

Association of the European Self-Care Industry

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

On 6 January 2023, the European Commission published its legislative proposal to amend Regulation (EU) 2017/745 on medical devices (MDR), in which the extension of the transitional provisions for certain medical devices is introduced.

The Association of the European Self-Care Industry (AESGP), representing manufacturers of self-care medical devices, welcomes the Commission's proposal to conditionally extend the transition period for devices in conformity with previous Directives 90/385/EEC and 93/42/EEC, aimed at addressing the imminent risk of shortages of medical device and, therefore, ensuring access to safe medical devices for patients across Europe.

Given the urgency of this proposal and in order to allow the draft Regulation to enter into force as soon as possible, a rapid adoption of the proposal by the European Parliament and the Council is essential.

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

9 January 2023

