



Notification Number: 2001/14/F

Draft Decree on starting materials for pharmaceutical use amending the Public Health Code (second part: Council of State Decrees).

Date received : 17/01/2001

End of Standstill : 18/04/2001 (**18/01/2002**)

Postponement : Yes

Message

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Message 002



Communication from the Commission - SG(2001) D/50122
Directive 98/34/EC
Translation of the message 001
Notification: 2001/14/F

(MSG: 200100122.EN)

1. Structured Information Line

MSG 002 IND 2001 0014 F EN 18-04-2001 17-01-2001 F NOTIF 18-04-2001

2. Member State

FRANCE

3. Department Responsible

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3. Originating Department

Service responsable de l'élaboration du texte :
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4. Notification Number

2001/14/F - COOP

5. Title

Draft Decree on starting materials for pharmaceutical use amending the Public Health Code (second part: Council of State Decrees).

6. Products Concerned

Starting materials for pharmaceutical use

7. Notification Under Another Act

This notification is made pursuant to Article 8 of amended Directive 98/34/EC of the European Parliament and 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 has been drafted to implement Articles L. 5138-1 to L. 5138-3 of the Public Health Code with a view to legislate for the manufacture, importation and distribution of starting materials for pharmaceutical use.

It proposes a definition of starting materials for pharmaceutical use and specifies the rules of declaration regarding the manufacture, importation and distribution of these starting materials by the French Agency for the Safety of Health Products. Penal sanctions are laid down for natural and legal persons who do not adhere to this procedure.

Furthermore, this draft Decree stipulates the rules regarding the issuing of certificates of conformity with good practices as specified in Article L. 5138-3 of the Public Health Code.

9. Brief Statement of Grounds

The global safety of a health product is not guaranteed to the same extent as each stage in the production process, its distribution and use is. The quality of a medicinal product, which must be guaranteed for the user, can only result from applying to the starting material destined for the final product at each stage of the production process rigorous principles relating to quality assurance.

Given these circumstances, it seems necessary to legislate for the manufacture, importation and distribution of starting materials for pharmaceutical use in order to ensure the quality of a medicinal product. The aim of this draft is therefore:

- to ensure the safety of starting materials for pharmaceutical use by stipulating:
- the registration of establishments by means of a declaration of the activity performed by them, addressed to the French Agency for the Safety of Health Products, and the creation of a file regarding each establishment based on an explanatory file relating to the activity provided with the declaration, which is required to gain knowledge about the establishments in question;
- a definition of the materials subject to inspection (in accordance with the monographs used as evidence from the pharmacopoeia where these exist and in accordance with good manufacturing practices as regards the manufacture and distribution of starting materials) allowing, if the need arises, for the necessary administrative measures to be adopted to maintain the safety of these products;
- the provision at the request of manufacturers or distributors (particularly to facilitate the export of starting materials for pharmaceutical use), through certification by the French Agency for the Safety of Health Products, of proof that these materials are adhered to.

10. Reference Documents - Basic Texts

- Proposal for a Directive of the European Parliament and of the Council on good manufacturing practice for starting materials of medicinal products and inspection of manufacturers;
- Public Health Code, in particular Articles L.5138-1, L.5138-2, L.5138-3, L. 5311-1, R. 5115-4 and R. 5171;
- Penal Code, in particular Articles 121-2, 131-38, 132-11 and R. 610-1.



11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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13. Confidentiality

No

14. Fiscal measures

No

David O'Sullivan
Secretary-General
European Commission