Notification Number: 2010/621/F

Draft decree relating to vigilance of the health products referred to in Article L.5311-1, points 18 and 19 of the French Public Health Code

Date received : 15/09/2010

End of Standstill : 16/12/2010

Message

Message 002

Communication from the Commission - SG(2010) D/52288
Directive 98/34/EC
Translation of the message 001
Notification: 2010/0621/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 - Nao 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: 201002288.EN)

1. Structured Information Line
MSG 002 IND 2010 0621 F EN 15-09-2010 F NOTIF

2. Member State
F

3. Department Responsible
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3. Originating Department
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4. Notification Number
2010/0621/F - S00S

5. Title
Draft decree relating to vigilance of the health products referred to in Article L.5311-1, points 18 and 19 of the French Public Health Code

6. Products Concerned
The introduction of a vigilance system
The products concerned are:
- software programs that are not medical devices used by biomedical laboratories;
- devices with a purpose that is not strictly medical used in biomedical laboratories for performing biomedical examinations.

7. Notification Under Another Act
-

8. Main Content
The purpose of the draft decree is to introduce a vigilance system for the products referred to in point 6 after they have been placed on the market. For the user, it involves reporting to the Agence française de sécurité sanitaire des produits de santé (French agency for the safety of healthcare products) any incident consisting of a failure or alteration of the characteristics or performances of the product or an inadequacy in the labelling or instructions for use likely to have effects that are harmful to human health. The Agency logs, assesses and uses the information in order to protect people, carries out research or work to determine the causes of the reported incidents, takes corrective measures and performs monitoring.
To this end, the manufacturers, publishers, distributors and users of the software and equipment shall provide the Agency with any information it may request within the context of fulfilling its missions (design, manufacture, storage, distribution, availability, update and use of the products and equipment).

9. Brief Statement of Grounds
This text falls under the scope of implementation of the medical biology reform which provides for the compulsory accreditation of biomedical laboratories. The objective of this text is to optimise the quality and safety of the biomedical examination process by providing for vigilance of products which were until now exempt. Yet malfunction of these products (diagnosis support software, centrifuge, etc.) calls the reliability of the results into question.

10. Reference Documents - Basic Texts
Reference texts: - Law No. 2009-879 of 21 July 2009 on hospital reforms, patients, health and territories, in particular Article 69 thereof;
- Order No. 2010-49 of 13 January 2010 on biomedicine, in particular Article 3, point 10 thereof.

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

No - The draft has no significant effect on international trade.

SPS

No - The draft has no significant effect on international trade.

Catherine Day
Secrétaire général
Commission européenne

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Sarah Jane Meli

Ministry of Economy and Commerce Division for Internal Market
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