Commissioner Kyriakides welcomes Council vote on the Medical Device Regulation extension

Brussels, 7 March 2023

Today, the Council of the European Union has adopted the Commission's proposal to give notified bodies and manufacturers more time to certify medical devices and thereby mitigate the risk of shortages. This follows the positive vote by the European Parliament last month. The legislative proposal provides a longer transition period to adapt to new rules foreseen under the Medical Devices Regulation, ensuring continued access to medical devices for patients in need.

Welcoming the adoption by the Council, Commissioner for Health and Food Safety, Stella **Kyriakides**, said:

"*I would like to express my gratitude to the European Parliament, the Council, and the Swedish Presidency in particular for swiftly agreeing on our proposal to extend the transitional periods of the Medical Devices Regulation. This is an important step that will help address the short-term difficulties Member States are facing and ensure a continued access to needed medical devices for patients in the EU.*

This revised timeline will provide more flexibility to industry for the ongoing certification of needed medical devices and reduce short-term risks of shortages. This will ensure access for patients most in need without jeopardising their safety. It is important to recall that only devices that are safe and for which manufacturers have already taken steps to transition to the Medical Devices Regulation can benefit from this additional time. Patient safety will always be paramount.

The Commission, together with Member States, notified bodies and the medical industry will continue to work on additional measures to address the structural problems and identify medium and long-term solutions. Ensuring the transition to the new Regulations must be our collective priority to safeguard patient safety and foster innovation in Europe."

Next steps

Following today's adoption by the Council, the proposed amendment to the Medical Devices Regulation is expected to be formally adopted by both the European Parliament and the Council on 15 March 2023. Shortly after, it will be published in the Official Journal and enter into force on the day of its publication.

The Commission will work together with Member States and all stakeholders to provide the necessary support to implement this legislative amendment.

Background

The Medical Devices Regulation has been applicable since 26 May 2021. It provides for a transition period until 26 May 2024. The transition to the new Regulation has been slower than anticipated and healthcare systems in the EU are facing a risk of shortages.

At the EPSCO Council on 9 December 2022, EU Health Ministers called on the Commission to swiftly submit a proposal to extend the transition period in the Medical Devices Regulation. The Commission submitted a proposal on 6 January 2023, which was negotiated by the European Parliament and the Council in an urgency procedure.

For More Information

Proposal for a Regulation amending Regulation 2017/745

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

Questions and Answers

Medical devices – new Regulations

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