Transitional provisions for certain medical devices and in vitro diagnostic medical devices

2023/0005(COD) - 06/01/2023 - Legislative proposal

PURPOSE: to ensure that patients across Europe have access to safe medical devices.

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: Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) of the European Parliament and of the Council establish a new regulatory framework to ensure the proper functioning of the internal market for medical devices and in vitro diagnostic medical devices, based on a high level of health protection for patients and users.

In addition, the two regulations :

- set high quality and safety standards for medical devices and in vitro diagnostic medical devices in order to address the common safety issues related to these devices

- significantly strengthen key aspects of the previous regulatory framework such as the supervision of notified bodies, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, while introducing provisions to ensure transparency and traceability of medical devices and in vitro diagnostic medical devices.

BACKGROUND: Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council establish a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and in vitro diagnostic medical devices, taking as a base a high level of protection of health for patients and users.

In addition, the two Regulations:

- set high standards of quality and safety for medical devices and in vitro diagnostic medical devices in order to meet common safety concerns as regards such devices;

- significantly reinforce key elements of the previous regulatory framework, such as the supervision of notified bodies, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, whilst introducing provisions ensuring transparency and traceability regarding medical devices and in vitro diagnostic medical devices.

Due to the impact of the COVID-19 pandemic, the date of application of the MDR was postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council, while the date of 26 May 2024 was maintained as end of the transition period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC may be placed on the market or put into service.

Despite considerable progress over the past years, the overall capacity of conformity assessment (‘notified’) bodies remains insufficient to carry out the tasks required of them. In addition, many

manufacturers are not sufficiently prepared to meet the strengthened requirements of the MDR by the end of the transition period. This is threatening the availability of medical devices on the EU market.

The overall goal of the proposed amendments is to maintain patients' access to a wide range of medical devices while ensuring the transition to the new framework.

CONTENT: this proposal does not alter the MDR or IVDR in substance, nor does it impose any new obligations on the parties concerned. The main purpose of this proposal is to amend the transitional provisions, allowing for an **additional period of time to transition to the MDR's requirements** to avoid shortages.

In concrete terms, the proposal therefore aims to:

- **extend the current transition period** in Article 120 of the MDR, subject to certain conditions, so that only those devices that are safe and for which manufacturers have already taken steps to transition to the MDR will benefit from the additional time. The transition period would be extended from 26 May 2024 to **31 December 2027** for higher risk devices and to **31 December 2028** for lower and medium risk devices;

- **delete the 'sell off'** deadline in the relevant provisions of the MDR and IVDR, i.e. the date until which devices that are placed on the market before or during the transition period and are still in the supply chain when the extended transition period is over can be made available.

The extension of the transition period is complemented by an **extension of the validity of certificates** issued under the previous Council Directives 90/385/EEC and 93/42/EEC for the devices benefiting from the extended transition period. Also the validity of certificates that have already expired since 26 May 2021 would be extended, subject to certain conditions.