Notification Number: 2000/155/F

Draft decree on imports of certain medicinal products for human use, amending the Public Health Code (second part: Decrees at the Council of State).

Date received	:	11/04/2000
End of Standstill	:	12/07/2000
Issue of detailed opinion by	:	Commission

Message

Departement of Trade and Industry - Stan dards and Technical Regulations - Dir 2
Mrs Brenda O'Grady

EFTA Surveillance Authority
Ms Solveig Georgsdottir

ELOT
Mr E. Melagrakis

European Free Trade Association
Ms Anne-Lise Bakke-D'Aloya

Kauppa-ja teollisuusministeriö
Mr Petri Kuurma

Kommerskollegium
Fru Kerstin Carlsson

Min. of Industry, Energy & Technology
Mr K. Polychronidis

Ministerie van Financiën - Belastingsdie nst - Douane / CDIU
De Heer IJ.G. van der Heiden

NSAI
Mr Owen Byrne

Représentation Permanente de l'Irlande
.

Représentation Permanente du Royaume-Uni
.

Message 002

Communication from the Commission - SG(2000) D/50809
Directive 98/34/EC
Translation of the message 001
Notification: 2000/155/F

(MSG: 200000809.EN)

1. Structured Information Line
MSG 002 IND 2000 0155 F EN 12-07-2000 11-04-2000 F NOTIF 12-07-2000

2. Member State
FRANCE

3. Department Responsible
Secrétariat général du Comité interministériel pour les Questions de Coopération Economique Européenne - 2, Bd Diderot 75012 Paris
Délégué interministériel aux Normes - 22, rue Monge - 75005 Paris

3. Originating Department
Service responsable de l'élaboration du texte :
Ministère de l'emploi et de la solidarité
Direction générale de la santé
Sous-direction de la pharmacie
8, avenue de Ségur
75350 Paris 07 SP

4. Notification Number
2000/0155/F

5. Title
Draft decree on imports of certain medicinal products for human use, amending the Public Health Code (second part: Decrees at the Council of State).

6. Products Concerned
Medicinal product for human use.

7. Notification Under Another Act
This notification implements article 8 of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, amended, laying down the procedure for the provision of information in the field of technical standards and regulations and within the framework of a reasoned opinion of 26 January 2000 of the Commission of the European Communities issued to the French Republic pursuant to Article 226 of the EC Treaty regarding a complaint relating to barriers to parallel imports of medicinal products in France (PA/98/4032 of 31 March 1999).

8. Main Content
This draft decree amends a number of provisions relating to imports of medicinal products for human use (Chapter II of Title II of Book V of the Public Health Code) and lays down a new legal system for parallel imports of these medicinal products.

9. Brief Statement of Grounds
Following two complaints by economic operators to the Commission of the European Communities, it seemed necessary to amend and supplement the current provisions of the rules regarding imports of medicinal products for human use in France.

The first complaint (P/99/4056 of 21 January 1999) concerns the provisions under which, when an imported medicinal product receives a market authorisation in France, a certified copy of this authorisation must be presented upon request to customs officials (where the medicinal product has Community status) or in support of a customs declaration (in other cases). The obligation to provide a certified copy of the market authorisation issued in France constitutes a customs formality, aiming to allow the customs office to monitor imports of medicinal products. However, following the complaint submitted to the European Commission, this procedure has been re-examined and it seems that the import of medicinal products could be monitored by means of measures that are less restrictive for economic operators, while protecting the interests of public health equally effectively.

In these circumstances, the formality of the certified copy of the market authorisation shall be withdrawn and replaced by the monitoring of the market authorisation number or corresponding registration number that appears on the packaging, by customs officials (article R. 5142-15).

Following the second complaint relating to barriers to the parallel import of medicinal products in France (PA/98/4032 of 31 March 1999) giving rise to the reasoned opinion of 26 January 2000 of the Commission of the European Communities, it seemed that the provisions of the rules specifying application methods for article 17 of Act No 92-144 of 31 December 1992 on products subject to certain restrictions on movement and complementarity between the police, the gendarmerie and the customs office contain no specific provisions relating to parallel imports. Furthermore, both the aforementioned Commission (communication of 6 May 1982) and the Court of Justice of the European Communities, in abundant case law, have found in favour of parallel imports. It is therefore necessary to draw up specific legislation relating to the parallel import of medicinal products for human use.

10. Reference Documents - Basic Texts
Council Directive 65/65/EEC of 26 January 1965, amended, on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products; Council Directive 75/319/EEC of 20 May 1975, amended, on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, particularly articles 16 and 22; Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use, particularly article 3;

- Communication from the Commission on the withdrawal of the proposal for a directive published in OJEC C 143 of 12 June 1980 on parallel imports;

- Public Health Code, particularly articles R. 5000, R. 5106, R. 5135, R. 5142-12 to R. 5142-15, R. 5143 to R. 5143-5 and R. 5144-20 ;

- Social Security Code, particularly articles L. 138-1, L. 138-10, L. 162-16-4, L. 162-17-4, L. 245-1 and L. 245-6-1 ;

- General Tax Code, particularly article 277 A;

- Customs Code, particularly article 38;

- Act No 92-1477 of 31 December 1992, amended, on products subject to certain restrictions on movement and complementarity between the police, the gendarmerie and the customs office, and in particular article 17;

- Response to the reasoned opinion of 26 January 2000 of the Commission of the European Communities issued to the French Republic pursuant to Article 226 of the EC Treaty regarding a complaint relating to barriers to parallel imports of medicinal products in France (Complaint A/98/4032);

- Note supplementing point 9 (explanatory statement of the draft text) of this notification sheet;

- Procedure for notifications of parallel distribution of centrally authorised medicinal products (EMEA - H-30313-98-Rev. 1, March 1999).

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
-

13. Confidentiality
No

14. Fiscal measures
No

Carlo Trojan
General Secretary
European Commission