AESGP welcomes MDR amendment and highlights need to tackle MDR systemic issues

AESGP statement on Regulation (EU) 2023/607 amending the Medical Devices Regulation 2017/745 (MDR) and In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

The Association of the European Self-Care Industry (AESGP), representing manufacturers of self-care medical devices, welcomes the adoption and today's publication of Regulation (EU) 2023/607 extending the transition period of devices in conformity with the previous Directives 90/385/EEC and 93/42/EEC. In doing so, it mitigates the imminent risk of medical device shortages and ensures continued access to safe medical devices for patients throughout Europe.

To ensure the uniform and swift implementation of Regulation (EU) 2023/607, **it is important that the technical and practical details of its individual provisions are further clarified** through the publication of a European Commission Q&A document and other relevant publications.

In parallel, AESGP calls upon all actors, including the European Commission, Member States and Notified Bodies, to **address systemic and resource issues related to the regulatory structure and governance** of the MDR – covering for example, limited Notified Body capacities and duration of conformity assessment procedures – to ensure its full and effective implementation.

AESGP and its members remain committed to successfully completing the transition to the MDR and ensuring its full application.

Brussels, 20 March 2023

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