Simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and support of the European Medicines Agency for the expert panels on medical devices and the list of Union harmonisation legislation

2025/0404(COD) - 16/12/2025 - Legislative proposal

PURPOSE: to simplify the current medical device and in vitro diagnostic regulations with a view to reducing regulatory burdens on device manufacturers.

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: Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) aimed to establish a robust, transparent, predictable and sustainable regulatory framework for medical and in vitro diagnostic devices, ensuring a high level of safety and health whilst supporting innovation. They have been applicable since 26 May 2021 and 26 May 2022 respectively. The Regulations are a set of rules governing the development, production, and distribution of medical devices and in vitro diagnostics within the EU. The rules of those regulations aimed at establishing a modernised and more robust EU legislative framework to ensure better protection of public health and patient safety. However, an evaluation of the legislation identified shortcomings having a negative impact on competitiveness, innovation and patient care. For example, at present, coordination mechanisms are inefficient, there is a divergent application of legal requirements by notified bodies and competent bodies and some procedures are overly complex and costly.

CONTENT: the Commission proposal lays down **targeted amendments** to improve the functioning of the current regulatory framework, in particular with regard to the smooth functioning of the internal market, while ensuring a high level of health protection for patients. It responds to implementation challenges identified since the application of the Regulations, particularly for manufacturers, notified bodies and healthcare systems. It seeks to ensure a leaner and more cost-effective regulatory framework and further strengthen the existing level of harmonisation, creating a more competitive and innovative EU market.

The specific objectives of the proposal are as follows:

- to **increase the cost-effectiveness and overall competitiveness** of the EU medical devices and in vitro diagnostic medical devices industry by supporting innovation (including through adaptive regulatory pathways for breakthrough technologies, and through further digitalisation), while ensuring a high level of protection of human health for patients and users;

- to **simplify and streamline** certain requirements and procedures for medical devices and in vitro diagnostic medical devices identified as particularly burdensome and disproportionate, especially for low and medium risk devices and for orphan devices;

- to improve **coordination** at EU level through more coordinated and streamlined oversight of notified bodies, and the provision of EU-level scientific, technical, regulatory and administrative support through stronger involvement of experts panels and the European Medicines Agency (EMA);

- to reinforce international cooperation by empowering the Commission to determine EU participation in high-standard international cooperation and information sharing mechanisms with reliable partners and strengthened uptake of international guidance.

Budgetary implications

The proposal has budgetary implications for the EU, primarily with regard to additional resources needed to ensure: (1) a stronger oversight of notified bodies and a uniform application of the regulatory framework; (2) access to external additional scientific, technical and regulatory expertise to support evidence-based decision-making; and (3) support from the European Medicines Agency (EMA) for better coordination of activities undertaken by national authorities in relation to the implementation of the MDR and IVDR, in particular in the areas of vigilance and market surveillance, borderline and classification decisions, clinical investigations and performance studies, and derogations in exceptional cases relating to patient health and safety.

The proposal authorises the Commission to set **fees** for certain activities required under the existing MDR and IVDR and the proposed amendments, such as the assessment and monitoring of notified bodies and the provision of scientific and regulatory advice. Those activities may therefore be funded, at least partially, through fees, with the possibility to introduce reduced rates for SMEs.

The impact on the EU budget of the costs of enhanced coordination will **eventually reduce costs for economic operators** thanks to benefits stemming from uniform practices in the single market, streamlined procedures and a more robust and predictable regulatory infrastructure that enhances competitiveness and stimulates innovation. Moreover, the proposed amendment strengthens the EU's ability to effectively prevent and respond to public health threats, such as shortages in the supply of medical devices and safety concerns, thereby minimising the costs associated with any inefficiencies in the regulatory framework.

The combination of these measures is expected to generate overall cost savings of EUR 3.3 billion per year, including EUR 2.4 billion in administrative savings.