Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (Text with EEA relevance)

COMMISSION REGULATION (EU) No 207/2012

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on electronic instructions for use of medical devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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[(1)], and in particular Article 9(10) thereof,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(2)], and in particular Article 11(14) thereof,

Whereas:

(1) For some medical devices the provision of instructions for use in electronic form instead of in paper form can be beneficial for professional users. It can reduce the environmental burden and improve the competitiveness of the medical devices industry by reducing costs, while maintaining or improving the level of safety.

(2) Such 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 in specific conditions. In any case, for reasons of safety and efficiency users should always have the possibility to obtain those instructions for use in paper form on request.

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

(4) In order to ensure that users have access to the instructions for use, appropriate information about access to those instructions for use in electronic form and about the right to request the instructions for use in paper form, should be provided.

(5) To ensure unconditional access to the instructions for use in electronic form and to facilitate the communication of updates and of product alerts, the instructions for use in electronic form should also be available through a website.

(6) Regardless of the language obligations imposed on manufacturers by the law of the Member States, manufacturers who provide instructions for use in electronic form should indicate on their website in which Union languages those instructions are available.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 207/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(7) Except for medical devices of Class I, as defined in Annex IX to Directive 93/42/EEC, the fulfilment of the obligations laid down in this Regulation should be reviewed by a notified body during the procedure applicable for conformity assessment based on a specific sampling method.

(8) As the protection of the right to privacy of natural persons with respect to the processing of personal data should be ensured by manufacturers and notified bodies as well, it is appropriate to provide that websites containing instructions for use of a medical device fulfil the requirements of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[(3)].

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

(10) It is appropriate to provide for a deferred application of this Regulation so as to facilitate the smooth transition to the new system and to allow all operators and Member States time to adapt to it.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up by Article 6(2) of Directive 90/385/EEC,

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation establishes the conditions under which the instructions for use of medical devices referred to in point 15 of Annex 1 to Directive 90/385/EEC and in point 13 of Annex I to Directive 93/42/EEC may be provided in electronic form instead of in paper form.

It also establishes certain requirements concerning instructions for use in electronic form which are provided in addition to complete instructions for use in paper form relating to their contents and websites.

Article 2

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

(a) ‘instructions for use’ means information provided by the manufacturer to inform the user of the device of its safe and proper use, of its expected performances and of any precautions to be taken as outlined in the relevant parts of point 15 of Annex 1 to Directive 90/385/EEC and of point 13 of Annex I to Directive 93/42/EEC;

(b) ‘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 instructions for use available through a website;

(c) ‘professional users’ means persons using the medical device in the course of their work and in the framework of a professional healthcare activity;

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(d) '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 healthcare facility 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 facility.

Article 3

1 Subject to the conditions set out in paragraph 2, 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 active implantable medical devices and their accessories covered by Directive 90/385/EEC intended to be used exclusively for the implantation or programming of a defined active implantable medical device;

b implantable medical devices and their accessories covered by Directive 93/42/EEC intended to be used exclusively for the implantation of a defined implantable medical device;

c fixed installed medical devices covered by Directive 93/42/EEC;

d medical devices and their accessories covered by Directives 90/385/EEC and 93/42/EEC fitted with a built-in system visually displaying the instructions for use;

e stand-alone software covered by Directive 93/42/EEC.

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;

b the use by other persons is not reasonably foreseeable.

Article 4

1 Manufacturers of devices referred to in Article 3 that provide instructions for use in electronic form 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 facility as well as the safety measures available to cope with such a situation;

i evaluation of the time period within which the instructions for use shall be provided in paper form at the users request.

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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 may provide instructions for use 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 printed 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 on 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 in 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 the users in electronic form for 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 for implantable devices, they shall keep the instructions for use available for the users in electronic form for a period of 15 years after the last device has been manufactured.

Article 6

1 Manufacturers shall clearly indicate 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.