Notification Number: 2003/65/F

Order on the rules of good practice relating to the manufacture, packaging, storage, importation, transport and distribution of 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/50389
Directive 98/34/EC
Translation of the message 001
Notification: 2003/0065/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: 200300389.EN)

1. Structured Information Line
MSG 002 IND 2003 0065 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
Ministère de la santé, de la famille et des personnes handicapées.
Direction générale de la santé
Sous-direction de la politique des produits de santé
Bureau des produits de santé d'origine humaine
1, Place de Fontenoy-75700-Paris
Personnes référentes : Madame Hornez tél. : 01-40-56-52-03

Madame Flament tél. : 01-40-56-41-32

4. Notification Number
2003/0065/F - C00P

5. Title
Order on the rules of good practice relating to the manufacture, packaging, storage, importation, transport and distribution of 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 Act 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.
At the time of the preparatory work for this Act it was observed that a number of products were being used for therapeutic purposes without undergoing any assessment as regards their quality and efficiency. Following this observation a working group was instructed to compile a list of all the products not subject to a precise legal status and develop proposals for a regulatory framework for these products, according to the potential risks.
Those products without status included the related therapeutic products used as a means of preserving grafts or in the preparation of health products of human origin (culture media, etc.).

7. Notification Under Another Act
No.

8. Main Content
The Order lays down the rules of good practice relating to the manufacture, packaging, storage, importation, transport and distribution of related therapeutic products.
These rules stipulate the basic requirements as regards personnel, premises, material, processes and documentation, in order to guarantee the quality of these products.
They consist of four sections dedicated respectively to quality control, preparation of related therapeutic products, the storage, distribution and transport thereof and finally to their importation.

Key words: related therapeutic products, manufacturers, importers, distributors, marketing authorisation, good manufacturing practices.

9. Brief Statement of Grounds
Related therapeutic products of chemical or biological origin are not subject to any safety checks or to any assessment. Some of these products may have undergone 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, in French legislation or in 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 applying to the implementation of 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 (Agreement on technical barriers to trade)
a) 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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SPERATI Marie
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