Notification Number: 2001/18/F

Draft Decree implementing Article L. 5138-4 of the Public Health Code (second part: Council of State Decrees).

Date received : 17/01/2001

End of Standstill : Closed

Fiscal Measures : Yes

Message

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Représentation Permanente de l'Irlande
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Représentation Permanente du Royaume-Uni
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Message 002

Communication from the Commission - SG(2001) D/50125
Directive 98/34/EC
Translation of the message 001
Notification: 2001/18/F

(MSG: 200100125.EN)

1. Structured Information Line
MSG 001 IND 2001 0018 F FR 17-01-2001 17-01-2001 F NOTIF 17-01-2001

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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Direction générale de la santé
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4. Notification Number
2001/18/F - COOP

5. Title
Draft Decree implementing Article L. 5138-4 of the Public Health Code (second part: Council of State Decrees).

6. Products Concerned
Starting materials of medicinal products

7. Notification Under Another Act
This notification is made pursuant to Article 8 of amended Directive 98/34/EC of the European Parliament and of 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 Article L. 5138-4 of the Public Health Code, which states "Every application made by an establishment involved in the manufacture, import or transport of starting materials of medicinal products with a view to obtaining the certificate specified in Article L. 5138-3 shall result in the payment, to the French Agency for the Safety of Health Products, of a fixed fee, the amount of which is laid down by decree up to a limit of FRF 15 000".

Article 1 of this draft Decree therefore stipulates that the amount of this fixed fee shall be set at FRF 5000 for each application for the certificate of conformity specified in Article L. 5138-3 of the Public Health Code. Should the inspection relating to the issue of certificates last longer than one day, then this fixed fee shall be raised by FRF 5000 for each day of additional inspection. However, the total amount of the fixed fee may not exceed FRF 15 000.

9. Brief Statement of Grounds
Insofar as the certification procedure stipulated in Article L. 5138-3 of the Public Health Code shall be based on an inspection of the relevant processes used by the establishment applying for the certificate, a fee of FRF 15 000 has been laid down corresponding to a fixed contribution to the inspection costs.

However, as all those within this industry who were consulted regarded the fixed fee of FRF 15 000 as excessive, particularly for SMEs and businesses in this sector whose share of the turnover generated in the pharmaceutical industry is minimal, it was considered preferable to set a scale according to the number of inspection days up to a limit of 15 000 francs.

The inspection period regarding the certification of a manufacturing process allowing one or more products from the same chemical family to be obtained, shall last 2 to 4 days according to the scale or complexity of the process. The time required for the inspection of an establishment involved in transport or import activities should not exceed two days.

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. 5138-4, 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
Yes

David O'Sullivan
Secretary-General
European Commission