AESGP Statement on Regulation (EU) 2024/1860 amending the IVDR and MDR

On 9 July 2024, Regulation (EU) 2024/1860 amending both the *In Vitro* Diagnostic Medical Devices Regulation 2017/746 (IVDR) and the Medical Devices Regulation (EU) 2017/745 (MDR) was published in the Official Journal of the European Union. It extends the transitional period for certain IVDs, enables a gradual roll-out of the European database on medical devices (EUDAMED), and introduces a requirement for manufacturers to notify interruption or discontinuation of supply of certain medical devices and IVDs.

With the publication in the Official Journal, the Regulation entered into force on the same day (i.e. 9 July 2024), while the notification obligations for manufacturers in case of interruption or discontinuation of supply of certain devices will be subject to a six-month transition period and only be applicable as from 10 January 2025.

AESGP welcomes the ongoing efforts from the European Commission to develop questions and answers documents addressing the three areas of amendments introduced by Regulation 2024/1860.[1] This is in particular relevant for the new Article 10a of the MDR and IVDR regarding the obligations of manufacturers to notify interruption or discontinuation of supply of certain medical devices and IVDs, where further clarification is of importance to ensure a proportionate and pragmatic implementation of this new provision.

Brussels, 10 July 2024

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[1] The Q&A on the extension of the IVDR transitional periods has already been published on the Commission website here.