Notification Number: 2003/284/F

Draft Order on good distribution practices for raw materials for pharmaceutical purposes

Date received	:	01/08/2003
End of Standstill	:	Closed
Issue of comments by	:	Commission,United Kingdom

Message

Message 002

Communication from the Commission - SG(2003) D/51494
Directive 98/34/EC
Translation of the message 001
Notification: 2003/0284/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: 200301494.EN)

1. Structured Information Line
MSG 002 IND 2003 0284 F EN 03-11-2003 01-08-2003 F NOTIF 03-11-2003

2. Member State
FRANCE

3. Department Responsible
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3. Originating Department
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4. Notification Number
2003/0284/F - C10P

5. Title
Draft Order on good distribution practices for raw materials for pharmaceutical purposes

6. Products Concerned
Raw materials for pharmaceutical purposes

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

8. Main Content
This draft Order aims to define the good practices applicable to the distribution of raw materials for pharmaceutical purposes laid down in Article L 5138-2 of the Public Health Code. According to this Article, raw materials for pharmaceutical purposes must comply with pharmacopoeial specifications where these exist and must be manufactured and distributed in accordance good practices whose principles are defined by Order of the Minister responsible for Health, adopted on the proposal of the French Agency for the Safety of Health Products (AFSSAPS). These good practices have been prepared by adapting the requirements needed for the wholesale distribution of medicinal products and the distribution of raw materials used in their composition.

The draft Order covers all raw materials for pharmaceutical purposes that are distributed in France, regardless of their origin, and intended to be used in the composition of a medicinal product (active ingredients, excipients and outer-coatings intended to be administered to a patient). It states the basic essential principles to be respected regarding the distribution and products and defines an organisational framework for all operations performed by establishments providing distribution. It also lays down provisions on security of supply, the speed of deliveries and recall procedures.

9. Brief Statement of Grounds
The global health safety of a health product is only guaranteed provided each of the constituent stages in its production, distribution and use is guaranteed. The quality of medicinal product, which must be guaranteed for the user, can only be provided through the application of rigorous quality assurance principles at all stages of its production from the raw materials to the end product. It has however become necessary to define a reference system, in the form of good practices, which allows, the necessary administrative measures, where applicable, to be adopted to maintain the health safety of these products.

The aim of this draft Order is therefore to enable the quality of raw material for pharmaceutical purposes to be guaranteed up to their delivery, in a pharmaceutical establishment manufacturing medicinal products, in a pharmacy or a internal dispensary for internal use of a health care establishment in the case of extemporaneous or hospital preparations.

The establishment of this reference system will go hand in hand with the possibility for operators to request

conformity certificates for these good practices, in application of Article L. 5138-3 of the Public Health Code. The holding of these certificates from AFSSAPS should facilitate industrial exports since these certificates represent a "quality label" which can be recognised by third countries.

10. Reference Documents - Basic Texts
Public Health Code, in particular Articles L.5138-1, L.5138-2 and L.5138-3, good practices in wholesale distribution of medicinal products.

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
-

David O'Sullivan
Secretary-General
European Commission

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