13 January 2012
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Veterinary Medicines and Product Data Management

EMEA/V/A/070

Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for all veterinary medicinal products containing systemically administered (parenteral and oral) 3rd and 4th generation cephalosporins intended for use in food producing species

International non-proprietary names (inn): ceftiofur and cefquinome

Background information

On 17 March 2011, the European Commission presented to the Agency a referral notification under Article 35 of Directive 2001/82/EC, regarding all veterinary medicinal products containing systemically administered (parenteral and oral) 3rd and 4th generation cephalosporins intended for use in food producing species. The CVMP was requested to give its opinion regarding the inclusion of prudent use advice for these antimicrobials in line with the revised reflection paper on the use of 3rd and 4th generation cephalosporins in food producing animals in the European Union: development of resistance and impact on human and animal health (EMEA/CVMP/SAGAM/81730/2006-Rev.1)[2] and to address the risk associated with potential misuse in poultry and the need for specific measures, in particular the need for warning sentences in the product information.

The referral procedure started on 6 April 2011. The Committee appointed Dr Karolina Törneke as rapporteur and Dr Claire Chauvin as co-rapporteur. Written explanations were provided by the applicants/marketing authorisation holders on 22 August 2011.

Based on the rapporteurs' assessment of the currently available data, the CVMP considered that the overall benefit-risk balance for these products remains positive subject to the recommended changes of the product information and that variations are necessary to the terms of the marketing authorisation for all veterinary medicinal products containing systemically administered (parenteral and

[1] Article 35 of Directive 2001/82/EC
[2] Revised reflection paper on use of 3rd and 4th generation cephalosporins in food producing animals in the EU: development of resistance and impact on human and animal health (EMEA/CVMP/SAGAM/81730/2006-Rev.1) - http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004307.pdf

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

oral) 3rd and 4th generation cephalosporins intended for use in food producing species. The Committee adopted a positive opinion on 13 October 2011.

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 13 January 2012.