10 June 2010
EMA/189829/2010
Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for veterinary medicinal formulations containing colistin at 2 000 000 IU per ml and intended for administration in drinking water to food producing species

Background information

Colistin sulfate is a polypeptide antibiotic belonging to the polymyxins group of antibiotics. Veterinary medicinal formulations containing colistin sulfate at 2 000 000 IU per ml and intended for administration via drinking water to calves, pigs, lambs and poultry are used for the treatment of infections of the gastrointestinal tract caused by *Escherichia coli* and *Salmonella spp* susceptible to colistin.

Due to concerns that the differences in posology and withdrawal periods established across the European Union for veterinary medicinal formulations containing colistin at 2 000 000 IU per ml and intended for administration in drinking water to food producing species may present a potential serious risk to public and animal health, the United Kingdom referred the matter to the Agency on 1 April 2009, under Article 35 of Directive 2001/82/EC.

The referral procedure started on 16 April 2009. The rapporteur and co-rapporteur appointed were: Prof. Christian Friis and Dr Karolina Törneke, respectively. Written explanations were provided by the applicants/marketing authorisation holders on 15 July 2009 and 13 January 2010.

Based on the rapporteurs' assessment of the currently available data, the CVMP, adopted, on 10 February 2010, an opinion recommending variations of the marketing authorisations for veterinary medicinal formulations containing colistin at 2 000 000 IU per ml and intended for administration in drinking water to food producing species in order to amend the summary of the product characteristics (SPC), labelling and package leaflet to harmonise the posology and withdrawal periods (where applicable) for 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 10 June 2010.

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

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