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ALERT

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Reality is Tricky Business in Effective Implementation of the EU Medical Devices Regulation

EU Health Council Supports Delay of MDR Transitional deadlines

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On the afternoon of 9 December 2022, the EU Employment, Social Policy, Health and Consumer Affairs Council (the "Health Council")—consisting of the health ministers of the EU Member States or their respective representatives—considered an 'information note' prepared by the European Commission. The Health Council supported the European Commission's proposal to delay the transitional deadlines to avoid causing harm to EU health systems and, most critically, patient care. According to the European Commission, the urgent targeted legislative amendment will be provided to the EU legislature for consideration at the beginning of 2023.

The Information Note was presented by the EU Health and Food Safety Commissioner, Stella Kyriakides, regarding implementation of Regulation (EU) 2017/745 on medical devices ("Medical Devices Regulation" or the "MDR").

The Information Note highlighted the current state-of-play of MDR implementation and the concerns expressed by several Member States (including the key 'non-papers' provided by France and Germany), members of the European Parliament, the Medical Device Coordination Group ("MDCG") and feedback from Notified Bodies ("NBs").

The reality check

Simply put, these key stakeholders have collectively considered the ambitious transitional deadlines currently set out in Article 120 of the MDR as unrealistic. The most critical deadline is that European Conformity certificates issued under the directives for active implantable medical devices and general medical devices (the "Directives") will become void on 27 May 2024 at the latest.

- As of October 2022, NBs received 8,120 applications and issued 1,990 conformity certificates under the MDR.
- According to the current trajectory, approximately 7,000 certificates could be issued by May 2024. This is in sharp contrast with 22,793 valid certificates which were issued under the Directives and will expire by 26 May 2024. But, according to the European Commission, there are at present only 36 NBs designated under the MDR to perform the third-party conformity assessment. Further, 26 applications for designation are underway and three of them are in the advanced stage.
- Out of those 22,793 certificates, 1,387 certificates will have expired by the end of 2022, 4,311 certificates will expire in 2023 and 17,095 certificates will expire in the first five months of 2024.

Despite the MDCG's efforts to improve certain operational and structural aspects under the MDR through non-legislative guidance documents, the EU legislature now recognises that if not appropriately addressed legislatively, it is very likely that a significant number of life-saving medical devices would be taken off the market because they could not comply with the new requirements under the MDR.

European Commission's position

In order to mitigate the risk of losing these critical medical devices on the EU market, the European Commission has now proposed an urgent, targeted legislative initiative to amend the MDR. The Legislative Proposal will be put forward for consideration by the EU legislature in the beginning of 2023.

The European Commission's current proposal is as follows:

- Staggered deadlines with regard to an extension of the transitional period in Article 120(3) of MDR:
    - Class III and Class IIb devices (devices with a higher risk): 2027
    - Class IIa and Class I (devices with lower risk) requiring the involvement of a Notified Body in the conformity assessment: 2028
- Extension of the transitional period to be coupled with an extension of the validity of certificates issued under the directives for active implantable medical devices and general medical devices if needed for 'legal and practical reasons' under Article 120(2) of MDR
- Extension to apply only to devices that meet the following conditions:
    - those that do not present any unacceptable risk to health and safety;
    - those that have not undergone significant changes in design or intended purpose; and
    - where manufacturers have already undertaken the necessary steps to launch certification under the MDR (e.g., the adaptation of their quality management system), submission and/or acceptance of manufacturer's application for conformity assessment by a Notified Body before, for example, the current deadline of 26 May 2026.
- Removal of the 'sell-off' deadline provided in Article 120(4) of the MDR and Article 110(4) of the In Vitro Diagnostic Regulation to avoid devices unnecessarily being removed from the EU market by 27 May 2025.
- In response to Health Council, the European Commission has committed to a comprehensive review of the MDR in May 2027 to assess whether it achieves its legislative objectives or has a negative impact on patients, public health and the medical technology sector.
- The European Commission will plan to address progressively the 'structural issues' relating to 'niche' or orphan medical devices.

Health Council's reactions

The respective health ministers of 25 Member States spoke in favour of the proposal. Members of the Health Council shared the following common ground:

- There is a general agreement on delaying the proposed transitional deadlines. But some Members preferred one single feasible or otherwise realistic deadline—instead of staggered deadlines as proposed—for ease of administration.
- The revised deadlines should seek to mitigate the risk of compromising health systems and patient access to life-saving medical devices. In that regard, there is a need to protect the medical technology market to avoid supply shortages.
- Members spoke out the need to ensure efficiency in and practical implementation of the administrative certification procedure.