AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

AESGP Statement on the MDCG Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices (MDCG 2022 – 5)

10 May 2022

On 26 April, the European Commission published the MDCG Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices. The Association of the European Self-Care Industry (AESGP), representing manufacturers of self-care medical devices, including substance-based medical devices, and non-prescription medicines, generally welcomes the efforts undertaken by regulators, in consultation with stakeholders, leading to the publication of this Guidance.

AESGP believes that a balanced demarcation between the different product categories of medical devices and medicinal products is paramount to ensure continued access to safe and effective devices for patients and consumers, healthcare professionals and healthcare systems in Europe and abroad.

The publication of the MDCG Borderline Guidance represents an important step in the ongoing journey towards the full implementation of the MDR system. The demarcation and qualification of a given product as a medical device marks the obvious very first step for any manufacturer, before addressing classification and ensuring compliance of the product with MDR requirements. At the same time, and like any other MDCG Guidance, the published document is not legally binding as its main purpose is to assist stakeholders in implementing the medical devices regulations and by that ensuring uniformity in the application of the regulations. It must, therefore, be implemented in conjunction with the legal text of the MDR and other applicable pieces of legislation as interpreted by the jurisprudence of the Court of Justice of the European Union in ongoing[1] and future court cases.

Given its complexity and structure, AESGP believes that the practical impact of the Borderline Guidance is still unknown. Consequential actions will depend on the collaborative efforts of all the MDR actors to apply the document as a whole, while individual sections are put into context, notably regarding general principles, and, where relevant and as indicated in the document, in complement to the *MEDDEV 2.1/3 rev. 3 Guidance on borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative*

Acknowledging that certain compromises have been made during the long drafting process of this Guidance, AESGP considers that any remaining uncertainties and challenges on specific aspects of the MDCG Borderline Guidance are best to be addressed through a coordinated implementation process between manufacturers, notified bodies and competent authorities alike. In this respect, AESGP remains committed to cooperating with EU regulators and other stakeholders in the implementation of the MDCG Guidance document, aiming to achieve a consistent and coherent approach to borderline products.

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[1] See in particular, the pending request for a preliminary ruling to the Court of Justice of the European Union in Case-496/21.

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