



Notification Number: 2016/629/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 : 01/12/2016

End of Standstill : Closed

Message

Message 002

Communication from the Commission - TRIS/(2016) 03659

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2016/0629/F

No abre el plazo - Nezhahajuje 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 késések - Ma' jiftaħ 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 - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201603659.EN)

1. Structured Information Line

MSG 002 IND 2016 0629 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

2016/0629/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 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 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

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.



EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

SPS aspect

No - the draft has no significant impact on international trade.

European Commission

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