EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

Notification Number: 2016/635/F

Order issued pursuant to Article R. 5121-139 of the French Public Health Code and relating to 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) 03681
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2016/0635/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: 201603681.EN)

1. Structured Information Line
MSG 002 IND 2016 0635 F EN 02-12-2016 F NOTIF

2. Member State
F

3. Department Responsible
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3. Originating Department

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4. Notification Number
2016/0635/F - C00P

5. Title
Order issued pursuant to Article R. 5121-139 of the French Public Health Code and relating to 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
This draft order determines the templates for the three pictograms that should be placed on the outer packaging of medicinal products that have teratogenic or foetotoxic effects, and of medicinal products containing sodium valproate or its derivatives, depending on the circumstances.

The first pictogram warns patients about medicinal products that it is advisable not to use during pregnancy unless no alternative therapy is available.
This pictogram consists of a red equilateral triangle with sides of at least one centimetre on a white background, containing an image of a pregnant woman in black. To the right of this, or below it, the following wording appears: ‘NOM DE LA SPECIALITE + GROSSESSE = DANGER’ [‘NAME OF THE PROPRIETARY MEDICINAL PRODUCT + PREGNANCY = DANGER’]. Below it is the following message: ‘Ne pas utiliser chez les adolescentes ou femmes en âge de procréer et sans contraception efficace, ou enceintes, sauf en l’absence d’alternative thérapeutique’ [‘Not to be used by adolescents or women of childbearing age not using effective contraception or already pregnant, unless no alternative therapy is available’].

The second pictogram warns patients about medicinal products that are contraindicated during pregnancy and which they should not use.
This pictogram is a crossed-through red circle on a white background, at least a centimetre in diameter, containing an image of a pregnant woman in black. To the right of this, or below it, the following wording appears: ‘NOM DE LA SPECIALITE + GROSSESSE = INTERDIT’ [‘NAME OF THE PROPRIETARY MEDICINAL PRODUCT + PREGNANCY = FORBIDDEN’]. Below it is the following message: ‘Ne pas utiliser chez les adolescentes ou femmes en âge de procréer et sans contraception efficace, ou enceintes’ [‘Not to be used by adolescents or women of childbearing age not using effective contraception or already pregnant’].

The third pictogram warns patients about medicinal products containing valproate or its derivatives, which it is advisable not to use during pregnancy unless other treatments have failed.

This pictogram consists of a red equilateral triangle with sides of at least one centimetre on a white background, containing an image of a pregnant woman in black. To the right of this, or below it, the following wording appears: 'NOM DE LA SPECIALITE + GROSSESSE = DANGER' ['NAME OF THE PROPRIETARY MEDICINAL PRODUCT + PREGNANCY = DANGER']. Below it is the following message: 'Ne pas utiliser chez les filles, adolescentes ou femmes en âge de procréer ou enceintes, sauf en cas d'échec des autres traitements' ['Not to be used by girls, adolescents or women of childbearing age, or who are pregnant, unless other treatments have failed'].

9. Brief Statement of Grounds
This draft order 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 for 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 R. 5121-139

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 (CPD) 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 the 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
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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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