Notification Number: 2006/550/F

Draft Decree on the resale of second-hand medical devices, laid down in implementation of Article L. 5212-1, and amending the Public Health Code

Date received	:	10/10/2006
End of Standstill	:	Closed
Issue of comments by	:	Commission
Issue of detailed opinion by	:	Commission

Message

Message 002

Communication from the Commission - SG(2006) D/52455
Directive 98/34/EC
Translation of the message 001
Notification: 2006/0550/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.

(MSG: 200602455.EN)

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MSG 002 IND 2006 0550 F EN 11-01-2007 10-10-2006 F NOTIF 11-01-2007

2. Member State
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4. Notification Number
2006/0550/F - S10S

5. Title
Draft Decree on the resale of second-hand medical devices, laid down in implementation of Article L. 5212-1, and amending the Public Health Code

6. Products Concerned
Medical devices

7. Notification Under Another Act
This notification is made in application of Article 8 of the amended Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, laying down a procedure for the provision of information in the field of technical standards and regulations.

8. Main Content
This draft Decree aims to define the rules for implementation of Article L. 5212-1 of the Public Health Code covering the resale of certain second-hand medical devices by inserting a new section into the chapter on materials vigilance, entitled: “resale of second-hand medical devices” containing eight articles (R. 5212-36 to R. 5212-43).
Article R. 5212-36 requires that a technical certificate provided for by the above-mentioned Article L 5212-1 be obtained for the resale of second-hand medical devices that, during their normal use, are subject, in implementation of Article R. 5212-26 of the Public Health Code, to checks on their continued performance by an independent body, known as "external quality control", and to the maintenance requirement pursuant to the Order of 3 March 2003 laying down the list of medical devices subject to these obligations. This relates to devices that emit ionising radiation.
Article R. 5212-37 defines second-hand medical devices as medical devices “in working order” as opposed to new or refurbished medical devices, the transfer of which is interpreted as placing on the market in implementation of Article R. 5211-4 of the Public Health Code.
Article R. 5212-38 lays down the list of documents that must be provided by the reseller to the approved body responsible for issuing technical certificates, to support their request for certification.
General procedures for granting approval by the Director-General of the French Health Products Safety Agency to bodies responsible for issuing technical certificates are stated in Articles R. 5212-39 and R. 5212-40.
Article R. 5212-41 specifies the criteria for granting technical certificates.
By virtue of Article R. 5212-42, at the time of resale, the reseller shall pass on the technical certificate to the beneficiary of the resale. The second paragraph stipulates that the reseller shall however be exempted from having this certificate drawn up in the event that the beneficiary of the resale is a manufacturer of medical devices, unless the latter makes an express request for it.
The technical certificate shall be valid for five months from the date of its issue (Article R. 5212-43).
Finally, a penalty is added to Article R. 5461-1 of the Public Health Code in order to punish breaches of the obligation imposed by Article L. 5212-1 and the provisions of this draft.

9. Brief Statement of Grounds
Currently, the provisions of the Public Health Code transposing Directives 90/385/EEC of 20 June 1990 and 93/42/EEC of 14 June 1993 on medical devices (Articles L. 5211-1 to L. 5211-6 and R. 5211-1 to R. 5211-70) cover the placing on the market of medical devices, understood to mean the transfer free of charge or sale of new or refurbished devices (Article R. 5211-4), making this transfer or sale subject to procedures for certifying that devices comply with key health and safety requirements set by the Directive and to obtaining a CE marking in advance. However, the resale of second-hand medical devices, which are by nature neither new nor refurbished, was not covered at national or Community level. It therefore seems necessary for health safety reasons to oblige the holders of particularly sensitive medical devices, who undertake to resell these items, to provide proof that the devices are in working order compliant with the manufacturer's specifications and have been correctly maintained. For this reason, this draft Decree laid down in implementation of Article L. 5212-1 of the Public Health Code provides that the resale of medical devices that emit ionising radiation shall be subject to obtaining a technical certificate guaranteeing:
1.) that the second-hand medical device has been correctly maintained during its use by the reseller, which will be justified by providing the specific approved body referred to in the above-mentioned Article L. 5212-1 with documents regarding the maintenance of the device drawn up by the holder in implementation of Article R. 5212-28 of the Public Health Code.
2.) that its characteristics and performance are maintained, which will be justified by producing the most recent external quality control report, established in implementation of Directive 97/43/Euratom of 30 June 1997 for medical devices emitting ionising radiation.

10. Reference Documents - Basic Texts
a) Public Health Code (Articles L. 5212-1, R. 5211-4, R. 5212-26 to R. 5212-35 and R. 5461-1)
Penal Code (Article R. 610-1)

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 (Agreement on Technical Barriers to Trade)
a) No
b) iii) The draft will not have any notable impact on international trade.

SPS aspect (Agreement on Sanitary and Phytosanitary Measures)
a) No
b) iii) The draft will not have any notable impact on international trade.

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