Notification to ANSM for Class 3 and 2b implantable Medical Devices (Free translation by MediMark Europe)

Modalities for the transmission of the Summary of the Characteristics of the Device Medical (RCD) at the ANSM – May 2017

Preamble:
Decree No. 2016-1716 of 13 December 2016 relating to the summary of the characteristics of the device (RCD) is to clarify the content and procedures for the transmission of the summary Characteristics of the product to be supplied by the manufacturer of class medical devices III and implantable medical devices at the ANSM, or its European Authorized Representative (EAR).

In accordance with that decree, the elements to be provided in this summary are relative, In particular, the identification of the device, its performance and its clinical evaluation, Elements which belong to the EC marking file constituted in the context of the conformity Assessment.

In this respect, the objective of this FAQ is to guide manufacturers in the Transmission of RCDs to ANSM.

1. What devices are involved?

The medical devices to be transferred by the RCD are, pursuant to Article 1 of Decree No. 2016-1716 of 13 December 2016:
- Implantable medical devices,
- Class III medical devices.

In addition, an RCD is to be provided for Active Implantable Medical Devices (AIMD), to the extent where they belong to the category of implantable MD.

This provision does not apply to:
- customs MDs,
- DMs which are the subject of research involving the human person defined in the first paragraph of Article L.1121-1 of the CSP,
- MD accessories; They are in fact described in the information to be provided, pursuant to 3 °) C, II of Article R 5211-66-1 of the CSP (see question 7),

Finally, ANSM will not require the transmission of an RCD for the following MDs: sutures, staples, Dental fillings, orthodontic appliances, dental crowns, screws, wedges, plates,Guides, pins, clips and connecting devices.

RCDs must be forwarded to the ANSM for each trade name, not for each Product reference.

2. When should RCDs be forwarded to ANSM?

The RCDs must be sent to the ANSM when they are put into service on the national territory of the MD Implantable and Class III MDs, for each trade name; 'Put into service' means In accordance with article R. 5211-4 of the Public Health Code (PSC) as " Disposal of a medical device ready to be used for the first time on the Community market in accordance with its intended purpose '. They are therefore addressed to ANSM at the First made available to the end user in France.

As such, the RCD may be attached to the communication already provided for in Article R. 5211-66 of the CSP, the latter which must also be carried out during putting into service of the DM.

Transmission is carried out only on the occasion of the first commissioning of each commercial designation.

3. Should a RCD be provided for devices already in service?

The date of entry into force of Decree 2016-1716 of December 13, 2016 is scheduled for July 1, 2017. Also, the provisions of the aforementioned decree are not retroactive; They will only concern Implantable MD and Class III MD, put into service on the national territory as from 1 July 2017. Therefore the devices made available to the end-user before 1 July 2017 will not be concerned and will not be the subject of an RCD.

4. Does the transmission of the RCD to the ANSM determines the placing on the market of the Medical Device?

Neither the placing in service nor the placing on the market of the DMs concerned by the provisions of Article R.5211-66-1, are not conditional on the transmission of the RCD by the manufacturer or his Representative, to the ANSM. Indeed, the placing on the market of implantable MD and Class III MD, and the transmission from the RCD to the ANSM, are two different operations, independent of one another.

5. Which operator must transmit the RCD?

Article L. 5211-4 of the CSP, provides that the transmission of RCDs to ANSM is carried out either by Manufacturers, or by the EAR

In this regard :
- whether Decree No 2016-1716 of 13 December 2016, taken on the basis of the provision above, adds a new operator responsible for the said transmission, namely the Distributor, it should be considered that in practice it is accepted that the transmission of the RCD must be made either by the manufacturer or by the authorized representative.
- in the same sense, even though the drafting of the decree imposes this obligation transmission to manufacturers and authorized representatives, the placing on the market for a same commercial designation is carried out only by one of the two.

The decree is thus interpreted as meaning that the transmission of the RCD falls to the manufacturer or his authorized representative.

6. How should the RCD be forwarded to ANSM?

RCDs are to be transmitted electronically using the mailbox Communications.DM@ansm.sante.fr , or via Eudralink, to the mailbox Communications.DM@ansm.sante.fr

This document may be attached to the communication made during the placing on the market of the medical device, such as discussed above (cf. question 2).

The subject of the transmission message must be explicit and contain at least the Commercial name of the product and the abbreviation "RCD".

.7. What should be included in the RCD?

The RCD to be transmitted, for each trade name, comprises the elements listed below, In accordance with article R. 5211-66-1 of the CSP.

In order to facilitate operations for each concerned party, it is requested to provide for each transmission, the Instructions for Use (IFU) of the product, and consequently, either to make a reference for the information requested or to respond to the item if the information is not contained in the IFU.

- The identification elements of the medical device, the manufacturer and, where applicable, the European Authorized Representative, namely:

a) The name or trade name of the medical device, its class of risk and the applicable classification rules; (See IFU + inform the risk class and the rules of classification)

b) The name, trade name or trade mark of the manufacturer, the address of its head office and contact information; Where applicable, the same information concerning the authorized representative ; (Cf.IFU)

c) The date of compilation of the summary of characteristics and its version number; (to be filled in)

- Elements on the use of the medical device:

a) The purpose of the medical device, including medical indications, contraindications and target population ; (Cf IFU)

b) The place of the medical device in the diagnostic or therapeutic strategy, or the therapeutic alternatives; (to be filled in)

c) The users concerned and the training required for them; (Cf IFU)

d) Information on residual risks, adverse reactions and precautions for use; (Cf.IFU)

- A description of the medical device, including:

a) The operating principle of the medical device; (Cf IFU)

b) Where applicable, a reference to the previous model and a description of the changes made; (to be filled in ; In relation with question 9)

c) A description of the accessories, other medical devices or products or substances which are not medical devices, for use in combination with the medical device; (Cf.IFU)

d) A description or the list of the different presentations or variants of the medical device that will be available; (Cf IFU)

e) A reference to the standards used by the manufacturer and, where appropriate, the authorized representative; (Cf IFU)

- Elements relating to clinical evaluation and post-marketing follow-up:

a) A summary of the results of the clinical evaluation referred to in Article R. 5211-36-1; (to ibe filled in)

b) Information on the systematic review of data acquired on the medical device provided for in Article R. 5211-39. (to be filled in)

8. In which language should the RCD be written?

RCDs must be in French. In this respect, the use of the French language is mandatory by the Act No. 94-665 of 4 August 1994 on the use of the French language, known as the Toubon Act.

If by way of derogation, certain documents are transmitted in English, the ANSM reserves the right when it considers it is necessary and useful, to require its translation into French.

9. What to do if there is a change in at least one of the elements contained in the RCD?

Any significant modification of an element present in the RCD must be the subject of a new transmission to ANSM without delay.

A change is considered significant when it is likely to have an impact In terms of safety, vigilance, modification of its performance or claims.

10. Does the failure to comply with the obligations under Article R.5211-66-1 of the PSC penalties?

Failure to comply with the obligations laid down in Article R.5211-66-1 of the PSC may be subject to criminal and financial penalties pursuant to Articles L.5461-6-1 and L.5461-9 of the CSP (Public Health Code)