WORLD TRADE ORGANIZATION

G/TBT/N/EU/1044

31 January 2024

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** EUROPEAN UNION **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** European Commission **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:** European Commission, EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu Website: http://ec.europa.eu/growth/tools-databases/tbt/en/
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical devices and *in vitro* diagnostic medical devices
5.	**Title, number of pages and language(s) of the notified document:** Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical devices (COM(2024) 43 final); (26 page(s), in English)
6.	**Description of content:** Regulation (EU) 2017/745 on medical devices (MD Regulation) and Regulation (EU) 2017/746 on in vitro diagnostics medical devices (IVD Regulation) establish a new regulatory framework for medical devices and *in vitro* diagnostic medical devices. Their objectives are a high level of protection of health for patients and users and the smooth functioning of the internal market for these products. The MD Regulation has been applicable since 26 May 2021. It was notified to the WTO as notification G/TBT/N/EU/71. In March 2023, the European Parliament and the Council adopted a staggered extension of its transition period, ranging from 31 December 2027 for high risk devices to 31 December 2028 for medium and lower risk devices. It was notified to the WTO as notification G/TBT/N/EU/943. The IVD Regulation has been applicable since 26 May 2022. It was notified to the WTO as notification G/TBT/N/EU/72. In January 2022, the European Parliament and the Council adopted a staggered extension of its transition period, ranging from 26 May 2025 for high risk *in vitro* diagnostics to 26 May 2027 for lower risk *in vitro* diagnostics. It was notified to the WTO as notification G/TBT/N/EU/845.

	Despite considerable progress over the past years, the capacities of conformity assessment ('notified') bodies designated in accordance with the IVD Regulation remain insufficient and manufacturers are not sufficiently prepared to meet the strengthened requirements of the IVD Regulation on time. This is threatening the availability of *in vitro* diagnostics on the EU market. This proposal extends the current transition period laid down in Article 110 of the IVD Regulation, based on certain conditions. The conditions would ensure that only devices that are safe and for which manufacturers have already taken steps to transition to the MDR will benefit from the additional time. This would give manufacturers and notified bodies more time to conduct the conformity assessment procedures in accordance with the IVD Regulation, if those conditions are fulfilled. The draft measure proposes to keep the staggering of the transition periods depending on the risk class of the device and proposes their extension until 2027 for class D IVDs, until 2028 for class C IVDs and until 2029 for class B and class A sterile IVDs. The extension of the transition period is complemented by an extension of the validity of certificates issued under the previous Directive 98/79/EC for the devices benefiting from the extended transition period. Also the validity of certificates that have already expired since 26 May 2022 would be extended under certain conditions. The proposal also aims to allow a gradual roll-out of the electronic systems integrated in EUDAMED that are finalised (e.g. systems for the registration of economic operators, devices and certificates), instead of delaying the mandatory use of EUDAMED until the last of the six modules is completed. This way, the mandatory use of EUDAMED will be implemented stepwise and in a more timely manner. In addition, the proposal aims to introduce an information mechanism for signalling interruption of supply of certain medical devices and IVDs, where the manufacturer has reasons to believe that the interruption may lead to serious harm or pose a risk of serious harm to patients or public health.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** The notified draft maintains the objectives of Regulations (EU) 2017/745 and (EU) 2017/746 to ensure a high level of safety and performance of devices by enhancing their oversight by notified bodies. It only provides for the necessary additional time to achieve this objective whilst ensuring the protection of human health and safety, in particular to prevent shortages of medical devices. Having regard to the usual length of conformity assessment procedures, the amendment to Regulation 2017/746 needs to be adopted as quickly as possible in order to ensure legal certainty for all actors, including manufacturers and notified bodies, ahead of the date on which the current transition period will end for class D IVDs (26 May 2025). This notified draft extends its transitional provisions' timelines (regarding Regulation (EU) 2017/746). Given the need for legal certainty and the short period for adoption of the measure, the commenting period has been reduced to 20 days; Protection of human health or safety
8.	**Relevant documents:** Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). EUR-Lex - 02017R0745-20200424 - EN - EUR-Lex (europa.eu) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117 5.5.2017, p. 176). EUR-Lex - 02017R0746-20170505 - EN - EUR-Lex (europa.eu)

9.	**Proposed date of adoption:** April 2024 (as early as possible) **Proposed date of entry into force:** On the day of its publication in the Official Journal of the European Union
10.	**Final date for comments:** 20 days from notification
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** European Commission, EU-TBT Enquiry Point, Fax: + (32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu The text is available on the EU-TBT Website : http://ec.europa.eu/growth/tools-databases/tbt/en/ EUR-Lex - 52024PC0043 - EN - EUR-Lex (europa.eu) https://members.wto.org/crnattachments/2024/TBT/EEC/24_00907_00_e.pdf