Notification Number: 2015/252/F

Draft Decree on the ethical label for medicinal products derived from blood.

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) 01430
Directive 98/34/EC
Translation of the message 001
Notification: 2015/0252/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 - 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: 201501430.EN)

1. Structured Information Line
MSG 002 IND 2015 0252 F EN 15-05-2015 F NOTIF

2. Member State
F

3. Department Responsible
Délégué interministériel aux normes – SQUALPI – Bât. Sieyès -Teledoc 151 – 61, Bd Vincent Auriol - 75703 PARIS Cedex 13
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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
2015/0252/F - C00P

5. Title
Draft Decree on the ethical label for medicinal products derived from blood.

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 Decree sets out the conditions for use of the “label éthique” pictogram 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 Decree introduces the possibility of an “ethical label”, the details of which are specified by Order (also subject to notification), to identify 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.

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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