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

THE EUROPEAN COMMISSION,

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) For some medical devices, the provision of instructions for use in electronic form instead of in paper form can be beneficial. It can reduce the environmental burden and reduce costs for the medical device industry while maintaining or improving the level of safety.

(2) Commission Regulation (EU) No 207/2012 ([2]) has established conditions under which instructions for use of medical devices subject to Council Directive 90/385/EEC ([3]) and Council Directive 93/42/EEC ([4]) could be provided in electronic form instead of in paper form. Both Council Directives have been repealed and replaced by Regulation (EU) 2017/745. The rules as regards electronic instructions for use should therefore be adapted to the new requirements of Regulation (EU) 2017/745 and technological developments in the field.

(3) The possibility of providing instructions for use in electronic form instead of in paper form should be limited to certain medical devices and accessories intended to be used under specific conditions. For reasons of safety and efficiency, users should always have the possibility to obtain those instructions for use in paper form upon request.

(4) In order to reduce potential risks as far as possible, the appropriateness of the provision of instructions for use in electronic form instead of in paper form should be subject to a specific risk assessment by the manufacturer.

(5) To ensure unconditional access to the instructions for use in electronic form and to facilitate the communication of updates, those instructions should be available on the website of the manufacturer in an official language(s) of the Union determined by the Member State in which the device is made available to the user or patient.

(6) In order to ensure safety and consistency, instructions for use in electronic form which are provided in addition to instructions for use in paper form should be covered by this Regulation as regards limited requirements in relation to their contents and websites.

(7) The possibility of providing instructions for use in electronic form should be without prejudice to obligations related to the provision of implant cards in accordance with Article 18 of Regulation (EU) 2017/745.

([1]) OJ L 117, 5.5.2017, p. 1.

([2]) Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).

([3]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

([4]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

(8) As the protection of the right to privacy of natural persons with respect to the processing of personal data should be ensured by both manufacturers and notified bodies, it is appropriate to provide that websites containing instructions for use of a medical device fulfil the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council ([5]).

(9) In order to ensure that the rules as regards electronic instructions for use are adapted to the new requirements of Regulation (EU) 2017/745, Commission Regulation (EU) No 207/2012 should be therefore repealed. It should however continue to apply to devices placed on the market or put into service during the transitional period set out in Article 120(3) of Regulation (EU) 2017/745.

(10) 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

This Regulation establishes the conditions under which information in the instructions for use, as defined by Article 2(14) of Regulation (EU) 2017/745 and detailed in Annex I, Chapter III, point 23.4 to Regulation (EU) 2017/745 may be provided by manufacturers in electronic form, as referred to in Annex I, Chapter III, point 23.1(f), to Regulation (EU) 2017/745.

It also establishes certain requirements concerning contents of and websites for instructions for use that are provided in electronic form in addition to instructions for use in paper form.

This Regulation does not cover products listed in Annex XVI to Regulation (EU) 2017/745.

Article 2

For the purposes of this Regulation, the following definitions shall apply:

(1) 'instructions for use in electronic form' means instructions for use displayed in electronic form by the device, contained in portable electronic storage media supplied by the manufacturer together with the device, or made available through a software or a website;

(2) 'professional users' means persons using the medical device in the course of their work in the framework of a professional healthcare activity;

(3) 'fixed installed medical devices' means devices and their accessories which are intended to be installed, fastened or otherwise secured at a specific location in a health institution so that they cannot be moved from this location or detached without using tools or apparatus, and which are not specifically intended to be used within a mobile healthcare institution.

Article 3

(1) Manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to any of the following devices:

(a) implantable and active implantable medical devices and their accessories covered by Regulation (EU) 2017/745;

(b) fixed installed medical devices and their accessories covered by Regulation (EU) 2017/745;

(c) medical devices and their accessories covered by Regulation (EU) 2017/745 and fitted with a built-in system visually displaying the instructions for use.

([5]) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

(2) Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions:

(a) the devices and accessories are intended for exclusive use by professional users; and

(b) the use by other persons is not reasonably foreseeable.

(3) For software covered by Regulation (EU) 2017/745, manufacturers may provide instructions for use in electronic form by means of the software itself instead of in paper form.

Article 4

(1) Manufacturers of devices referred to in Article 3, paragraphs 1 and 3, that provide instructions for use in electronic form to users instead of in paper form shall undertake a documented risk assessment which shall cover at least the following elements:

(a) knowledge and experience of the intended users in particular regarding the use of the device and user needs;

(b) characteristics of the environment in which the device will be used;

(c) knowledge and experience of the intended user of the hardware and software needed to display the instructions for use in electronic form;

(d) access of the user to the reasonably foreseeable electronic resources needed at the time of use;

(e) performance of safeguards to ensure that the electronic data and content are protected from tampering;

(f) safety and back-up mechanisms in the event of a hardware or software fault, particularly if the instructions for use in electronic form are integrated within the device;

(g) foreseeable medical emergency situations requiring the provision of information in paper form;

(h) impact caused by the temporary unavailability of the specific website or of the internet in general, or of their access in the healthcare institution as well as the safety measures available to cope with such a situation;

(i) evaluation of the period within which the instructions for use shall be provided in paper form at the user's request;

(j) assessment of the website's compatibility displaying the electronic instructions for use with different devices which could be used to display those instructions;

(k) management of different versions of the instructions for use, where applicable in accordance with Article 5(8).

(2) The risk assessment for the provision of the instructions for use in electronic form shall be updated in view of the experience gained in the post-marketing phase.

Article 5

Manufacturers of devices referred to in Article 3, paragraphs 1 and 3, may provide instructions for use to users in electronic form instead of in paper form under the following conditions:

(1) the risk assessment referred to in Article 4 shall demonstrate that providing instructions for use in electronic form maintains or improves the level of safety obtained by providing the instructions for use in paper form;

(2) they shall provide instructions for use in electronic form in all Member States where the product is made available or put into service unless duly justified in the risk assessment referred to in Article 4;

(3) they shall have a system in place to provide the instructions for use in paper form at no additional cost for the user, within the time period set out in the risk assessment referred to in Article 4 and at the latest within 7 calendar days of receiving a request from the user or at the time of delivery of the device if so requested at the time of order;

(4) they shall provide, on the device or a leaflet, information on foreseeable medical emergency situations and, for devices fitted with a built-in system visually displaying the instructions for use, information on how to start the device;

(5) they shall ensure the proper design and functioning of the instructions for use in electronic form and provide verification and validation evidence to this effect;

(6) for medical devices fitted with a built-in system visually displaying the instructions for use, they shall ensure that displaying the instructions for use does not impede the safe use of the device, in particular, life-monitoring or life-supporting functions;

(7) they shall provide, in their catalogue or other appropriate device information support, information on software and hardware requirements needed to display the instructions for use;

(8) they shall have a system in place to clearly indicate when the instructions for use have been revised and to inform each user of the device thereof if the revision was necessary for safety reasons;

(9) for devices with a defined expiry date, except implantable devices, they shall keep the instructions for use available for users in electronic form for 10 years after the last device has been placed on the market and at least 2 years after the end of the expiry date of the last produced device;

(10) for devices without a defined expiry date and implantable devices, they shall keep the instructions for use available for the users in electronic form for 15 years after the last device has been placed on the market;

(11) the instructions for use shall be available on their website in an official language of the Union determined by the Member State in which the device is made available to the user or patient;

(12) effective systems and procedures shall be in place to ensure that device users having downloaded instructions for use from the website can be informed in case of updates or corrective actions with regards to those instructions for use;

(13) all issued historical electronic versions of the instructions for use shall be available on the website.

Article 6

(1) Manufacturers shall clearly indicate on the label that the instructions for use of the device are supplied in electronic form instead of in paper form.

That information shall be provided on the packaging for each unit or, where appropriate, on the sales packaging. In the case of fixed installed medical devices, that information shall also be provided on the device itself.

In the case of software, the information shall be provided at the location from where access to the software is granted.

(2) Manufacturers shall provide information on how to access the instructions for use in electronic form.

That information shall be provided as set out in the second subparagraph of paragraph 1 or, if not practicable, in a paper document supplied with each device.

(3) The information on how to access the instructions for use in electronic form shall also contain the following:

(a) any information needed to view the instructions for use;

(b) the Basic UDI-DI and/or the UDI-DI of the device, as respectively referred to in Article 27(6) and Article 27(1), point (a)(i), of Regulation (EU) 2017/745, and any additional information allowing the identification of the device, including its name and if applicable the model;

(c) relevant manufacturer contact details e.g. manufacturer's name, address, email address or other means of online communication and website;

(d) where and how instructions for use in paper form can be requested and within which time they shall be obtained at no additional cost in conformity with Article 5, point (3).

(4) Where, for devices and accessories referred to in Article 3(1), point (a), a part of the instructions for use is intended to be provided to the patient, that part shall not be provided in electronic form.

(5) The instructions for use in electronic form shall be available entirely as text, which may contain symbols and graphics, with at least the same information as the instructions for use in paper form. Video or audio files may be provided in addition to the text.

Article 7

(1) Where manufacturers provide the instructions for use in electronic form on an electronic storage medium together with the device, or where the device itself is fitted with a built-in system visually displaying the instructions for use, the instructions for use in electronic form shall also be made accessible to the users through a website.

(2) Any website containing instructions for use of a device which are provided in electronic form instead of in paper form shall comply with the following requirements:

(a) the instructions for use shall be provided in a commonly used format that can be read with freely available software;

(b) it shall be protected against unauthorised access and tampering of content in accordance with Article 4(1), point (e);

(c) it shall be provided in such a way that the server downtime and display errors are reduced as far as possible;

(d) it shall fulfil the requirements of Regulation (EU) 2016/679;

(e) the internet address as displayed in accordance with Article 6(2) shall be stable and directly accessible during the periods set out in Article 5, points (9) and (10);

(f) all previous versions of the instructions for use issued in electronic form as referred to in Article 5, point (13), and their date of publication shall be available on the website.

Article 8

Where applicable, the fulfilment of the obligations laid down in Articles 4 to 7 of this Regulation shall be reviewed by a notified body during the procedure applicable for conformity assessment as referred to in Article 52 of Regulation (EU) 2017/745.

Article 9

Instructions for use in electronic form, which are provided in addition to complete instructions for use in paper form, shall be consistent with the content of the instructions for use in paper form.

Where such instructions for use are provided through a website, this website shall fulfil the requirements set out in Article 7(2), points (b), (d), (e) and (f).

Article 10

Commission Regulation (EU) No 207/2012 is repealed.

However, it shall continue to apply to devices placed on the market or put into service in accordance with Article 120(3) of Regulation (EU) 2017/745 until 26 May 2024.

References to Regulation (EU) No 207/2012 shall be construed as references to this Regulation and read in accordance with the correlation table in the Annex.

Article 11

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, 14 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Correlation table

Commission Regulation (EU) No 207/2012	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3(1)	Article 3(1)
Article 3(2)	Article 3(2)
-	Article 3(3)
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6
Article 7	Article 7
Article 8	Article 8
Article 9	Article 9
-	Article 10
Article 10	Article 11