Notification Number: 2016/377/F

Decree on the restriction of the sale, resale or use of ultrasound scanners for human foetal imaging

Date received : 21/07/2016

End of Standstill : 24/10/2016

Message

Message 002

Communication from the Commission - TRIS/(2016) 02264
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2016/0377/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: 201602264.EN)

1. Structured Information Line
MSG 002 IND 2016 0377 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
2016/0377/F - S10S

5. Title
Decree on the restriction of the sale, resale or use of ultrasound scanners for human foetal imaging

6. Products Concerned
Medical ultrasound devices

7. Notification Under Another Act
-

8. Main Content
The decree concerns the marketing and use of ultrasound scanners for human foetal imaging. Article 1 prohibits the sale or resale, with a view to their use, of ultrasound scanners for human foetal imaging to individuals other than doctors and midwives. It is also prohibited to sell and resell them to legal entities other than healthcare facilities and companies whose incorporation is permitted by the Public Health Code [Code de la santé publique]. These legal entities are listed in Article 2 of the decree.
In addition, the use of ultrasound scanners is henceforth reserved for doctors and midwives under the conditions stipulated in the Public Health Code. The decree will enter into force three months after it is published in the Official Journal of the French Republic.

9. Brief Statement of Grounds
Ultrasound scanners are medical devices placed on the market for the purpose of diagnosis. They are used for medical purposes under the conditions specified in the manufacturer's instructions. To use such devices, it is necessary to conduct a prior assessment of the risks and benefits which are expected from using this technology and may affect the patient. Ultrasound scanning involves the production of a sound wave which is reflected inside the body and which creates thermal and mechanical effects on human tissue when passing through it. These effects are greater when the ultrasonic beam is focused; the output power of the ultrasound scanner is high and the exposure time increases. During a medical foetal ultrasound scan, the foetus's exposure is brief because the beam is constantly moving. Foetal ultrasound scans for non-medical purposes have been developed over the last few years and expose foetuses to risks with no known medical benefits. The exposure conditions are different from those of a medical ultrasound scan because for a high-quality 3D/4D image to be obtained, the exposure time and the signal strength have to be increased. Therefore, the potential risks associated with the biophysical effects of ultrasound on the foetus are greater than those associated with the uses envisaged by the manufacturer and bring no medical benefits.
The aim of this decree, therefore, is to remedy the dangers posed by the use of medical ultrasound devices by persons who are not healthcare professionals without a medical prescription and without training on how to use them. It therefore limits the sale and resale of these devices solely to healthcare professionals and healthcare facilities. The decree also prohibits their use by non-qualified persons, in accordance with the stipulations of the manufacturer of these medical devices.

10. Reference Documents - Basic Texts
Reference(s) to basic text(s): Article L. 5211-6, point 8 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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Commission européenne

Point de contact Directive (UE) 2015/1535
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