European Commission - Press release

Commission welcomes adoption by European Parliament of measures to improve the availability of in vitro diagnostics

Brussels, 25 April 2024

The Commission welcomes the adoption by the European Parliament today of measures, proposed by the Commission in January 2024, to **improve the availability of in vitro diagnostics (IVDs)** for patients and healthcare providers. These measures include **granting more time to companies** to transition to the new EU rules on IVDs, introducing a new obligation on manufacturers to **inform national authorities** and the health sector in case of disruption of supply of certain medical devices and allowing for the **gradual roll-out of the European Database on Medical Devices** - Eudamed. The measures **give more time to consider possible actions to safeguard patient care** in instances where certain devices are discontinued and **increase transparency** regarding medical devices on the market.

The availability of IVDs, such as HIV or hepatitis tests, is crucial for patients. A considerable number of IVDs currently on the market do not yet comply with the EU rules which have been applicable since May 2022. Subject to certain conditions, the new rules **give more time for manufacturers to transition to the new requirements without compromising safety and mitigate the risk of shortages**.

The additional time granted to companies depends on the type of device:

- **high individual and public health risk devices** such as **HIV or hepatitis tests** (class D) will have a transition period until December 2027;
- **high individual and/or moderate public health risk devices** such as **cancer tests** (class C) will have a transition period until December 2028;
- **lower risk devices** (class B) such as pregnancy tests and (class A) sterile devices such as blood collection tubes have a transition period until December 2029.

Manufacturers are also required to give **prior notice if they anticipate a disruption** in the supply of certain IVDs or medical devices. They must provide this information **6 months in advance** to competent authorities, as well as distributors and healthcare providers. This will allow them enough time to take action to guarantee patient care.

Today's agreement by the Parliament will also facilitate the **launch of parts of the European database on medical devices, Eudamed**. From the beginning of 2026, the use of several parts of Eudamed will become mandatory. This will increase transparency in the EU and provide an overview of medical devices available on the European market.

Next steps

The Council will now formally adopt the amending Regulation. It will enter into force on the day of its publication in the *Official Journal of the European Union*.

The Commission will work together with Member States and all stakeholders to provide the necessary support to implement this legislative amendment. This will include clarifying in which cases manufacturers must notify a disruption of supply.

For More Information

Revision of the In Vitro Diagnostic Devices Regulation (europa.eu)

Questions and Answers

Factsheet

Proposal for a Regulation

In Vitro Diagnostic Medical Devices Regulation

Medical Devices Regulation

Overview | Public Health (europa.eu)

IP/24/2291

Quotes:

"I warmly welcome today's adoption by the European Parliament of this amending Regulation. In a strong European Health Union, essential medical devices and diagnostics must be available for patients at all times. Today's adoption will help to ensure patient safety, grant more time to manufacturers to adapt to new rules on medical devices, and give more time for healthcare systems to take appropriate actions when devices are discontinued. I call on the Council to adopt the proposal as soon as possible so that the provisions can enter into force without delay."
Stella Kyriakides, Commissioner for Health and Food Safety - 25/04/2024

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