Notification Number: 2015/562/F

Decree on the pictogram envisaged in the new Article R. 5121-139-1 of the Public Health Code

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) 03091
Directive 98/34/EC
Translation of the message 001
Notification: 2015/0562/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: 201503091.EN)

1. Structured Information Line
MSG 002 IND 2015 0562 F EN 06-10-2015 F NOTIF

2. Member State
F

3. Department Responsible
Direction générale des entreprises – SQUALPI – Bât. Sieyès -Teledoc 151 – 61, Bd Vincent Auriol - 75703 PARIS Cedex 13
d9834.france@finances.gouv.fr
tél : 01 44 97 24 55

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
2015/0562/F - C10P

5. Title
Decree on the pictogram envisaged in the new Article R. 5121-139-1 of the Public Health Code

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

7. Notification Under Another Act
-

8. Main Content
A model pictogram has been created as envisaged in the new Article R5121-139-1 of the Public Health Code. This model aims to ensure that all citizens can read and understand the device.

9. Brief Statement of Grounds
The faith that our fellow citizens place in the quality of their medicinal products must be encouraged, indeed increased, particularly with regard to generic medicinal products, for which doubts remain among the public.

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 conducted by the competent authorities of the EU are not the same when one or more stages of manufacture take place outside the EU. Therefore, in accordance with Article 46 ter of Directive 2001/83/EC, the competent authorities of the third country are responsible for certifying that the manufacture of the active substances imported into the EU complies with good manufacturing practices that are equivalent to those of the EU. Now, many of our fellow citizens do not place the same trust in the competent authorities of third countries 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 where the different stages of manufacture of a medicinal product take place, and providing information on which competent authority(ies) check/s the quality of a medicinal product and how they do so.

Moreover, EFTA countries share quality requirements equivalent to those of EU countries; therefore, manufacture in these countries should also be able to benefit from the pictogram in the same way.

Use of a common pictogram model will help citizens read and understand the device.

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.

****
European Commission

Contact point Directive 98/34
Fax: +32 229 98043
email: grow-dir83-189-central@ec.europa.eu