Notification Number: 2008/226/F

Decision of xx xxx 2008 on good manufacturing practice for veterinary medicinal products

Date received : 11/06/2008

End of Standstill : 12/09/2008

Message

Message 002

Communication from the Commission - SG(2008) D/51088
Directive 98/34/EC
Translation of the message 001
Notification: 2008/0226/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 - Nao 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: 200801088.EN)

1. Structured Information Line
MSG 002 IND 2008 0226 F EN 12-09-2008 11-06-2008 F NOTIF 12-09-2008

2. Member State
FR

3. Department Responsible
Délégué interministériel aux normes – SQUALPI – 12, rue Villiot – 75572 PARIS Cedex 12
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3. Originating Department
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tél : 02 99 94 78 53 – Fax : 02 99 94 78 99

4. Notification Number
2008/226/F - C00P

5. Title
Decision of xx xxx 2008 on good manufacturing practice for veterinary medicinal products

6. Products Concerned
Veterinary medicinal products
Establishments manufacturing or importing veterinary pharmaceutical products.

7. Notification Under Another Act
a) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 establishing a Community code relating to veterinary medicinal products amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 on the labelling and presentation of foodstuffs (JO L 311 of 28 November 2001 p.1 and JO L 336 of 30 April 2004 p 58),

b) Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (JO L 228 of 17 August 1991 p.70),

8. Main Content
This new Decision enables the transposition into national law of the European provisions implementing Article 51 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 amended establishing a Community code on veterinary medicinal products, of Article 3 of Commission Directive 91/142/EC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products, published in Volume 4 "EU guidelines of good manufacturing practices for medicinal products for human use and veterinary use", Eudralex "the rules governing medicinal products in the European Union".
This draft standard takes up the provisions set out in a previous Order of 5 May 1997 which guaranteed the transposition of prevailing European texts and complements by the addition of new related guidelines numbered 15, 16 and 17 published in July 2001, Annex number 1 published in May 2003 and Annex number 19 published in December 2005 and the amendments made to chapters 1 and 6 in October 2005 and to chapter 8 in December 2005 published in respect of Volume 4 aforementioned.

This Decision regarding good manufacturing practice for active substances refers to a decision on the matter of the Director General of the French Food Safety Agency, the competent authority in France.

9. Brief Statement of Grounds
This compilation exercise has become necessary owing to the multiplication of amendments and additions to guidelines.

10. Reference Documents - Basic Texts
a) This Decision completes the statutory provision relating to good practice opposable to establishments manufacturing or importing veterinary medicinal products and to their conditions of authorisation and operation.

Articles L. 5142-3 and L.5138-3 of the Public Health Code statutory part.

11. Invocation of the Emergency Procedure
NO

12. Grounds for the Emergency
-

13. Confidentiality
-

14. Fiscal measures
-

b) NO

15. Impact assessment
-

16. TBT and SPS aspects
TBT and SPS aspects (Agreements concluded in the framework of the TBT)
TBT aspect (Agreement on Technical Barriers to Trade)
a) YES Draft shall be notified in the TBT framework

SPS aspect (Agreement on Sanitary and Phytosanitary Measures)
a) The Member State originating the notification must indicate whether – YES or NO – it will request that the draft be notified within the SPS framework.

b) If the Member State answers NO, it indicates the reasons in support of its answer:
i) The draft is not a sanitary or phytosanitary measure in the sense of Annex A of the SPS Agreement.

Catherine Day
Secrétaire général
Commission européenne

Point de contact Directive 98/34
Fax: (32-2) 296 76 60
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European Free Trade Association
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Mrs Vesna Stazisar

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Frau Christina Jäckel

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Office of standards, metrology & Testing Director of the department of European I
Mrs Kvetoslava STEINLOVA

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