AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

AESGP Statement on the European Commission's legislative proposal amending the IVDR and MDR

On 23 January 2024, the European Commission published its legislative proposal amending both the *In Vitro* Diagnostic Medical Devices Regulation 2017/746 (IVDR) and the Medical Devices Regulation (EU) 2017/745 (MDR). The proposal aims to extend the transitional period for certain IVDs, enable a gradual roll-out of the European database on medical devices (EUDAMED), as well as introduce a requirement for manufacturers to notify interruption of supply of certain medical devices (MDs) and in vitro diagnostics (IVDs).

AESGP fully supports the availability of EUDAMED as an integral part of the MDR and IVDR. However, we want to highlight that certain preconditions are needed before any modules of EUDAMED become mandatory.

We welcome the Commission's intention to start preparatory work for a targeted evaluation of the MDR and IVDR in 2024, as clarified in the explanatory memorandum accompanying the proposal. We will engage in the associated processes and discussions with all stakeholders.

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