AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

AESGP Statement on the European Parliament's Call to Urgently Revise the Medical Devices Regulation

Brussels, 23 October 2024 - The European Parliament adopted a resolution on the urgent need to revise the Medical Devices Regulation (MDR), calling on the European Commission to address current challenges in the implementation of the MDR.

AESGP welcomes the European Parliament's call for the Commission to propose, by the end of the first quarter of 2025, delegated and implementing acts to address the most pressing challenges and bottlenecks in the implementation of the MDR.

This action is in line with AESGP recommendations to improve the current regulatory framework by pursuing targeted reforms building on existing provisions, which were published in the **AESGP White Paper "Lessons learned with the MDR Implementation".**

In addition, AESGP supports the call for the Commission to **make full use of legislative and non-legislative tools to resolve issues of divergent interpretation and practical application** to streamline the regulatory process, improve transparency, and eliminate unnecessary administrative work for notified bodies and manufacturers, particularly SMEs.

Furthermore, AESGP agrees with the Parliament's call to **improve predictability and transparency concerning conformity assessment timelines and costs** associated with conformity assessment procedures, as well as the need for correct and consistent classification of products.

AESGP believes that any concrete measures must be based on a high level of health outcomes for patients and users, as reflected in the current safety and quality requirements of the MDR.

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