European Commission adopted proposal to extend transition period of MDR

Mitigate the risk of shortages

The European Commission developed the new proposal following a 9 December 2022 meeting of the EPSCO Council, where EU Ministers of Health called on the Commission to swiftly submit a proposal to extend the transition period in the Medical Device Regulation. The proposal will now be negotiated by the European Parliament and the Council.

On 6 January the European Commission adopted a proposal to give more time to certify medical devices under EU MDR to mitigate the risk of shortages. The proposal needs to be adopted by the European Parliament and the Council.

The proposal introduces a longer transition period based on the medical devices' risk class. It will also allow medical devices placed on the market in accordance with the current legal framework and that are still available to remain on the market (i.e., no "sell-off" date).

The proposal does not change any of the current safety and performance requirements provided for in the EU MDR. It only amends the transitional provisions to give more time for manufacturers to transition from the previously applicable rules to the new requirements of the Regulation.

The length of the proposed extension of the transition periods depends on the type of device: higher risk devices such as pacemakers and hip implants would benefit from a shorter transition period (until December 2027) than medium and lower risk ones, such as syringes or reusable surgical instruments (until December 2028).

Key elements of the proposal:

- For medical devices covered by a certificate or a declaration of conformity issued before 26 May 2021 the transition period to the new rules is extended from 26 May 2024 to 31 December 2027 for higher risk devices and until 31 December 2028 for medium and lower risk devices. The extension will be subject to certain conditions, so that only devices that are safe and for which manufacturers have already taken steps to transition to the rules provided for by the Medical Devices Regulation will benefit from the additional time.
- The proposal introduces a transition period until 26 May 2026 for class III implantable custom-made devices, which would give their manufacturers more time to obtain certification by a notified body. Also in this case, the transition period is subject to the application of the manufacturer for a conformity assessment of devices of this type before 26 May 2024.
- To reflect the transition periods put forward by these amendments, the proposal extends the validity of certificates issued up until 26 May 2021, the day when the Medical Devices Regulation became applicable.
- The Commission also proposes to remove the 'sell-off' date currently established in the MDR and in the IVDR. The 'sell-off' date is the end date after which devices that have already been placed on the market, and remain available for purchase, should be withdrawn.

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"Our rules on medical devices will always prioritise patient safety and support for innovation. A combination of factors has left healthcare systems across the EU facing a risk of shortages of life-saving medical devices for patients," said Stella Kyriakides, Commissioner for Health and Food Safety. "Today, we propose a revised regulatory timeline to provide certainty to industry in order to continue producing essential medical devices, reducing any short-term risk of shortages and safeguarding access for patients most in need. I call on the European Parliament and the Council to quickly adopt the proposal. Member States and notified bodies should also work with industry to ensure transition to the new rules provided for by the Medical Devices Regulation, without further delay."