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

2021/0323(COD) - 14/10/2021 - Legislative proposal

PURPOSE: to propose a progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 to prevent disruption in the supply of these essential healthcare products.

PROPOSED ACT: Regulation of the European Parliament and 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) 2017/746 on *in vitro* diagnostic medical devices establishes a new regulatory framework for in vitro diagnostic medical devices, such as HIV tests, pregnancy tests or SARS-CoV-2 tests. The new Regulation will replace the current Directive 98/79/EC on in vitro diagnostic medical devices from 26 May 2022 and introduce substantial changes in the sector.

One of the main changes concerns the **involvement of independent conformity assessment bodies** ('notified bodies'). Currently, only a relatively small number of high-risk devices (about 8% of all in vitro diagnostics on the market) is subject to notified body control under Directive 98/79/EC. Under the Regulation, around 80% of in vitro diagnostic medical devices will be under the control of notified bodies, the vast majority of them for the first time.

The COVID-19 public health crisis has created extraordinary circumstances that demand substantial additional resources, as well as increased availability of vitally important in vitro diagnostic medical devices, that could not reasonably have been anticipated at the time of adoption of Regulation (EU) 2017/746. Data on market readiness collected by the European Commission show that Member States, health institutions, notified bodies and economic operators **will not be in a position to comply with the new rules within the timeframe foreseen**.

In vitro diagnostic medical devices are essential for the health and safety of Union citizens and SARS-CoV-2 tests, in particular, are vital for the fight against the pandemic. Therefore, it is necessary to **revise the transitional arrangements** to allow for a gradual implementation of the Regulation in order to ensure an uninterrupted supply of these devices on the Union market.

The **European Parliament**, in a cross-party letter of 11 May 2021 signed by several political groups, called on the Commission to present a legislative proposal to smooth the transition to the new regulatory framework and to ensure the availability of in vitro diagnostic medical devices on the EU market.

CONTENT: in order to ensure legal certainty and to avoid potential market disruption, the Commission proposes to **extend the existing transitional period** for devices covered by a certificate issued under Directive 98/79/EC and to introduce tailored transitional periods for devices that are to be subject to conformity assessment involving notified bodies for the first time under 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, and

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

The Commission proposes to also introduce a **transitional period for the requirements for devices manufactured and used within the same health institution** (‘in-house devices’). This will give health institutions extra time to comply with the new requirements and ensure that in-house tests, which are often essential –especially for rare diseases, can continue to be developed in clinical laboratories.