EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2024/2826
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[…](2025) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[1], and in particular Article 5(6) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2021/2226[2] limits its application to certain medical devices and their accessories.

(2) The results of a survey on replacing paper-based instructions for use by electronic instructions for use the Commission carried out from 1 August to 10 October 2024 show a clear preference, among healthcare professionals, for receiving instructions for use in electronic form than in paper. Providing instructions for use in electronic form helps the health sector deliver better and faster solutions.

(3) The scope of application of Implementing Regulation (EU) 2021/2226 should therefore be extended to all medical devices and their accessories covered by Regulation (EU) 2017/745 that are intended for professional users.

(4) From the moment in which the registration of devices in the European database on medical devices (Eudamed) becomes mandatory, manufacturers should provide to Eudamed's Unique Device Identifier ('UDI') database the Uniform Resource Locator ('URL') under which the electronic instructions for use are persistently accessible.

(5) For devices that fall under the transitional provisions provided for in Article 120 of Regulation (EU) 2017/745, Commission Regulation (EU) No 207/2012[3], now repealed, should continue to apply until the end of the transitional period provided for in paragraph 3a, point (b), of Article 120 of Regulation (EU) 2017/745.

(6) Implementing Regulation (EU) 2021/2226 should therefore be amended accordingly.

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[1] OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj.

[2] Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices (OJ L 448, 15.12.2021, p. 32, ELI: http://data.europa.eu/eli/reg_impl/2021/2226/oj).

[3] Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OL L 72, 10.3.2012, p. 28, ELI: http://data.europa.eu/eli/reg/2012/207/oj).

(7) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2021/2226 is amended as follows:

(1) in Article 3, paragraph (1) is replaced by the following:

'(1) Manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to medical devices and their accessories covered by Regulation (EU) 2017/745 intended for use by professional users.';

(2) in Article 6, paragraph (4) is replaced by the following:

'(4) Where, for implantable medical devices and their accessories covered by Regulation (EU) 2017/745, a part of the instructions for use is intended to be provided to the patient, that part shall not be provided in electronic form.';

(3) in Article 7, the following paragraph is added:

'(3) The instructions for use in electronic form shall be available through a persistently accessible Uniform Resource Locator (URL), which the manufacturer shall provide to the UDI database in accordance with Part B, point 22, of Annex VI to Regulation (EU) 2017/745, at the latest when the registration of devices in Eudamed applies in accordance with Article 123(3), points (d) and (e), of that Regulation.';

(4) in Article 10, second subparagraph, the date '26 May 2024' is replaced by '31 December 2028, at the latest'.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN