European Commission - Press release

Public health: more time to certify medical devices to mitigate risks of shortages

Brussels, 6 January 2023

Today, the Commission adopted a proposal to **give more time to certify medical devices to mitigate the risk of shortages**. The proposal introduces a longer transition period to adapt to new rules, as foreseen under the Medical Devices Regulation. The new deadlines depend on the medical devices' risk class and will ensure continued access to medical devices for patients. 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 availability of safe medical devices for European patients is our priority. This proposal does not change any of the current safety and performance requirements provided for in the Medical Devices Regulation. 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 will 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 also for class III implantable custom-made devices, giving 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 Medical Devices Regulation and in the In Vitro Diagnostic Medical Devices Regulation**. 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. Removing this 'sell-off' date will ensure that safe and essential medical devices that are already on the market remain available to healthcare systems and to patients in need.

Next Steps

The proposal now needs to be adopted by the European Parliament and the Council through an accelerated co-decision procedure.

Background

Medical devices have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, treatment or alleviation of disease. In April 2017, the European Parliament and the Council adopted Regulation (EU) 2017/745 and Regulation (EU) 2017/746 to reinforce the regulatory framework for medical devices and *in vitro* diagnostic medical devices.

They aim to provide a high level of health protection for patients and users and the smooth functioning of the internal market for these products. To achieve these objectives and in light of

issues identified with the previous regulatory framework, the Regulations set out a more robust system of conformity assessment to ensure the quality, safety, and performance of devices placed on the EU market. The Medical Devices Regulation has been applicable since 26 May 2021. It provides for a transition period until 26 May 2024.

At the EPSCO Council on 9 December 2022, 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.

For More Information

Questions and Answers

Factsheet European Health Union: Supporting the transition to the new medical device framework

Proposal for a Regulation amending Regulation (EU) 2017/745

Medical devices – new Regulations

IP/23/23

Quotes:

> Medical devices save lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring and treatment of diseases. There are more than 500,000 types of medical devices on the market. Most people will need to use a medical device at some point in their lives. Medical devices range from simple contact lenses and sticking plasters to sophisticated pacemakers and hip replacements. Our proposal for an extension of the transitional periods for the application of the Medical Devices Regulation will address the risk of shortages of medical devices on the EU market. We will not allow any risk of significant disruption in the supply of various medical devices on the market, which would affect healthcare systems and their ability to provide care to European patients.
> Margaritis Schinas, Vice-President for Promoting our European Way of Life - 06/01/2023

> 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. 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.
> Stella Kyriakides, Commissioner for Health and Food Safety - 06/01/2023

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