



Notification Number: 2008/217/F

Draft Decree relating to the collection and elimination of unused medicines amending the Public Health Code (Regulatory Provisions)

Date received : 05/06/2008

End of Standstill : 08/09/2008

Message

Message 002

Communication from the Commission - SG(2008) D/51059

Directive 98/34/EC

Translation of the message 001

Notification: 2008/0217/F

No abre el plazo - Ne zahajuje 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 atlikšanu - 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 - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 200801059.EN)

1. Structured Information Line

MSG 002 IND 2008 0217 F EN 08-09-2008 05-06-2008 F NOTIF 08-09-2008

2. Member State

France

3. Department Responsible

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3. Originating Department

Ministère de la santé, de la jeunesse et des sports



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Sous-direction de la politique des pratiques et des produits de santé
Bureau du médicament
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4. Notification Number

2008/217/F - C00P

5. Title

Draft Decree relating to the collection and elimination of unused medicines 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 organises the collection sector for unused medicines (MNU) brought back by private individuals to dispensing pharmaceutical chemists and stipulates the methods of destruction of such MNU. It stipulates the methods of collection (provision of suitable receptacles, transport) and destruction of MNU, at the charge of pharmaceutical companies operating in the medicines sector, in application of the principle of broadened producer liability. It stipulates that the destruction of MNU must be done by incineration. It provides that companies may discharge their obligations by becoming members of an "eco-body" approved by the public authorities on the basis of a range of specifications the wording of which may be stipulated by order as needed.

9. Brief Statement of Grounds

This draft Decree aims to provide a safe MNU collection and elimination circuit from the point of view of public health and in an environmentally friendly manner.

The organisation of a special collection provision is justified by the specific risks that medicinal waste constitute, which require that its incineration, currently the safest method of destruction, be guaranteed.

The system relies on dispensing pharmacists, extending its scope to the health objectives of the system, i.e. information and accountability on the consumption of medicines.

10. Reference Documents - Basic Texts

Article L. 4211-2 of the Public Health Code

a) Article L. 541-10 of the Environmental Code

11. Invocation of the Emergency Procedure

-



12. Grounds for the Emergency

-

13. Confidentiality

-

14. Fiscal measures

-

15. Impact assessment

No impact assessment.

16. TBT and SPS aspects

TBT and SPS aspects (Agreements concluded in the framework of the TBT)

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 within the meaning of Appendix A to
the SPS Agreement.

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GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

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