Notification Number: 2015/561/F

Decree on the specification of the place of manufacture on the external packaging of pharmaceutical products

Date received	:	06/10/2015
End of Standstill	:	07/01/2016 **(07/04/2016)**
Issue of detailed opinion by	:	Commission,Germany

Message

Message 002

Communication from the Commission - TRIS/(2015) 03088
Directive 98/34/EC
Translation of the message 001
Notification: 2015/0561/F

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 késéseket - Ma' jiftaħx 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: 201503088.EN)

1. Structured Information Line
MSG 002 IND 2015 0561 F EN 06-10-2015 F NOTIF

2. Member State
F

3. Department Responsible
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3. Originating Department
Ministère de l'économie, de l'industrie et du numérique
Direction générale des entreprises

Service de l'industrie
Sous-direction des industries de santé et des biens de consommation
67, rue Barbès
94201 Ivry-sur-Seine-Cedex

4. Notification Number
2015/0561/F - C10P

5. Title
Decree on the specification of the place of manufacture on the external packaging of pharmaceutical products

6. Products Concerned
Medicinal product or product mentioned in Article R. 5121-150 of the French Public Health Code

7. Notification Under Another Act
-

8. Main Content
An Article R. 5121-139-1 of the French Public Health Code shall be created, authorising the inclusion on the external packaging of medicinal products or, in the absence of any external packaging, on the primary packaging of medicinal products, of a pictogram indicating that the manufacturing operations of excipients, the manufacturing of the active substance and the production of the external packaging were carried out within the territory of the European Union or Member States of the European Free Trade Association.

9. Brief Statement of Grounds
The faith of our fellow citizens must be encouraged, indeed increased, in the quality of their medicinal products, notably in that of generic medicinal products, about which doubts remain in public opinion.
European citizens place their trust in the competent authorities of the EU to carry out the appropriate checks at the different stages of manufacture of a medicinal product. However, for mainly practical reasons, the checks carried out by the competent authorities of the EU are not the same when one or more stages of manufacture take place outside the EU. Thus, in accordance with Article 46b of Directive 2001/83/EC, the competent authorities of the non-Member State are responsible for certifying that the manufacture of the active substances imported into the EU complies with good manufacturing practices equivalent to those of the EU. Now, many of our fellow citizens do not have the same trust in the competent authorities of non-Member States as they do in the competent authorities of the European Union. This gives rise to a lack of faith in the quality of medicinal products and generic medicinal products in particular.
It would therefore appear to be necessary to promote transparency in this respect, informing citizens of where the different stages of manufacture of a medicinal product take place, and providing information as to which competent authority/authorities control(s) the quality of a medicinal product and the way in which they do so.

Moreover, with countries of the EFTA sharing equivalent quality requirements to those of EU countries, manufacturing in these countries should also be able to benefit from the pictogram in the same way.

10. Reference Documents - Basic Texts
No basic text(s) available

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 has no significant impact on international trade.

SPS aspect

No - the draft is neither a sanitary nor phytosanitary measure.

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European Commission

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