14 June 2010
EMA/190025/2010
Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for all strengths of water soluble powders and oral solutions containing doxycycline hyclate indicated for use in poultry and intended for administration via drinking water

Background information

Doxycycline is a tetracycline derivative with uses similar to those of tetracycline antibiotics. The water soluble powders and oral solutions containing doxycycline hyclate indicated for use in poultry and intended for administration via drinking water, are used for treatment of respiratory and gastrointestinal infections caused by different bacterial pathogens susceptible to doxycycline.

Due to concerns that the differences in the posology, dose range, duration of treatment and withdrawal periods established across the European Union for all strengths of water soluble powders and oral solutions containing doxycycline hyclate indicated for use in poultry and intended for administration via drinking water may present a potential serious risk to public and animal health, the United Kingdom referred the matter to the Agency on 11 February 2009, under Article 35 of Directive 2001/82/EC.

The referral procedure started on 11 February 2009. The rapporteur and co-rapporteur appointed were: Dr Cornelia Ibrahim and Prof. Christian Friis, respectively. Written explanations were provided by the applicants/marketing authorisation holders on 21 April 2009 and 16 September 2009.

During its 13-15 October 2009 meeting, the Committee agreed on a request from one marketing authorisation holder to provide an oral explanation to the CVMP which was subsequently withdrawn by the marketing authorisation holder.

Based on the rapporteurs' assessment of the currently available data, the CVMP did not identify emerging risks to human or animal health arising as a result of differences in the posology, dose range, duration of treatment and withdrawal periods established across the European Union and did not therefore recommend changes to these aspects of the summary of the product characteristics (SPC), labelling and package leaflet. However, due to the known prevalence of resistance to this antimicrobial, changes to the product literature of the relevant products were recommended to reflect the principles for prudent use. Therefore the Committee, adopted on 11 February 2010, an opinion recommending variations of the marketing authorisations for all strengths of water soluble powders

[1] Article 35 of Directive 2001/82/EC

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and oral solutions containing doxycycline hyclate indicated for use in poultry and intended for administration via drinking water in order to amend the SPC, labelling and package leaflet to include appropriate standard prudent use statements in line with recommendations of the CVMP revised guideline on the SPC for antimicrobial products[2] and to include additional information regarding the correct administration of the concerned products.

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

The final opinion was converted into a Decision by the European Commission on 14 June 2010.

[2] CVMP revised guideline on the SPC for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005) - http://www.ema.europa.eu/pdfs/vet/sagam/38344105enfin.pdf