Notification Number: 2016/379/F

Decree establishing the list of medical devices for which the summary of characteristics of the device referred to in Article L. 5211-4-1 of the Public Health Code must be submitted

Date received	:	21/07/2016
End of Standstill	:	24/10/2016
Issue of comments by	:	Commission

Message

Message 002

Communication from the Commission - TRIS/(2016) 02270
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2016/0379/F

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201602270.EN)

1. Structured Information Line
MSG 002 IND 2016 0379 F EN 21-07-2016 F NOTIF

2. Member State
F

3. Department Responsible
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3. Originating Department
Ministère des affaires sociales et de la santé.
Direction générale de la santé.

Sous-direction de la politique des produits de santé et de la qualité des pratiques et des soins.
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4. Notification Number
2016/0379/F - S10S

5. Title
Decree establishing the list of medical devices for which the summary of characteristics of the device referred to in Article L. 5211-4-1 of the Public Health Code must be submitted

6. Products Concerned
Implantable and class III medical devices

7. Notification Under Another Act
-

8. Main Content
The decree establishes the list of medical devices for which manufacturers will be required to submit to the competent French authority (French National Agency for the Safety of Medicine and Health Products – ANSM) a summary of characteristics of the device. It establishes the obligation to submit the summaries of the characteristics of medical devices to ANSM which are referred to in Article L. 5211-4-1 of the Public Health Code [Code de la santé publique], in accordance with the template set forth in Article R. 5211-66-1 thereof. It relates to class III and implantable medical devices (including active implantable ones) in accordance with current legislation.

9. Brief Statement of Grounds
The placing of medical devices on the market came to be regulated at European level at the beginning of the 1990s. Health safety problems such as faulty PIP breast implants have highlighted gaps in current legislation, particularly with regard to class III medical devices and implantable medical devices. For example, the SCENHIR opinion of October 2014 on metal-on-metal hip implants demonstrates the need to carry out enhanced monitoring of the most sensitive implantable medical devices. The competent authorities do not currently have all of the information they need to carry out their market surveillance tasks.
In order to supplement the decree that requires manufacturers to provide a summary of the characteristics of medical devices when declaring to ANSM that they have been put into service in France, the decree identifies the medical devices concerned by targeting class III and implantable medical devices. This regulatory system targets these medical devices due to their nature and their effects on the health of patients to whom special attention must be paid with regard to evaluation in clinical investigations by the market surveillance authorities. The aim of the national authorities is therefore to improve market surveillance by providing the competent authorities with the relevant information about the performance and clinical evaluation of class III and implantable medical devices.

10. Reference Documents - Basic Texts

Reference(s) to basic text(s): Article L. 5211-4-1 of the Public Health Code

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
-

13. Confidentiality
No

14. Fiscal measures
No

15. Impact assessment
-

16. TBT and SPS aspects
TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft has no significant impact on international trade.

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European Commission

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