



Notification Number: 2015/311/F

## Decree on medicinal products containing one or more critically important antibiotics

Date received : 17/06/2015

End of Standstill : 18/09/2015

### Message

Message 002

Communication from the Commission - TRIS/(2015) 01815

Directive 98/34/EC

Translation of the message 001

Notification: 2015/0311/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 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: 201501815.EN)

#### 1. Structured Information Line

MSG 002 IND 2015 0311 F EN 17-06-2015 F NOTIF

#### 2. Member State

F

#### 3. Department Responsible

Direction générale des entreprises – SQUALPI – Bureau de la réglementation des produits - Bât. Sieyès

-Teledoc 151 – 61, Bd Vincent Auriol - 75703 PARIS Cedex 13

d9834.france@finances.gouv.fr

tél : 01 44 97 24 55

#### 3. Originating Department

Direction générale de l'alimentation

Service des actions sanitaires en production primaire

Sous-direction de la santé et de la protection animales

Bureau des intrants et de la santé publique en élevage



251, rue de Vaugirard - 75732 Paris Cedex – FRANCE  
Mél : bispe.sdspa.dgal@agriculture.gouv.fr  
Tél 00 33 1 49 55 56 43

#### **4. Notification Number**

2015/0311/F - C90A

#### **5. Title**

Decree on medicinal products containing one or more critically important antibiotics

#### **6. Products Concerned**

Medicinal products for veterinary use containing one or more critically important antibiotics (CIAs).

#### **7. Notification Under Another Act**

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#### **8. Main Content**

The draft decree establishes the situations in which CIAs can be used in veterinary medicine, the needs and applicable exception, namely:

I - The situations:

- ban on prescribing CIAs for preventive uses;
- authorisation, in accordance with the conditions laid down below, of the prescription of CIAs for curative or metaphylactic purposes.

II - The needs applicable in the event of the use of CIAs for curative or metaphylactic use only, are as follows:

- 1 ) The preliminary conduct of a clinical examination by the prescribing veterinary surgeon or a necropsy examination carried out at its request and the analysis of the epidemiological context;
- 2 ) The preliminary conduct of a complementary examination aiming to identify the bacterial strain responsible for the infection, starting from a sample taken by the prescribing veterinary or under his responsibility, from one or more live or dead animals; this condition does not apply if the location of the infection, the type of infection or general condition of the animal or animals prevents a sample from being taken.
- 3 ) The preliminary conduct of a complementary examination aiming to show the sensitivity of the bacterial strain identified to this antibiotic by means of a sensitivity test carried out according to one of the methods established by decree of the ministers in charge of health and agriculture.

III - The exception envisaged is:

The veterinary surgeon is not required to carry out the complementary examinations described under points 2 ) and 3 ), if there is knowledge of the results of complementary examinations obtained less than six months previous for the same animal or same group of animals and for the same disorder.

#### **9. Brief Statement of Grounds**

In accordance with the recommendations of the European Commission, the FAO of the WHO and the OIE,



France is committed to a plan to reduce the risks of antibiotic resistance in veterinary medicine (the Ecoantibio plan).

To fight antibiotic resistance, France would like to see specific, suitable measures adopted with regards to certain antibiotic substances whose efficacy must be preserved as a priority in the interests of human and animal health. These critically important antibiotics (CIAs) are listed in the draft decree attached to this notification. At this stage, it is proposed that this list should include fluoroquinolones and 3rd- and 4th-generation cephalosporins. This list will evolve naturally and will be regularly reviewed.

The draft decree concerned by this notification therefore aims to fight against antibiotic resistance using specific suitable, proportional measures regarding the use of CIAs in veterinary medicine. It is a text prepared in the interests of human and animal health, aiming to encourage prudent, reasoned use of these CIAs.

This text complies with the specific considerations on CIAs given in the draft directives on prudent, reasoned use of such provided by the European Commission.

- CIAs are only used if the veterinary surgeon has evaluated, after an evaluation based on a test to determine sensitivity and/or pertinent epidemiological data, that there are no other non-critically important antibiotics that may be effective.
- Use under the scope of the cascade remains possible on an exceptional basis. It is limited only to cases where there is no alternative antibiotic available apart from a CIA and must in any case be recorded.

Draft European regulations on veterinary medicinal products and medicinal foods have specific measures on antibiotics in order to deal with the risk represented by resistance to antibiotics.

France wishes this notified draft text to come into force immediately, before all draft European regulations currently being discussed, in turn, come into force. In fact, it is very important for France that the draft text notified be applied as quickly as possible, as France has set itself the target of reducing use of these CIAs in veterinary medicine by 25 % in three years (2014-2016). If the notified draft should only come into force after the two draft European regulations, this would postpone its application to after 2018. Effectively, almost all provisions regulating veterinary medicinal products will come into force 24 months after publication of this regulation (Article 150 of the regulation on veterinary medicinal products). It is unlikely that this text will be published this year; it is more likely to be published in 2016 to come into force 24 months later.

#### **10. Reference Documents - Basic Texts**

Reference(s) to basic text(s): - Public Health Code: Articles L5141-16, Article L5144-1-1  
Law No 2014-1170 of 13 October 2014 on the future of agriculture, food and forests - Article 49

#### **11. Invocation of the Emergency Procedure**

No

#### **12. Grounds for the Emergency**

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#### **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

Contact point Directive 98/34

Fax: +32 229 98043

email: [dir83-189-central@ec.europa.eu](mailto:dir83-189-central@ec.europa.eu)