, Drug Administration shall issue a written response and state the reasons accordingly. The timeline for each of the steps involved shall be as follows:

a) Within 10 working days from the date of receipt of a complete dossier, Drug Administration shall examine, classify and send the dossier to the evaluation subcommittees. Within 01 months from the date of receipt of the dossier from Drug Administration, the evaluation subcommittees must complete the evaluation minutes and send it to Drug Administration for the latter to synthetize and conclude the minutes in accordance with the provisions of clause 4 Article 37 of this Circular;

b) Within 15 working days from the date of receipt of the evaluation minutes from the evaluation subcommittees, Drug Administration shall issue a written response to cases that are evaluated as not yet or not meeting the requirements and state the reasons accordingly. With regard to cases of which the dossier is evaluated as satisfactory or cases requiring further appraisal opinions, advices from the Advisory council for the issuance of marketing registration certificate, Drug Administration shall present them to the Council in the upcoming next meeting;

c) Within 15 working days from the date of the Council's meeting, Drug Administration shall declare the drug as brand name drug, as drug with bioequivalence study report, Drug Administration shall approve major variations in indications, dosage, target users of cases meeting the requirements. Drug Administration shall issue a written response in line with the Council's conclusion to cases of which the dossier is evaluated as not yet or not satisfactory and state the reasons accordingly.

2. Modification, supplementation of marketing registration certificate of drugs, drug raw materials; other than the cases stipulated in clause 1, 3 of this Article

Within 03 months from the date of receipt of a complete dossier, Drug Administration shall approve the modified, supplementary content. If approval is not, not yet granted, Drug Administration shall issue a written response and state the reasons accordingly. The timeline for each of the steps involved shall be as follows:

a) Within 10 days from the date of receipt of a complete dossier, Drug Administration shall examine, classify and send the dossier to the evaluation subcommittees. Within 60 days from the date of receipt of the dossier from Drug Administration, the evaluation subcommittees must complete the evaluation minutes and send it to Drug Administration for the latter to synthetize and conclude the minutes in accordance with the provisions of clause 4 Article 37 of this Circular;

b) Within 20 days from the date of receipt of the evaluation minutes from the subcommittees, Drug Administration shall approve the content modified, supplemented of the marketing registration certificate for cases meeting the requirements; Drug Administration shall issue a written response to cases of which the dossier is evaluated as not yet or not satisfactory.

3. Modification, supplementation of marketing registration certificate involving notification-only minor variations

Within 15 working days from the date of receipt of a complete dossier, Drug Administration shall approve the modification, supplementation of marketing registration certificate for cases meeting the requirements; Drug Administration shall issue a written response to cases of which the dossier is evaluated as not yet or not satisfactory and state the reasons accordingly.

4. Within 36 months for the cases requiring follow up supplementation of pre-clinical document and clinical document, bioequivalence study document, stability study document or within 12 for the cases requiring supplementation of other documents, from the date Drug Administration issue the written notice, the registrant must submit the supplementary documentation as requested. Past this timeline, if the registrant fails to respond with supplementary submission the dossier submitted earlier shall become void.

The registrant shall inform Drug Administration in writing of any update information relating to the safety and efficacy of the drug in relation to the registration dossier submitted pending evaluation.

The time interval from the date Drug Administration's follow up notice becomes available to the date the registrant submits the supplementary documentation shall not be counted against the time limit stipulated in clause 5 Article 56 of Pharmaceutical law.

5. Within 02 months from the date of receipt of the complete supplementary documentation from the cases stipulated in clause 1 of this Article, 10 working dates from the date of receipt of the complete supplementary documentation from the cases stipulated in clause 3 of this Article, Drug Administration shall approve the modification, supplementation of marketing registration certificate for cases meeting the requirements; Drug Administration shall issue a written response to cases of which the dossier is evaluated as not yet or not satisfactory and state the reasons accordingly.

The procedures for examining supplementary documentation shall follow the provisions of clause 1, 2, 3 of this Article.

6. The transition period for variation of approved drugs, drug materials is not more than 12 months in the case of vaccines, biologics and not more than 06 months for other drugs, drug raw materials, from the signing date of the Drug Administration's approval letter for the variation, supplementation, unless otherwise requested by Drug Administration.

7. The changes, supplementations that the registrant, the manufacturer shall update themselves on the drug's label, package insert and not be required to submit a registration dossier or to notify Drug Administration are:

a) The labelling of drugs, drug raw materials, including package inserts, according the provision of clause 2 Article 35 of Ministry of Health's Circular 01/2018/TT-BYT of 18 Jan 2018 regulating the labelling and package insert of drugs, drug raw materials;

b) Changing, supplementing the content of labels, package inserts of drugs, drug raw materials as instructed in Drug Administration's written request;

c) Apart from changes, supplementation requiring resubmission of samples of labels, package inserts as stipulated in provision of Appendix II of this Circular, the registrant, the manufacturer must themselves update any other changes related to information on labels, package inserts upon obtaining Drug Administration's respective approval;

d) Other contents:

- Information changes pertaining to the importer of drugs, drug raw materials recorded on labels or package inserts;

- Correction of typographical errors on labels, package inserts;

- Changes in layout, but not the content, of the sections on package inserts that has been approved;

- Adding information regarding quality specification on labels, package inserts consistent with the dossier that has been approved by Drug Administration;

- Contents that are changed, supplemented in accordance with the written notice from Drug Administration regarding the results of dossier evaluation.

Article 41. Procedures for the issuance of marketing registration certificate for drugs under fast track dossier evaluation scheme, simplified evaluation scheme and the issuance of marketing registration certificate for drug raw materials

1. Within 06 months from the date of receipt of a complete dossier, Drug Administration shall issue a marketing registration certificate for the drug, the drug raw material. If the certificate is not or not yet issued, Drug Administration shall issue a written response and state the reasons accordingly. The timeline for each of steps involved shall be as follows:

a) Within 10 working days from the date of receipt of a complete dossier, Drug Administration shall classify and send the dossier to the evaluation committees. Within 03 months from the date of receipt of the dossier from Drug Administration, the evaluation experts and the evaluation units must complete the evaluation minutes and send it to Drug Administration for the latter to synthetize and conclude the minutes in accordance with the provision of clause 4 Article 37 of this Circular;

b) Within 20 working days from the date of receipt of the evaluation minutes from the subcommittees, Drug Administration shall issue a written response to cases not yet or not meeting the requirements and state the reasons accordingly. With regard to the dossiers of which Drug Administration recommends certificate issuance or recommends seeking the Advisory council's appraisal opinion, advice, Drug Administration shall present them to the Council in the upcoming next meeting;

c) Within 30 working days from the date of the Council's meeting, Drug Administration shall issue to decision to issue a marketing registration certificate to cases meeting the requirements; Drug Administration shall issue a written response in line with the Council's conclusion to cases of which the dossier is evaluated as not yet or not satisfactory and state the reasons accordingly.

2. Within 36 months for the cases requiring follow up supplementation of pre-clinical document and clinical document, bioequivalence document, stability study document, or within 12 months for the cases requiring supplementation of other documents, from the date Drug Administration issue the written notice, the registrant must respond with supplementary

submission as requested. Past this timeline, if the registrant fails to do so, the dossier submitted earlier shall become void.

The registrant shall inform Drug Administration in writing of any update information related to the safety and efficacy of the drug in relation to the registration dossier submitted pending evaluation.

The time interval from the date Drug Administration's follow up notice becomes available to the date the registrant submits the supplementary documentation shall not be counted against the time limit stipulated in clause 5 Article 56 of Pharmaceutical law.

3. Within 03 months from the date of receipt of a complete follow up submission, Drug Administration shall issue the decision to issue marketing registration certificate for cases meeting the requirements; Drug Administration shall issue a written response in line with the Council's conclusion to cases of which the dossier is evaluated as not yet or not satisfactory and state the reasons accordingly.

The procedures for examining supplementary documentation shall follow the provision of clause 1 of this Article.

Chapter V

WITHDRAWING MARKETING REGISTRATION CERTIFICATE, SUSPENDING THE ACCEPTANCE OF APPLICATION DOSSIER FOR THE ISSUANCE, EXTENSION OF MARKETING REGISTRATION CERTIFICATE

Article 42. Dossiers, formalities, competence for the withdrawal of certificate of marketing registration of drugs, drug raw materials

1. Competence in certificate withdrawal and responsibility for notification of certificate withdrawal:

a) The Minister of Health assigns to the Director of Drug Administration the function to withdraw certificate of marketing registration of drugs, drug raw materials from the cases categorized under clause 1 Article 58 of Pharmaceutical law;

b) Health Department of provinces, centrally affiliated cities, line agency Health services shall notify [relevant entities] in the jurisdiction the Drug Administration's decisions to withdraw certificates of marketing registration of drugs, drug raw materials.

2. The dossier for the withdrawal of certificate of marketing registration of drugs, drug raw materials under the provision of point g clause 1 Article 58 of Pharmaceutical law shall comprise:

- Request for the withdrawal of certificate of registration for marketing the drug, drug raw material in Vietnam by the manufacturer or registrant conforming to Form 01/TT of this Circular;

- Original copy of the certificate of marketing registration;

- Substantiating documents (as applicable);

3. Procedures for the withdrawal of certificate of marketing registration of drugs, drug raw materials under the provisions of point a, b clause 1 Article 58 of Pharmaceutical law

Within 30 days from the date of the withdrawal decision is made by the competent regulatory authority, Drug Administration shall issue the decision to withdraw the concerned certificate of marketing registration of the drug, drug raw material;

4. Procedures for the withdrawal of certificate of marketing registration of drugs, drug raw materials under the provisions of point c and e clause 1 Article 58 of Pharmaceutical law

Within 10 days from the date the competent regulatory authority of Vietnam [?] or from the date of receipt of an advisory from World Health Organization or from the country of origin that a drug is not safe, not effective for users or that the relevant foreign regulatory authority has withdrawn the certificate of pharmaceutical product, the Director of Drug Administration shall issue a decision to withdraw the concerned certificate of marketing registration of the drug, the drug raw material.

5. Procedures for the withdrawal of certificate of marketing registration under the provisions of point d, đ clause 1 Article 58 of Pharmaceutical law

Within 30 days from the date a written conclusion is made by the competent regulatory authority that the registration dossier based on which a certificate of marketing registration was issued was falsified, or that the drug, drug raw material is not produced at the address indicated in the registration dossier, Drug Administration shall issue the decision to withdraw the concerned certificate of marketing registration;

6. Procedures for the withdrawal of certificate of marketing registration of drugs, drug raw materials under the provision of point g clause 1 Article 58 of Pharmaceutical law

Within 20 days from the date of receipt of a dossier in accordance with the provision of clause 2 of this Article, Drug Administration shall issue the withdrawal decision. If not concurring with the applicant's request for certificate withdrawal, Drug Administration shall issue a written response stating the reasons.

Article 43. Provisions on suspending the acceptance of receiving application dossiers for issuance, extension of certificate of marketing registration of drugs, drug raw materials

1. The suspension of acceptance of application dossiers for issuance, extension of certificate of marketing registration of drugs, drug raw materials shall proceed in accordance with the provisions of clause 2, 3 and 4 Article 100 of Decree no 54/2017/ND-CP dated 07 May 207 of the Government detailing a number of articles and measures for implementing Pharmaceutical law.

2. Drug Administration shall provide notification of the suspension of the acceptance of application dossiers for the issuance, extension of marketing registration certificate for a drug, a drug raw material.

Chapter VI

ORGANIZATION AND OPERATING PRINCINCPLES OF DOSSIER FOR IMPORTATIONS AND ADVISORY COUNCIL FOR ISSUANCE OF CERTIFICATE OF MARKETING REGISTRATION OF DRUGS, DRUG RAW MATERIALS

Article 44. Organization, operations of the Advisory council for issuance of certificate of marketing registration of drugs, drug raw materials

1. The Minister of Health shall set up an Advisory council for the issuance of marketing registration certificate of drugs, drug raw materials. The Council shall be made up of members who are suitably qualified and experienced experts to ensure they are capable to evaluate dossiers, to give counter opinions to those of the evaluation experts and to Drug Administration recommendations, to advise the Minister of Health on pharmaceutical regulatory issues, on quality documents, on the safety, efficacy of drugs, of drug raw materials.

2. The Advisory Council shall be responsible for appraising dossiers, for advising the Prime Minister on the issuance, extension, modification, supplementation of marketing registration certificate of drugs, of drug raw materials; on the licensing for importation of drugs not yet licensed for marketing in Vietnam on the basis of Drug Administration's recommendations and on associated issues at the Minister's request. The Council shall be responsible before the Minister of Health for their appraising opinions and advices.

3. The Council's operating principles:

a) The Council operates on the principle of consensus, centralized democracy, objectivity, public disclosure, transparency. The Council's opinion shall be legally and scientifically sound, taking into account the evaluation results of evaluation experts, clinical reality and Drug Administration's recommendations.

b) The Council shall only hold meeting where there is a quorum of 2/3 Council's members participating, Council's members who are not present in person but do submit their opinion in writing shall be considered as participating in the meeting;

The Council's Chair or the person delegated by the Council's Chair to chair the meeting shall make the concluding decision on the basis of at least 2/3 consenting opinions obtained from participating members. Dissenting opinions shall be included for consideration.

The opinions of Council's members and the Council's conclusion shall be recorded in the minutes of the Council's meeting, including the dissenting opinions.

c) Where a Council meeting is not convened, the Council's Chair shall collect members' opinions in writing;

Past the time limit for opinion collecting, the Council's Chair or the delegated person shall put forward the Council's conclusion after obtaining at least 2/3 of the members' opinions submitted to the Council' Standing committee.

The Council's concluding opinion shall be made on the basis of consensus obtained from at least 2/3 of the members submitted to the Council's standing committee and of Drug Administration's synthetized report and recommendations;

The Council's concluding opinions shall be recorded on a Submission sheet presenting the Council's Chair or the person delegated by the Chair's concluding opinions.

d) Where necessary the Council's Chair shall have the right to solicit additional input from independent experts other than the Council's members before drawing the final conclusion. These experts may participate in the Council's meeting in person or give their input in writing, shall have the same responsibilities and rights with the Council's members;

đ) No breach of the principle on conflict of interest shall be allowed.

4. Drug Administration shall advise and present to the Minister of Health the organization and operating charter for the Advisory council on the issuance of marketing registration certificate of drugs, drug raw materials, the coordination mechanism between the Council and evaluation experts in the process of issuing renewing, modifying, supplementing marketing registration

certificate of drugs, drug raw materials, import licensing of drugs not yet licensed for marketing in Vietnam.

5. The Council's operating budget shall be regulated in accordance with applicable laws.
6. The Council's standing committee is based at the office of Drug Administration

Article 45. Organization, operations of evaluation experts for registration dossiers of drugs, of drug raw materials, for import application dossiers of drugs not yet covered by a marketing registration certificate

1. Drug Administration within its mandate and assigned functions shall be responsible for setting up subcommittees of evaluation experts for registration dossiers of drugs, of drug raw materials, for import application dossiers of drugs not yet covered by a marketing registration certificate (hereafter referred to as evaluation experts). Subcommittees of evaluation experts shall have the structure suitable with the class of product being registered, the class of product being subject of importation request and the type of registration, the form of import licensing under review.

2. Evaluation experts shall operate on the principle that: evaluation opinions shall be legally and scientifically sound and be reflected on the evaluation minutes of registration dossiers or the evaluation minutes of import application dossiers. The evaluation experts shall be responsible to the Director of Drug Administration regarding the evaluation they perform, the recommendations regarding the evaluation work on registration dossiers, import application dossiers.

3. Drug Administration within its mandate and assigned functions shall be responsible to develop and promulgate the organization and operating charter for groups of evaluation experts for the evaluation of registration dossiers of drugs, of drug raw materials, of import application dossiers of drugs not yet covered by a marketing registration certificate; to enter into service contracts with evaluation experts or units participating in holding the dossier evaluation; to conduct training courses for evaluation experts; to assess evaluation experts for professional competencies and regulatory compliance so as to make adjustment and appoint additional evaluation experts accordingly.

4. The budget for holding dossier evaluations shall be regulated by applicable laws.

Chapter VII IMPLEMENTATION PROVISIONS

Article 46. Entry into force

1. This Circular shall take effect from 01 September 2019.

2. Circular No. 44/2014/TT-BYT dated 25 November 2014 of the Minister of Health regulating drug registration shall be repealed from the date this Circular takes effect, except for the provisions regulating the registration of in vitro diagnostic biologics.

Article 47. Transitional provisions

1. Registration dossiers that are submitted before the effective date of this Circular shall continue to be processed under the provisions of Circular 44/2014/TT-BYT dated 25

November 2014 of the Minister of Health regulating drug registration, unless the registrant voluntarily opts to follow the provisions of this Circular from the date it is promulgated.

2. Drugs, drug raw materials with certificate of marketing registration expiring between 01 January 2018 and 30 June 2020 shall be allowed to have the certificate validity maintained for another 12 months, providing the all of the following conditions are satisfied:

a) The drug is not of the categories that the competent authority suspends the acceptance of applications for certificate issuance, certificate extension as stipulated in clause 2 Article 100 Decree no. 54/2017/NĐ-CP of 08 May 2017 of the Government detailing a number of articles and implementation measures for Pharmaceutical law; clause 54 Article 4 and point a clause 53 Article 5 Decree no 155/2018/ND-CP of 12 November 2018 of the Government amending, supplementing a number of provisions related to the conditions for investment in Ministry of Health-regulated sectors;

b) The drug, the drug raw material is not the subject of World Health Organization's, Vietnam pharmaceutical regulatory authority's warning regarding its safety and efficacy;

c) The registrant does file an application to have the validity of the Certificate of marketing registration maintained using Form 6/TT enclosed with this Circular.

Within 20 days from the date of receipt of such application, Drug Administration shall respond in writing.

3. During the period where the validity of the old marketing registration certificate is maintained, if the registrant is allowed to have the certificate renewed, the old certificate still remains valid in parallel with the new one for a period of 06 months counting from the date the new one takes effect.

4. The brand name drugs that have been publicized by Drug Administration before the effective date of this Circular shall continue to be recognized as such. The registrant may undertake to update the brand name drug status in accordance with the provisions of Appendix II of this Circular while the Certificate of marketing registration is still valid.

Article 48. Implementation roadmap

1. The timelines for the registration for marketing of excipients, capsule shells shall be in accordance with the provisions of clause 8 Article 143 of the Government's Decree no 54/2017/ND-CP dated 08 May 2017 detailing a number of articles and measures for implementing Pharmaceutical law.

2. The timelines for the registration for marketing of semi-finished medicinal materials shall be in accordance with the provision of point c clause 78 Article 5 Chapter II of the Government's Decree no 155/2018/NĐ-CP of 12 Nov 2018 amending, supplementing a number of provisions related to conditions for investment in Ministry of Health's regulated sectors.

3. With regard to application dossiers for the extension, modification, supplementation of marketing registration certificate that are submitted before 01 January 2020: The CPP covering complete information regarding specification of finished drug products; specification of pharmaceutical substances, of medicinal materials; name, address of manufacturers of pharmaceutical substances, of medicinal materials shall not be required.

4. With regard to dossiers registering drug raw materials in the form of semi-finished medicinal materials, excipients, capsule shells and the raw materials of excipients, capsule

shells, medicinal materials, semi-finished medicinal materials included in registration dossiers that are submitted before 01 January 2021: The legal papers stipulated in clause 11 Article 24 of this Circular shall not be required.

Article 49. Provision on references

When there are changes to, supplementation or replacement of the legal normative documents and regulations invoked in this Circular, the new normative documents, regulations shall prevail.

Article 50. Implementation responsibilities

1. Drug Administration, within its mandate, assigned functions and in line with the ASEAN harmonization roadmap for drug registration, shall be responsible to:

a) Provide guidance for and carry out the implementation of the provisions of this Circular;

b) Update the list of drugs, drug raw materials for which a marketing registration certificate has been issued, renewed within 05 days from the date of issuance, the date of extension and other registration pertinent information on Drug Administration's webpage;

c) Update on Drug Administration's webpage the list of bioequivalence-proven drugs within 05 days from the date of issuance of marketing registration certificate and information about the changes, supplementation relating to bioequivalence-proven drugs within 07 days from the approval date of the respective certificate modification;

d) Update on Drug Administration the list of brand name drugs within 05 days from the date of issuance of marketing registration certificate and information about changes, supplementation related to brand name drugs within 07 days from the approval date of the respective certificate modification;

đ) Examine review the drugs that have been publicly declared as brand name drugs when there is basis to determine that they no longer satisfy the regulatory qualifying criteria;

e) Develop, institute standard operating procedures (SOP) in drug registration and drug registration manual (QM);

g) Coordinate with Traditional Medicine Administration in the extension, modification, supplementation of certificate of marketing registration for traditional drugs, medicinal materials already licensed for marketing in accordance with the provisions of Circular no. 44/2014/TT-BYT dated 25 Nov 2014 of the Minister of Health regulating drug registration.

h) In the event a registrant falsifies or unilaterally alters records, documents, legal papers issued by Vietnam or foreign competent authorities; uses counterfeit seals or falsifies the signature or seal of the registrant establishment of a drug, Drug Administration shall issue a warning letter to the registrant and holding off receiving application dossiers for issuance, extension of certificate of marketing registration in accordance with the provisions of clause 2, 3 and 4 Article 100 Decree 54/2007/NĐ-CP dated 08 May 2017 of the Government detailing a number of articles of and implementation measures for Pharmaceutical law.

Apart from the above measures, Drug Administration shall make public the violations committed by the concerned establishment on its webpage, and at the same time inform the Inspectorate agency and competent authorities for review and prosecution of the case in accordance with applicable legislation.

i) Where necessary Drug Administration shall be responsible for holding meetings with the registrant, the manufacturer, the evaluation experts to clarify issues of scientific nature associated with dossier evaluation.

k) Publish on Drug Administration's webpage the list of registrants, manufacturers of drugs, drug raw materials in accordance with the provision of clause 11, 15 Article 23 of this Circular.

l) Develop regulations and roadmap for the implementation of the requirement to have bar code, QR code, Data Matrix Code (DMC) printed on outer packaging component of drugs, drug raw materials in order to facilitate the management, identification and traceability of drugs, drug raw materials in market circulation, present them to the Minister of Health for promulgation;

m) Within 30 days from the date of issuance, extension of a certificate of marketing registration, Drug Administration shall return the labels, package inserts to the registrant;

n) Within 15 days from the day of issuance, extension of a certificate of marketing registration for a drug, a drug raw material, 07 days from the date of approval of changes, supplementation of a certificate of marketing registration for a drug, drug raw material, Drug Administration shall publish on its webpage the source of draw raw materials for the drugs that are produced in Vietnam.

2. Health Department of provinces, centrally affiliated cities shall be responsible for inspecting, auditing the implementation of this Circular by pharmaceutical manufacturing, trading entities in the respective jurisdiction.

3. Units affiliated to Ministry of Health, Vietnam General Pharmaceutical Corporation, drug business establishments shall be responsible for implementing this Circular.

Any problems, issues encountered by agencies, organizations, individuals during the implementation process should be reported to Ministry of Health (Drug Administration) for consideration and resolution./.

Recipients:
- *The Committee on Social Affairs of the National Assembly*
- *Government Office (Official Gazette, Government web Portal);*
- *Minister of Health;*
- *Vice Ministers of Health;*
- *Ministry of Justice (Department of Legal Document Inspection);*
- *Ministry of Science and Technology;*
- *Ministry of Industry and Trade;*
- *Ministry of Defence (Military Health Administration);*
- *Ministry of Public Security (Health Administration);*
- *The Ministry of Transport (Health Administration);*
- *Ministry of Finance (General Department of Customs);*
- *Departments, Administrations, Inspectorates under Ministry of Health;*
- *Provincial/municipal Health Services;*
- *Vietnam Pharmaceutical General Corporation;*
- *Vietnam Pharmaceutical Companies Association;*
- *Vietnam Pharmacy Association;*
- *General Department of Customs;*
- *MOH web portal, DAV's webpage;*
- *Domestic and foreign pharmaceutical manufacturers and traders;*
- *File: VT, PC, QLD (5)*

PP. THE MINISTER

[Signed]

Truong Quoc Cuong

MINISTRY OF HEALTH ------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
Number: 15/2019/TT-BYT	*Hanoi, July 11, 2019*

CIRCULARS

REGULATION ON BIDDING FOR DRUGS AT PUBLIC HEALTH ESTABLISHMENTS

Pursuant to the Law on Bidding dated November 26, 2013;

Pursuant to the Law on Pharmacy dated April 6, 2016;

Pursuant to the Government's Decree No. 63/2014/ND-CP dated June 26, 2014 detailing the implementation of a number of articles of the Bidding Law regarding contractor selection;

Pursuant to the Government's Decree No. 54/2017/ND-CP of May 8, 2017, providing a number of articles and guidelines for implementation of the Pharmacy Law;

Pursuant to the Government's Decree No. 75/2017/ND-CP of June 20, 2017 defining the functions, tasks, powers and organizational structure of the Ministry of Health;

At the request of the Director of the Drug Administration of Vietnam, the Director of Planning - Finance Department;

The Minister of Health promulgates a Circular on bidding for drugs at public health facilities.

Chapter I

GENERAL RULES

Article 1. Scope

1. This Circular prescribes the bidding for drugs (pharmaco-chemical medicines, materia medica, traditional medicines, vaccines and biologicals) and materia medica at public medical establishments, including: division of bidding packages, drug group; planning, form, mode and organization of selection of drug supply contractors; regulations on concentrated drug procurement and negotiation of drug prices using state capital, health insurance fund, revenues from medical examination and treatment services and other lawful revenue sources of public medical establishments.

2. The purchase of drugs by a drug retailer within the premises of a public medical examination and treatment facility complies with Clause 76, Article 5 of Decree No. 155/2018/ND-CP of November 12, 2018 of The Government amends and supplements a number of regulations related to business investment conditions under the Ministry's Health management scope. In cases where a medical examination and treatment facility organizes a bidding for purchasing drugs for a drug retailing establishment on the premises of the medical examination and treatment facility itself, the guidance in this Circular shall apply.

3. The purchase of drugs ordered or delivered by the State shall comply with the Government's Decree No. 32/2019/ND-CP of April 10, 2019, assigning tasks, placing orders or bidding to supply products. public products and services funded by the state budget from recurrent expenditures.

4. The purchase of drugs used in medical examination and treatment at the military medical offices and agencies of the armed forces complies with the guidance of the Ministry of Defense and the Ministry of Public Security.

5. The purchase of medical oxygen, nitric oxid (NO), invitro diagnostic bio-products complies with the Finance Minister's Circular No. 58/2016 / TT-BTC of March 29, 2016. details of the use of state capital for procurement to maintain the regular operation of state agencies, units of the people's armed forces, public non-business units, political organizations and socio-political organizations societies, socio-political organizations, social organizations and professional social organizations.

6. The purchase of whole blood and qualified blood products complies with the Health Minister's Circular No. 05/2017 / TT-BYT of April 14, 2017, setting the maximum price and service charge for the determination of the price of a whole blood unit, blood product standard and Circular No. 20/2018 / TT-BYT dated August 30, 2018 of the Minister of Health amending and supplementing a number of articles of the Circular Circular No. 05/2017 / TT-BYT dated April 14, 2017 of the Minister of Health prescribing the maximum price and expenses for the determination of the price of a whole blood unit and standard blood preparations.

7. For anti-HIV drugs using the fund of medical examination and treatment with health insurance, the elaboration, evaluation and approval of contractor selection plans, organization of contractor selection and signing framework agreement with house The successful bid shall comply with this Circular. Other issues related to demand planning; enter into contracts with suppliers; manage the use, advance, payment and settlement of costs of ARVs; Regimes, funding sources and methods of support and co-payment of ARVs for HIV-infected people with health insurance cards comply with the Ministry of Health's Circular No. 28/2017 / TT-BYT of June 28, 2017. The Minister of Health prescribes the management of ARVs using the fund of medical examination and treatment with health insurance and supports the cost of co-payment for ARVs for HIV-infected people with health insurance cards and Thong Circular No. 08/2018 / TT-BYT dated April 18, 2018 of the Minister of Health amending and supplementing a number of articles of the Minister of Health's Circular No. 28/2017 / TT-BYT dated June 28, 2017 stipulating the management of ARVs using the fund of medical examination and treatment with health insurance and support for the cost of co-payment for ARVs for PLHIV with health insurance cards dull.

Article 2. Subjects of application

1. This Circular applies to agencies, organizations and individuals participating in or related to drug bidding activities.

2. Medical establishments operating under the Law on State-Owned Enterprises shall comply with the provisions of this Circular.

3. Private medical establishments participating in medical examination and treatment with medical insurance shall comply with Article 52 of the Bidding Law and the provisions of Clause 7, Article 50 of this Circular.

Article 3. Interpretation of terms

In this Circular, the terms below are construed as follows:

1. *Strict pharmaceutical management agency (SRA - Stringent Regulatory Authorities)* is the pharmacy management agency specified in Clause 10, Article 2 of Circular No. 32/2018 / TT-BYT dated November 12, 2018 of the Minister Health regulates the registration of circulation of drugs and medicinal ingredients.

2. *Reference management agency* is a pharmaceutical management agency defined by the Ministry of Health of Vietnam under Clause 9, Article 2 of Circular No. 32/2018 / TT-BYT of November 12, 2018 of the Minister of Health. regulating the registration of drugs and medicinal ingredients.

3. *ICH (International Conference on Harmonization)* is the English abbreviation of the International Conference on harmonization of pharmaceutical registration procedures for human use.

4. *PIC/s (Pharmaceutical Inspection Co-operation Scheme)* is the English abbreviation of the Cooperative System for Pharmaceutical Inspection.

5. *GMP* principles and standards are medicine manufacturing principles and standards.

6. *GACP* principles and standards are Good principles and standards of planting and collecting medicinal herbs.

7. *The medicine production line that meets the EU-GMP principles and standards* is a drug production line certified by the competent agency of the country participating in the European Drug Administration (EMA). rules, EU-GMP standards.

8. *Medicine production line meeting EU-GMP principles and standards* means a drug production line certified by a competent agency of the country on the SRA list of SRA-compliant standards. Good drug manufacturing (GMP).

9. *Medicine production line meeting PIC/s-GMP principles and standards* means a drug production line accredited by a competent agency of a country participating in the Pharmaceutical Inspection System (PIC/S) Certification of PIC/S-GMP principles and standards.

10. *CIF* price means the import price, inclusive of the value of drugs calculated according to the selling price of the exporting country, insurance cost, freight from the exporting country to the Vietnamese port.

11. *Reference biological products (also called reference biological drugs)* are biological products licensed for circulation in Vietnam on the basis of adequate data on quality, safety and effectiveness.

12. *Pharmaceutical Equivalence* means a drug that contains the same pharmaceutical substance with the same content in the same dosage form, has the same route of administration and meets the same quality standard.

13. *Therapeutic Equivalence* is a bioequivalent drug that has been shown to have bioequivalence and when used on a patient under specific conditions according to the medication guide, has the same clinical effect. and safety.

Article 4. Responsibilities for formulating plans and organizing the selection of drug supply contractors

1. Heads of health facilities shall organize the elaboration of contractor selection plans according to the provisions of Article 14 of this Circular and the following provisions:

a) For drugs on the List of drugs subject to national-level concentrated bidding, the List of drugs with price negotiation: The National Center for concentrated drug procurement is responsible for formulating plans on selection of drug suppliers. The plan was made based on the demand for drugs of medical facilities built according to the notice of the National Centralized Drug Shopping Center. The maximum duration of the contract is 36 months, divided into groups of medicines and the supply progress by quarter, year;

b) Regarding drugs on the List of drugs in local-level concentrated bidding: Local-level concentrated drug procurement units shall formulate a plan to select drug suppliers. The plan is made based on the demand for drugs of medical facilities built according to the notice of the local-level concentrated drug-purchasing unit. The maximum duration of the contract is 36 months, divided into groups of medicines and the supply progress by quarter, year;

c) For drugs selected by the contractor by the contractor: The health facility is responsible for formulating the plan to select drug suppliers. Plans are scheduled periodically or irregularly when needed. The maximum duration of the contract is 12 months, divided by drug groups.

2. Heads of health facilities shall organize the selection of contractors to ensure the following provisions:

a) For drugs on the List of drugs subject to national-level concentrated bidding, the List of drugs with price negotiation: The National Center for concentrated drug procurement shall organize the selection of contractors to supply drugs according to the provisions of Chapter IV and Chapter V of this Circular;

b) Regarding drugs on the List of drugs of local-level concentrated bidding: Local-level concentrated drug procurement units shall organize the selection of contractors to supply drugs according to the provisions of Chapter IV of this Circular;

c) For drugs other than the List of drugs subject to national-level concentrated bidding, the List of drugs of concentrated bid at local level and the List of drugs with price negotiation: Medical establishments shall have to organize the selection of contractors Drugs prescribed in Chapter III of this Circular.

Article 5. Reporting on bidding implementation

1. Within 10 days after the contractor selection results are approved, the heads of medical establishments shall have to report the contractor selection results as follows:

a) Hospitals and hospitals with beds under the Ministry of Health report the result of drug contractor selection to the Ministry of Health.

b) The local-level centralized procurement unit and health facilities shall carry out bidding for drugs under the management of the People's Committee of the province or city directly under the Central Government (hereinafter referred to as the People's Committee), at the provincial level) report the contractor selection result to the Department of Health of the province or city in the area.

c) The health facilities affiliated to the health sector and other health facilities shall report the contractor selection results to the agency competent to approve the contractor selection plan.

2. Within 10 days from the date of receiving the contractor selection result report of the units specified at Point b, Clause 1 of this Article, the provincial / municipal Health Services summarize and report to the Ministry of Health.

3. Forms of sending reports:

a) The report form is made in ***Appendix 1*** and ***Appendix 2*** enclosed herewith;

b) Reports sent in writing and email to the Ministry of Health are made as follows:

- 01 copy of the Planning - Finance Department, the Ministry of Health, email address: dauthau.khtc@moh.gov.vn for all bidding packages for drug procurement;

- 01 copy to the Drug Administration of Vietnam, Ministry of Health, email address: qlgiathuoc.qld@moh.gov.vn for bidding package of original brand-name drug or equivalent treatment; generic medicine bidding package.

- 01 copy to the Department of Management of Traditional Medicine and Pharmacy, the Ministry of Health, email address: quanlyduoclieu@moh.gov.vn for bidding packages of herbal medicines and traditional medicines; herbal bidding package; traditional medicine tender package.

4. Before October 31 every year, the health management agencies of the ministries and branches; hospitals and hospitals with beds under the Ministry of Health; Provincial-level Health Departments shall sum up and send reports on violations committed by contractors in the course of bidding and drug supply in the previous period of medical establishments in their localities. in accordance with the provisions in ***Appendix 3*** issued with this Circular to the Ministry of Health (Department of Planning - Finance for all bidding packages; Drug Administration of Vietnam for bidding packages of generic drugs and original brand name bidding packages or equivalent of treatment; Traditional Medicine Management Department, for bidding packages of herbal medicines, traditional medicines, bidding packages of traditional medicines, herbal bidding packages) for summarizing and announcing, serving as a basis for The unit shall consider and evaluate and select contractors in the next period.

Article 6. Expenses and record keeping in contractor selection

1. Expenses in the process of selecting a contractor comply with Article 9 of Decree No. 63/2014 / ND-CP of June 26, 2014 of the Government detailing the implementation of a number of articles of Bidding law on contractor selection (hereinafter referred to as Decree No. 63/2014 / ND-CP).

2. Keeping records in the process of selecting contractors complies with Article 10 of Decree No. 63/2014 / ND-CP.

chapter II

DIVISION OF BIDDING PACKAGES AND MEDICINE GROUP

Article 7. Bidding packages of generic drugs

A generic drug bidding package may have one or more generic drugs, each generic drug list must be divided into groups, each generic drug in a group is part of the bidding package. Generic drug packages are divided into 05 (five) groups according to technical criteria, specifically as follows:

1. Group 1 includes medicines meeting 01 (one) of the following 03 (three) criteria:

a) Being manufactured entirely on a drug production line that meets the EU-GMP principles or standards or a drug production line meeting the same EU-GMP principles and standards in the SRA list;

b) Drugs on the list of brand-name drugs or reference biological products published by the Ministry of Health, except for brand-name drugs on the list of drugs subject to price negotiation promulgated by the Ministry of Health and announced. price negotiation results;

c) It is allowed to manufacture all stages in Vietnam and must simultaneously meet the following criteria:

- Manufacturing all drugs on a medicine production line that meets EU-GMP principles or standards or a drug production line up to EU-GMP principles and standards and assessed by the Vietnamese pharmaceutical management agency as meeting the standards. rules, EU-GMP standards or EU-GMP equivalent principles and standards;

- Being licensed by the pharmaceutical management agency of the country on the list of SRA under the guidance in Clause 8, Article 50 of this Circular;

- Drugs circulating in Vietnam and drugs licensed from the SRA list must have the same formulation, manufacturing process, quality standards and testing methods; active ingredients and excipients must have the same quality standards, manufacturing facilities, and manufacturing location according to Clause 8 Article 50 of this Circular.

2. Group 2 includes medicines meeting 01 (one) of the following 02 (two) criteria:

a) Being manufactured entirely on a drug production line that meets the EU-GMP principles or standards or a drug production line meeting the same EU-GMP principles and standards and evaluated by a Vietnamese pharmaceutical management agency. meeting EU-GMP principles or standards or equivalent principles or standards of EU-GMP.

b) Being manufactured entirely on the drug production line in a country that is a PIC / s member and an ICH member, and is certified by the country's competent management agency to meet the PIC's principles and standards. s-GMP and is assessed by Vietnam Drug Administration to meet PIC / s-GMP principles and standards.

3. Group 3 includes drugs manufactured on drug production lines assessed by Vietnamese pharmaceutical management agencies up to GMP principles and standards and having bioequivalence studies approved by Vietnam's pharmaceutical management agencies. announced.

4. Group 4 includes drugs produced entirely on the production line in Vietnam and assessed by the Vietnamese pharmaceutical management agency to reach WHO-GMP principles and standards.

5. Group 5 includes medicines manufactured on drug production lines assessed by Vietnam's pharmaceutical management agencies up to WHO-GMP principles and standards and not falling into the cases specified in Clauses 1 and 2, 3 and Clause 4 of this Article.

Article 8.- Package of original brand-name drug or equivalent treatment

1. Heads of health facilities may decide to buy original brand-name drugs or equivalent treatment with original brand-name drugs or reference biologicals on the basis of the proposals of the Council of medicines and treatment of the medical establishment. .

2. A package of original brand-name drug or equivalent drug may contain one or more original brand-name drugs or an equivalent treatment with brand-name brand-name drugs or reference biologicals, each of which is part of a tender package. Drugs participating in the bidding for original brand-name drug packages or equivalent drugs include drugs that meet the following 02 (two) criteria:

a) Being on the list of brand-name drugs, drugs equivalent to the brand-name drug and reference biological products published by the Ministry of Health, except for brand-name drugs on the list of drugs subject to price negotiation by the Ministry. Health issued and published results of price negotiations.

b) Being manufactured entirely in countries on the list of SRA, except where the applicant requests to prove that the original brand-name drug or reference biological product is first circulated in the country not on the list of SRA or manufactured one. or many stages in Vietnam.

Article 9.- Bidding packages of materia medica and traditional medicines (excluding traditional herbs)

Tender packages of herbal drugs and traditional drugs may have one or more herbal drugs and traditional drugs, each list of drugs must be divided into groups, each drug in a group is part of

the bidding package. Bidding packages of herbal drugs and traditional medicines are divided into 03 (three) groups according to the following technical criteria:

1. Group 1 includes drugs that simultaneously meet the following 02 (two) criteria:

a) Being produced entirely from medicinal materials grown, harvested or naturally exploited by the Ministry of Health of Vietnam assessing GACP principles and standards;

b) Being manufactured entirely on the drug production line in Vietnam and assessed by the Ministry of Health of Vietnam to meet GMP principles and standards for herbal medicines or traditional medicines.

2. Group 2 includes herbal drugs and traditional medicines produced entirely on the drug production line in Vietnam, which are evaluated by the Ministry of Health of Vietnam to meet GMP principles and standards for herbal or traditional medicines. infused.

3. Group 3 includes herbal drugs and traditional medicines that fail to meet the criteria in Clauses 1 and 2 of this Article.

Article 10.- Traditional medicine bidding packages

Traditional herbal bidding packages may have one or more traditional herbs, each category of medicinal herbs must be divided into groups, each medicine in a group is part of a tender package. Traditional medicine bidding packages are divided into 03 (three) groups according to the following technical criteria:

1. Group 1 consists of traditional medicines that simultaneously satisfy the following 02 (two) criteria:

a) It is manufactured from medicinal raw materials that are grown, harvested or naturally harvested by the Ministry of Health of Vietnam, meeting GACP principles and standards;

b) Being produced entirely on the drug production line in Vietnam, which is assessed by the Ministry of Health of Vietnam to meet GMP principles and standards for traditional medicines (including medicines made in the form of: high , cereals, powders, extracts, essential oils, plastics, gums, standardized jelly).

2. Group 2 includes traditional medicines produced entirely on the medicine production line in Vietnam, which are evaluated by the Ministry of Health of Vietnam to meet GMP principles and standards for traditional medicines (including medicinal herbs are formulated in the form of: tall, nuggets, powders, extracts, essential oils, resins, gums, standardized jellies).

3. Group 3 includes traditional medicines that fail to meet the criteria in Clauses 1 and 2 of this Article.

Article 11.- Bidding packages of materia medica

A bidding package of materia medica may have one or several materia medica, each list of materia medica must be divided into groups, each medicinal ingredient in a group is part of the bidding package. The bidding package of medicinal herbs is divided into 03 (three) groups according to the following technical criteria:

1. Group 1 includes natural farming, harvesting or exploiting pharmaceutical materials assessed by the Ministry of Health of Vietnam to meet GACP principles and standards.

2. Group 2 includes pharmaceutical semi-finished products: tall, nuggets, powders, extracts, essential oils, plastics, gums and standardized jelly manufactured on-line in Vietnam, beaten by

Vietnam's Health Ministry. price reaching to GMP principles and standards for medicinal materials from medicinal materials.

3. Group 3 includes pharmaceuticals that do not meet the criteria in Clauses 1 and 2 of this Article.

Article 12. Provisions on bidding for drug groups

1. Bidding principles of drug groups in bidding packages

a) Contractors with drugs that meet technical criteria of any group are allowed to bid for that group. For drugs meeting the technical criteria of many groups, the bidder may bid for one or more groups of drugs that meet the technical criteria and must have a uniform bid price in all groups of bidders.

b) If there are many establishments participating in the bidding process, all establishments participating in the manufacturing process must meet the technical criteria of the group of bidders.

2. Bidding package of generic drugs:

a) Drugs that meet the criteria in Group 1 are eligible to bid for Group 1, Group 2, and Group 5;

b) Drugs that meet the criteria in Group 2 are allowed to bid for Group 2, Group 5;

c) Drugs that meet the criteria in Group 3 are eligible to bid for Group 3, Group 5;

d) Drugs that meet the criteria in Group 4 are eligible to bid for Group 4 and Group 5;

d) If the drug does not meet the criteria of Group 1, Group 2, Group 3 and Group 4, it may only bid for Group 5.

3. Bidding package of herbal medicines and traditional medicines:

a) Drugs that meet the criteria in Group 1 are allowed to bid for Group 1, Group 2 and Group 3;

b) Drugs that meet the criteria in Group 2 are allowed to bid for Group 2 and Group 3;

c) Medicines that do not meet the criteria of Group 1, Group 2 are only bid in Group 3.

4. Traditional medicine bidding packages:

a) Traditional herbs that meet the criteria in Group 1 are bid to join Group 1, Group 2, Group 3;

b) The traditional medicine that meets the criteria in Group 2 is bid to join Group 2, Group 3;

c) Traditional medicines that do not meet the criteria of Group 1 and Group 2 are only bid in Group 3.

5. Package of materia medica:

a) Medicinal materials that meet the criteria in Group 1 are allowed to bid for Group 1 and Group 3;

b) Medicines that meet the criteria in Group 2 are only allowed to bid for Group 2;

c) Medicinal materials that do not meet the criteria of Group 1 and Group 2 are only bid for Group 3.

6. Bidding for foreign drugs manufactured, processed or transferred technologies in Vietnam into bidding packages of generic medicines and original brand-name drug packages or equivalent treatment is done as follows:

a) Foreign drugs manufactured and processed in Vietnam and eligible for technology transfer may participate in the bidding according to Point b of this Clause when the following criteria are simultaneously satisfied:

- There must be a technology transfer contract which specifies the comprehensive technology transfer roadmap for the processee or transferee for the production of all stages of the drug manufacturing process. products in Vietnam for a maximum period of 5 years from the date of issuance of registration certificate for circulation in Vietnam;

- Drugs manufactured and processed, transferred with technology and drugs, before being processed or transferred, must have the same preparation formula, the same production process and the same quality standards for raw materials and finished medicines. ;

- Drugs not on the list of domestically manufactured drugs meeting the treatment, price and supply requirements promulgated by the Ministry of Health according to the group of technical criteria (except for whole production in Vietnam). when issuing the registration certificate for circulation in Vietnam).

b) The bidding for foreign drugs manufactured, processed or transferred in Vietnam that meets the provisions of Point a of this Clause is done as follows:

- Foreign drugs manufactured and processed in technology transfer in Vietnam shall be announced by the Ministry of Health in the List of original brand-name drugs or List of reference biological products and meet the provisions of Point b, Clause 2, Article 8 of this Circular. be allowed to bid for original brand name drug package or equivalent treatment. For cases of being on the List of drugs subject to price negotiation promulgated by the Ministry of Health, the procurement of these drugs shall be conducted in the form of price negotiation;

- Foreign drugs specified at Point a, Clause 1, Article 7 of this Circular produce processing, technology transfer in Vietnam on drug production lines up to EU-GMP principles or standards or drug production lines. principles and standards equivalent to EU-GMP and assessed by the Vietnamese pharmaceutical management agency to achieve EU-GMP principles or standards or EU-GMP equivalent principles and standards may be bid to Group 1, Groups 2, Group 4 and Group 5;

- Foreign drugs specified in Clause 2, Article 7 of this Circular process, technology transfer in Vietnam on medicine production lines up to EU-GMP principles or standards or drug production lines up to principles and standards. standards equivalent to EU-GMP and assessed by the Vietnamese pharmaceutical management agencies to meet EU-GMP principles or standards or EU-GMP equivalents may be bid for Group 2, Group 4 and Group 5;

- Other medicines processed and technology transferred in Vietnam may be bid in Group 4 and Group 5.

c) If the foreign drug processing or technology transfer does not meet the criteria specified at Point a of this Clause, bidding shall comply with Clause 1 and Clause 2 of this Article.

Chapter III

REGULATIONS ON PURCHASE OF DRUGS AT MEDICAL ESTABLISHMENTS

Section 1. PLANNING OF SELECTION OF CONTRACTORS OF MEDICINE SUPPLIER

Article 13.- Bases for making contractor selection plans

1. A contractor selection plan is made annually or when there is a need to organize a contractor selection with the following grounds:

a) State budget sources:

The estimate of buying drugs from the state budget in the plan year is assigned by the competent authority. In case the budget estimate has not yet been assigned, based on the actual purchase and use of drugs from the state budget of the preceding year and the estimated demand for medicine use in the year to make a plan;

b) Revenues from medical examination and treatment services and revenues paid by social insurance agencies:

- Medical insurance medical examination and treatment contract signed between the medical establishment and the social insurance agency;

- Actual purchase of drugs, use of drugs from revenues of medical examination and treatment services of the preceding year and expected demand for drugs in the planned year of medical establishments.

c) For drugs purchased from other lawful revenue sources of the unit: Based on the actual purchase of drugs, use of drugs from other lawful revenue sources of the preceding year and expected demand for drug use in the planning year of medical facilities.

2. In cases where a medical establishment has selected a contractor and signed a contract but the demand for use exceeds 20% of the number in the signed contract (according to each part of the bidding package), the medical establishment must elaborate a plan to select additional contractors to meet the medical examination and treatment needs of their units.

Article 14. Contents of a contractor selection plan

1. Name of bidding package:

The division of bidding packages and drug groups conforms to Articles 7 to 12 of this Circular. If a bidding package is divided into several parts, the name of each part must match the contents of that part. Specific information in the contractor selection plan is as follows:

a) Each part of the generic drug bidding package contains the following information: the name of the active ingredient; concentration or content; route of administration, dosage form; drug group; unit; amount; unit price and total value of such drug;

b) Each part of the bidding package of original brand-name drug or equivalent treatment includes the following information: name of the drug together with the phrase "or equivalent of treatment"; active ingredient name; concentration or content; route of administration, dosage form; unit; amount; unit price and the total value of that medicine. In case an active ingredient has many names of original brand-name drugs or equivalent drugs treated with original brand-name drugs or reference biologicals, which have been announced by the Health Ministry on the List of original brand-name drugs or the List of generic drugs treated with original brand name drug or reference list of drugs, the name of the brand name must contain the name of the brand name brand name drug or the drug being treated with the brand name brand name drug or reference product;

c) Each part of the bidding package of herbal medicine or traditional medicine includes the following information: drug name; route of administration, dosage form; unit; amount; drug group;

unit price and the total value of that medicine. The writing of drug names complies with Clause 3 of this Article.

d) Each part of a bidding package of herbal ingredients or traditional herbal bidding package includes the following information: name of herbal material or traditional medicine; science name; quality standards; primary processing or processing methods; drug group; unit; amount; unit price and the total value of that medicine.

2. Form of preparation of drugs belonging to bidding packages of generic drugs, bidding packages of herbal medicines, traditional medicines in the contractor selection plan shall comply with the provisions in ***Appendix 4*** to this Circular. The dosage forms (with an asterisk (*)) are recorded separately in the contractor selection plan on the following principles:

a) Separate only when there is the same dosage form as the original brand-name drug or reference product with the same active ingredient, route of administration or drug with the same active ingredient and route of use licensed for circulation in the SRA country;

b) If the drug does not fall into Point a Clause 2 of this Article, the health facility must clearly explain the need for use of this dosage form in terms of necessity, expected amount of use and use only in the school. necessary when it is impossible to use other dosage forms or use other dosage forms but do not meet treatment;

3. The inscription of names of medicines in bidding packages of materia medica and traditional medicines shall be carried out as follows:

a) Only the ingredients are listed, not the trade names;

b) If the drug has the same composition and dosage form: only the concentration and content of the drug ingredient must be shown only when the difference in concentration or content leads to the difference in dose and indications of treatment of and must consult with the Council of Drugs and Treatment.

4. Bidding package prices:

a) Bidding package price is the total value of bidding package, including all expenses for implementation of bidding package;

b) In case the bidding package is divided into many parts, apart from writing the total value of the bidding package, each part must clearly state the unit price and the total value of such part according to the provisions of Clause 1 of this Article. The unit price of drugs in the contractor selection plan is proposed by the health facility and takes responsibility for the suitability of the unit price of drugs;

c) When preparing the contractor selection plan, the unit must refer to the winning prices of drugs and materia medica within the previous 12 months of medical facilities managed by the Ministry of Health (the Drug Administration of Vietnam, the Drug Administration of Medicine and Pharmacy traditional medicine) published on the website as a basis to formulate the unit price of each drug and medicinal herb, specifically:

- Refer to the winning prices of drugs and herbal ingredients on the websites of the Drug Administration of Vietnam, the Administration of Traditional Medicine, Traditional Medicine as a basis for setting the unit price of each drug on the following principles: The planned price of each drug drugs and materia medica must not be higher than the highest bid-winning price of such drug or medicinal ingredient in each group of announced technical criteria;

- For drugs and medicinal materials not yet announced winning bid prices or prices at the time of planning are higher than the winning prices announced by the Ministry of Health (the Drug

Administration of Vietnam, the Medicine Administration, Traditional Medicine) announced Within the previous 12 months, the health facility must refer to the quotation or sales invoice of at least 03 vendors on the market at the time of contractor selection planning; at the same time, ensure that the plan prices proposed by establishments do not exceed the effective wholesale and re-declared wholesale prices of the drugs referenced (except for traditional medicines and herbs). For drugs and pharmaceutical materials that have few suppliers, do not have full 03 quotations or sale invoices, heads of medical establishments shall base themselves on quotation or sale invoices of suppliers, explain and take responsibility. The prices proposed by the establishments are consistent with the prices of such drugs and pharmaceuticals on the market at the time of making contractor selection plans.

d) The formulation of planned prices of goods of the same active ingredient, concentration or content, dosage form of a generic drug bidding package must ensure the following principles:

- The price of Group 1 plan is not higher than the price of original brand-name drug or reference biological product;

- The prices of Group 2 and Group 3 prices are not higher than the prices of original brand-name drugs or reference biological products and Group 1;

- The price of Group 4 plans is not higher than the prices of original brand-name drugs or reference biologicals; Group 1; Group 2 is manufactured in Vietnam and Group 3;

- The price of Group 5 plan is not higher than the price of original brand-name drug or reference biological product; Group 1; Group 2; Group 3 and Group 4.

5. Capital sources: Medical establishments must clearly state the capital sources used for drug purchase; in case of using official development assistance capital or concessional loans, the donor name and capital structure and capital structure must be clearly stated. including aid capital, domestic reciprocal capital (if any).

6. Forms and methods of contractor selection:

a) Contractor selection method:

Health facilities shall base on the size and nature of each bidding package to select one of the contractor selection forms prescribed from Article 20 to Article 25 of the Bidding Law and the specific guidance in this Circular.

b) Method of contractor selection:

The health facility shall base on the form of contractor selection, the size of bidding package to propose methods of selecting contractors as prescribed in Articles 28 and 29 of the Bidding Law, Decree No. 63/2014 / ND- CP and specific guidance in this Circular. For bidding packages of small-sized drug procurement but need to be selected based on a combination of quality and price, the method of selecting a two-stage bidding package may be applied.

7. Time to start selecting contractors:

Enter the estimated time for issuing bidding documents, request dossiers by month or quarter in the year.

8. Type of contract:

Based on the size and nature of the bidding package and the mode of supply to select and apply the form of contract as prescribed in Article 62 of the Bidding Law accordingly.

9. Contract performance time:

Stipulated in the contractor selection plan but not later than 12 months from the day the contract takes effect.

Article 15. Submitting for approval of contractor selection plan

1. Responsibility to submit contractor selection plans:

a) The head of the health facility must be responsible for making a plan to select drug procurement contractors to ensure the supply of drugs for treatment at the health facility.

b) No later than 03 months prior to the expiry date of the signed drug supply contract, the Head of the health facility shall submit the annual contractor selection plan to the competent person or the authorized person. approve the contractor selection plan specified in Clause 1 Article 17 of this Circular for consideration and approval.

2. A document to submit a plan to select a drug supply contractor includes the following basic contents:

a) Bases for making a plan to select drug suppliers shall comply with Article 13 of this Circular;

b) The contents of the contractor selection plan comply with Article 14 of this Circular and must be specified as follows:

- Name of bidding packages, price of each part and price of bidding package, total value of bidding packages in contractor selection plan and basis of division of bidding packages. In case of purchasing drugs from state budget estimates, the total value of bidding packages in the contractor selection plan must not exceed the approved total drug purchase estimate;

- The form and mode of contractor selection for each bidding package is in one of the forms and modes of contractor selection prescribed from Article 19 to Article 26 of this Circular. In case of not applying the open bidding method, the document on the submission of a plan on contractor selection must clearly state the reason for proposing the application of another form of contractor selection to the competent person for consideration and decision;

- Explanation on increasing the use rate of drugs manufactured in Vietnam under the guidance of the Ministry of Health.

3. Documents attached to the submission of a contractor selection plan for approval:

a) Summary report on the results of contractor selection, the situation of drug use in the preceding year and a brief explanation of the contractor selection plan being submitted;

b) Documents serving as a basis for making the plan to select drug suppliers as prescribed in Article 13 of this Circular;

c) The minutes of meeting of the Drug and Treatment Council of the health facility regarding the list, quantity of drugs, the need to use the original brand-name drug or an equivalent drug treated with the original brand-name drug or reference product, such as The demand for drugs in the form of dosage form is specified in the contractor selection plan as prescribed in Clause 2 Article 14 of this Circular, the name of the drug and the concentration or content of the drug in the bidding package of herbal medicine or antique medicine transmission;

d) The investor's decision approving the source of capital, the approved list, quantity and planned price of items in the contractor selection plan.

4. Dossiers of submission of plans for approval shall be sent by post or directly or in writing according to instructions of competent agencies to units assigned to appraise contractor

selection plans. The document submitted to the contractor selection plan for approval is made according to the form prescribed in Appendix 5 enclosed herewith.

Article 16. Appraisal of contractor selection plans

The plan to select drug suppliers must be verified before submitting to the competent person specified in Clause 1 Article 17 of this Circular for approval.

1. Organization of evaluation:

a) Public health facilities under the management of Ministries, Ministerial-level agencies and Government-attached agencies: The competent persons defined at Point a, Clause 1, Article 17 of this Circular shall decide units to act as focal points for organization. appraising contractor selection plans;

b) Public medical facilities under local management:

- For bidding packages for drug purchase with the Chairman of the provincial People's Committee competent to approve the contractor selection plan, the Health Service is responsible for appraising the contractor selection plan.

- For bidding packages for drug purchase that the President of the provincial-level People's Committee decentralizes approves the contractor selection plan, the decentralized person shall appoint a unit with functions and tasks suitable to the nature of the group bidding package. appraise the contractor selection plan before approval.

c) For health facilities other than Points a and b, Clause 1 of this Article, the person responsible before the law of the establishment or the person authorized by the person responsible before the law of the establishment decides the unit. act as the focal point in organizing the evaluation of contractor selection plans.

2. Tasks of the evaluation unit:

a) Inspect and evaluate the contents as prescribed from Article 7 to Article 15 of this Circular within 20 days from the date of receipt of all relevant documents. In case of insufficient documents as prescribed, the appraisal unit is responsible for notifying, requesting additional documents or returning documents to the health facility within 05 working days from the date of receiving the documents. ;

b) Make a report on appraisal of contractor selection plan using the form in ***Annex 6*** enclosed with this Circular. Appraisal report enclosed with 01 set of application for approval of contractor selection plan of the approved health facility (original copy) to submit to the competent person specified in Clause 1 Article 17 of this Circular for consideration and approval contractor selection plan.

Article 17. Approval of contractor selection plan

1. Competence to approve contractor selection plans:

a) Ministers, heads of ministerial-level agencies, heads of government-attached agencies shall approve plans on selection of drug supply contractors of medical establishments under their management. Ministers, heads of ministerial-level agencies, heads of government-attached agencies are authorized to approve plans to select contractors for a number of bidding packages to supply drugs to heads of medical establishments under their management. In this case, the decentralized person shall appoint a unit with functions and tasks suitable to the nature of the bidding package to organize the plan evaluation before approval.

b) The President of the People's Committee of the province is responsible for approving the selection of drug suppliers of health facilities under the management of the province or city. The President of the People's Committee of the province is decentralized to approve the contractor selection plan for a number of bidding packages to supply drugs to the heads of health facilities under the management of the province or city. In this case, the decentralized person shall appoint a unit with functions and tasks suitable to the nature of the bidding package to organize the evaluation of contractor selection plan before approving it.

c) The person responsible before the law of the health facility or the person authorized by the person responsible before the law of the health facility is responsible for approving the plan to select drug suppliers for the facility. The health insurance does not belong to Points a and b, Clause 1 of this Article.

d) The decentralization and approval of plans on selection of contractors for drug procurement by medical establishments of the armed forces comply with the guidance of the Ministry of Defense and the Ministry of Public Security.

2. Within 5 working days after receiving the appraisal report and the dossier submitted for approval of contractor selection plan of a medical establishment, the competent person defined in Clause 1 of this Article shall: approve the contractor selection plan.

3. A plan to select a drug supply contractor must be posted on the national bidding network system according to Article 8 of the Bidding Law and its guiding documents.

Article 18. Provisions on self-selection of contractors for drugs on the list of concentrated bidding drugs and the List of medicines negotiating prices of medical establishments

1. Medical establishments may themselves select contractors for drugs on the list of concentrated bidding medicines and the list of medicines subject to price negotiation and must ensure that the time and quantity must not exceed the use demand. within 12 months (counting from the date the concentrated procurement unit gives written notice) when falling into one of the following cases:

a) Medical establishments wishing to use drugs on the List of drugs subject to concentrated bidding, the List of drugs subject to price negotiation but no results of selection of concentrated contractors or results of price negotiation have been announced;

b) The drug is on the List of drugs in concentrated bidding, the List of drugs with price negotiation and signed a supply contract but the successful bidder fails to supply the drug and there is a notice of the concentrated procurement unit about the establishment. health may organize the selection of contractors to ensure the supply of drugs in service of medical examination and treatment;

c) The health facility has exhausted the amount of drugs distributed in the framework agreement and exceeds the regulatory capacity specified in Clause 5 Article 37, Clause 13 Article 40 and Clause 12 Article 41 of this Circular;

d) Medical establishments are established after completing the consolidation of drug purchase demands, which exceeds the regulating capacity of the National Centralized Drug Shopping Center and local-level concentrated drug procurement units.

2. Medical establishments shall not organize selection of contractors for drugs on the list of national-level concentrated bidding drugs, drugs on the list of locally-focused concentrated bidding drugs and medicines on the list of drugs subject to price negotiation if at By the time of issuance of the tender invitation documents, results of contractor selection and framework agreement have been announced, except for the cases specified at Points b, c and d, Clause 1 of this Article. Where the medical establishment still organizes contractor selection and signs a contract with another contractor, the contractual payment shall not be made.

Section 2. FORMS OF SELECTION OF CONTRACTORS

Article 19. Open bidding

Open bidding applies to all bidding packages under the scope of regulation of this Circular, except for the cases from Article 20 to Article 24 of this Circular.

Article 20. Restricted bidding

1. Restricted bidding is applied in the case of purchasing drugs subject to special control on the list promulgated by the Ministry of Health and drugs of a specific nature that only a number of contractors satisfy the requirements of the bidding package.

2. Drug manufacturers and suppliers that have been pre-selected by the Ministry of Health to be on the list of drug manufacturers and suppliers that satisfy the requirements on capacity, experience and prestige according to the provisions of Point dd Clause 1 Article 77 of Decree No. 63/2014 / ND-CP is invited to participate in the limited bidding process if drugs are available in accordance with the bidding package.

Article 21 Appointment of contractors

1. Cases of appointment of common contractors and shortened appointment of contractors:

a) The appointment of a common bidder applies to bidding packages for drug purchase with a limit not exceeding VND 1 billion as prescribed at Point e, Clause 1, Article 22 of the Bidding Law;

b) Shortened appointment of contractor is applied to bidding packages in the cases specified at Point a, Clause 1, Article 22 of the Bidding Law and Article 79 of Decree No. 63/2014 / ND-CP.

2. The process of appointment of general contractors and shortened appointment of contractors:

a) The process of appointment of a common contractor is specified in Article 55 of Decree No. 63/2014 / ND-CP.

b) The shortened process of appointment of contractors complies with Article 56 of Decree No. 63/2014 / ND-CP after the approved contractor selection plan.

In case of appointment of contractor under the provisions of Point a, Clause 1, Article 22 of the Bidding Law, except for bidding packages to be performed to ensure state secrets, the provisions of Clause 8, Article 6 of Circular No. 10/2015 are complied with. / TT-BKHDT October 26, 2015 of the Minister of Planning and Investment detailing the contractor selection plan.

Article 22. Competitive quotation

1. Bidding packages shall be conducted in the form of competitive quotation when fully satisfying the following requirements:

a) The value of the bidding package does not exceed 05 billion;

b) Drugs on the List of essential drugs promulgated by the Ministry of Health or common drugs, which are available on the market with standardized specifications and quality of drugs;

c) Having a plan to select contractors approved by competent persons;

d) In case of buying from the state budget, there must be an approved drug purchase estimate. In case of purchasing medicines from other revenue sources, medical establishments must ensure the capital sources for payment according to the implementation schedule of bidding packages.

2. The process of competitive offers complies with Articles 58 and 59 of Decree No. 63/2014 / ND-CP .

Article 23. Direct procurement

1. Bidding packages are allowed to apply direct procurement when fully satisfying the following requirements:

a) The contractor has won the tender through the open bidding or limited bidding and has signed a contract to perform the previous bidding package;

b) The bidding package has the same content, similar nature and the scale is 130% smaller than the bidding package signed the previous contract. If a drug in a direct procurement package is one of many drugs belonging to a similar bidding package that has previously signed a contract, the quantity of the drug applied for direct procurement must be less than 130% of that of the same type of drug belonging to the same package. Similar contractors have signed previous contracts;

c) The unit price of drugs belonging to the bidding package applying the form of direct procurement must not exceed the unit price of the corresponding drug under the previously signed bidding package, and must be consistent with the successful bid of the successful bid. announced at the time of approving the contractor selection plan;

d) The time limit from the signing of the previous bidding package to the date of approval for direct procurement results shall not exceed 12 months. Within 12 months, the health facility may only procure directly once for each item of the bidding package that was signed in the previous contract. In special cases, the health facility must send a written request to the competent person. rights prescribed in Clause 1, Article 17 of this Circular for consideration and decision.

2. Where contractors performing previous contracts are unable to continue performing direct procurement bidding packages, the form of direct procurement may apply to other contractors if they satisfy the capability requirements. , experience, techniques, prices required by the bidding documents, and results of previous contractor selection.

3. The process of direct procurement complies with Article 60 of Decree No. 63/2014 / ND-CP .

Article 24. Self-implementation

1. Self-implementation is applicable to bidding packages specified in Article 25 of the Bidding Law when all the requirements specified in Article 61 of Decree No. 63/2014 / ND-CP are fully met.

2. The process of self-implementation complies with Article 62 of Decree No. 63/2014 / ND-CP .

Section 3. METHODS OF SELECTION OF SUPPLIERS OF DRUGS

Article 25. Single-stage one-file procedures

Methods of selection of one-stage one-supply drug supply contractors apply in the following cases:

1. Bidding packages for buying medicines in the form of open bidding, limited bidding but with small scale as prescribed in Article 63 of Decree No. 63/2014 / ND-CP ;

2. Bidding packages for purchasing medicines in the form of competitive offering;

3. Bidding packages of purchasing drugs in the form of direct procurement;

4. Bidding packages for purchasing medicines in the form of bidder appointment

Article 26. Mode of a two-stage dossier bag

The method of selecting a one-stage contractor with two dossiers bags is applied in the following cases:

1. Bidding packages for drug procurement in the form of open bidding, limited bidding, with bidding packages valued at over 10 billion dong.

2. Bidding packages for procurement of medicines in the form of open bidding or limited bidding shall have a bidding package price of no more than VND 10 billion but such drug should be selected on the basis of a combination of quality and price.

Section 4. BIDDING DOSSIER, DOSSIERS FOR REQUIREMENT OF DRUGS

Article 27. Preparation of bidding documents, dossier of requirements

1. The compilation of bidding dossiers and dossiers of request for drug purchase must comply with the Bidding Law, the documents detailing the implementation and the following provisions:

a) Bidding documents, dossier of request for bidding packages of original brand-name drugs or equivalent treatment, bidding packages of generic drugs and bidding packages of herbal medicines, traditional medicines shall comply with the form of bidding dossier to purchase medicines applying the method final phase of a bag of documents specified in ***Appendix 7*** or the form of bidding dossier for drug procurement shall apply the method of one stage of two dossier bags specified in ***Appendix 8*** promulgated together with this Circular.

b) Bidding documents, request for traditional herbal bidding packages and bidding packages for herbal ingredients comply with the Ministry of Health's instructions detailing the bidding documents for bidding for procurement of traditional herbal ingredients and herbs at health facilities.

2. Based on the contractor selection plan approved by the competent authority, the bid solicitor shall make a bidding dossier, a dossier of request for medicine purchase and send a dossier of approval to the unit in charge of evaluation. bidding documents, request for proposals.

3. For drugs on the list of home-made drugs that meet the treatment, drug price and supply capability requirements, promulgated together with Circular No. 03/2019 / TT-BYT of March 28, 2019 of The Minister of Health (hereinafter referred to as Circular No. 03/2019 / TT-BYT), when making bidding documents, the dossier requires health facilities to clearly state not to offer import drugs. The same group of technical criteria, specifically:

a) For drugs with technical specifications in the List enclosed with Circular No. 03/2019 / TT-BYT being WHO-GMP, contractors are not allowed to offer imported drugs with Group 5 technical criteria as prescribed in Clause 5. Article 7 of this Circular.

b) If the drug has technical criteria in the List enclosed with Circular No. 03/2019 / TT-BYT is EU-GMP, the contractor is not allowed to offer imported drugs with Group 2 technical criteria as prescribed in Clause 2 Article 7 of this Circular.

4. For herbal ingredients on the List of pharmaceutical materials grown and collected domestically, meeting the treatment and supply capacity requirements, reasonable prices announced by the Health Ministry under the technical criteria of any group In bidding dossiers, dossiers of requirements must not offer imported pharmaceutical materials of that group.

5. For drugs on the list of home-made drugs that meet the treatment, price and supply requirements or pharmaceuticals on the list of domestically grown and collected medicinal herbs that meet the treatment, supply capacity, reasonable price and sudden increase in demand

exceed the supply capacity of domestic manufacturing facilities, medical facilities need to use imported drugs or pharmaceutical materials to meet treatment needs. Basing itself on the reports of medical establishments and the situation of drug supply, the Minister of Health shall decide on the bidding for imported drugs or materia medica of the same group of technical criteria with drugs on the list of drugs manufactured in The country meets the treatment, drug price, and supply or medicinal ingredient requirements of the List The list of medicinal materials that are cultivated and collected domestically meets treatment requirements, supply capacity and reasonable prices within a specified period of time to ensure adequate supply of drugs or materia medica serving treatment needs.

Article 28.- Evaluation of bidding dossiers and request for proposals

1. Bidding dossiers and dossiers of request for drug supply must be appraised before being submitted to heads of medical establishments for consideration and approval.

2. Units appraising bidding dossiers and dossier of requirements shall be decided by heads of medical establishments.

3. Tasks of evaluation units:

a) Examining the contents of the bidding documents, request for proposals in accordance with the Bidding Law, documents guiding the implementation of contractor selection and the provisions of this Circular;

b) Make a report on evaluation of bidding documents, request for proposals according to regulations of law on contractor selection, enclose 01 set of bidding documents, request for proposals (original copy) and submit them to the Head of the establishment. Medical review and approval within 20 days from the date of receipt of all relevant documents.

Article 29. Approving bidding documents, request for proposals

The head of a health facility is responsible for approving the bidding documents and request for proposals within 10 days from the day on which the satisfactory application is received and the appraisal report issued by the unit appraising the bidding documents. profile required.

Section 5. ORGANIZATION OF SELECTION OF CONTRACTORS OF DRUGS

Article 30. Bid security, submission of bids and proposals

1. The head of a health establishment (or the tenderer) must specify the value of bidding security equal to the specific sum of money in the bidding dossier and dossier of requirements according to the following principles:

a) The bid guarantee value of the bidding package is equivalent to 1% to 3% of the bidding package price, for small-sized bidding packages, the value of bidding guarantee is from 1% to 1.5% of the bidding package price.

b) If the bidding package is divided into several parts, the value of bidding guarantee of each part is expressed by the specific value equivalent to 1% to 3% of that part of the price in the bidding package price, for bidding package small-scale bid security value from 1% to 1.5% of that part of the bidding package price.

2. Contractors may participate in one or some or all parts of a bidding package. In case of participating in some parts of a bidding package, the value of bidding security which must be guaranteed by contractors is equal to the total value of bidding security of the parts of such contractors.

3. Contractors may select by themselves one of the following bid security forms:

a) Deposit;

b) Deposit;

c) Letter of guarantee from a credit institution or branch of a foreign bank established under the laws of Vietnam.

Investors are not required to perform any of the above three forms by the contractor.

4. The effective period of bids, dossiers of proposals shall be prescribed by the bid solicitor in the bidding dossiers and dossiers of requirements but must not exceed 180 days from the date of bid closure. In case of necessity, extension of the period of validity of bids and proposals may be extended and the schedule of drug supply by the medical establishment must be ensured. Bidders must submit at least 02 sets (01 original and 01 photocopy) of the bid or proposal as prescribed in the bidding documents, request for proposals to bid solicitors before the deadline for bid closure.

Article 31. Evaluation of bids, dossiers of proposals

1. Depending on the nature and scale of the bidding package and the form and mode of contractor selection, the head of a medical establishment may select a method to evaluate bids and proposals specified in Article 39 and Article 41 Law on tendering accordingly. The method of evaluation of bids and proposals must be specified in the bidding documents and request for proposals.

2. The bid solicitor shall evaluate bids and proposals according to each part of each bidding package, for bidding packages consisting of many parts on the basis of compliance with the provisions of the Bidding Law and the Health Ministry's regulations on preparing bidding documents, dossiers of request for purchase of medicines in medical establishments. For the evaluation of the contractors' capability and experience, the total part of the bidding package that the contractor attends.

3. Criteria for evaluation of bid dossiers, dossiers of proposals shall comply with the form of bidding dossier prescribed in ***Appendix 7*** or ***Appendix 8*** promulgated together with this Circular and must be specifically written in bidding dossiers , required records. The tenderer must be responsible for implementing incentives in contractor selection in accordance with Articles 3, 5 and 6 of Decree No. 63/2014 / ND-CP .

4. The process of evaluation of bids and dossiers of proposals: Depending on the mode of selection of contractors already approved by competent authorities, specifically:

a) A one-stage method of dossier bag: comply with Article 15 to Article 18 of Decree No. 63/2014 / ND-CP ;

b) A two-stage method of dossier bags: comply with Article 27 to Article 30 of Decree No. 63/2014 / ND-CP .

5. The maximum time for evaluation of a proposal is 30 days; The maximum bid is 45 days; For small-sized bidding packages, the time limit for bid evaluation is 25 days, counting from the date of bid closure to the date the bid solicitor submits to the head of the medical establishment for approval the contractor selection result. In case of open bidding, limited bidding according to the method of one stage of two bags of documents, the time for evaluation of bid shall be equal to the total time of evaluation of technical proposals (calculated from the date of time). point of bid closure till the date the bid solicitor submits to the Head of the health facility for approval a list of contractors meeting technical requirements) plus the time to evaluate the financial proposal (calculated from the date of opening the dossier). financial proposals are up to the date the bid

solicitor submits to the Head of the health facility for approval the contractor selection result). In necessary cases, the time limit for evaluation of bids and proposals may be extended but must not exceed 20 days and must ensure the schedule of drug supply to medical establishments.

Article 32. Contract negotiation and proposal of winning bid

1. Contract negotiation shall comply with the provisions of Article 19 of Decree No. 63/2014 / ND-CP and conducted before the bid solicitor proposes to win the bid.

The tenderer has the bid price after error correction and deviation adjustment, minus the lowest discount (if any) for the lowest price method; has the lowest evaluation price for the evaluation method; has the highest overall score for the first-ranked combination of technology and price and is invited to negotiate a contract.

In case the bidder is invited to negotiate the contract but does not come to negotiate or refuses to negotiate the contract, the contractor will not get back the bid security.

2. Conditions for consideration of bid-winning proposals comply with Article 43 of the Bidding Law and the form of bidding dossier are provided in ***Appendix 7*** or ***Appendix 8*** to this Circular.

The bid solicitor shall propose to win each part of the approved contractor selection plan on the basis of compliance with the provisions of the Bidding Law, this Circular and documents detailing the implementation of management. drug quality and drug price management. Each part of a bidding package may propose to win only one drug or medicinal ingredient that satisfies the technical and quality requirements specified in the bidding dossier, dossier of requirements and has bid price after error correction and deviation adjustment. , minus the lowest discount (if any) to the lowest price method; has the lowest evaluation price for the evaluation method; has the highest overall score for the combination of technology and price in that drug group.

3. In case the bid price after error correction, deviation adjustment and discount deduction (if any) of all contractors that satisfy technical requirements and are included in the ranking list exceeds the price of that part of the approved bidding package shall be considered and handled as follows:

a) If the price of that part of the contractor selection plan has been approved and determined to be reasonable, the bid solicitor shall request the contractor to re-bid in accordance with Clause 8 Article 117 of Decree No. 63/2014. / ND-CP ;

b) In case the price of that part of the contractor selection plan is unreasonable, the bid solicitor must make a written report, explanation and proposal for adjustment of that part's price and bidding package price for the competent person to see. review and decision;

c) In case of necessity, there must be enough drugs to meet the medical examination and treatment needs of health facilities, the bid solicitor may consider and decide on the winning bid according to the principle of consideration in the order of rating. bidders when fully meeting the following conditions:

- The price of the approved drug does not exceed the valid wholesale price declared and re-declared by that drug;

- The total value of drugs proposed to be won by the bidders does not exceed the total value of those parts in the contractor selection plan approved by competent authorities.

Article 33. Reports submitted to evaluation of contractor selection results

1. The bid solicitor shall send 1 set of dossier to the unit assigned with the task of evaluating the result of contractor selection, including:

a) 01 original copy of the bid evaluation report;

b) 01 set of bidding documents, request for proposals (copy) that have been appraised and approved in accordance with Articles 27, 28 and 29 of this Circular and other provisions of the bidding law.

2. The process of reporting, evaluating, approving and publicizing contractor selection results complies with Article 20 of Decree No. 63/2014 / ND-CP.

Article 34. Appraisal and submission of contractor selection results

1. The head of a medical establishment is responsible for establishing or assigning a unit to organize the evaluation of drug supply contractor selection results.

2. Tasks of the evaluation organization:

a) Within 20 days (for small-sized bidding packages within 10 days), from the date of receipt of all relevant documents, the appraisal unit organizes to inspect and evaluate the selection process. contractors defined in Articles 30, 31 and 32 of this Circular;

b) Prepare appraisal report and submit it to the Head of the health facility for consideration and approval of contractor selection result in accordance with this Circular and the law on bidding.

3. A dossier of submission for approval of contractor selection results comprises:

a) 01 original copy of the contractor selection result evaluation report;

b) 01 set of dossier for approval of contractor selection result (original copy) of the bid solicitor.

Article 35. Approval and notification of contractor selection results

1. Within 10 days (for small-sized bidding packages for a maximum of 5 working days), counting from the date of receipt of complete dossiers of submission of contractors' selection results for appraisal units prescribed in Clause 3, Article 34 of this Circular, the head of the health facility is responsible for approving the contractor selection result.

2. When the contractor selection results are approved, the bid solicitor shall notify in writing the contractor selection results to the contractors according to the provisions of bidding law.

3. For unselected contractors, written notices on contractor selection results must clearly state the reasons why contractors fail to win them.

4. In cases where a bidding package has many separate parts but the bid evaluation time may affect the medicine supply schedule of a medical establishment, the bid solicitor may consider and approve the selection results. The contractor shall allow one or more components into different batches to ensure the medicine supply schedule.

5. When bidding packages of medicines have no bidders or no successful bidders or cannot be handled under Clause 3, Article 32 of this Circular, the bid solicitor shall cancel bidding of those drugs and separate. into another bidding package for submission to the competent person for approval to adjust the contractor selection plan. The time limit for appraisal and approval of adjustment plans complies with Articles 16 and 17 of this Circular. In case information of drug items in the bidding package includes: name of active ingredient; concentration or content; route of administration, dosage form; drug group; unit; amount; the unit price and total drug value do not change from the previously approved plan, the person competent to approve the plan adjustment shall not have to re-evaluate the contractor selection plan.

Article 36. Winning drug prices

The winning bid of each drug must not be higher than the price of that drug in the contractor selection plan approved by an authorized person and must not exceed the valid wholesale price declared and re-declared by that drug, except for cases where In accordance with Clause 3, Article 32 of this Circular.

Article 37. Contract signing, contract performance assurance and drug use that have won the bid

1. Prior to the time of signing the contract, the bid solicitor may increase or decrease the maximum quantity of no more than 10% of the quantity of drug in the bidding plan, provided that there is no change in the unit price or the Other conditions and terms of bids and bidding documents.

2. The selected contractor must apply a contract performance guarantee before the contract takes effect. The value of contract performance guarantee is specified in the bidding documents, request for proposals from 2% to 10% of the contract price. For small-sized bidding packages, the value of contract performance guarantee is specified in the bidding dossier, dossier of requirements at the rate of between 2% and 3% of the contract price.

3. Heads of health facilities and winning bidders shall have to perform drug supply contracts strictly according to the relevant provisions of law on economic contracts, and must implement at least 80% of the value of the medicine. each part of the signed contract. For emergency medicine, antidote, rare medicine, special control medicine, infusion and other situations after reporting to the competent authority, the health facility must ensure at least 50% of the value of each part of the signed contract.

If the health facility fails to perform at least 80% of the value of each part of the signed contract, the head of the health facility must report and explain the reason to the competent person.

4. Medical establishments must not buy more than the quantity of drugs of a group of drugs in the contractor selection results if they have not yet purchased the whole quantity of drugs in other drug groups of the same active ingredient, the same concentration or content, and the same form. The manufacturer has won the contract under the signed contracts.

5. The following cases are allowed to be purchased in excess, but the quantity must not exceed 20% of the quantity of that group of drugs in the signed contract and must not submit to the plan for additional contractor selection:

a) The quantity of drugs of other groups has the same active ingredient, concentration or content, and only the number of drugs in the original brand-name drug package or the equivalent of the drug is retained;

b) Other groups of drugs have the same active ingredients, the same concentration or content has been bid winning but they are forced to stop supplying or the drug is suspended from circulation, the drug is withdrawn from the list of drugs proving bioequivalence after after winning the bid;

c) The contractor has not fully supplied the quantity of drug of a group of drugs in the signed contract but is unable to continue supplying it due to force majeure reasons, in this case, there must be a written notice enclosed with the contract. proof material.

6. In case the bidder has a change in the process of selecting a tenderer or supplying the winning medicine but the substitute drug has not been offered in the bid, the investor may be considered for the contractor to replace the medicine in order to ensure adequate supply of drugs for timely medical examination and treatment work of the units, specifically:

a) Changes related to drug names; name of manufacturing factory; specifications of packaging during the circulation process but the number of registration papers or import licenses has not changed;

b) Change of the number of certificates of free sale or new import licenses but other information remains unchanged (name of drug, manufacturer, quality standards, shelf life, classification of bidders; specific criteria quality standards may vary, but standards and quality standards must not be lower than those of winning drugs (or offered in bids) or updated with new versions of the Pharmacopoeia;

When performing the substitution, the contractor must provide all necessary information so that the bid solicitor can evaluate the replacement, including: photocopy (certified by contractor) products (MA) or Certificate of Pharmaceutical Products (CPP), official dispatches permitting changes or additions of state management agencies (if any) and explanation of unchanged quality standards of the projected drugs. thầu, thuốc đề xuất thay thế;

c) Original brand-name drugs or reference biological products that have won the bidding (or offered in the bid package) with information about circulation registration numbers or other information and substitutes announced by the Ministry of Health announced in the List of original brand-name drugs or the List of reference biological products;

d) Changing the way of writing the name of the medicinal material without changing the nature of the ingredients in the formula and approved by the competent state management agency.

Chapter IV

REGULATIONS ON CONCENTRATION DRUG PURCHASE

Article 38. General provisions on concentrated drug purchase

1. Units purchasing concentrated drugs shall:

a) Summarize the need for drug use, prepare and submit for approval of contractor selection plan, organize contractor selection, finalize and sign framework contract or framework agreement with selected and announced contractors contractor selection results and framework agreement on the website of the Ministry of Health and the website of the Department of Health for health facilities to serve as a basis for completing and signing contracts with contractors. Selection.

b) Supervise the process of implementation of framework agreements and contracts with selected contractors.

2. Local-level concentrated drug-procurement units shall not organize to select contractors for drugs on the list of national-level concentrated bidding drugs and drugs on the list of drugs subject to price negotiation if at the time of issuing the invitation The contractor has the results of contractor selection and framework agreement published on the Ministry of Health website.

3. When formulating and summarizing to report demand for drugs on the List of drugs for national-level concentrated bidding and the List of drugs subject to price negotiation, medical establishments shall not formulate and summarize the remaining drug quantities. in the contract signed with the supplier according to the results of the previous contractor selection.

4. Forms of contractor selection: domestic open bidding;

5. Method of selecting contractors: one phase with two dossiers;

6. Evaluation of bids: Using a combination of techniques and prices for each part of a bidding package.

7. Method of implementation: The concentrated procurement of drugs shall be effected in the manner of signing a framework agreement, except for the following cases where direct contracting is applied:

a) Purchasing drugs and vaccines in service of expanded vaccination under programs and projects funded by the state budget under decisions of the Minister of Health or presidents of provincial-level People's Committees;

b) Purchasing drugs belonging to ODA-funded programs and projects, aid sources and grants of domestic and foreign organizations and individuals that belong to the state budget source, which donors request to apply in the following manner. mode of direct contracting;

8. Organization of evaluation of contractor selection plans:

a) The Department of Planning - Finance is responsible for organizing the appraisal of plans on selection of national-level concentrated drug supply contractors.

b) The Department of Health is responsible for organizing the appraisal of the plan for selection of local-level concentrated drug supply contractors.

c) The appraisal of the plan to select concentrated drug suppliers shall comply with Clause 1 Article 37 of the Bidding Law and Article 16 of this Circular.

9. Contract negotiation:

The contract negotiation shall comply with Clause 1 Article 32 of this Circular. In the process of selecting concentrated contractors, to ensure the economic efficiency of the bidding package, the contract negotiation shall comply with the provisions of Clause 3, Article 19 of Decree 63/2014/ND-CP and may be considered. handle the situation as follows:

a) In case of having a bulk drug item divided into bidding packages as prescribed in Point a Clause 4 Article 40 of this Circular and having the same goods item proposed for winning bid in many bidding packages with the The price difference may be considered in the direction that requires the contractor to analyze the components of the bid price, explain and clarify the price difference of the same item but provided at other locations. together. These analyzes are used as a basis for negotiating a contract towards the price of that medicine item at the tender package with the proposed lower bid price to ensure economic efficiency of the bidding package.

b) In case there is a drug item in a drug group with only 01 registration certificate on the market, there is only one bidder participating, there is no competition in price and the proposed winning price in this group is higher. the proposed winning bid for the same active ingredient, concentration or content, dosage forms of sugar used in other groups with higher technical standards and more competitive prices due to the participation of many contractors, may be viewed consider negotiating a contract with the contractor on the proposed bid-winning price to ensure compliance with the drug grouping according to technical criteria on the following principles:

- The winning bid for Group 1 is not higher than the bid for the brand-name drug or reference biological product;

- The bid winning prices for Group 2 and Group 3 are not higher than the bid for the original brand-name drug or reference biological product and Group 1;

- The winning bid of Group 4 is not higher than the winning price of brand-name brand name drugs or reference biologicals; Group 1; Group 2 is manufactured in Vietnam and Group 3;

- The winning bid of Group 5 is not higher than the winning price of the brand-name drug or reference biological product; Group 1; Group 2; Group 3 and Group 4.

10. In case of a bid change in the process of selecting a contractor or supplying a successful bid but the substitute drug has not been offered in the bid package, the substitution shall comply with Clause 6 Article 37 This Circular aims to ensure adequate supply of drugs for timely medical examination and treatment.

11. The functions, tasks, organizational and operational regulations of the National Centralized Drug Shopping Center shall be decided by the Minister of Health; The functions, tasks, organizational and operational regulations of the local-level concentrated drug procurement unit shall be decided by the President of the provincial People's Committee based on the proposal of the Department of Health.

Article 39. Responsibilities of parties concerned and effect of framework agreement

1. Medical establishments wishing to purchase medicines on the list of concentrated bidding medicines must base themselves on the contractor selection results and framework agreement contents to complete and sign contracts with selected contractors. through centralized procurement under the principle that the contractual unit price cannot exceed the price stated in the published framework agreement. The contractor must take the contract performance guarantee as prescribed in Article 66 of the Bidding Law and Clause 2 Article 37 of this Circular with the health facility before the effective date of the contract.

2. The focal units specified in Clause 1, Article 40 and Clause 2, Article 41 of this Circular shall review and sum up the demand for lists and quantities of drugs of each medical establishment under their management and regulate the implementation of the plan to ensure the use of at least 80% of the amount of drug reported to the concentrated drug buying unit. For emergency medicine; antidote; rare medicine; special control drugs; fluid transfusions and drugs used in other emergency situations after reporting to competent agencies and health establishments to ensure at least 50% of the value of each part of the signed contract.

3. Contractors selected through concentrated drug procurement shall supply medicines according to the quantities and schedules stated in the contracts signed with each medical establishment. During the performance of the contract, the health facility and the contractor may negotiate and adjust the amount of increase or decrease compared to the number of the contract signed on the basis of the provisions of the bidding dossier issued by the unit. Concentrated drug purchase released. The unit in charge of concentrated drug procurement shall coordinate with coordinating units and winning contractors in regulating the implementation of the plan to ensure adequate supply of drugs for medical establishments.

4. The time limit for the performance of concentrated drug purchase contracts (national or local level) is specified in the contractor selection plan approved by competent authorities but must not exceed 36 months from the date of conclusion. concentrated drug purchasing and framework agreement are in effect.

Article 40. Organization of national-level concentrated drug procurement

1. The formulation and synthesis of demands for medicine use are implemented as follows:

a) The health facilities affiliated to the Ministry of Health shall formulate the demand for the list, the quantity of details to each drug, each group and the supply schedule to send to the National Centralized Drug Shopping Center together with the Materials specified in Clause 2 of this Article.

b) Medical facilities managed by local authorities, ministries, regulatory bodies, and health authorities shall prepare the list, quantity of details for each drug, each group and schedule of supply sent to the Purchasing Unit. Centralized concentrated drug procurement.

Local-level concentrated drug procurement units aggregate demand; submit a report to the Department of Health for appraisal and send the plan of drug use to the National Centralized Drug Shopping Center together with documents specified in Clause 2 of this Article.

c) The deadline for sending the summary of drug procurement needs to the National-level concentrated shopping center is before June 15 of every year or at a specific time announced by the National Drug Mall.

2. Documents attached to the written request for concentrated drug purchase demand:

a) Summary report on the result of contractor selection, the situation of drug use in the preceding year, the number of unsold drugs and quantity in the unrealized plan at the time of making the estimate health facilities;

b) A brief explanation of the proposed drug purchase plan; If there is any change in the increase or decrease of over 30% of the used amount of the previous year, there must be specific explanations and explanations;

c) Documents serving as a basis for making the medicine purchase plan specified in Article 13 of this Circular;

d) Minutes of meetings of the Council of Medicines and Treatment of health facilities affiliated to the Ministry of Health or Minutes of review meetings of the Department of Health on the list, quantity of drugs and demands for use of drugs by health facilities. localities, ministries, branches manage and health agencies in the area.

3. The National Centralized Drug Shopping Center organizes a review of the needs of the list and quantity of drugs of each medical establishment managed by the Ministry of Health; summing up demands on the list, quantity and schedule of supply of each drug to formulate a contractor selection plan.

4. A plan to select a construction contractor according to the following principles:

a) If the drug has great demand and a contractor is unable to provide the whole bidding package, it may be divided into different bidding packages by region or by socio-economic region or by the size of bidding package. ensure competition in bidding;

Example: Drug A is on the list of national-level concentrated purchasing drugs, the total demand for use is 100 million tablets / year but no contractor is capable of supplying 100 million tablets / year, the quantity may be divided. Drug A becomes bid packages:

- Divide into 03 packages to provide for 3 regions: Package 1 for health facilities in the North: 40 million tablets; Package 2 for health facilities in Central region: 20 million tablets; Package 3 for health facilities in the South: 40 million tablets;

- Or it may be divided into bidding packages according to 7 socio-economic regions: Northeast, Northwest, Red River Delta; North Central; South Central; South East; Mekong Delta.

b) Division of drug categories in bidding packages and contents of contractor selection plans shall comply with Articles 7 to 14 of this Circular. Contract performance time is specified in Clause 4 Article 39 of this Circular.

5. Organization of evaluation of contractor selection plans:

a) The National Center for concentrated drug procurement shall submit the application for approval of contractor selection plan to the Department of Planning - Finance, Ministry of Health.

b) The appraisal of the plan for selection of drug suppliers on the List of drugs of national concentrated bidding shall comply with the provisions of Clause 2, Article 16 of this Circular. Department of Planning - Finance is the focal point organizing the appraisal of the list, number of bidding packages, planned unit price and quantity of medicines; centralized drug supply contractor selection plan. In case of necessity, the Planning and Finance Department shall consult with the National Advisory Council on drug bidding before submitting it to the Minister of Health for consideration and approval of contractor selection plans.

6. Approving contractor selection plans:

The Minister of Health shall consider and approve the contractor selection plan at the proposal of the Department of Planning and Finance.

7. Prepare contractor selection:

Based on the contractor selection plan approved by the Minister of Health, the National Center for concentrated drug procurement shall formulate bidding documents, organize appraisal and approval of bidding documents as prescribed in Article 27, 28 and Article 29 of this Circular.

8. Organization of contractor selection:

The National Centralized Drug Shopping Center shall organize the selection of contractors, evaluate bids, negotiate contracts and propose winning bids, and submit reports on evaluation of contractor selection results according to The provisions of Articles 30, 31, 32 and 33 of this Circular.

9. Evaluation, approval and publicization of contractor selection results:

a) Based on the results of bid evaluation and negotiation of the contract or framework agreement with contractors, the National Center for concentrated drug procurement shall organize the evaluation and approval of contractor selection results according to regulations. Article 34 and Article 35 of this Circular. In case of necessity, consult with the National Advisory Council on drug bidding before approving the contractor selection results;

b) The National Centralized Procurement Center shall notify and publicize the result of contractor selection in accordance with the Law on Bidding.

10. Completing, signing contract or framework agreement:

a) The National Center for concentrated drug procurement is responsible for completing, signing contracts or framework agreements with the winning bidders according to the provisions of the Bidding Law; publicize the framework agreement on the Ministry of Health web portal and notify in writing to medical establishments under the Ministry of Health, branches and local Departments of Health;

b) The unit collecting and proposing drug use requirements as prescribed in Clause 1 of this Article shall notify the result of contractor selection and framework agreement to health facilities under the scope of supply. of the framework agreement.

11. Completing and concluding drug supply contracts:

National Centralized Drug Shopping Center (in the case of direct contracting); Health facilities shall base themselves on the results of selection of drug suppliers, framework agreements, demands and drug use plans of registered medical establishments with focal points to complete and sign contracts. contract with the contractor on the following principles:

a) Conform to the conditions provided within the framework agreement;

b) The price of each drug in the contract must not exceed the bid-winning price announced by the National Center for concentrated drug procurement;

c) Contract performance period: specified in the contractor selection plan approved by the competent authority, but not later than 36 months from the day on which the results of concentrated drug purchase and the framework agreement take effect. to the date the parties fulfill their obligations under the contract.

12. Report on implementation of results of selection of national-level concentrated contractors:

a) Before the 10th day of every month and the first 10 months of each quarter or unexpectedly upon request, the contractor shall report the process of performance of drug supply contracts on the List of national-level concentrated bidding drugs according to a set form specified in ***Appendix 9*** and ***Appendix 10*** issued with this Circular and sent to the National Centralized Drug Shopping Center.

b) Before the first 10 months of each quarter or irregularly upon request, the health facilities managed by the local authorities, the health facilities managed by the Ministries and branches in the area shall send reports to the drug procurement units. Concentrate at the local level according to the form in ***Appendix 11*** enclosed herewith.

c) Before the first 15 months of each quarter or unexpectedly upon request, the local-level concentrated drug procurement unit or health facility affiliated to the Ministry of Health shall report the process of implementation of the drug supply contract under The list of drugs for national-level concentrated bidding is made according to the form provided in ***Appendix 11*** to this Circular and sent to the National Center for concentrated drug procurement.

13. Supervising and regulating the process of implementing framework agreements:

The National Centralized Drug Shopping Center and local-level concentrated drug procurement units shall supervise and regulate the supply of drugs at medical establishments in accordance with the signed framework agreement under the guidance of The National Centralized Drug Shopping Center is on the following principle:

a) If the demand for drugs of a health facility is managed by a local authority, the health facility managed by the ministry or branch in the area where the demand for drugs exceeds 20% of the amount of medicine distributed in the agreement The framework must be reported to the local-level concentrated drug-purchasing unit in order to synthesize and regulate the quantity of drugs among medical establishments within the scope of local supply but ensure that it does not exceed 20% of the total amount supplied. allocate in framework agreement to units within the scope of local supply. Within 10 days after receiving a written request for regulation of a medical establishment, the unit in charge of concentrated drug procurement at the local level must reply in writing to the unit.

b) In case the demand for drugs of a health facility affiliated to the Ministry of Health exceeds the amount of drugs allocated in the framework agreement or the demand of a health facility managed by the local authority, Ministries and regulatory agencies in the area that exceed the regulatory capacity of local-level concentrated drug procurement units or health facilities have a need to use drugs but have not synthesized the needs when developing a plan If the contractor selects to buy drugs, it must report to the National Centralized Drug Shopping Center to regulate the quantity of drugs between units. Within 05 days from the receipt of the regulatory request report from a health facility in the area, the local-level concentrated shopping unit shall send a report to the National concentrated drug shopping center according to the prescribed form. in Appendix 12 issued together with this Circular.

Within 10 days after receiving a written request for regulation of a medical establishment, the National Centralized Drug Shopping Center must reply in writing to the unit.

The quantity of regulated drugs of the National Centralized Drug Shopping Center must not exceed 30% of the total amount approved in the plan for selection of drug contractors on the national list of concentrated bidding drugs. The regulation of drugs shall comply with the process of drug regulation on the List of national-level concentrated bidding drugs promulgated by the National Center for concentrated drug procurement.

14. Payment and settlement of drug supply contracts:

National Centralized Drug Shopping Center (in the case of direct contracting); Health facilities (in the case of applying a framework agreement) are responsible for payment and settlement with suppliers in accordance with the current provisions of law and the terms of the signed contracts.

The written agreement on drug regulation between units of the concentrated procurement unit is a part of the medicine sale and purchase contract and serves as a basis for medical establishments and contractors to sign the contract annex (for goods items) have been regulated in the framework agreement) or signed a contract (for regulated items not yet allocated in the framework agreement).

Article 41. Organization of concentrated drug purchase at the local level

1. Formulating and synthesizing demands for medicine use:

a) List of drugs for local-level concentrated bidding applied to local health facilities, including local health facilities, central health facilities, and health facilities affiliated to Ministries and branches. local health management and agencies. Central health facilities, health facilities affiliated to Ministries, regulatory bodies, and health authorities are responsible for formulating drug use plans and complying with regulations on selection of concentrated drug contractors in their localities. as a locally managed health facility. Local-level concentrated drug procurement units shall sum up demands and organize selection of drug contractors for local medical establishments, central-level medical establishments and ministerial-level medical establishments. management and health agencies are locally based as for local health facilities.

b) Based on the List of drugs in centralized bidding at local level, health facilities affiliated to provinces and centrally run cities (including local health facilities, central health facilities, health departments under the management of the Ministry of Health and agencies) formulate demand for use and send it to the local-level concentrated drug-purchasing unit;

c) List and quantity of drugs sent to the local-level concentrated drug-purchasing unit before July 15 every year or at a specific time announced by the local-level concentrated drug-purchasing unit;

2. The local-level concentrated drug-purchasing unit shall organize the review of the need for the list and quantity of medicines of each medical establishment participating in the concentrated-level drug purchase at the local level; summing up demands on the list, quantity and schedule of supply of each drug to formulate a contractor selection plan.

3. Making contractor selection plans: The local-level concentrated drug-purchasing units shall divide drugs groups in bidding packages and the contents of contractor-selection plans comply with Articles 7 to Article 14 of this Circular Contract performance time is specified in Clause 4 Article 39 of this Circular.

4. Organization of evaluation of contractor selection plans:

a) The local-level concentrated drug procurement unit submits the application for approval of the plan to select drug suppliers to the Department of Health.

b) The appraisal of the plan for selection of drug suppliers that are on the list of local-level concentrated bidding shall comply with Clause 2 Article 16 of this Circular. Department of Health appraises contractor selection plan, submits to Chairman of provincial People's Committee for consideration and approval of contractor selection plan;

5. Approving the contractor selection plan:

The President of the People's Committee of the province shall consider and approve the plan to select local concentrated drug suppliers at the request of the Department of Health.

6. Prepare for contractor selection:

Based on the approved contractor selection plan, the local-level concentrated drug-purchasing unit shall prepare a bidding dossier, report it to the Health Service for organizing the appraisal and approval of the bidding dossier according to the provisions of Article 27, 28 and Article 29 of this Circular.

7. Organization of contractor selection:

The local-level concentrated drug-purchasing unit shall organize the selection of contractors, evaluate bids, negotiate contracts and propose winning bids, and submit reports on evaluation of contractor selection results according to regulations. in Article 30, 31, 32 and Article 33 of this Circular.

8. Evaluation, approval and publicization of contractor selection results:

a) The local-level concentrated drug procurement unit prepares a report and submits to the Department of Health to organize the appraisal and approval of result of selection of concentrated medicine supply contractor in the locality;

b) The Department of Health is responsible for evaluating and approving the result of selection of concentrated drug supply contractors in accordance with Article 34 and Article 35 of this Circular;

c) The local-level concentrated drug procurement unit shall notify and publicize the result of contractor selection in accordance with the Law on Bidding.

9. Completing, signing contract or framework agreement:

a) Based on the approved contractor selection result, the local-level concentrated drug procurement unit shall complete, sign a contract or framework agreement with the successful bidder in accordance with the Law. Bidding;

b) The unit in charge of local-level concentrated drug procurement shall publish the signed framework agreement in accordance with the Law on Bidding on the website of the People's Committee of the province and the Department of Health website and notice. to health facilities covered by the framework agreement.

10. Completing and concluding drug supply contracts:

Central-level concentrated purchasing unit (in case of application of the direct contracting method); Health facilities shall base themselves on the results of selection of drug suppliers, framework agreements, demands and drug use plans of registered medical establishments with focal points to complete and sign contracts. contract with the contractor on the following principles:

a) In accordance with the conditions provided within the framework agreement;

b) The price of each drug in the contract must not exceed the successful bid announced by the local concentrated procurement unit.

c) Contract performance period: specified in the contractor selection plan approved by the competent authority, but not later than 36 months from the day on which the results of concentrated drug purchase and the framework agreement take effect. to the date the parties fulfill their obligations under the contract.

11. Report on implementation of centralized contractor selection results

a) Before the first 10 months of each quarter or unexpectedly upon request, the contractor shall report the situation of implementation of drug supply contracts on the List of drugs of concentrated concentrated bidding according to the form prescribed in ***Appendix 10*** Issued together with this Circular, is sent to the local concentrated drug procurement unit.

b) Before the first 10 months of each quarter or irregularly upon request, health facilities managed by localities, health facilities managed by the Ministry of Health, health facilities managed by ministries or branches in the locality, send a report to the local-level concentrated drug-purchasing unit for synthesis, according to the form prescribed in ***Appendix 11*** to this Circular (not printed herein).

12. Supervise and regulate the process of implementing framework agreement:

Local-level concentrated drug-purchasing units shall supervise and regulate the supply of drugs at medical establishments in compliance with the signed framework agreements on the following principles:

a) If the demand for drugs of a health facility exceeds 20% of the amount of drugs distributed in the framework agreement or the health facility has a need to use drugs but has not synthesized the demand when construction plans on selection of drug-buying contractors must report to local-level concentrated drug-purchasing units according to the form provided in ***Appendix 12*** to this Circular for summarizing and regulating drug quantities between establishments. health care is provided at the local level. Within 10 days after receiving a written request for regulation of a health facility, the local-level concentrated drug-purchasing unit shall reply in writing to the unit.

The quantity of regulating drugs of a local-level concentrated drug-purchasing unit must not exceed 30% of the total approved amount in the plan for selection of drug contractors on the list of locally-focused concentrated bidding. The regulation of drug compliance shall comply with the process of drug regulation on the list of drugs in centralized concentrated bidding promulgated by local-level concentrated drug procurement units.

13. Payment and finalization of drug supply contracts: Medical establishments shall have to make payment and settlement with suppliers strictly according to current provisions of law and provisions of the signed contracts. The written agreement on drug regulation between units of the concentrated procurement unit is a part of the medicine trading contract and serves as a basis for medical establishments and contractors to sign the appendix of contract (for goods items). have been regulated in the framework agreement) or signed a contract (for regulated items not yet allocated in the framework agreement).

Chapter V

REGULATIONS ON PRICE DISPUTE

Article 42. General provisions on price negotiation

1. Council of drug price negotiation:

a) The Drug Price Negotiation Council is set up by the Minister of Health. The Minister of Health shall specify the functions, tasks, powers and working mechanism of the Drug Price Negotiation Council. The operation of the Price Negotiation Council is allocated from the state budget's allocation to the National Centralized Drug Shopping Center and other lawful funding sources as prescribed by law.

b) The composition of the Drug Price Negotiation Council includes:

- Council Chairman is Leader of Ministry of Health;

- 02 Vice Chairmen are Leaders of Vietnam Social Insurance and Director of the National Centralized Drug Shopping Center.

- Council members are representatives of relevant Departments, Departments and Units under the Ministry of Health, Ministry of Planning and Investment, Ministry of Finance, Vietnam Social Insurance and a number of independent experts in various fields. relate to.

c) Tasks of the Drug Price Negotiation Council:

- Considering and deciding on a price negotiation plan developed by the National Centralized Drug Shopping Center;

- Conduct drug price negotiation according to the approved price negotiation plan;

2. The National Centralized Drug Shopping Center is a permanent unit of the Drug Price Negotiation Council that has the following tasks:

a) Develop a price negotiation plan and roadmap;

b) Organize the development, appraisal and approval of the request for proposals;

c) Organizing the evaluation of dossier of proposals;

d) Develop plans for negotiation of expected prices;

d) Publicizing the results of price negotiation;

e) Monitor and regulate the supply and use of selected drugs through price negotiation;

g) Participate in all stages of the drug price negotiation process and summarize and provide relevant information in the price negotiation process;

h) Perform other duties as assigned by the Chairman of the Council.

3. The National Advisory Council for Drug Bidding is responsible for advising the Minister of Health in all stages of the drug price negotiation process upon request.

4. In case of bid drugs having changes in the process of contractor selection or supply of winning medicines but substitute drugs have not been offered in bids, the focal units specified in Clause 1, Article 40 of this Circular consider allowing contractors to replace drugs under Clause 6, Article 37 of this Circular to ensure adequate supply of drugs.

Article 43. Formulation, appraisal and approval of price negotiation plans

1) Summary of demand for drugs on the List of drugs subject to price negotiation:

The National Centralized Drug Shopping Center shall aggregate demand for drugs according to the provisions of Clause 1, Article 40 of this Circular

2. Planning of drug price negotiation:

The National Centralized Drug Shopping Center is responsible for formulating price negotiation plans. The content of a drug price negotiation plan complies with Article 14 of this Circular and must specify the following information:

a) Name of bidding package, bidding package price, total value of bidding packages and each part value of bidding package in contractor selection plan;

b) The planned price of each medicine item that is expected to negotiate a price is formulated as prescribed in Clause 4 Article 14 of this Circular;

c) Requirements for quality standards, delivery time, and specific purchasing conditions for each drug subject to price negotiation;

d) Expected time for price negotiation for each drug on the List of drugs subject to price negotiation;

d) In case of necessity, the National Center for Centralized Drug Shopping shall consult the price negotiation council on the price negotiation plan before submitting it to the unit tasked with evaluation.

3. Evaluation of price negotiation plans:

a) The National Center for concentrated drug procurement shall submit a dossier of submission for approval of the plan for selection of drug suppliers to the Department of Planning - Finance for appraisal of the contractor selection plan;

b) The Department of Planning - Finance is responsible for appraising the list, number of bidding packages, planned unit price and quantity of drugs. The appraisal of price negotiation plans complies with Clause 2, Article 16 of this Circular.

4. Approving the price negotiation plan: The Minister of Health shall consider and approve the price negotiation plan based on the report of the Planning - Finance Department. In case of necessity, the Minister of Health shall consult with the National Advisory Council on drug bidding before approval.

Article 44. Preparation, appraisal and approval of request dossiers

Based on the plan to select contractors in the form of price negotiation approved by the Minister of Health, the National Center for concentrated drug procurement shall set up a dossier of requirements, organize the appraisal and approval of request documents. bridge.

1. Make a request dossier:

a) Compilation of a dossier of request for purchase of drugs in the form of price negotiation shall comply with the provisions of the Bidding Law, documents detailing the Bidding Law and the National Centralized Procurement Center;

b) The content of the request dossier includes summary information about the bidding package; direct the preparation and submission of proposals; standards of contractors' capabilities and experience; criteria for technical evaluation and determination of bidding package price. Use the pass and fail criteria to evaluate technical capability, experience and assessment;

c) The request for instructions to the contractor provides information about prices, specific technical and economic criteria expected to be applied during the process of drug price negotiation requested by the contractor in the bidding documents. , Specifically:

- Ex-factory price, CIF price, selling price for medical examination and treatment facilities in manufacturing countries and countries in the Association of Southeast Asian Nations (ASEAN) provided by contractors;

- Ex-factory price, CIF price, selling price for medical examination and treatment facilities in Vietnam market;

- Indication of drug treatment and assessment of clinical effectiveness of the drug in treatment; Assessment report comparing clinical effectiveness in drug treatment with standard drugs (if any);

- The analysis data of the pharmacy economy include: cost - effectiveness, cost - benefits and cost - utilities provided by the contractor (if any);

- Contractor's commitment and plan on quantity, quality of goods sources and supply schedule if winning the bid.

2. Evaluation of request dossier:

a) Dossiers of request for drug supply in the form of price negotiation must be appraised before being submitted to the Director of the National Center for concentrated drug procurement for consideration and approval.

b) The composition of the dossier-appraisal unit is decided by the Director of the National Drug Center.

3. Approving the request file

Based on the evaluation report of the dossier-appraising unit, the Director of the National Center for Centralized Drug Shopping is responsible for approving the dossier as prescribed.

Article 45. Organizing drug price negotiation

1. A notice of invitation for drug supply in the form of price negotiation and a dossier of request is made publicly available.

2. Contractors prepare and submit proposal documents according to the requirements of the dossier of requirements.

a) Implementation of bid security and submission of proposals in accordance with Article 30 of this Circular;

b) The contractor shall, based on the notice of invitation to supply drugs and the request for proposals in the form of price negotiation, make a proposal and send the proposal to the National Drug Center by sending directly. Or send by post.

3. Evaluating proposals and preparing price negotiation plans

a) The National Drug Center shall organize the evaluation of proposals in accordance with the application. These proposals will be open to the public. During the evaluation process, the bid solicitor may invite the contractor to negotiate, clarify or amend and supplement necessary information contents of the proposal dossier to prove the contractor's satisfaction as required. on capacity, experience, progress, volume, quality, technical solutions and measures to organize the implementation of a bidding package.

b) The National Centralized Procurement Center shall base on bidders' proposals and report on evaluation of proposals of expert groups to formulate price negotiation options. In case of necessity, the Center shall invite clinical and pharmaceutical economists to participate in developing price negotiation plans for each drug. The price negotiation plan should include a

summary of information on the pharmacological effects of the drug, the proposed price of the negotiated drug, the bid-winning price of the negotiated drug and drugs of the same active ingredient, concentration or content, and dosage form However, different bidding groups and drugs with similar pharmacological effects can be substituted for treatment (if any), factors related to price negotiation and terms of framework agreement will be negotiated..

c) The Chairman of the price negotiation council approves the drug price negotiation plan before conducting the price negotiation.

4. Price negotiation and decision:

a) The National Centralized Drug Shopping Center shall send an invitation for price negotiation to contractors that fully meet the conditions of the required dossier. In case of necessity, the National Centralized Drug Shopping Center may invite representatives of drug-manufacturing establishments or representatives of license owners in Vietnam (including representative offices) to clarify relevant contents. to the items negotiating prices;

b) The tenderer is invited to negotiate when the following conditions are fully met: Having valid status, meeting the requirements on capability, experience and technical proposals of the request dossier and the price proposition. the export does not exceed the approved package estimate;

c) Depending on each specific case, the Drug Price Negotiation Council may decide whether to negotiate directly or via text. The negotiation of the Council for price negotiation is based on the contractor's proposal, the evaluation report of the proposal, relevant information and the price negotiation already approved;

d) In case there are 02 or more drug suppliers participating in the negotiation of drug prices with the same active ingredient, concentration or content, dosage form, after negotiation, based on the negotiation results, the Negotiating Council proposed prices of drug suppliers re-offering prices; The written request for re-bid must specify the time and place for receiving the price re-opening dossier, the time for opening of re-bid dossiers and invite drug suppliers to attend the re-opening ceremony. price. When re-bidding, bidders must not offer higher bids than previously negotiated. The tenderer with the lowest offering price shall be recognized as winning tender;

d) In case the first negotiation fails, depending on each specific case, the price negotiation Council shall decide whether to invite or not invite contractors to negotiate the second price. The National Centralized Drug Shopping Center will notify each contractor of the official conclusion of the price negotiation council after the first negotiation session;

e) In case the contractor is invited to re-negotiate the next time, the contractor needs to submit a new price quotation and proposal within the time limit specified in the invitation letter for negotiation of the National Center for concentrated drug procurement;

g) The winning price through price negotiation is agreed upon by the Negotiating Council and the supplier. After price agreement, the price negotiation council and supplier finalize the framework agreement and terms and conditions;

h) After the Council of price negotiation and the contractor's representative sign the price negotiation record, the National Center for concentrated drug procurement shall send a written request to the contractor requesting confirmation of agreed price within 7 days.

Article 46. Appraisal and approval of results of drug price negotiation and implementation of drug price negotiation results

1. Evaluation and approval of results of price negotiation:

The National Centralized Drug Shopping Center is responsible for summarizing the results of price negotiation and sending it to the Planning and Finance Department for evaluation. The maximum time for appraisal is 20 days from the date of receiving complete dossiers. The Minister of Health considers and approves the results of price negotiation based on the report of the Planning - Finance Department.

- In case the Council for price negotiation and the contractor cannot reach a price agreement after the negotiation sessions, the National Centralized Drug Shopping Center shall report to the Department of Planning and Finance and notify the contractor and contractors. Medical facilities nationwide.

2. Publicization of results of price negotiations:

a) The National Center for concentrated drug procurement shall publicize the results of contractor selection through price negotiation and guide the implementation of price negotiation results for all medical establishments according to the provisions of law. the law.

b) For drugs on the List of drugs negotiating unsuccessful prices, the National Centralized Drug Shopping Center shall, based on the opinion of the Price Negotiation Council, propose a procurement or alternative solution. submit to Ministry leaders for consideration and decision. For original brand name drugs having many circulation registration certificates under Group 1 prescribed in Article 7 of this Circular promulgated by the Health Ministry, medical establishments may organize by themselves the selection of contractors in the form of open bidding. widely available in the generic medicine bidding package under the Health Ministry's notice.

3. Payment, signing of contracts and settlement of supply contracts:

a) The National Center for concentrated drug procurement shall finalize, sign a framework agreement with the winning bidders, publish the results of price negotiation and framework agreement on the Ministry of Health Web Portal. Responsibilities of parties concerned and the validity of framework agreement shall comply with Article 39 of this Circular. The selected contractor must apply contract performance guarantee as prescribed in Clause 1 Article 39 of this Circular;

b) The health facilities shall base themselves on the results of price negotiation and framework agreement, the quantity of drugs already allocated and the drug use budget plan of the units approved by competent authorities to sign the combined contracts. contract with the contractor on the principle that the price of the drug in the contract must not exceed the winning drug price through price negotiation and framework agreement announced by the National Center for Drug Collection;

For valid drug supply contracts, medical establishments must make adjustments to drug prices not exceeding the announced negotiated prices, the time of application according to the time the framework agreement takes effect.

c) Contractors selected through price negotiation shall supply drugs according to quantity, schedule and terms stated in the framework and contractual agreements signed with each health facility;

d) Contract execution period: specified in the price negotiation plan approved by a competent authority but not exceeding 36 months from the date the price negotiation results and framework agreement take effect to the date The parties fulfill the obligations prescribed in the contract.

e) The health insurance agency shall make payment uniformly on all public health facilities according to the price negotiation results announced by the National Center for concentrated drug procurement.

4. Report on implementation of drug price negotiation results:

Contractors supplying drugs in the form of price negotiation and health facilities shall report results of drug supply contracts in the form of price negotiation to the National Center for Centralized Medicine according to regulations. in Clause 12, Article 40 of this Circular.

5. Supervising and regulating the process of implementing framework agreements:

The National Centralized Drug Shopping Center shall supervise and regulate the supply and use of selected drugs through price negotiation according to the signed framework agreement as prescribed in Clause 13, Article 40 of the Circular. from this.

Chapter VI

TERMS ENFORCEMENT

Article 47. Effect

1. This Circular takes effect on October 1, 2019.

2. The Minister of Health's Circular No. 11/2016 / TT-BYT dated May 11, 2016, stipulating that bidding for drugs at public health facilities will cease to be effective on the effective date of this Circular. enforcement effect.

Article 48. Transitional provisions

1. Approved bidding packages for contractor selection before the effective date of this Circular comply with the Minister's Circular No. 11/2016 / TT-BYT of May 11, 2016. The Ministry of Health shall stipulate the bidding for drugs at public health facilities, except for the cases specified in Article 2 of this Circular voluntarily comply with this Circular from the date of signing.

2. For drug manufacturers that achieve EU-GMP principles and standards; a drug manufacturer that meets the EU-GMP principles and standards and a manufacturer that meets PIC / S-GMP principles and regulations issued by a water management agency that is a PIC / S member and a member ICH has been published by the Drug Administration of Vietnam on the website before the effective date of this Circular, these establishments are not required to assess the attainment of EU-GMP principles or standards or equivalent principles and standards. EU-GMP or PIC / S-GMP principles and standards implemented by the Vietnam Drug Administration within 6 months from the effective date of this Circular.

Article 49. Terms of reference

In case the documents referred to in this Circular are replaced or amended, the amended or supplemented documents shall apply.

Article 50. Organization of implementation

1. Heads of central agencies shall direct their attached medical establishments to select drug supply contractors according to the provisions of this Circular and the provisions of law on contractor selection.

2. Ministers and heads of ministerial-level agencies shall decide on the decentralization and inspection of decentralization of a number of bidding packages for procurement of drugs by medical establishments under their management according to the provisions of law.

3. Presidents of provincial-level People's Committees shall:

a) Assigning the task of a unit in charge of local-level concentrated drug procurement to purchase drugs on the List of drugs in local-level concentrated bidding for health facilities participating in concentrated bidding in localities as prescribed specified in this Circular;

b) Direct health facilities to select drug suppliers from the List of drugs organized by the bidding organization in accordance with this Circular;

c) Based on local realities, the President of the People's Committee of the province shall decide to add to the List of drugs in the central-level centralized bidding for drugs that are not on this list (except for drugs on the list). The drug can be applied in the form of national-level centralized price negotiation and bidding) for use at local health establishments at the proposal of directors of provincial / municipal Health Departments. Contract performance time is specified in Clause 4 Article 39 of this Circular.

In this case, if the health facilities under central authority, health facilities under the management of ministries and health agencies located in the local area use the list of additional local drugs (outside the List). At the central-level concentrated bidding drug promulgated by the Ministry of Health, the managing agencies of the ministries, ministerial-level agencies, government-attached agencies (branch health management agencies) and direct management agencies of The health facility under the management of the Ministry and the Ministry of Health shall reach a written agreement with the Department of Health to report to the provincial People's Committee to organize the selection of contractor according to regulations.

d) Based on the actual situation in the locality, the President of the provincial People's Committee shall decide to decentralize and inspect the implementation of decentralization of a number of bidding packages for procurement of drugs of medical establishments under their management. Based on the proposal of the Director of the Department of Health of the province or city directly under the Central Government.

4. The Drug Administration of Vietnam, Traditional Medicine Administration, shall update and publish on the website the following information:

a) Lists for contractor selection, including:

- List of reference management agencies;

- List of pharmaceutical regulatory authorities in the SRA list;

- List of pharmaceutical regulatory authorities of the countries that are members of the PIC / s and ICH;

- List of drug manufacturers in Vietnam assessed by the Vietnamese pharmaceutical management agency to reach WHO-GMP principles and standards;

- List of medicine manufacturers meeting EU-GMP principles or standards or manufacturers producing drugs with EU-GMP equivalent principles and standards;

- List of production facilities that meet PIC / s-GMP principles and standards in the country that is a PIC / s member and an ICH member and are assessed by the Vietnamese pharmaceutical management agency to meet PIC principles and standards / s-GMP;

- List of production facilities assessed by the Ministry of Health of Vietnam to meet GMP principles and standards for herbal or traditional medicines;

- List of drug manufacturers in Vietnam which are assessed by the Ministry of Health of Vietnam to meet GMP principles and standards for traditional medicines;

- List of drug manufacturers in Vietnam assessed by the Ministry of Health of Vietnam to meet GMP principles and standards for medicinal ingredients from herbal ingredients.

b) List of drugs serving contractor selection, including:

- List of medicines granted circulation registration certificates or import permits;

- List of original brand name drugs;

- List of reference biologicals;

- List of drugs equivalent to the original brand-name drug;

- List of processed drugs and technology transfer in Vietnam;

- List of original brand-name drugs and biologicals referenced for processing or technology transfer in Vietnam;

- List of medicines with documents proving bioequivalence;

- List of drugs licensed for circulation by one of the reference management agencies;

- List of drugs licensed for circulation by one of the pharmaceutical management agencies of the country on the SRA list;

- List of drugs produced entirely on the production line in Vietnam that meets the criteria of Group 1 specified at Point c, Clause 1, Article 7 of this Circular;

- The list of medicinal herbs is formulated in the form of: tall, nuggets, powders, extracts, essential oils, resins, gums, jellys of quality assurance under the Health Ministry's regulations on quality control of traditional medicines and drugs;

- List of semi-finished pharmaceutical materials: tall, nuggets, powders, extracts, essential oils, resins, gums, jellys of quality assurance under the Health Ministry's regulations on quality control of medicinal materials;

- List of drugs on the National Product List;

- List of medicines with the award of "Vietnamese medicine star" of the Ministry of Health;

- List of medicinal herbs that are naturally cultivated, collected or exploited by the establishment and evaluated by the Ministry of Health of Vietnam to meet GACP principles and standards;

- List of drugs manufactured in Vietnam that meet the treatment, drug price and supply requirements;

- List of medicinal materials that are cultivated and collected domestically to meet treatment requirements and supply capacity, at reasonable prices;

- List of medicines manufactured from raw materials (pharmaceutical substances) manufactured in countries on the list of SRA, raw materials (pharmaceutical substances) granted CEP certificates;

- List of drugs, manufacturers, and suppliers that violate quality standards or regulations on bidding and drug supply;

c) Information about declared and re-declared drug prices;

d) Information on winning prices of drugs and materia medica at medical establishments;

dd) List of drug manufacturers and suppliers meeting requirements on capacity, experience and reputation as the basis for the invitation to participate in restricted bidding.

5. When purchasing drugs from the health insurance fund, the Social Insurance Agency shall have to appoint officials to participate in the following steps:

a) Making, appraising contractor selection plan;

b) Making and appraising bidding documents;

c) Evaluation of bids, evaluation of contractor selection results.

6. Medical facilities or organizations that carry out the steps in the process of selecting contractors must send documents (except those not made public under the provisions of the Bidding Law) to participating members. To join the Council or the Expert Group at the steps specified at Points a, b and c, Clause 5 of this Article, before holding a 5-day meeting (except for urgent purchase of medicines to serve treatment needs). After the above time limit, the health facility or the organizing unit shall take steps in the process of selecting contractors to organize Council or Expert Group meetings. Members participating in the above-mentioned Councils or experts 'groups must comply with the operation regulations of the Councils or experts' groups according to the regulations and assignment of the Council's President or the Head of the Expert Group.

When participating in the steps of the process of selecting the above contractor, Members have their opinions right at the meeting. If the participating members have opinions different from the other members, the report, evaluation report and evaluation report must clearly state the authorized level for consideration and decision.

7. Private medical establishments purchasing medical insurance drugs according to the following regulations:

a) Private health facilities may participate in concentrated drug purchase (national, local and price negotiation) in the locality where their headquarters are located. In this case, the private health facility is responsible for formulating drug use plans, complying with regulations on concentrated drug procurement in the locality such as local health facilities under management; Department of Health and local-level concentrated drug procurement units are responsible for organizing the purchasing of drugs for private health facilities as for local health facilities.

b) If private health facilities do not participate in concentrated drug procurement (national, local, and price negotiation), they may organize the selection of drug suppliers according to the Law on Bidding., documents guiding the Bidding Law and this Circular.

c) If the private health facility fails to select drug suppliers according to regulations in points a and b of this Clause, the social insurance agency shall only pay the drug price according to the concentrated drug purchase results of localities, results of national-level concentrated drug procurement, price negotiation results have been published according to the following criteria: trade name, circulation registration number or import permit, concentration or content, sugar used, dosage form, packaging specifications, manufacturing facilities, manufacturing countries.

In case drugs are not included in the results of local concentrated drug procurement, results of national-level concentrated drug procurement, announced price negotiation results, payment shall be made according to the winning bid prices of the medical facilities. The provincial public sector in the same area is publicized by the Vietnam Social Insurance under the provisions of Point b, Clause 3, Article 77 of Decree No. 63/2014 / ND-CP.

8. Bases for information disclosure prescribed in Point c Clause 1 Article 7 of this Circular shall provide and take responsibility before law for the accuracy of the following documents:

a) The circulation permit of the drug is issued by the pharmacy authority of the country on the list of SRA and is consular legalized (original or certified copy).

b) A list of information proving that the drug is circulated in Vietnam and the drug is listed on the SRA list of drugs licensed for circulation with the same preparation, manufacturing process, quality standards, and testing methods.; pharmaceutical substances and excipients must have the same quality standards, production establishments and production locations according to **Appendix 13** promulgated together with this Circular.

9. Establishments requesting the first announcement of proving that the original brand-name drug or reference biological product is circulated for the first time in the country not on the SRA list specified at Point b, Clause 2, Article 8 of this Circular shall provide and take responsibility before law. The law of accuracy of the following documents:

a) Patent for a pharmaceutical drug granted by one of the competent intellectual property agencies for the active ingredient to a drug containing an active ingredient or a combination (mixture of active ingredients) For drugs containing many active ingredients, enclosed with the reference section requesting protection to establish protection for the corresponding drug (original or certified copy);

b) Periodic Safety Update Report (PSUR) clearly showing the world's first medicine (International Birth Date);

c) Other supporting documents (if any).

Article 51. Implementation responsibilities

Director of Department of Pharmacy Management, Director of Department of Traditional Medicine, Pharmacy, Director of Department of Planning - Finance, Chief of Ministry Office, Chief Inspector of Ministry, Director of the National Center for Centralized Drug Shopping, Prime Minister heads of units of and affiliated to the Ministry of Health, directors of provincial / municipal Health Services, pharmaceutical business establishments and other concerned agencies and organizations shall take responsibility for examination. Issue this Circular.

In the course of implementation, if any problems arise, agencies, organizations and individuals are requested to report them to the Ministry of Health (the Drug Administration of Vietnam, the Administration of Traditional Medicine and Pharmacy, the Department of Planning and Finance). to consider and resolve. /.

KT. PRIORITY MINISTRY
VICE PRESIDENT

National Highway Central

Recipients:
- Office of the Party Central Committee; Office of the President;
- Congress office; Ethnic Council and Committees of the National Assembly;
- Government Office (Department of Building Materials, Official Gazette, Government E-Portal);
- Minister Nguyen Thi Kim Tien (for report);
- Vice Ministers of MOH;
- Ministry of Justice (Legal Document Verification Department);
- Ministries, ministerial-level agencies, agencies under the Government;

- People's Committees of provinces and cities directly under the Central Government;
- State Audit;
- Central Committee of Vietnam Fatherland Front;
- Central agencies of mass organizations;
- Department of Finance, Department of Health of provinces and cities under central authority;
- Vietnam Chamber of Commerce and Industry;
- Units under or attached to the Ministry of Health;
- Vietnam Social Insurance;
- Sector health (QP, CA, MOIT, MOT);
- Vietnam Pharmaceutical Business Association;
- Vietnam Association of Private Hospitals;
- Vietnam Pharmaceutical Corporation;
- Web portal of the Ministry of Health;
- Electronic Information Department of QLD;
- Website of the Department of Public Health Administration;
- Filing: VT, KHTC (02), QLD (02), PC (02).

FORM 7/TT

CERTIFICATE OF A PHARMACEUTICAL PRODUCT (CPP)

This certificate conforms to the format recommended by the World Health Organization (General instruction and explanatory notes are attached) [1]

No. of certificate:

Exporting (certifying) country:

Importing (requesting) country:

1. Name, dosage form and *specification* of the product:

1.1. Active ingredient[2] and amount(s) per unit dose[3]:

Complete composition and strength, including excipients[4]

1.2. Is this product licensed to be placed on the market for use in the exporting country? [5]

☐ Yes ☐ No

1.3. Is this product actually on the market in the exporting country?

☐ Yes ☐ No

If the answer to 1.2 is yes, continue with section 2A and omit section 2B

If the answer to 1.2 is no, omit section 2A and continue with section 2B[6]

2A.1 Number of product license[7] and date of issue:

2A.2 Name and address of product license holder or owner of product:

2A.3 Status of the product license holder[8] (Key in appropriate category as defined in note 8)

☐ a ☐ b ☐ c

2A.3.1 For categories b and c, the name and address of the manufacturer producing the dosage form is [9]:

2A.4 Is a summary basis for approval attached[10] ?

☐ Yes ☐ No

2A.5 If attached, is the officially approved product information complete and consonant with the license?[11]

☐ Yes ☐ No ☐ Not provided

2A.6 Name and address of applicant for certificate, if different from license holder[12]:

2B.1 Name and address of applicant for certificate:

2B.2 Status of applicant for certificate (Key in appropriate category as defined in note 8)

☐ a ☐ b ☐ c

2B.2.1 For categories b and c, the name and address of the manufacturer producing the dosage form is [9]:

2B.3 Why is marketing authorization lacking?

☐ Not required ☐ Under consideration

☐ Not requested ☐ Refused

2B.4 Remarks[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? [14]

☐ Yes ☐ No ☐ Not applicable

If No or Not applicable, proceed to question 4.

3.1. Periodicity of routine inspections (years):

3.2. Has the manufacture of this type of dosage form been inspected?

☐ Yes ☐ No

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization? [14]

☐ Yes ☐ No ☐ Not applicable [15]

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product [16]

☐ Yes ☐ No

If no, explain:

Address of certifying authority:

Telephone:

Name, signature of authorized person:

Date, stamp of certifying authority:

Explanatory notes:

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names. It is obligatory to have information about the specification of active ingredients, medicinal materials; name and address of manufacturer of active ingredient, medicinal materials. This information can be described in enclosed appendix.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Complete description about composition, strength/concentration of each active ingredient, medicinal material and excipients. For the hard capsule and soft capsule, it is obligatory to add information about the composition of capsule shell.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
    a. manufactures the dosage form;
    b. packages and/or labels a dosage form manufactured by an independent company;
    c. is involved in none of the above.
9. This information can only be provided with the consent of the product-license holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.
   It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SmPC)
12. In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.
    a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
    b. the product has been reformulated with a view to improving its stability under tropical conditions;
    c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    e. any other reason, please specify.
14. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
15. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
16. This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

การศึกษากฎระเบียบการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

ประจำปีงบประมาณ พ.ศ. 2563

แบบสอบถาม

วัตถุประสงค์

เพื่อศึกษากฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

คำอธิบาย

แบบสอบถามนี้จัดทำขึ้นโดยความร่วมมือระหว่างสำนักงานคณะกรรมการอาหารและยา และผู้วิจัย ซึ่งประกอบด้วย 4 ส่วน คือ

ส่วนที่ 1 ข้อมูลเกี่ยวกับสถานประกอบการ

ส่วนที่ 2 กฎระเบียบที่เป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

ส่วนที่ 3 ข้อมูลด้านความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุน

ส่วนที่ 4 ประเด็นปัญหา อุปสรรค และข้อเสนอแนะ

โปรดทำเครื่องหมายหรือเติมคำลงในช่องว่างที่ตรงกับความเป็นจริง

คำตอบของท่านจะถูกเก็บเป็นความลับเพื่อการศึกษากฎระเบียบที่เกี่ยวข้องกับการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม เท่านั้น

ผู้วิจัยขอขอบพระคุณเป็นอย่างสูงในความอนุเคราะห์จากท่าน

<u>ส่วนที่ 1</u> ข้อมูลเกี่ยวกับสถานประกอบการ

1. ชื่อสถานประกอบการ.....

เลขที่ใบอนุญาต.....

2. เงินลงทุน/ทุนจดทะเบียน.....

3. จำนวนปีที่มีการดำเนินธุรกิจนับจากเริ่มก่อตั้ง.....ปี

4. ประเภทของสถานประกอบการของท่าน (ตอบได้มากกว่า 1 ข้อ)

❒ 4.1 ผู้ผลิต ❒ 4.2 ผู้นำเข้า ❒ 4.3 ผู้ส่งออก ❒ 4.4 ผู้จัดจำหน่ายส่ง ❒ 4.5 ผู้จัดจำหน่ายปลีก

5. ร้อยละของลักษณะ/รูปแบบการผลิต

5.1 ผลิตตามที่ลูกค้ากำหนด (OEM: Original Equipment Manufacturing) ร้อยละ .....

5.2 ผลิตโดยมีตราสินค้าเป็นของตนเอง (OBM: Original Brand Manufacturing) ร้อยละ .....

5.3 อื่น ๆ โปรดระบุ .....ร้อยละ .....

6. กำลังการผลิต (โปรดระบุ) .....แรงม้า

7. จำนวนคนงาน (โปรดระบุ) .....คน

8. ประเภทผลิตภัณฑ์ยาที่สถานประกอบการของท่านดำเนินการผลิต หรือจัดจำหน่าย (ตอบได้มากกว่า 1 ข้อ)

❒ 8.1 ยาแผนปัจจุบันบรรจุเสร็จที่ไม่ใช่ยาอันตรายหรือยาควบคุมพิเศษ ตัวอย่างชื่อผลิตภัณฑ์ .....

❒ 8.2 ยาสามัญประจำบ้านแผนปัจจุบันตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.3 ยาสามัญประจำบ้านแผนโบราณ ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.4 ยาสมุนไพรแผนโบราณ ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.5 ยาสมุนไพรแผนปัจจุบัน ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.6 วัคซีน ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.7 ยาแผนปัจจุบันที่เป็นยาอันตราย ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.8 ยาแผนโบราณที่เป็นยาอันตราย ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.9 ยาแผนปัจจุบันที่เป็นยาควบคุมพิเศษ ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.10 ยาแผนโบราณที่เป็นยาควบคุมพิเศษ ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.11 ยาใช้เฉพาะที่ ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.12 เภสัชเคมีภัณฑ์ ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.13 เภสัชเคมีภัณฑ์กึ่งสำเร็จรูป ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.14 ยาใหม่ ตัวอย่างชื่อผลิตภัณฑ์.....

❒ 8.15 อื่นๆ โปรดระบุ.....

ตัวอย่างชื่อผลิตภัณฑ์.....

9. ประมาณการรายได้รวมของกิจการ

❒ 9.1 น้อยกว่า 10 ล้านบาทต่อปี ❒ 9.2 11-30 ล้านบาทต่อปี

❒ 9.3 31-50 ล้านบาทต่อปี ❒ 9.4 51-70 ล้านบาทต่อปี

❒ 9.5 71-80 ล้านบาทต่อปี ❒ 9.6 81-90 ล้านบาทต่อปี

❒ 9.7 90-100 ล้านบาทต่อปี ❒ 9.8 100 ล้านบาทต่อปี

หากมากกว่า 100 ล้านบาทต่อปี โปรดระบุประมาณการรายได้รวม.....บาท

10. สถานประกอบการของท่านมีการส่งออกไปยังต่างประเทศ

❒ 10.1 ใช่ 1) ผลิตภัณฑ์ที่ส่งออกไปได้ 3 อันดับแรก

ลำดับที่ 1.....

ลำดับที่ 2.....

ลำดับที่ 3.....

2) กลุ่มประเทศปลายทาง ❒ 1.1 กลุ่มประเทศอาเซียน (โปรดระบุ.....)

❒ 1.2 กลุ่มประเทศอื่น ๆ (โปรดระบุ.....)

3) ประมาณการมูลค่าการส่งออก (บาท/ปี) .....

❒ 10.2 ไม่ใช่ เพราะ.....

11. สถานประกอบการของท่านมีการส่งออกไปยังประเทศเวียดนาม

❒ 11.1 ใช่ 1) ผลิตภัณฑ์ที่ส่งออกไปได้ 3 อันดับแรก

ลำดับที่ 1.....

ลำดับที่ 2.....

ลำดับที่ 3.....

2) ประมาณการมูลค่าการส่งออก (บาท/ปี) .....

❒ 11.2 ไม่ใช่ เพราะ.....

12. สถานประกอบการของท่านมีแผนที่จะขยายตลาดไปยังต่างประเทศ

❒ 12.1 ใช่ 1) ผลิตภัณฑ์ที่คาดว่าน่าจะส่งออกไปได้ 3 อันดับแรก

ลำดับที่ 1.....

ลำดับที่ 2.....

ลำดับที่ 3.....

2) กลุ่มประเทศปลายทาง ❒ 1.1 กลุ่มประเทศอาเซียน (โปรดระบุ.....)

❒ 1.2 กลุ่มประเทศอื่น ๆ (โปรดระบุ.....)

3) ประมาณการมูลค่าการส่งออก (บาท/ปี) .....

❒ 12.2 ไม่ใช่ พราะ.....

13. สถานประกอบการของท่านมีแผนที่จะขยายตลาดไปยังประเทศเวียดนาม

❒ 13.1 ใช่ 1) ผลิตภัณฑ์ที่คาดว่าน่าจะส่งออกไปได้ 3 อันดับแรก

ลำดับที่ 1.....

ลำดับที่ 2.....

ลำดับที่ 3.....

2) ประมาณการมูลค่าการส่งออก (บาท/ปี) .....

❒ 13.2 ไม่ใช่ เพราะ.....

14. สถานประกอบการของท่านมีการตั้งโรงงานผลิตในต่างประเทศ

❒ 10.1 ใช่ 1) ผลิตภัณฑ์ที่ผลิตในต่างประเทศ 3 อันดับแรก

ลำดับที่ 1.....

ลำดับที่ 2.....

ลำดับที่ 3.....

2) กลุ่มประเทศปลายทาง ❒ 1.1 กลุ่มประเทศอาเซียน (โปรดระบุ.....)

❒ 1.2 กลุ่มประเทศอื่น ๆ (โปรดระบุ.....)

3) ประมาณการมูลค่าการผลิต (บาท/ปี) .....

❒ 10.2 ไม่ใช่ เพราะ.....

15. สถานประกอบการมีการลงทุนด้านการวิจัยและพัฒนา หรือมีฝ่ายวิจัยและพัฒนา

❒ 14.1 ใช่ เพราะ.....โดยงบประมาณในการวิจัยและพัฒนา.....% ของรายได้

❒ 14.2 ไม่ใช่ เพราะ.....

16. หากไม่มีการลงทุนด้านการวิจัยและพัฒนา หรือไม่มีฝ่ายวิจัยและพัฒนา ท่านต้องการการสนับสนุนหรือไม่

❒ 15.1 ใช่ เพราะ.....

❒ 1 5.2 ไม่ใช่ เพราะ.....

<u>ส่วนที่</u> 2 กฎระเบียบที่เป็นอุปสรรคต่อการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

2.1 อุปสรรคจากเนื้อหาของกฎระเบียบของประเทศเวียดนาม

กฎระเบียบของประเทศเวียดนาม	ระดับความรุนแรงของอุปสรรค/ปัญหา					
	มากที่สุด	มาก	ปานกลาง	น้อย	น้อยที่สุด	ไม่มีปัญหา
2.1.1 การขึ้นทะเบียนผลิตภัณฑ์						
ผู้ที่สามารถยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ยาและวัตถุดิบเกี่ยวกับยา						
ผู้ประกอบการผลิต ผู้ประกอบการขายส่ง ผู้ประกอบการนำเข้าหรือส่งออก ยาหรือวัตถุดิบเกี่ยวกับยา โดยผู้ประกอบการดังกล่าวต้องมีใบอนุญาตประกอบธุรกิจยา (Certificate of eligibility for pharmaceutical business) ในประเทศเวียดนาม						
สำนักงานตัวแทนในประเทศเวียดนาม กรณีผู้ประกอบการต่างประเทศ						
รายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ กรณียาแผนปัจจุบัน วัคซีน และยาชีวภาพ หรือยาสามัญ (generic drug)						
คำขอขึ้นทะเบียนผลิตภัณฑ์						
หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ						
ตัวอย่างฉลากที่จะใช้วางจำหน่ายในประเทศเวียดนาม						
สรุปคุณสมบัติของผลิตภัณฑ์						
หนังสือรับรองผู้ผลิตสารออกฤทธิ์ สารเพิ่มปริมาณ แคปซูล และส่วนผสมสมุนไพร						
หนังสือรับรองผลวิเคราะห์ Good Laboratory Practice (GLP) หรือ Good Manufacturing Practice (GMP) ของผู้ผลิต						
แผนการบริหารจัดการความเสี่ยง						
เอกสารรับรองแหล่งที่มาของวัตถุดิบ						

กฎระเบียบของประเทศเวียดนาม	ระดับความรุนแรงของอุปสรรค/ปัญหา					
	มากที่สุด	มาก	ปานกลาง	น้อย	น้อยที่สุด	ไม่มีปัญหา
เอกสารแสดงคุณภาพของผลิตภัณฑ์ตาม ACTD หรือ ICH-CTD						
ข้อมูลที่ไม่ใช่การศึกษาทางคลินิกตาม ACTD หรือ ICH-CTD						
ผลการศึกษาทางคลินิก						
เอกสารเพิ่มเติม กรณียาที่ผลิตภายใต้ข้อตกลงด้านการถ่ายทอดเทคโนโลยี (pharmaceutical technology transfer) โดยยาต้นแบบ (source drug of transfer)						
ข้อตกลงด้านการถ่ายทอดเทคโนโลยี						
รายงานความปลอดภัยและความมีประสิทธิภาพ (safety and efficacy report)						
รายงานการจำหน่ายผลิตภัณฑ์ (marketing report)						
สำเนาหนังสือรับรองการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม						
เอกสารเกี่ยวกับยาต้นแบบ (source drug)						
รายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ กรณียาสมุนไพร						
คำขอขึ้นทะเบียนผลิตภัณฑ์						
หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ						
ตัวอย่างฉลากที่จะใช้วางจำหน่ายในประเทศเวียดนาม						
หนังสือรับรองผู้ผลิตสารออกฤทธิ์ สารเพิ่มปริมาณ แคปซูล และส่วนผสมสมุนไพร						
หนังสือรับรองผลวิเคราะห์ Good Laboratory Practice (GLP) หรือ Good Manufacturing Practice (GMP) ของผู้ผลิต						
เอกสารรับรองแหล่งที่มาของวัตถุดิบ						
เอกสารแสดงคุณภาพของส่วนผสม (Ingredient) ซึ่งครอบคลุมถึงวิธีการทดสอบ (Test method)						

กฎระเบียบของประเทศเวียดนาม	ระดับความรุนแรงของอุปสรรค/ปัญหา					
	มากที่สุด	มาก	ปานกลาง	น้อย	น้อยที่สุด	ไม่มีปัญหา
เอกสารแสดงคุณภาพของผลิตภัณฑ์ยา ซึ่งครอบคลุมถึงกรรมวิธีการผลิต กระบวนการควบคุมการผลิต บรรจุภัณฑ์ และวิธีการทดสอบ						
เอกสารรับรองความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์ตาม ACTD หรือ ICH-CTD						
ผลการศึกษาทางคลินิกในกรณียาใหม่						
รายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ กรณีวัตถุดิบเกี่ยวกับยา						
คำขอขึ้นทะเบียนผลิตภัณฑ์						
หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ						
ตัวอย่างฉลากที่จะใช้วางจำหน่ายในประเทศเวียดนาม						
หนังสือรับรองผู้ผลิตสารออกฤทธิ์ สารเพิ่มปริมาณ แคปซูล และส่วนผสมสมุนไพร						
หนังสือรับรองผลวิเคราะห์ Good Laboratory Practice (GLP) หรือ Good Manufacturing Practice (GMP) ของผู้ผลิต						
เอกสารรับรองแหล่งที่มาของวัตถุดิบ						
เอกสารแสดงคุณภาพวัตถุดิบเกี่ยวกับยา						
รายการเอกสารที่ใช้ประกอบการยื่นคำขอขึ้นทะเบียนผลิตภัณฑ์ กรณียาแผนโบราณ						
คำขอขึ้นทะเบียนผลิตภัณฑ์						
หนังสือรับรองของสำนักงานตัวแทน (กรณีผู้ประกอบการต่างชาติ) หรือใบอนุญาตประกอบธุรกิจยา (กรณีผู้ประกอบการเวียดนาม)						
หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP) (กรณียานำเข้า)						

กฎระเบียบของประเทศเวียดนาม	ระดับความรุนแรงของอุปสรรค/ปัญหา					
	มากที่สุด	มาก	ปานกลาง	น้อย	น้อยที่สุด	ไม่มีปัญหา
ตัวอย่างฉลาก และเอกสารอื่นที่แสดงข้อมูลเกี่ยวกับผลิตภัณฑ์ยา						
เอกสารรับรองความปลอดภัยและความมีประสิทธิภาพของผลิตภัณฑ์ยา						
ตัวอย่างฉลากผลิตภัณฑ์ยาที่จำหน่ายในประเทศแหล่งกำเนิดหรือประเทศอ้างอิง (กรณียานำเข้า)						
เอกสารเพิ่มเติมสำหรับผู้ประกอบการต่างชาติ						
ใบอนุญาตจัดตั้งสำนักงานตัวแทนในประเทศเวียดนาม						
ใบอนุญาตการผลิต การขายส่ง การนำเข้า การส่งออก ผลิตภัณฑ์ยาหรือวัตถุดิบเกี่ยวกับยา อย่างใดอย่างหนึ่ง ที่ออกโดยหน่วยงานรัฐต่างประเทศ						
เอกสารเพิ่มเติมสำหรับยาต่างประเทศ						
หนังสือรับรองผลิตภัณฑ์ยา (Certificate of Pharmaceutical Product: CPP)						
ตัวอย่างฉลาก และเอกสารกำกับยาแบบ Package insert ที่ใช้ในประเทศแหล่งกำเนิด หรือประเทศที่ออก CPP						
การประเมินการปฏิบัติตามมาตรฐาน GMP กรณีผู้ผลิตต่างประเทศ ซึ่งได้มีการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนามเป็นครั้งแรก						
2.1.2 การต่ออายุทะเบียนผลิตภัณฑ์ยา						
คำขอต่ออายุทะเบียนผลิตภัณฑ์						
หนังสือมอบอำนาจ (authorization letter) ว่าบุคคลที่ยื่นคำขอเป็นผู้ได้รับมอบอำนาจให้ยื่นคำขอและลงนามในคำขอ						
แผนการบริหารจัดการความเสี่ยง						
รายงานความปลอดภัยและความมีประสิทธิภาพ (safety and efficacy report)						
รายงานการจำหน่ายผลิตภัณฑ์ (marketing report)						

กฎระเบียบของประเทศเวียดนาม	ระดับความรุนแรงของอุปสรรค/ปัญหา					
	มากที่สุด	มาก	ปานกลาง	น้อย	น้อยที่สุด	ไม่มีปัญหา
เอกสารรับรองแหล่งที่มาของวัตถุดิบ						
สำเนาหนังสือรับรองการขึ้นทะเบียนผลิตภัณฑ์ในประเทศเวียดนาม						
ในกรณีเอกสารที่ได้ยื่นไว้ตอนขึ้นทะเบียนผลิตภัณฑ์มีการเปลี่ยนแปลง ให้ผู้ประกอบการยื่นเอกสารฉบับใหม่ด้วย						
2.1.3 การแก้ไขเนื้อหาทะเบียนผลิตภัณฑ์						
คำขอแก้ไขเนื้อหาในทะเบียนผลิตภัณฑ์						
ข้อมูลที่มีการเปลี่ยนแปลงไป เช่น มีการเปลี่ยนแปลงสถานที่ผลิต (manufacturing location)						

ข้อกำหนดอื่น ๆ ที่ท่านต้องปฏิบัติเพิ่มเติมตามกฎระเบียบที่เกี่ยวกับผลิตภัณฑ์ยาในประเทศเวียดนาม

ข้อกำหนด	เอกสารที่เกี่ยวข้อง	กฎระเบียบที่เกี่ยวข้อง
1).....	.....	.....
2).....	.....	.....
3).....	.....	.....

2.2 อุปสรรคด้านขั้นตอนการขึ้นทะเบียนผลิตภัณฑ์ยาในประเทศเวียดนาม

ขั้นตอน	ระดับความรุนแรงของอุปสรรค/ปัญหา					
	มากที่สุด	มาก	ปานกลาง	น้อย	น้อยที่สุด	ไม่มีปัญหา
1. ความไม่แน่นอนของการใช้บังคับกฎระเบียบ						
2. ข้อมูลเกี่ยวกับกฎระเบียบไม่ได้รับการตีพิมพ์หรือเผยแพร่อย่างเพียงพอ						
3. กฎระเบียบมักไม่จัดทำเป็นภาษาอังกฤษ						
4. เอกสารยากแก่การกรอก						

ขั้นตอน	ระดับความรุนแรงของอุปสรรค/ปัญหา					
	มากที่สุด	มาก	ปานกลาง	น้อย	น้อยที่สุด	ไม่มีปัญหา
5. การปฏิบัติงานของเจ้าหน้าที่ที่เกี่ยวข้องไม่แน่นอน						
6. ความล่าช้าในการดำเนินการของเจ้าหน้าที่ที่เกี่ยวข้อง						
7. อื่น ๆ (โปรดระบุ.....)						

<u>ส่วนที่ 3 ข้อมูลด้านความต้องการให้ภาครัฐช่วยเหลือหรือสนับสนุน</u>

3.1 โปรดระบุประเด็นความต้องการเพื่อให้ภาครัฐช่วยเหลือหรือสนับสนุนให้สถานประกอบการของท่านมีความสามารถในการส่งออกสินค้า โดยการทำเครื่องหมาย ✓ และเรียงลำดับความต้องการ

- ❒ ความต้องการลำดับที่..... การให้ความช่วยเหลือด้านการถ่ายทอดเทคโนโลยี เช่น การจัดอบรม การจัดกิจกรรมเพิ่มพูนความรู้
- ❒ ความต้องการลำดับที่..... การจัดทำคู่มือเกณฑ์ความตกลงอาเซียนที่เข้าใจง่ายและสามารถนำไปปฏิบัติได้จริง
- ❒ ความต้องการลำดับที่..... การจัดทำสรุปข้อกฎหมายของกลุ่มประเทศสมาชิกอาเซียนที่เกี่ยวกับผลิตภัณฑ์ยา
- ❒ ความต้องการลำดับที่..... การจัดศึกษาดูงานด้านผลิตภัณฑ์ยาของกลุ่มประเทศสมาชิกอาเซียน
- ❒ ความต้องการลำดับที่..... การสนับสนุนด้านการวิจัยพัฒนาผลิตภัณฑ์ทั้งในรูปตัวเงินและไม่เป็นตัวเงิน
- ❒ ความต้องการลำดับที่..... การกำหนดมาตรการด้านแรงจูงใจ อาทิ มาตรการลดหย่อนภาษี
- ❒ ความต้องการลำดับที่..... การจัดหาแหล่งเงินทุนในอัตราดอกเบี้ยต่ำ
- ❒ ความต้องการลำดับที่..... ส่งเสริมภาพลักษณ์ และความน่าเชื่อถือในคุณภาพและมาตรฐานของผลิตภัณฑ์ส่งออกของประเทศไทย
- ❒ ความต้องการลำดับที่..... อื่น ๆ (โปรดระบุ).....
- ❒ ความต้องการลำดับที่..... อื่น ๆ (โปรดระบุ).....

<u>ส่วนที่ 4 ประเด็นปัญหา อุปสรรค และข้อเสนอแนะ</u>

4.1 โปรดแสดงความคิดเห็นในประเด็นปัญหาและอุปสรรค

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4.2 โปรดแสดงความคิดเห็นในประเด็นข้อเสนอแนะ

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*** ขอขอบพระคุณเป็นอย่างสูงที่กรุณาเสียสละเวลาและให้ข้อมูลที่เป็นประโยชน์ยิ่ง ***