



Notification Number: 2015/253/F

Draft Order on the “label éthique” pictogram mentioned in Article R. 5121-139-1 of the Public Health Code (CSP).

Date received : 15/05/2015
End of Standstill : 17/08/2015 (17/11/2015)
Issue of detailed opinion by : Austria,Commission,Germany

Message

Message 002

Communication from the Commission - TRIS/(2015) 01433
Directive 98/34/EC
Translation of the message 001
Notification: 2015/0253/F

No abre el plazo - Ne zahajuje 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 - 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: 201501433.EN)

1. Structured Information Line

MSG 002 IND 2015 0253 F EN 15-05-2015 F NOTIF

2. Member State

F

3. Department Responsible

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3. Originating Department

Ministère des affaires sociales, de la santé et des droits des femmes
Direction générale de la santé.



Sous-direction de la politique des produits de santé et de la qualité des pratiques et des soins.
Bureau de le bioéthique et des éléments et produits du corps humain (PP4).
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4. Notification Number

2015/0253/F - C00P

5. Title

Draft Order on the “label éthique” pictogram mentioned in Article R. 5121-139-1 of the Public Health Code (CSP).

6. Products Concerned

medicinal products derived from blood

7. Notification Under Another Act

- Article 110 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

8. Main Content

The draft Order establishes the characteristics of the pictogram provided for in the draft Decree ruling on the conditions for use of the “ethical label” that may be applied to medicinal products derived from blood, the raw materials for which have been drawn in accordance with the ethical principles mentioned in Articles L. 1221-3 to L. 1221-7 of the Public Health Code, i.e. that the donor should be unpaid, over the age of consent, anonymous and consent freely.

9. Brief Statement of Grounds

Article 110 of the “Medicinal Products Directive” stipulates that Member States “shall encourage the voluntary unpaid donation of blood and plasma and shall take the necessary measures to develop the production and use of products derived from human blood or human plasma coming from voluntary unpaid donations”.

The text of the Order specifies the form taken by the “label éthique” pictogram intended for medicinal products derived from blood, the raw materials for which have been drawn in accordance with the ethical principles that the donor should be unpaid, over the age of consent, anonymous and consent freely.

The addition of such a pictogram is intended to inform hospital public buyers, pharmacists, prescribing doctors, nurses and patients of the “ethical”, i.e. unpaid, origin of the raw material used to make the medicinal product, the blood donation. This measure is therefore part of a process of transparency and equal access to information.

Provided that the regulatory conditions are respected, it is the marketing authorisation holder's decision whether or not to apply the pictogram.

The ethical label is neither a marketing condition for medicinal products derived from blood in France, nor a unique criterion for gaining access to a public hospital market.



10. Reference Documents - Basic Texts

Reference(s) to basic text(s): Paragraph 2 of Article L. 5121-11 of the Public Health Code, based on Article 6 of Law No 2014-201 of 24 February 2014 bringing various provisions into line with European Union law, Article L. 5121-20 of the Public Health Code, draft Decree on the ethical label for medicinal products derived from blood (MDS) (creating an Article R. 5121-139-1 in the CSP) - notification 2015/252/F

The basic texts were forwarded with an earlier notification: 2015/252/F

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.

European Commission

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