Notification Number: 2016/628/F

Decree on the placement of a pictogram on the outer packaging of certain medicines or products

Date received : 01/12/2016

End of Standstill : Closed

Message

Message 002

Communication from the Commission - TRIS/(2016) 03656
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2016/0628/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 - Não 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: 201603656.EN)

1. Structured Information Line
MSG 002 IND 2016 0628 F EN 01-12-2016 F NOTIF

2. Member State
F

3. Department Responsible
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3. Originating Department
Ministère des affaires sociales et de la santé
Direction générale de la santé.
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4. Notification Number
2016/0628/F - C00P

5. Title
Decree on the placement of a pictogram on the outer packaging of certain medicines or products

6. Products Concerned
Medicinal product for human use

7. Notification Under Another Act
-

8. Main Content
The draft decree on the placement of a pictogram on the outer packaging of certain medicines or products is issued pursuant to Article L5121-20 of the French Public Health Code. This provision stems from Article 62 of Directive 2001/83/EC, which provides that the outer packaging of medicinal products may include pictograms designed to clarify certain information compatible with the summary of the product characteristics for the patient.

The main purpose of this draft decree is to display a pictogram on the outer packaging of medicinal products or products having teratogenic or foetotoxic effects, when this is mentioned in the marketing authorisation (MA). The pictogram templates shall be determined by Order of the Minister for Health on the advice of the Director General of the French National Agency for the Safety of Medicine and Health Products (ANSM). The pictograms can only be used in respect of medicinal products for which an MA has been issued under a mutual recognition procedure, a decentralised procedure or under a national procedure. Pharmaceutical laboratories affected by this provision must send ANSM for information purposes a sample copy of the outside packaging bearing the pictogram. Pharmaceutical laboratories shall have three months from the publication of the order establishing these pictogram templates to apply this provision. If the above provisions are not complied with, the Director-General of ANSM may suspend the MA of the medicinal product in question.

9. Brief Statement of Grounds
This draft decree follows the recommendations of the Pharmacovigilance Risk Assessment Committee (PRAC), issued in October 2014 in the context of re-evaluating the risks and benefits of proprietary medicinal products containing valproate and its derivatives in girls, women of childbearing age and pregnant women. These recommendations are particularly intended to restrict the use of valproate in patients and better inform them regarding the risks of using valproate during pregnancy. These recommendations were adopted by the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) in November 2014 and have been applicable since this date by those Member States in which these treatments are marketed.

France is very concerned about the consequences of using valproate in pregnant women since these treatments have been widely used and patients have not been sufficiently informed of their risks.
France is learning from this case and wishes more generally to improve patient information regarding the teratogenic and foetotoxic effects of all of the medicinal products concerned by applying a clear, simple and

legible pictogram to the outer packaging of medicinal products.

10. Reference Documents - Basic Texts
Reference(s) to basic text(s): Article L5121-20 of the French Public Health Code

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 has no significant impact on international trade.

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European Commission

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