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Veterinary Medicines and Product Data Management

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 34¹ referral for Baytril 10% oral solution and associated names

International non-proprietary name (INN): enrofloxacin

Background information

Enrofloxacin is a synthetic chemotherapeutic agent from the class of the fluoroquinolone carboxylic acid derivatives. It has antibacterial activity against a broad spectrum of Gram-negative and Gram-positive bacteria. Enrofloxacin is for veterinary use only.

Baytril 10% oral solution and its associated names contain 100 mg enrofloxacin per ml oral solution for use in drinking water. The products are authorised for use in the target species chickens, turkeys and rabbits for treatment of the respiratory tract and of the digestive tract infections caused by bacteria susceptible to enrofloxacin.

Due to divergent national decisions taken by Member States with respect to e.g. target species, indications, amounts to be administered and withdrawal periods concerning the authorisations of Baytril 10% oral solution and its associated names, on 15 October 2010 the United Kingdom referred the issue to the CVMP under Article 34(1) of Directive 2001/82/EC, in order to resolve divergences amongst the nationally authorised product information across the European Union.

The referral procedure started on 11 November 2010. The Committee appointed Mrs Ruth Kearsley, who was later replaced by Ms Helen Jukes, as rapporteur and Dr Lotte Winther, who was later replaced by Dr Ellen-Margrethe Vestergaard, as co-rapporteur.

Written explanations were provided by the marketing authorisation holders on 12 August 2011 and 14 February 2012. Oral explanations were given on 14 May 2012.

Based on the rapporteurs' assessment of the currently available data, the CVMP considered that the benefit-risk profile of Baytril 10% oral solution and its associated names remains positive, subject to variation of the marketing authorisations in accordance with the recommended product information,

¹ Article 34 of Directive 2001/82/EC



and subject to a condition on the marketing authorisations. The Committee adopted a positive opinion by majority on 14 June 2012.

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, labelling and package leaflet are in the Annex III. The condition on the marketing authorisations is in Annex IV.

The final opinion was converted into a Decision by the European Commission on 8 October 2012.