



Notification Number: 2016/237/F

Order establishing the list of vaccines that should be subject to the shortage management plans mentioned in Article L5121-31 of the French Public Health Code

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) 01511

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2016/0237/F

No abre el plazo - Nezaahajuje 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: 201601511.EN)

1. Structured Information Line

MSG 002 IND 2016 0237 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

2016/0237/F - C00P

5. Title

Order establishing the list of vaccines that should be subject to the shortage management plans 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 vaccines according to which marketing authorisation holders and operators dealing in medicinal products should implement the shortage management plans provided for in Article L5121-31 of the French Public Health Code. These plans are set out in the future Articles R5124-49-4 and R5124-49-5. The vaccines featuring in this list correspond to the vaccines provided for in the French vaccination calendar and cover 25 diseases.

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 the Safety of Medicine and Health Products (ANSM). These stock shortages are particularly due to new industrial strategies to streamline production costs, which lead laboratories to produce strictly according to demand, as well as the existence of only one manufacturing site worldwide for certain medicinal products and certain raw materials for pharmaceutical use. Vaccines, medicinal products considered indispensable in the preventive arsenal, are not spared by these shortage phenomena (BCG, hexavalent vaccines containing a component against whooping cough, etc.). These vaccine shortages lead to major public health risks. These immunological medicinal products are indispensable in ensuring the necessary vaccine coverage, thereby guaranteeing protection for the whole population. The French authorities are therefore, in accordance with Article 81 of the 'Medicines Directive', 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 the vaccines for 25 types of diseases listed in this Order. These shortage management plans will contribute to ensuring that the national territory is appropriately and continuously supplied. These measures will make it possible to guarantee adherence to the French vaccination calendar and ensure vaccine coverage in France.



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 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 in the category of medicinal products of major therapeutic significance, which includes the vaccines listed in the draft order. Since vaccine coverage for the French population is a major public health issue, the French authorities find themselves facing the overwhelming need to adopt this draft order as swiftly as possible.

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

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