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) - 25/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 511 votes to 20, with 21 abstentions, a legislative resolution on the proposal for a regulation 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, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic (IVD) medical devices.

The European Parliament adopted its position at first reading under the ordinary legislative procedure, taking over the Commission's proposal.

The proposed regulation aims to alleviate the risk of shortages of in vitro diagnostic medical devices in the EU and to facilitate the timely deployment of Eudamed.

With a view to 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.

Secondly, the proposal aims to allow a gradual roll-out of the electronic systems integrated into the European database on medical devices (Eudamed) that have already been completed, instead of waiting for the completion of the last of the six modules for the mandatory use of Eudamed. The use of Eudamed, and in particular its systems for registering economic operators, devices and certificates, should improve transparency and provide information on devices present on the EU market, thus helping to monitor device availability.

Lastly, the proposal aims to impose an obligation on manufacturers to give notice before discontinuing the supply of certain critical medical devices and IVDs.

This 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 electronic system on clinical investigations and performance studies of Eudamed. In order to attain the intended effect of amending Regulations (EU) 2017 /745 and (EU) 2017/746 and to ensure the availability of such devices the certificates of which 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 on the day of its publication in the Official Journal of the European Union.