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The implementation of **Regulation (EU) 2017/745 on medical devices** (MDR) was discussed on the second day of the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) on 9 December 2022. The European Commission proposes to extend the transition period currently foreseen in the MDR for devices certified in accordance with the Medical Device Directive (MDD) and the Active Implantable Medical Device Directive (AIMDD) through legislative amendment of the transitional provisions of the MDR. The extension of the transition period would be in the form of a staggered approach based on the risk classification of devices.

The transition period foreseen in the MDR provides that the deadline for recertification of medical devices in accordance with the regulation is 26 May 2024. A broad range of stakeholders, including the medtech industry, consider this timeline to be unattainable and have called on the European Commission to extend the recertification deadline. This extension would be based on the risk classification of devices and would mean that devices certified in accordance with the MDD and the AIMDD will remain on the market in the European Economic Area (EEA) after the end of the currently applicable transition period.

The European Commission proposes the following targeted legislative amendments:

- Extension of the transitional provisions foreseen in the MDR based on the risk class of each device.
  - 26 May 2027 for high-risk (Class III and Class IIb) medical devices
  - 26 May 2028 for medium- and low-risk (Class IIa and Class I) medical devices
- Elimination of the sell-off date of 26 May 2025 for medical devices that are already available on the EEA market to prevent safe medical devices from being removed from the market.

EU Commissioner for Health and Food Safety Stella Kyriakides noted that the proposed amendments would apply solely to medical devices that are safe for patients.

Following discussion with the health ministers of the EU member states, Kyriakides acknowledged the need for interim measures in relation to CE certificates of conformity previously issued for medical devices that have expired or will expire soon.

Shortly after the EPSCO meeting concluded, the European Commission published a **position paper** prepared by the Medical Device Coordination Group. The purpose of the position paper is to ensure a uniform approach to the application of market surveillance measures to bridge the gap between the expiration of certificates and the issuance of new certificates. The position paper provides guidance on how competent authorities should apply Article 97 MDR to devices that do not comply with the MDR due to expiration of their CE certificates of conformity issued in accordance with the MDD and the AIMDD before being certified under the MDR.

In addition to the proposed legislative amendments, the European Commission intends to undertake a comprehensive evaluation of the MDR by May 2027. The purpose of the evaluation is to identify structural problems with the MDR, as well as potential medium- and long-term solutions to these concerns. Moreover, the European Commission intends to fund actions to support the implementation of the MDR under the EU4Health programme starting in early 2023.

If you have any questions about the effect of the extension of the MDR transition period, please reach out to a member of your Cooley life sciences regulatory team.

Key Contacts

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