European Commission

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

There are more than 500,000 types of medical devices on the market, ranging from low-risk products such as thermometers to high-risk devices such as pacemakers. The 2017 medical devices Regulation and the Regulation on in vitro diagnostics, establish a **modernised and more robust EU legislative framework** to ensure **better protection of public health and patient safety.**

Despite considerable progress with the implementation, the transition to the new rules has been slower than anticipated. Today, healthcare systems throughout the EU are facing a risk of shortages of life-saving medical devices for patients. Additional efforts are needed to address:

- **Limited capacities** of notified bodies
- **Insufficient preparedness** by market operators

The Commission is supporting the transition to enhance:

- **Market readiness**
- **Coordination** among authorities and notified bodies
- **Efficiency of procedures** and reduction of administrative burden

What are notified bodies?
Organisations designated by EU Member States to assess a device's compliance with EU legislation before it is placed on the market and can be used safely by doctors and patients.

Short term actions to mitigate risk of shortages of life-saving devices and disruption of supply

Legislative proposal:

- **Staggered and conditional extension of the transition period** until 2027/2028, according to risk class of the device
- **Extended validity of certificates**
- **Cancellation of "sell-off" date** i.e., allowing devices placed onthe market before or during the transition period to continue to be made available without time limitation

Bridging measures based on application of market surveillance provisions[1]

Gaining momentum to increase number of notified bodies

Implementation **of actions to enhance notified body capacity and ensure availability of medical devices and in vitro diagnostics,** as agreed by the Medical Device Coordination Group[2]

1 MDCG 2022-18 position paper
2 MDCG 2022-14 position paper

Measures for a successful transition in the longer term

- Pilot project on **scientific advice for clinical development strategies** for high-risk devices
- Targeted **support for SMEs** through the Enterprise Europe Network
- Tailored **solutions for orphan devices**

Orphan devices are crucial for treating relatively small group of patients, especially children.

Small and Medium sized Enterprises (SMEs) represent around **95% of medical device manufacturers** in Europe.

Financial support through the EU4Health Programme

- Survey on **implementation** progress
- Grant for **capacity-building of notified bodies,** facilitated **access of SMEs** to notified bodies and increased **preparedness of manufacturers**
- Joint Action on **market surveillance**
- **Orphan devices support** programme, focussed on **paediatrics**
- Support for stronger coordination of the **Notified Bodies Coordination Group**
- Study on **innovation and governance**

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