



Notification Number: 2008/165/F

Draft Decree on the application of a security device on the exterior packaging of the medicine, and amending the Public Health Code (regulatory provisions)

Date received : 24/04/2008
End of Standstill : 25/07/2008 (27/04/2009)
Issue of comments by : Germany
Postponement : Yes

Message

Message 002

Communication from the Commission - SG(2008) D/50795
Directive 98/34/EC
Translation of the message 001
Notification: 2008/0165/F

No abre el plazo - Nezaahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanū - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 200800795.EN)

1. Structured Information Line

MSG 002 IND 2008 0165 F EN 25-07-2008 24-04-2008 F NOTIF 25-07-2008

2. Member State

F

3. Department Responsible

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3. Originating Department

Ministère de la santé, de la jeunesse et des sports
Direction générale de la santé
Sous-direction de la politique des pratiques et des produits de santé
Bureau du médicament
14, avenue Duquesne
75 350 Paris 07 SP

4. Notification Number

2008/0165/F - C10P

5. Title

Draft Decree on the application of a security device on the exterior packaging of the medicine, and amending the Public Health Code (regulatory provisions)

6. Products Concerned

Medicines for human use

7. Notification Under Another Act

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8. Main Content

The draft Decree to which this notification relates requires the application of a security device on the exterior packaging of medicines on the list of voluntary prescription medicines that can be made directly accessible within pharmacies, as laid down by the Director-General of the French Agency for the Safety of Health Products.

It specifies that the head pharmacist of the pharmaceutical establishment who is responsible for attaching the device shall attest to having done so by means of a declaration to the Director-General of the French Agency for the Safety of Health Products, indicating the device used. If the establishment is located in another State signatory to the Agreement on the European Economic Area, the declaration shall be made by the qualified person referred to in Article 48 of Directive 2001/83/EC of the European Parliament and of the Council.

9. Brief Statement of Grounds

The draft Decree fits in with the context of patients being given direct access to certain voluntary prescription medicines in pharmacies, which means that they are freely accessible.

The purpose of using a security device on the exterior packaging of these medicines is to enable patients and pharmacists to satisfy themselves of the integrity of the packaging. It thus responds to a health safety need, by minimising the potential risks of sabotage, and to a need to guarantee the nature of medicines and guarantee trust on the part of patients, as part of the new method of direct access in pharmacies.

10. Reference Documents - Basic Texts

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11. Invocation of the Emergency Procedure

NO

12. Grounds for the Emergency

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13. Confidentiality

France does not request that information sent pursuant to Article 8(4) be handled confidentially.

14. Fiscal measures

b) NO

15. Impact assessment

No impact assessment.

16. TBT and SPS aspects

TBT and SPS aspects (Agreements drawn up within the framework of the WTO)

TBT aspect (Agreement on Technical Barriers to Trade)

Yes, France requests that the draft be notified within the framework of the TBT Agreement.

SPS aspect (Agreement on Sanitary and Phytosanitary Measures)

No, France does not request that the draft be notified within the framework of the SPS Agreement.

SPS aspect (Agreement on Sanitary and Phytosanitary Measures)

i) The draft is not a sanitary or phytosanitary measure pursuant to Annex A to the SPS Agreement.

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