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) - 09/07/2024 - Final act

PURPOSE: to address risks of shortages of in vitro diagnostic medical devices in the Union and ensure the gradual roll-out of the European database on medical devices (EUDAMED).

LEGISLATIVE ACT: Regulation (EU) 2024/1860 of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices.

CONTENT: the regulation updates law on medical devices in order to help **prevent shortages of in vitro diagnostic medical devices** (IVDs) in the EU and to facilitate the timely deployment of Eudamed.

In order to guarantee the availability of in vitro diagnostics, the regulation **extends the deadline for transitioning** to the new system under certain conditions, to avoid shortages of critical IVDs without compromising on safety.

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 new regulation also enables a **gradual roll-out of the European database on medical devices (EUDAMED)** by requiring manufacturers to provide information about their products to existing EUDAMED modules without needing to wait for the remaining modules to be completed. This mandatory registration is expected to take effect as of late 2025.

The revision also introduces an **obligation for manufacturers** to give prior notice about any interruption of supply of certain critical medical devices or IVDs to relevant authorities, health institutions, healthcare professionals and economic operators to whom they supply the device.

ENTRY INTO FORCE: 9.7.2024.