EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

Notification Number: 2016/634/F

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

Date received	:	02/12/2016
End of Standstill	:	15/12/2016
Invocation of the Emergency Procedure	:	Yes

Message

Message 002

Communication from the Commission - TRIS/(2016) 03679
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2016/0634/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: 201603679.EN)

1. Structured Information Line
MSG 002 IND 2016 0634 F EN 02-12-2016 F NOTIF

2. Member State
F

3. Department Responsible
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4. Notification Number
2016/0634/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
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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 L. 5121-20 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 reevaluating 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 Co-ordination 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 L.5121-20 of the French Public Health Code

11. Invocation of the Emergency Procedure
Yes

12. Grounds for the Emergency
Medicinal products based on valproic acid and its derivatives, particularly those prescribed for epilepsy or bipolar conditions in women, have potentially serious toxic effects on their unborn children if taken during pregnancy. These are medicines or products that have a teratogenic or foetotoxic effect, which must be avoided during pregnancy as mentioned in the marketing authorisation for the products in question.
New prescription and dispensing conditions (CPDs) have been applicable in France since May 2015 for all new treatments and have been in force since 1 January 2016 for all ongoing treatments.

In addition to the general public communication measures (letters targeting prescribers responsible for these prescriptions to alert them to the risks and the CPDs, letters to the patients concerned and online information on the agency website), there is a very urgent need to enable the patients concerned and those around them to be as well informed as possible of the potential consequences of their treatments, as well as of the possible damaging consequences for their offspring.

Therefore, given the urgent need, for health reasons, to relay clear and complete information to patients as directly as possible, the French authorities invoke the emergency procedure under Article 6 of Directive (EU) 2015/1535.

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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