Transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices

2021/0323(COD) - 15/12/2021 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 687 votes to 6, with 4 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2017 /746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices.

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

The objectives of this amending Regulation are to extend the transitional periods provided for in Regulation (EU) 2017/746 on in vitro diagnostic medical devices, to introduce additional transitional provisions in that Regulation and to defer the application of the provisions of that Regulation with regard to devices manufactured and used internally.

In vitro diagnostic medical devices are essential for the health and safety of EU citizens and SARS-CoV-2 tests are particularly important for the fight against the COVID-19 pandemic. Given the unprecedented scale of the current challenges, it is very likely that Member States, healthcare

institutions, notified bodies, economic operators and other stakeholders will not be in a position to ensure the proper implementation and full application of that Regulation from 26 May 2022.

In order to ensure legal certainty and to avoid any disruption in the supply of these essential health products, this Regulation extends the existing transitional period for devices covered by certificates issued under Directive 98/79/EC and introduces tailor-made transitional periods for devices that are to be subject to conformity assessment involving notified bodies for the first time in accordance with Regulation (EU) 2017/746.

The length of the transitional period should depend on the risk class of the device concerned:

- for high-risk devices such as HIV or hepatitis tests (class D) and certain influenza tests (class C), the transitional period ends on 26 May 2025 and 26 May 2026 respectively, and

- for low-risk devices such as Class B devices and Class A sterile marketed devices, 26 May 2027.

The amending regulation also introduces a transitional period for the requirements applicable to devices manufactured and used within the same health institutions (in-house devices).