WORLD TRADE ORGANIZATION

G/TBT/N/VNM/253

23 March 2023

(23-2102)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** VIET NAM **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Drug Administration of Viet Nam Ministry of Health 138A Giang Vo Street – Ba Dinh District – Ha Noi Tel: (84-4) 37366483 - Fax: 38234758 - Email: cqldvn@moh.gov.vn **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**
3.	**Notified under Article 2.9.2 [ ], 2.10.1 [X], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:** Urgently amending and supplementing the contents of Decree No. 54 and Decree No. 155, which are not suitable with the actual situation, according to the shortened order and procedures to immediately remove difficulties and obstacles of the organization, individuals in the production and trading of pharmaceutical products in order to ensure the timely and sufficient supply of quality drugs for the needs of disease prevention and treatment, and to strengthen the protection, care and improvement of the people's health.
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicaments (ICS code(s): 11.120.10)
5.	**Title, number of pages and language(s) of the notified document:** Draft Decree on amendments to some articles of Government's Decree No. 54/2017/ND-CP dated 08 May 2017 providing guidelines for some articles and implementation of the law on pharmacy and Government's Decree No. 155/2018 dated 12 November 2018 on amendments to some articles related to business conditions under state management of the Ministry of Health; (5 page(s), in Vietnamese)
6.	**Description of content:** - Amendments to regulations on export, import, registration of herbal ingredients, excipients, capsule shells, semi-finished herbal ingredients in Clause 1 Article 91, Article 93 of Decree No. 54 and point b Clause 47 Article 5 of Decree No. 155 to simplify administrative dossiers and procedures for export, import, registration of herbal ingredients, excipients, capsule shells, semi-finished herbal ingredients, creating more favourable conditions for enterprises, including allowing to replace "the Pharmacy Business License for enterprises supplying herbal ingredients, semi-finished herbal ingredients" with "Business license or equivalent documents with the trading scope in herbal ingredients", and allows to replace "Certificate of Good Manufacturing Practice (GMP) for herbal ingredients, semi-finished herbal ingredients" with "Manufacturing License or equivalent documents with Good Manufacturing Practice Certificate (GMP) within the scope of manufacture of herbal ingredients, semi-finished herbal ingredients".

	- Amendment to Point a Clause 1 Article 97 of the Decree 54 on inspection of foreign drug manufacturers in the direction of mandating the Advisory Council to consider and evaluate the conformity of exporting countries' GMP standards with GMP principles and standards prescribed by the Ministry of Health, if the exporting countries/territories apply GMP principles and standards that are not among the GMP principles and standards announced or promulgated by the Ministry of Health. - Amendment on review of stated drug prices and the composition of the intersectoral drug pricing Council
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Harmonization; Reducing trade barriers and facilitating trade
8.	**Relevant documents:** - Law on Food Safety - Decree 15/2018/ND-CP dated February 02, 2018 of the Government on the elaboration of some articles of the Law of Food Safety - Vietnam Pharmacopoeia V - TCVN 7924-2:2008 (ISO 16649-2:2001) - Circular 26/2012/TT-BKHCN dated December 12, 2012 of the Minister of Science and Technology on the state inspection of quality of goods in circulation - Circular 12/2017/TT-BKHCN dated September 28, 2017 of the Minister of Science and Technology on amendments and supplements to Circular 26/2012/TT-BKHCN dated December 12, 2012 of the Minister of Science and Technology on the state inspection of quality of goods in circulation - ASEAN Guidelines on Limits of Contaminants for Health Supplements (Annex III) at website: https://asean.org/wp-content/uploads/2017/09/ASEAN-Guidelines-on-Limts-of-contaminants-HS-V2.0-with-disclaimer.pdf
9.	**Proposed date of adoption:** The draft Decree is expected to be submitted to the Government in March 2023 to consider and approve. **Proposed date of entry into force:** immediately after the date of promulgation.
10.	**Final date for comments:** 1 April 2023
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Drug Administration of Viet Nam 138A Giang Vo Street – Ba Dinh District – Ha Noi Tel : (84-4) 37366483 - Fax: 38234758 - Email: cqldvn@moh.gov.vn https://members.wto.org/crnattachments/2023/TBT/VNM/23_8406_00_x.pdf