Communication of IIa, IIb, III class medical devices and AIMDD

Decree no. 2002-1221 of 30 september 2002 and Decree no. 2010-270 of 15 march 2010 relating to categories of medical devices subject to communication implementing and modifying Book V bis of the Code of Public Health. (article R.52111-66)

Object of this notice

Article R.5211-66 pursuant to article L.5211-4of the code of public health modified by the "rights of the patients" law N°2002-303 of March 4, 2002.
The above mentioned article L.5211-4 as well as the present decree represents measures of transposition of article 14 of European directive 93/42/EEC and 2007/47/EEC.

This article provides that all data allowing for identification of devices must be communicated to Afssaps when they are putting into service within French territory.

This provision enables Afssaps to be informed in a comprehensive manner and as soon as possible of its arrival on the market of IIa, IIb, III class medical devices and AIMDD.

Decrees specify the categories of medical devices which are to be the subject of the communication and the contents of this communication.
It also specifies the persons who are bound by this obligation of communication.

Medical devices concerned

Four categories of medical devices are concerned by this obligatory communication:

1. IIa class medical devices
2. IIb class medical devices
3. III class medical devices
The Class IIa, IIb and III medical devices are defined in annex IX of the directive 93/42/EEC fixing the rules of theses medical devices.
4. Active implantable medical devices (AIMDD) as defined in the directive 90/385/EEC.

Data which need to be communicated

The data which have to be communicated to Afssaps are :

- Trade description of the medical device
- Name and address of the person submitting the communication
- A specimen of labelling and instruction for use of the medical device

These elements have to be sent as one single specimen.

Medical devices having the same commercial name, the same EC declaration of conformity and the same instruction for use, in particular the same intended use are subject to only one communication.

The communication must specify whether an animal product, the species or species of origin, intervene in the manufacture of the medical devices. In accordance with subparagraph 4 of article 4 of the directive 93/42/EEC, instructions for use available to the user and to the patient, must be written in French.
Information which must appear in the instruction for use is described in subparagraph 13 of annex I of directive 93/42/EEC.

When must the communication be made?

The communication must be made at the time of the putting into service of the device on national territory.
"Putting into service" is defined in subparagraph i of article 1 of the directive 93/42/ECC.
This definition is as follows: One understands by " putting into service" the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose ".

Persons bound by this obligatory communication

The persons bound by this obligatory communication are the one who first undertake the putting into service on national territory for the final user.
Three categories of persons are thus concerned, namely:

- The manufacturer as defined as “the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name
- The authorised representative as defined as “any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter’s obligations”.
- The distributor as defined in subparagraph 5 of article R. 5211-4 of the code of the public health.

Only one communication per device is necessary.

To avoid multiple communications for the same device, it is recommended that the distributors check the communication has not been made beforehand by the manufacturer and/or the authorised representative.

It is recommended that the manufacturers and/or the authorised representatives inform the distributors concerned when they submit a communication

How to submit these data to Afssaps

By sending documents and information required by decree, with a cover letter summarising the content.

A model of the form to be filled in by the declaring party is available on Afssaps website.

With this form it is possible to specify the class of the medical device and the Global Medical Device Nomenclature GMDN. This non obligatory information is useful for processing by Afssaps.

An acknowledgement of delivery will be sent by Afssaps.

Correspondents in Afssaps

All requested documents should be sent by email to: Communications.DM@afssaps.sante.fr

Or if that is not possible to:

Afssaps
DEDIM/UGI
Communications DM
143/147 Bv Anatole France
93285 Saint Denis Cedex

Any request for information concerning the obligatory communication may be addressed to

Pierrette Toussaint : + 33 (0)1 55 87 36 83 – pierrette.toussaint@afssaps.sante.fr

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Fax : + 33 (0)1 55 87 42 62

Penalties in the event of non communication

If the communication is not submitted at the time the device is put into service, article R.5461-1of the code of public health lays down penalties incurred by the contravener.