27 July 2010
EMA/118068/2010
Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 34[1] referral for Tiamutin premix and associated names

Background information

Tiamulin is a semi-synthetic antibiotic belonging to the pleuromutilin group of antibiotics and it is used only in veterinary medicine. Tiamulin is used for the treatment and prevention of gastrointestinal and respiratory infections caused by different bacterial pathogens in pigs, poultry and rabbits.

Premixes containing tiamulin are marketed across the European Union under a variety of invented names and the authorised premix formulations are based on tiamulin hydrogen fumarate in a variety of concentrations: 0.8%, 2%, 10% and 80%. The target species are: pigs, chickens, turkeys and rabbits.

Due to differences among the nationally authorised summaries of product characteristics for Tiamutin premix and associated names across the European Union, especially as regards indications for use, amount to be administered and administration route and withdrawal periods, on 18 September 2008 Ireland and Belgium referred the matter to the European Medicines Agency under Article 34 of Directive 2001/82/EC.

The referral procedure started on 15 October 2008. The rapporteur and co-rapporteur appointed were: Prof. Stane Srčič and Dr Karolina Törneke respectively. Written explanations were provided by the marketing authorisation holders on 20 April 2009 and 16 November 2009. Oral explanations were given on 10 February 2010.

Based on the rapporteurs' assessment of the currently available data, the CVMP adopted, on 10 March 2010, an opinion recommending the amendment of the marketing authorisations in terms of the summary of the product characteristics and labelling in order to harmonise the indications for use, amount to be administered and administration route and withdrawal periods.

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 labelling in Annex III.

The final opinion was converted into a Decision by the European Commission on 27 July 2010.

[1] Article 34 of Directive 2001/82/EC

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