Resolution on the urgent need to revise the Medical Devices Regulation

2024/2849(RSP) - 23/10/2024 - Text adopted by Parliament, single reading

The European Parliament adopted a resolution on the urgent need to revise the Medical Devices Regulation.

The text adopted in plenary was tabled by the EPP, S&D, ECR, Renew and Greens/EFA groups.

The Medical Devices Regulation (MDR) and the In Vitro Medical Devices Regulation (IVDR) were adopted to strengthen the regulatory framework for medical devices and in vitro diagnostic medical devices, as a response to several high-profile scandals with unsafe medical equipment, with the purpose of ensuring higher standards of safety, transparency and clinical performance while also fostering innovation in the sector.

Many stakeholders, in particular small and medium-sized manufacturers, notified bodies and healthcare providers, have reported difficulties in navigating the complex regulatory procedures under the current MDR and IVDR framework, with potential risks posed to the continuous availability of life-saving medical devices and critical in vitro diagnostic tests in the EU.

Moreover, due to a lack of harmonised procedures across notified bodies in the EU, among other things, manufacturers can in some instances face unpredictable timelines for certification and market access, which creates unpredictability, alongside inconsistency in decisions and a lack of transparency in relation to the work of the notified bodies.

Against this background, Parliament encouraged the notified bodies to ensure that there are **sufficient resources** to meet the market demand in a timely manner. The Commission and the Member States are called on to enhance support and cooperation to ensure that the notified bodies have the optimal capacities and capabilities to fully implement the regulatory framework.

Parliament also advocated the creation of transparent and binding timelines, including clock stops for procedural steps in conformity assessment by notified bodies, thus creating predictability and certainty for manufacturers regarding the market access procedure and its duration within the EU. It called for **transparency in notified bodies' fees and fee structures**, to allow economic operators to compare notified bodies and make informed choices, ensuring that fees remain a fair compensation for the public service provided.

The resolution stressed the need to eliminate the unnecessary re-certification of products and underlined that certain product updates or adjustments should not necessarily lead to an entire re-certification of the product. It stressed the need to harmonise such provisions and ensure consistency across the EU. Cooperation is needed between the competent authorities and advisory bodies responsible for other regulatory frameworks, and for products to be classified correctly and consistently.

Parliament called on the Commission to:

- propose, by the end of Q1 2025, delegated and implementing acts to the MDR and the IVDR to address the most pressing **challenges and bottlenecks** in the implementation of the legislative frameworks and to propose the systematic revision of all relevant articles of these regulations, accompanied by an impact assessment, to be conducted as soon as possible;

- make full use of legislative and non-legislative tools to resolve issues of divergent interpretation and of practical application to streamline the regulatory process, improve transparency, and eliminate unnecessary administrative work for notified bodies and manufacturers, particularly **SMEs**, without compromising patient safety;

- consider **fast-track and prioritisation pathways** for the approval of innovative technologies in areas of unmet medical need and for devices linked to health emergencies.

The resolution also called for the introduction of adapted rules for **orphan and paediatric medical devices** as well as for more efficient conformity assessment procedures tailored to medical devices and in vitro diagnostics serving relatively small markets, such as products for the treatment of children or rare diseases.

Lastly, Parliament called on the Commission to continuously monitor the availability of devices and to take appropriate action to keep them available in the EU market. In this regard, it called for an **urgent full implementation of EUDAMED**, which will enable information about medical devices and manufacturers to be processed to enhance transparency, provide better access to information for the public and healthcare professionals, and enhance coordination between Member States.