Notification Number: 2003/486/F

Draft Decree on blood-derived medicinal products and medical devices incorporating a substance that, if used separately, may be considered to be a blood-derived medicinal product and amending Books V and Va of the Public Health Code (second part: Council of State Decrees).

Date received	:	29/12/2003
End of Standstill	:	30/03/2004
Issue of comments by	:	Commission

Message

Message 002

Communication from the Commission - SG(2004) D/50045
Directive 98/34/EC
Translation of the message 001
Notification: 2003/0486/F

Fristerne indledes ikke - Kein Fristbeginn - Καμμία έναρξη προθεσμίας - Does not open the delays - No abre el plazo - N'ouvre pas de délais - Non fa decorrere la mora - Geen termijnbegin - Nao inicia o prazo - Määräaika ei ala tästä - Inleder ingen frist.

(MSG: 200400045.EN)

1. Structured Information Line
MSG 002 IND 2003 0486 F EN 30-03-2004 29-12-2003 F NOTIF 30-03-2004

2. Member State
FRANCE

3. Department Responsible
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3. Originating Department
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Direction générale de la santé

Sous-direction de la politique des produits de santé
8, avenue de Ségur 75007 Paris

4. Notification Number
2003/0486/F - C10P

5. Title
Draft Decree on blood-derived medicinal products and medical devices incorporating a substance that, if used separately, may be considered to be a blood-derived medicinal product and amending Books V and Va of the Public Health Code (second part: Council of State Decrees).

6. Products Concerned
Active implantable medical devices covered by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.

7. Notification Under Another Act
-

8. Main Content
Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDs) was amended by Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 and by Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 in order to include within the scope of this Directive MDs that incorporate as an integral part a substance that, if used separately, may be considered to be a medicinal product or a constituent of a medicinal product derived from human blood or plasma and that may have an action on the human body secondary to that of the device.

In addition, these Directives introduce particular provisions as regards the procedure for assessing the compliance of these medical devices before they are marketed, the labelling and the release of batches of the substance and of MDs.

Directive 93/42/EEC concerning MDs covers all MDs except active implantable MDs (AIMDs). These are regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to AIMDs, which is not amended by Directives 2000/70/EC and 2001/104/EC. The draft Decree drawn up by the French authorities, however, which transposes into national law the provisions of Directives 2000/70/EC and 2001/104/EC in particular, extends these provisions to cover AIMDs.

For reasons of readability and understanding of the provisions, the whole of the draft Decree has been sent to the European Commission. However, only the provisions on AIMDs are notified within the framework of Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services. They are shown in underlined bold type in the text.

9. Brief Statement of Grounds
AIMDs incorporate a substance that, if used separately, may be considered to be a medicinal product falling within the scope of the abovementioned Directive 90/385/EEC, which expressly lays this down. On the other hand, the 1990 Directive specifies nothing on AIMDs that incorporate blood products of human origin. In the

face of this situation, the French authorities have decided to provide, in the draft Decree containing the provisions notified to the European Commission, that AIMDs that incorporate the substances targeted by Directives 2000/70/EC and 2001/104/EC must follow the same inspection rules as are laid down for MDs other than AIMDs incorporating identical substances. Other solutions would have been: either to expressly exclude AIMDs incorporating such substances from the regulations relating to MDs, which would have the disadvantage of leaving a legal vacuum for such AIMDs, or not to extend the specific procedures and checks provided for MDs to AIMDs. Such a divergence would have no logical basis linked to sanitary safety and would be all the more inconsistent in that it would lead to AIMDs being excluded from the procedures provided for MDs incorporating a substance that may be considered to be a blood-derived medicinal product, which lay down higher-level checks than other procedures, simply because they are "active".

10. Reference Documents - Basic Texts
Directive 90/385/EC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices;

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices;

- Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000, amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma;

- Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001, amending Council Directive 93/42/EEC concerning medical devices;

- Article R. 665-3 and R. 665-4 and Annex I to Book Va 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
No. It is emphasised that there are currently no such AIMDs on the market.

16. TBT and SPS aspects
TBT aspect
a) No.
b) The draft does not have any notable impact on international trade.

SPS aspect
a) No.
b) The draft does not have any notable impact on international trade.

David O'Sullivan
General Secretary
European Commission

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