Commission Decision of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (notified under document C(2010) 2363) (Text with EEA relevance) (2010/227/EU)

COMMISSION DECISION

of 19 April 2010

on the European Databank on Medical Devices (Eudamed)

(notified under document C(2010) 2363)

(Text with EEA relevance)

(2010/227/EU)

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 10b(3) thereof,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(2)], and in particular Article 14a(3) thereof,

Having regard to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices[(3)], and in particular Article 12(3) thereof,

Whereas:

(1) Directives 90/385/EEC, 93/42/EEC and 98/79/EC contain provisions on a European databank for medical devices which require the establishment of that databank.

(2) The aim of the European databank for medical devices is to strengthen market surveillance by providing competent authorities with fast access to information on manufacturers and authorised representatives, devices and certificates and to vigilance data, to share information on clinical investigation data, as well as to contribute to a uniform application of those Directives, in particular in relation to registration requirements.

(3) The databank should therefore contain the data required by Directives 90/385/EEC, 93/42/EEC and 98/79/EC, in particular on registration of manufacturers and devices, data relating to certificates issued or renewed, modified, supplemented, suspended, withdrawn or refused, data obtained in accordance with the vigilance procedure and data on clinical investigations.

(4) Such a databank has been developed by the European Commission in cooperation with the Member States under the name ‘European Databank for Medical Devices (Eudamed)’ and is being used by numerous Member States on a voluntary basis.

(5) The data should be entered into the databank using prescribed data transfer methods.

(6) It is appropriate to use an internationally recognised nomenclature for medical devices when entering data into Eudamed in order to allow a uniform description of the devices concerned and efficient use of that databank. Given that data can be entered in all official languages of the Community, a numeric code should be used so that devices can be easily searched.

(7) The Global Medical Device Nomenclature that has been developed based on EN ISO 15225:2000 *Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange* is such an internationally recognised nomenclature. The need to establish and maintain Eudamed and to start implementing the Global Medical Device Nomenclature as a basis for that databank was recalled in the Council Conclusions of 2 December 2003 on Medical Devices[(4)].

(8) An appropriate transitional period is necessary to allow Member States to prepare for the mandatory use of Eudamed and to take account of the changes introduced by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market[(5)].

(9) Member States should only be required to enter data existing before 1 May 2011 to the extent required for the future functioning of Eudamed. It is necessary for the completeness of Eudamed to enter data existing before 1 May 2011 on the manufacturer, the authorised representative and on device registration, which are required by Directives 93/42/EEC and 98/79/EC, in the form in which such data are available at national level.

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

HAS ADOPTED THIS DECISION:

Article 1

This Decision establishes the European Databank on Medical Devices (Eudamed) as databank for the purposes of Article 10b(3) of Directive 90/385/EEC, Article 14a(3) of Directive 93/42/EEC and Article 12(3) of Directive 98/79/EC.

Article 2

Member States shall ensure that the data referred to in points (a) and (b) of Article 10b(1) of Directive 90/385/EEC, points (a), (b) and (c) of Article 14a(1) of Directive 93/42/EEC and points (a), (b) and (c) of Article 12(1) of Directive 98/79/EC, are entered into Eudamed in accordance with the Annex to this Decision.

For clinical investigations Member States shall ensure that an extract of the notifications referred to in Article 10(1) of Directive 90/385/EEC and in Article 15(1) of Directive 93/42/EEC, as well as the information referred to in Article 10(3) and (4) of Directive

90/385/EEC and in Article 15(6) and (7) of Directive 93/42/EEC are entered into Eudamed in accordance with the Annex to this Decision.

Article 3

Eudamed shall use the Hypertext Transfer Protocol Secure (HTTPS) and the Extensible Mark-up Language (XML).

Article 4

When entering data in Eudamed, Member States may choose between on-line data entry and up-loading of XML files.

Member States shall ensure that when entering data into Eudamed medical devices are described using a code from an internationally recognised nomenclature for medical devices.

Article 5

As concerns data existing before the date referred to in Article 6, Member States shall ensure that the data on registration of manufacturers, authorised representatives and devices are entered into Eudamed in accordance with Article 14a(1)(a) of Directive 93/42/EEC and Article 12(1)(a) of Directive 98/79/EC.

That data shall be entered by 30 April 2012 at the latest.

Article 6

Member States shall apply this Decision from 1 May 2011.

Article 7

This Decision is addressed to the Member States.

Done at Brussels, 19 April 2010.

For the Commission

John DALLI

Member of the Commission

ANNEX

TABLE DETAILING THE MANDATORY DATA FIELDS IN THE RESPECTIVE MODULE IN THE EUDAMED DATABANK ACCORDING TO THE OBLIGATIONS ARISING FROM DIRECTIVES 93/42/EEC, 90/385/EEC AND 98/79/EC

Directive 93/42/EEC	**Minimum data required for Eudamed data entry**
Article 14a(1)(a) and Article 14(1) and (2)	1. Actor (manufacturer/authorised representative): (a) Name; (b) Street; (c) Locality; (d) Postcode; (e) Country; (f) Phone or E-mail; (g) Role. 2. Device: (a) Internationally recognised nomenclature code (for data generated after 1 May 2011); (b) Device Name/Make or, where not available, generic name.
Article 14a(1)(b)	3. Certificate: (a) Certificate number; (b) Certificate type; (c) Date of Issue; (d) Expiration Date; (e) Manufacturer and, if applicable, authorised representative (see fields under 1. Actor); (f) Notified Body (selected from system); (g) General Scope description and, where applicable, details on device (see fields under 2. Device); (h) Status and, where applicable, reasons for decision of Notified Body.
Article 14a(1)(c) and Article 10(3)	4. Incident (National Competent Authority Report): (a) Competent Authority reference; (b) Manufacturer, where applicable authorised representative (see fields under 1. Actor); (c) Manufacturer contact; (d) Manufacturer reference/Field Safety Corrective Action (FSCA) nr.;

	(e) Device (see fields under 2. Device), plus where applicable lot number, serial number, software version; (f) Notified Body (selected from system); (g) Device known to be in the market in; (h) Confidential; (i) Complete investigation; (j) Background Information (Description); (k) Conclusion; (l) Recommendation; (m) Action and action description.
Article 14a(1)(d) and Article 15(1), (6) and (7)	5. Clinical Investigation: (a) Manufacturer, where applicable authorised representative (see fields under 1. Actor); (b) Device (see fields under 2. Device); (c) Title of investigation; (d) Protocol number; (e) Primary objective; (f) Competent Authority Contact for this Clinical Investigation; (g) Decisions taken by Competent Authority pursuant to Article 15(6), date of decision and grounds; (h) Early termination on safety grounds pursuant to Article 15(7), date of decision and grounds.
Directive 90/385/EEC	**Minimum data required for Eudamed data entry**
Article 10b(1)(a)	6. Certificate (see fields under 3. Certificate)
Article 10b(1)(b) and Article 8(3)	7. Incident (see fields under 4. Incident)
Article 10b(1)(c) and Article 10(1), (3) and (4)	8. Clinical Investigation (see fields under 5. Clinical Investigation, (a) to (f)): (a) Decisions taken by Competent Authority pursuant to Article 10(3), date of decision and grounds; (b) Early termination on safety grounds pursuant to Article 10(4), date of decision and grounds.
Directive 98/79/EC	**Minimum data required for Eudamed data entry**

Article 12(1)(a) and Article 10(1), (3) and (4) and Annex VIII (4)	9. Actor (for all *in vitro* diagnostic medical devices (IVD's): Address of manufacturer, respectively authorised representative (see fields under 1. Actor). 10. Device: For all IVD's (a) Device (see fields under Device 2.); (b) Information on whether device is 'new'; (c) Discontinuation of placing on the market. In addition for Annex II and self-testing (d) Outcome of performance evaluation, where applicable; (e) Certificates (see fields under 3. Certificate); (f) Conformity with Common Technical Specifications, where applicable; (g) Identification of device.
Article 12(1)(b)	11. Certificate (see fields under 3. Certificate)
Article 12(1)(c) and Article 11(3)	12. Incident (see fields under 4. Incident)

(**1**) OJ L 189, 20.7.1990, p. 17.

(**2**) OJ L 169, 12.7.1993, p. 1.

(**3**) OJ L 331, 7.12.1998, p. 1.

(**4**) OJ C 20, 24.1.2004, p. 1.

(**5**) OJ L 247, 21.9.2007, p. 21.

Status:
Point in time view as at 19/04/2010.

Changes to legislation:
There are outstanding changes not yet made to Commission Decision of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (notified under document C(2010) 2363) (Text with EEA relevance) (2010/227/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.