



Notification Number: 2012/68/E

Draft Circular of the AEMPS on the prior notification of shipments of medicinal products to other member states

Date received : 03/02/2012

End of Standstill : 04/05/2012

Message

Message 002

Communication from the Commission - SG(2012) D/5272

Directive 98/34/EC

Translation of the message 001

Notification: 2012/0068/E

No abre el plazo - Nezahajuje 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 - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201200272.EN)

1. Structured Information Line

MSG 002 IND 2012 0068 E EN 03-02-2012 E NOTIF

2. Member State

E

3. Department Responsible

Subdirección General de Asuntos Industriales, Energéticos, de Transportes, Comunicaciones y Medio Ambiente.

Dirección General de Coordinación de Políticas Comunes y de Asuntos Generales de la Unión Europea. Secretaría de Estado para la Unión Europea.

Ministerio de Asuntos Exteriores y de Cooperación.

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3. Originating Department

Departamento de Inspección y Control de Medicamentos de la Agencia Española de Medicamentos y Productos Sanitarios.
Ministerio de Sanidad, Servicios Sociales e Igualdad

4. Notification Number

2012/0068/E - C10P

5. Title

Draft Circular of the AEMPS on the prior notification of shipments of medicinal products to other member states

6. Products Concerned

MEDICINAL PRODUCTS FOR HUMAN USE

7. Notification Under Another Act

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8. Main Content

The purpose of this circular is to regulate the procedure to be followed by distribution warehouses for notifying the Spanish Agency of Medicinal and Healthcare Products (AEMPS) of planned shipments to other Member States, exclusively in regard to medicinal products for human use, registered in Spain, the lack of which may cause a care issue and which are included on the corresponding list published on the AEMPS website (www.aemps.gob.es).

This list of medicinal products includes those for which, according to either the information available from AEMPS or to that issued by healthcare professionals and professional bodies or the health authorities of the Autonomous Communities, in the event of shortage, care-giving problems arise.

9. Brief Statement of Grounds

Parallel distribution has developed significantly in recent years, as a result of the differences in the prices of medicinal products in Member States of the European Union. As a consequence, there has been a large number of "parallel exports" originating in Spain, for which there is no specific regulation at either domestic or European level, and which has resulted in a large number of supply issues having had significant repercussions on patient care levels.

In this respect, the health authorities have no information whatsoever on this parallel trade, making it difficult to carry out preventive action in cases where, as a result of such shipments of medicinal products shortage of which would result in care issues, the needs of Spanish patients are not met, producing a public health problem.

In short, the fundamental objective of these prior notifications is to reinforce the protection of public health. The information system will make it possible to detect scheduled shipments of these medicinal products and avoid the care repercussions that their shortage would have on patients.

10. Reference Documents - Basic Texts



No basic texts exist

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

-

13. Confidentiality

No

14. Fiscal measures

No

15. Impact assessment

-

16. TBT and SPS aspects

TBT aspect:

No - The draft will have no noticeable effect on international trade.

SPS aspect:

No - The draft will have no noticeable effect on international trade.

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