EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

Notification Number: 2014/395/F

Decree amending the rules relating to the creation of temporary recommendations for use established pursuant to point I of Article L. 5121-12-1 of the French Public Health Code

Date received	:	07/08/2014
End of Standstill	:	10/11/2014
Issue of comments by	:	Commission

Message

Message 002

Communication from the Commission - TRIS/(2014) 02340
Directive 98/34/EC
Translation of the message 001
Notification: 2014/0395/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: 201402340.EN)

1. Structured Information Line
MSG 002 IND 2014 0395 F EN 07-08-2014 F NOTIF

2. Member State
F

3. Department Responsible
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3. Originating Department
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Direction générale de la santé.

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4. Notification Number
2014/0395/F - C10P

5. Title
Decree amending the rules relating to the creation of temporary recommendations for use established pursuant to point I of Article L. 5121-12-1 of the French Public Health Code

6. Products Concerned
medicinal products for human use: pharmaceutical specialities

7. Notification Under Another Act
-

8. Main Content
The draft Decree amending the rules relating to the creation of temporary recommendations for use (RTUs), pursuant to point I of Article L. 5121-12-1 of the French Public Health Code, specifies the purpose of temporary recommendations for use issued by the French National Agency for the Safety of Medicine and Health Products (ANSM), introduced by Article L. 5121-12-1 of the French Public Health Code to Law No 2011-2012 of 29 December 2011, as amended, on improving the safety of medicines and health products.

“The purpose of an RTU is to ensure safety when doctors prescribe a medicine outside the parameters of its marketing authorisation (AMM) on the basis of purely therapeutic considerations relating to the specific needs of their patients, as identified by examination, and in the absence of any specialist preparation suitable for the purpose in question that has the same active ingredient, pharmaceutical form and dosage, as well as an AMM.

9. Brief Statement of Grounds
In this regard, the draft Decree supplements the provisions of Article R. 5121-76-1 of the French Public Health Code in order to clarify, firstly, that the RTU mechanism falls within the provisions of paragraph 1 of Article 5 of Directive No 2001/83/EC of the European Parliament and of the Council of 6 November 2001 and, secondly, to take into account the consequences of the Ruling of the European Court of Justice of 11 April 2013 in case C-535/11.

The other provisions of the draft text clarify the rules for creating an RTU and for prescriber information.

10. Reference Documents - Basic Texts
References to basic texts: Articles L. 5121-12-1, R. 5121-76-1 and thereafter of the French 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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