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

2023/0005(COD) - 16/02/2023 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 537 votes to 3, with 24 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 the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

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

The aim of the regulation is to **address the risks of shortages of medical devices and in vitro diagnostic medical devices** and thus maintain patient access to a wide range of medical devices.

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.

The MDR is applicable from 26 May 2021. The transition period provided for in the Regulation will end on 26 May 2024.

The IVDR is applicable from 26 May 2022. A staggered extension of its transition period, from 26 May 2025 for high-risk in vitro diagnostics to 26 May 2027 for low-risk in vitro diagnostics and to 26 May 2028 for certain provisions concerning devices manufactured and used in health care facilities, has been adopted.

Despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued in accordance with Directive 90 /385/EEC or Directive 93/42/EEC before 26 May 2024. A large number of manufacturers, especially small and medium-sized enterprises, are not sufficiently prepared to demonstrate compliance with the requirements of Regulation (EU) 2017/745.

The amending Regulation therefore:

- **extends 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;

- **deletes 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.

- **extends 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.