



Notification Number: 2016/236/F

Order establishing the list of therapeutic classes containing medicinal products of major therapeutic significance mentioned in Article L5121-31 of the French Public Health Code

Date received : 19/05/2016
End of Standstill : 20/06/2016
Issue of comments by : Commission
Invocation of the Emergency Procedure : Yes

Message

Message 002

Communication from the Commission - TRIS/(2016) 01509
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2016/0236/F

No abre el plazo - Nezhajuje 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: 201601509.EN)

1. Structured Information Line

MSG 002 IND 2016 0236 F EN 19-05-2016 F NOTIF

2. Member State

F

3. Department Responsible

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3. Originating Department

Ministère des affaires sociales et de la santé
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4. Notification Number

2016/0236/F - C00P

5. Title

Order establishing the list of therapeutic classes containing medicinal products of major therapeutic significance mentioned in Article L5121-31 of the French Public Health Code

6. Products Concerned

Medicinal product for human use

7. Notification Under Another Act

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8. Main Content

This draft Order establishes the list of 22 therapeutic classes of medicinal products according to which marketing authorisation holders and operators dealing in medicinal products should identify medicinal products of therapeutic significance and implement the shortage management plans provided for in Article L5121-31 of the French Public Health Code. These management plans are set out in the future Articles R5124-49-4 and R5124-49-5 of the French Public Health Code.

9. Brief Statement of Grounds

In France, the number of shortages and risks of shortages of medicinal products, particularly medicinal products of major therapeutic significance, i.e. medicinal products whose unavailability is liable to result in a public health issue (life-threatening, patients' chances significantly reduced, etc.), increased tenfold in five years between 2008 (44 cases of shortages and risks of shortages reported) and 2013 (453 shortages and risks of shortages reported), according to data from the French National Agency for Medicine and Health Products (ANSM). The French authorities are therefore, in accordance with Article 81 of Directive 2001/83/EC, making marketing authorisation holders and operators responsible for developing management plans to anticipate the shortage situations that the French market might face in respect of medicinal products of major therapeutic significance. The draft Order identifies 22 therapeutic classes of medicinal products, from which private operators will have to determine which medicinal products qualify for a shortage management plan. These management plans will contribute to ensuring that the national territory is appropriately and continuously supplied with medicinal products.

10. Reference Documents - Basic Texts

Reference(s) to basic text(s): Articles L5121-29 to L5121-34 of the French Public Health Code



11. Invocation of the Emergency Procedure

Yes

12. Grounds for the Emergency

The number of shortages and risks of shortages of medicinal products is increasing rapidly. The number of reported shortages has increased tenfold since 2008 and almost fourfold between 2011 and 2013 (132 shortages or risks of shortages reported to the ANSM in 2011 and 453 shortages or risks of shortages reported in 2013). These shortages lead to public health risks, since they particularly affect medicinal products of major therapeutic significance. It therefore appears vital to adopt measures both to combat shortages of medicinal products and to facilitate the management of shortage situations, as soon as possible. The French authorities consider the emergency time frame to be justified with regard to the challenges presented by the risks of shortages of medicinal products of major therapeutic significance. The national authorities need to adopt measures as soon as possible in the interests of protecting public health.

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.

European Commission

Contact point Directive (EU) 2015/1535

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