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INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

EU updates regulation on electronic instructions for medical devices

On 26 June 2025, Commission Implementing Regulation (EU) 2025/1234 was adopted, amending Implementing Regulation (EU) 2021/2226 with regard to medical devices for which instructions for use may be provided electronically. The new regulation also amends Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021, which lays down rules for the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards electronic instructions for use of medical devices, with regard to medical devices for which instructions for use may be provided in electronic format.

Considering technological innovations in the healthcare sector and growing environmental concerns — which are now more relevant than ever — as well as consulting healthcare professionals on this issue, European lawmakers concluded that providing instructions for the use of medical devices and their accessories in electronic format instead of paper format would offer clear advantages. They found that this would enable the healthcare sector to deliver solutions more effectively and quickly.

Although limited to certain categories of medical devices, Article 3 of Implementing Regulation (EU) 2021/2226 already provided for this possibility. In view of the current situation, however, European lawmakers concluded that there were no longer any valid reasons for maintaining this restriction. The scope of Implementing Regulation (EU) 2021/2226 was therefore extended to cover the following:

i) All medical devices and their accessories provided for in Regulation (EU) 2017/745, of the European Parliament and of the Council of 5 April 2017 on medical devices ("**MDR**");

ii) Medical devices intended for professional users, including the devices covered by the transitional provisions laid down in Article 120 of the said Regulation;

Providing instructions for the use of medical devices and their accessories in electronic format instead of paper format would offer clear advantages. They found that this would enable the healthcare sector to deliver solutions more effectively and quickly.

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iii) The non-medical devices listed in Annex XVI to the MDR, provided they are intended for professional use.

However, with the clear intention of protecting recipients of instructions who are not qualified healthcare professionals, whenever medical devices intended for professional use may also be used by lay persons, such as patients themselves, specific requirements apply. In such cases, the instructions for use intended for these users must be provided in paper format.

In view of the phased implementation of the European medical device database ("**EUDAMED**"), it is also expected that, from the date when registration of devices on the platform becomes mandatory, manufacturers will make the internet address where electronic usage instructions can be accessed available.

Implementing Regulation (EU) 2025/1234 clarifies and amends some of the rules set out in Implementing Regulation 2021/2226, with the aim of eliminating uncertainties and overlaps.

The Regulation will enter into force on 16 July 2025, twenty days after its publication in the Official Journal of the European Union. ■