



Commission proposes measures to improve the availability of *in vitro* diagnostics

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Today, the European Commission is proposing **more time for companies to apply the In Vitro Diagnostic Medical Devices Regulation (IVDR)**, under certain conditions. With this revision, the Commission aims to **ensure patient care** by improving the availability of these essential healthcare products. The Commission is also proposing measures to **enhance transparency** in the Medical Device sector including by speeding up the launch of some elements of the European Database on Medical Devices – EUDAMED.

Ensuring the availability of *in vitro* diagnostics

In vitro diagnostics (IVDs) are tests used on biological samples to determine the status of a person's health, such as HIV tests, pregnancy tests or COVID-19 tests. The availability of safe and effective IVDs is therefore essential for patient care. The Regulation, applicable since May 2022, aims to modernise and upgrade the EU framework for these products to ensure their safety for patients.

However, the available data shows that today a considerable number of *in vitro* diagnostics currently on the market do not yet comply with the new rules nor have been replaced by new devices. The situation is especially critical for high-risk IVDs, which are devices used, for example, to test for infections in blood and organ donations. To **improve the availability** of such essential devices, today's proposal gives **more time for manufacturers** to apply the **new rules**, under certain conditions, without compromising safety requirements. This is very important, also taking into account the fact that many manufacturers producing IVDs are small and medium size enterprises.

Under the current provisions, these rules would apply from 26 May 2025 for high risk IVDs or 26 May 2027 for lower risk IVDs. 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) would have a transition period until December 2027;
- **high individual and/or moderate public health risk devices** such as **cancer tests** (class C), would 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.

The proposal also **requires manufacturers to give prior notice if they foresee the interruption of supply of IVDs or medical devices**, so that Member States have more time to take action to ensure patient care.

More transparency on medical devices

The mandatory use of the European database on medical devices, EUDAMED, is key for the effective and efficient implementation of the Medical Device and IVD Regulations. It will increase **transparency** in the EU, providing an overview of all medical devices available on the European market. Today's proposal of the Commission aims to speed up the launch of the parts of EUDAMED that are already finalised, so that it is mandatory earlier (as from late 2025).

Next steps

The Proposal will now be put forward to the European Parliament and Council for adoption.

The Commission will already start in 2024 its preparatory work for a targeted evaluation of the legislation on medical devices. The evaluation should assess how the legislation is affecting the availability of devices, in particular for devices with specific characteristics (e.g. paediatrics, orphan, innovative devices). In the assessment, special attention may also be given to costs and administrative burdens stemming from the implementation of legislation, especially for SMEs.

Background

Medical devices have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

The [In Vitro Diagnostic Medical Devices Regulation](#) (IVDR) established a new regulatory framework for *in vitro* diagnostic medical devices, such as HIV tests, pregnancy tests or COVID-19 tests. It is estimated that around 70% of clinical decisions are made using *in vitro* diagnostic medical devices.

For More Information

[Questions and Answers](#)

[Factsheet](#)

[Proposal for a Regulation](#)

[In Vitro Diagnostic Medical Devices Regulation](#)

[Overview | Public Health \(europa.eu\)](#)

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Quotes:

"A priority of a strong European Health Union is to ensure that medical devices and diagnostics are available to patients, whenever they need them. We must take immediate action to improve their availability. Today's proposal will provide relief for the sector, without compromising patient safety and care. Going forward, we are determined to analyse the root causes that slow the transition and committed to take appropriate action."

Stella Kyriakides, Commissioner for Health and Food Safety - 23/01/2024

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