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European Commission Proposes Amending Transitional Provisions in Medical Devices and In Vitro Diagnostics Regulations

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On 6 January 2023, the European Commission **adopted a proposal to amend the transitional provisions** of Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR).

The proposal aims to prevent medical device shortages on the European Economic Area (EEA) market. The proposed amendments introduce an extension to the transitional periods established in the regulations to provide medical device manufacturers more time to bring their devices into conformity with the requirements of the regulations. In the case of the MDR, the length of the proposed extension is contingent on the risk classification of devices.

The proposed amendments were discussed during a meeting of the Employment, Social Policy, Health and Consumer Affairs Council held on 9 December 2022. During the meeting, the overwhelming majority of health ministers of the EU member states welcomed the proposed prolongation of the transitional periods established in the MDR and the IVDR, and they underlined the urgency of delaying implementation of the regulations. (For more information on the meeting, refer to Cooley's **related Productwise blog post**.)

The European Commission's proposal to amend the transitional provisions established in the MDR and the IVDR includes the following elements:

- Extension of the transitional period for **higher risk (Class III and IIb implantable devices)** medical devices covered by a CE certificate of conformity issued before 26 May 2021 in accordance with the Medical Devices Directive (MDD) or the Active Implantable Medical Devices Directive (AIMDD) from 26 May 2024 to **31 December 2027**.
- Extension of the transitional period for **medium- and low-risk (other Class IIb devices, Class IIa and certain Class I devices)** medical devices certified prior to 26 May 2021 in accordance with the MDD to **31 December 2028.**
- Introduction of a transitional period for **Class III custom-made implantable devices** until **26 May 2026**, provided that an application for a conformity assessment is lodged with a notified body by the medical device manufacturer by 26 May 2024, and a contract with the notified body is signed before 26 September 2024.
- Extension of the period of validity of certificates issued in accordance with the MDD and the AIMDD based on the product's risk class.
- Removal of the "sell-off" deadline established in Article 120.4 of the MDR and Article 110.4 of the IVDR for medical devices and in vitro diagnostics (IVDs), respectively, which means that medical devices and IVDs certified in accordance with the MDD, the AIMDD and the In Vitro Diagnostics Directive (IVDD) before the end of the transitional period established in the MDR and the IVDR will be allowed to remain on the EEA market.

According to the proposal, medical devices and IVDs would benefit from the prolonged transitional periods if they fulfill certain conditions. Medical devices and IVDs must not present an unacceptable risk to patient and user health and safety. Moreover, the application of the extended transitional periods would not cover devices that have undergone significant changes in terms of their design and intended purpose. Manufacturers also must have started the process of transitioning their devices to the MDR's

requirements.

Reasons behind proposed extension of transitional periods

Despite progress in the implementation of the MDR and the IVDR, there have been significant delays in the transition of medical devices and IVDs to the new rules, as well as challenges in respecting the original transition deadlines provided in the regulations. Limited notified body availability and capacity, shortages in the supply of raw materials in the EU and lack of preparedness of manufacturers to bring their devices into conformity with the regulations are among the factors that have contributed to these delays and challenges. To avert the risk of disruption to the supply and availability of medical devices and IVDs on the EU market that could impact the protection of patient health, the European Commission proposed to allow safe legacy devices to remain on the market in the EEA after the end of the currently applicable transitional period.

Next steps

The proposal adopted by the European Commission will be considered for adoption by the European Parliament and the European Council through a co-decision procedure.

If adopted in its current form, the proposed extension of the transitional provisions would have many implications for the medical device industry. If you have any questions about the effect of the extension of the MDR's transitional period, please reach out to a member of Cooley's life sciences regulatory team.

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