

Gradual roll-out of Eudamed, information obligation in case of interruption of supply and transitional provisions for certain in vitro diagnostic medical devices

2024/0021(COD) - 23/01/2024 - Legislative proposal

PURPOSE: to address risks of shortages of in vitro diagnostic medical devices in the Union and ensure the timely roll-out of Eudamed.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Regulation (EU) 2017/745 (Medical Devices Regulation (MDR)) and Regulation (EU) 2017/746 (In Vitro Diagnostic Medical Devices Regulation (IVDR)) of the European Parliament and of the Council set a strengthened regulatory framework for medical devices and in vitro diagnostic medical devices (IVDs).

The MDR has been applied since 26 May 2021. A transitional period has been extended by Regulation (EU) 2023/607 and will end on either 31 December 2027 or 31 December 2028, depending on the device's risk class and subject to certain conditions.

The IVDR has applied since 26 May 2022. In January 2022, the European Parliament and the Council adopted a staggered extension of its transitional period, ranging from 26 May 2025 for high-risk IVDs to 26 May 2027 for lower-risk IVDs, and to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions.

CONTENT: this Commission proposal aims to ensure availability of safe devices, essential for healthcare systems, and protect patient care. The latest available data shows that a high number of IVDs currently on the market has not factored in the new rules (nor has been replaced by other devices), meaning that those devices would no longer be available. The number of devices which have not factored in the new rules and are **not expected to transition in time** is particularly high for high risk IVDs (class D). These include important tests detecting infections in the context of blood transfusions or organ donations.

Therefore, this proposal for targeted amendments addresses **two urgent issues**.

Ensuring the availability of in vitro diagnostics

The proposal aims to further **extend the transitional periods to give manufacturers and notified bodies more time to complete the necessary conformity assessment procedures for certain IVDs** to mitigate the risk of shortages of these products, especially of high-risk IVDs, which are used, for example, to test for infections in blood or organ donations or for blood grouping for transfusions. This extension will be subject to conditions and therefore safeguard the high level of requirements set out by the legislation and protect public health.

The changes extend the transitional periods that are applicable to ‘legacy devices’, i.e., those covered by a certificate or declaration of conformity. 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 introduces a requirement for manufacturers to **give prior notice** to authorities, as well as to distributors or health institutions, **if they foresee the interruption of supply of IVDs or medical devices**, which would pose risks to patient care. This measure would enable healthcare systems to have more time to take action to safeguard 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. The proposal to enable and **accelerate a gradual roll-out of Eudamed** and notably speed up the launch of the parts of Eudamed that are already finalised, so that it is mandatory earlier (as from late 2025).

Lastly, this draft Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of in vitro diagnostic medical devices and the associated risk of a public health crisis, as well as the significant delay in the development of the last electronic system of Eudamed. To attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure availability of devices whose certificates have already expired or are due to expire before 26 May 2025, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should **enter into force as a matter of urgency**.