Notification Number: 2016/235/F

Decree relating to the fight against shortages in the supply of medicinal products

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

Message

Message 002

Communication from the Commission - TRIS/(2016) 01507
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2016/0235/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 - Não 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: 201601507.EN)

1. Structured Information Line
MSG 002 IND 2016 0235 F EN 19-05-2016 F NOTIF

2. Member State
F

3. Department Responsible
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3. Originating Department
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4. Notification Number
2016/0235/F - C00P

5. Title
Decree relating to the fight against shortages in the supply of medicinal products

6. Products Concerned
Medicinal product for human use

7. Notification Under Another Act
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8. Main Content
The draft Decree relating to the fight against shortages in the supply of medicinal products is issued pursuant to Articles L5121-29 to L5121-34 of the French Public Health Code. These provisions are based on Article 81 of Directive 2001/83/EC and establish obligations to be met by marketing authorisation holders and operators dealing in medicinal products. These parties must guarantee that the national market is appropriately and continuously supplied in order to cover the needs of patients, and are required to implement shortage management plans for medicinal products of major therapeutic significance.
The main purpose of this draft Decree is to establish the characteristics of the medicinal products of major therapeutic significance that should be subject to the shortage management plans developed by the marketing authorisation holder and the operator. It defines supply shortage, as well as the procedure to be followed, where applicable. Marketing authorisation holders and operators are responsible for identifying the medicinal products of major therapeutic significance referred to in Article L5121-31 of the French Public Health Code, and for developing a shortage management plan (Article 4). The identification criteria used are as follows:
- unavailability in sufficient quantities on French territory of medicinal products containing the same active substance or belonging to the same therapeutic class
- fragility of the manufacturing or packaging process of the medicinal product concerned, particularly where this is due to the absence of other sites or the complexity of storage or transport
Marketing authorisation holders and operators will have to identify the medicinal products of major therapeutic significance that should be subject to shortage management plans from among the therapeutic classes established by Order of the Minister for Health. They will also have to develop these plans for a list of vaccines corresponding to the French vaccination calendar, established by Order of the Minister for Health.
The draft Decree also establishes the content of the shortage management plans. These plans could include measures relating to the stockpiling of medicinal products intended for the national market according to the market share of each pharmaceutical undertaking, of other manufacturing sites for raw materials for pharmaceutical use, and of other manufacturing sites for proprietary medicinal products. Proprietary medicinal products constituting an alternative to the proprietary medicinal product of which there is a shortage may also be identified in the management plan.
Finally, the draft Decree adapts the information procedures of the French National Agency for the Safety of Medicine and Health Products (ANSM) and health professionals in the event of shortages.

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 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 shortage management plans provided for in this draft Decree will contribute to ensuring that the national territory is appropriately and continuously supplied with medicinal products. The draft regulations make marketing authorisation holders and operators aware of their responsibility to anticipate the risks of shortages for specific categories of medicinal products. Private operators retain the independence to determine which of the medicinal products concerned falls within a therapeutic class determined by the French authorities, and also remain free with regard to developing the plan to meet the obligation to address the risk of shortages. The proposed national measure does not impose disproportionate costs on marketing authorisation holders and operators and contributes to the protection of public health.

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.

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European Commission

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