European Medicines Agency
Veterinary Medicines and Inspections

3 August 2009
Doc. Ref.EMEA/313849/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

OPINION FOLLOWING AN ARTICLE 33 (4)[1] REFERRAL FOR FENFLOR 300 MG/ML SOLUTION FOR INJECTION FOR CATTLE

International Non-Proprietary Name (INN)**:** Florfenicol

BACKGROUND INFORMATION

Florfenicol is a synthetic broad spectrum antibiotic with a range of activity, including many Gram-negative and Gram-positive organisms.

The Marketing Authorisation Holder, Gosmore Ltd, submitted an application via mutual recognition for Fenflor 300 mg/ml solution for injection for cattle, on the basis of the marketing authorisation granted by the United Kingdom. The application was submitted in the framework of Article 32 of Directive 2001/82/EC, as amended, where the Reference Member State was the United Kingdom and the Concerned Member States were Austria, Belgium, France, Germany, Ireland, Italy, The Netherlands, Poland, Portugal and Spain. The Mutual Recognition Procedure started on 28 February 2008.

Due to concerns raised by Germany and The Netherlands during the Mutual Recognition Procedure that Fenflor 300 mg/ml solution for injection for cattle could present a potential serious risk to the environment, the United Kingdom referred the matter to the EMEA on 31 July 2008 under Article 33(4) of Directive 2001/82/EC.

The referral procedure started on 16 September 2008. The rapporteur and co-rapporteur appointed were: Dr Bruno Urbain and Dr Michael Holzhauser-Alberti, respectively. Written explanations were provided by the Marketing Authorisation Holder on 15 January 2009. Oral explanations were given on 16 April 2009.

Based on the evaluation of the rapporteurs' assessment of the currently available data, the CVMP considered that the use of the product as recommended for therapeutic use only does not constitute a risk for the environment. However, the CVMP also considered that the wording of the therapeutic indication as authorised in the Reference Member State should be amended to clearly state the limitations of the approved use and avoid incorrect interpretation. Therefore the Committee adopted an opinion on 14 May 2009 recommending the variation of the Marketing Authorisation in line with the proposed amendments to the Summary of Product Characteristics and package leaflet.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amended Summary of Product Characteristics and package leaflet in the Annex III.

The final opinion was converted into a Decision by the European Commission on 3 August 2009.

[1] Article 33(4) of Directive 2001/82/EC, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu