Notification Number: 2003/66/F

Decree on the conditions of the marketing authorisation for related therapeutic products

Date received	:	20/02/2003
End of Standstill	:	21/05/2003
Issue of comments by	:	Commission

Message

Message 002

Communication from the Commission - SG(2003) D/50390
Directive 98/34/EC
Translation of the message 001
Notification: 2003/0066/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: 200300390.EN)

1. Structured Information Line
MSG 002 IND 2003 0066 F EN 21-05-2003 20-02-2003 F NOTIF 21-05-2003

2. Member State
France

3. Department Responsible
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3. Originating Department
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Sous-direction de la politique des produits de santé
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Madame Flament tél. : 01-40-56-41-32

4. Notification Number
2003/0066/F - C00P

5. Title
Decree on the conditions of the marketing authorisation for related therapeutic products

6. Products Concerned
Related therapeutic products: these products are defined in Article L. 1263-1 of the Public Health Code as "any product, with the exception of medical devices […], which comes into contact with organs, tissues, cells or products derived from the human body or of animal origin during their storage, preparation, processing, packaging or transport before use for therapeutic purposes in human beings, as well as any product which comes into contact with embryos as part of medically assisted procreation."
This legal category of products was created by Law No 98-535 of 1 July 1998 on more stringent health monitoring and health safety checks on health products intended for use on human beings.
During the preparatory work for this Law, it was observed that a number of products were being used for therapeutic purposes without undergoing any assessment as regards their quality and efficacy. Following this observation, a working group was instructed to compile a list of all the products without a precise legal status and develop proposals for categorising these products, according to the potential risks. Those products without status included related therapeutic products used as storage media for grafts or in the preparation of health products of human origin (culture media, etc.).

7. Notification Under Another Act
No.

8. Main Content
The draft Decree deals with the marketing authorisation procedure for related therapeutic products, in implementation of Article L. 1263-2 of the Public Health Code, as well as the methods for manufacturers or importers to inform the French Agency for the Safety of Health Products of unexpected or undesirable effects associated with related therapeutic products, in implementation of Article L. 1263-4 of the same Code. The authorisation request is submitted by the manufacturer or the importer to the Director-General of the French Agency for the Safety of Health Products. The criteria determining the issue of the authorisation are quality of the product, its safety and its efficacy for a specific usage. Authorisation is given for five years. Changes, for example in the manufacture of the product or its composition, must also be authorised. This authorisation may be amended or withdrawn in the event of a problem, particularly in the event of non-compliance with good manufacturing, packaging, storage, importation, transport and distribution practices for related therapeutic products, laid down by the aforementioned Order. Finally, manufacturers and importers must guarantee the traceability of their products from their manufacture up to their sale, and must implement a biovigilance system.

Key words: related therapeutic products, manufacturers, importers, distributors, marketing authorisation, vigilance.

9. Brief Statement of Grounds
These related therapeutic products, of chemical or biological origin, are not subject to any safety checks or any assessment. Some of these products may undergo an impact assessment and a safety check by the French Agency for the Safety of Health Products when they are used for other purposes (particularly as in-vitro

diagnostic medical devices) but these checks do not provide assurance of their safety when used in contact with products of human origin intended for transplanting or with embryos intended for implantation. These related therapeutic products, when used in this way, are currently without status, both at the level of French legislation and at the level of European legislation.
For this reason, the French health authorities felt it necessary to develop a regulatory framework for all related therapeutic products, largely based on existing checks within the field of medicinal products (marketing authorisation, rules of good manufacturing practices).

10. Reference Documents - Basic Texts
Articles of the Public Health Code implemented by the Decree and Order: Articles L. 1263-1, L.1263-2, L. 1263-3 and L. 1263-4.

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
-

13. Confidentiality
No

14. Fiscal measures
No

15. Impact assessment
No

16. TBT and SPS aspects
TBT aspect
Yes

SPS aspect (Agreement on sanitary and phytosanitary measures)
b) No
i) The draft is not a sanitary or phytosanitary measure pursuant to Annex A to the SPS Agreement.

David O'Sullivan
Secretary-General
European Commission

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sent to :

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