



Notification Number: 2015/370/F

Order issued pursuant to Article L. 5141-44-1-1 of the French Public Health Code establishing the list of antibiotic substances of critical importance and Article R. 5141-111-1 establishing the list of methods for performing the test to determine the sensitivity of bacterial strains

Date received : 10/07/2015

End of Standstill : 12/10/2015

Message

Message 002

Communication from the Commission - TRIS/(2015) 02148

Directive 98/34/EC

Translation of the message 001

Notification: 2015/0370/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 - Nao 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: 201502148.EN)

1. Structured Information Line

MSG 002 IND 2015 0370 F EN 10-07-2015 F NOTIF

2. Member State

F

3. Department Responsible

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3. Originating Department

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4. Notification Number

2015/0370/F - C90A

5. Title

Order issued pursuant to Article L. 5141-44-1-1 of the French Public Health Code establishing the list of antibiotic substances of critical importance and Article R. 5141-111-1 establishing the list of methods for performing the test to determine the sensitivity of bacterial strains

6. Products Concerned

Antibiotic substances of critical importance

7. Notification Under Another Act

-

8. Main Content

The draft establishes the list of antibiotic substances of critical importance (AIC) for veterinary use. The conditions under which these AICs should be used are defined in the draft Decree already notified to the European Commission under Directive 98/34/EC (file 2015/311/F).

The draft establishes the standardised method with which the sensitivity test should comply, as provided for in Article 1 of the draft Decree already notified to the European Commission under Directive 98/34/EC (file 2015/311/F).

The list of antibiotic substances of critical importance (AIC) used in veterinary medicines features in Article 1 of the draft Order.

The list of antibiotic substances of critical importance (AIC) used in human medicines suitable for equine use features in Article 2 of the draft Order.

The list of antibiotic substances of critical importance (AIC) used in human medicines suitable for animal use features in Article 3 of the draft Order.

Article 4 of the draft Order establishes the standardised method to be complied with for the sensitivity test provided for in Article 1 of the draft Decree already notified to the European Commission under Directive 98/34/EC (file 2015/311/F), i.e. standard NFU 47-107.

9. Brief Statement of Grounds

The list of AICs shall be established by Order, as provided for in Article L. 5144-1-1 of the French Public Health



Code currently in force. Articles 1 to 3 of the draft Decree address this Article of law.
The method to be used for performing the sensitivity test shall be established by Order as provided for by the future III-3°) of Article R. 5141-111-1 of the French Public Health Code. This Article L. 5141-111-1 is introduced by the Decree already notified to the European Commission under Directive 98/34/EC (file 2015/311/F).
Article 4 of the draft Order addresses this Article R. 5141-111-1.

10. Reference Documents - Basic Texts

Reference(s) to basic text(s): Article L. 5144-1-1 of the French Public Health Code (in force)
- Future III-3°) of Article L. 5141-111-1 of the French Public Health Code (introduced by the Decree already notified to the European Commission under Directive 98/34/EC - file 2015/311/F)
The basic texts were forwarded with an earlier notification: 2015/311/F

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.

European Commission

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EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

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