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SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products

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.

On 22 April 2013, Spain presented to the Agency a referral notification under Article 35 of Directive 2011/82/EC, regarding Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products. The CVMP was requested to consider what indications, dosage regimens and durations of treatments should be applied for the products concerned in order to ensure efficacy and target animal safety and to minimise the development of antimicrobial resistance, taking into account the available data. The CVMP was also requested to consider what withdrawal periods should be applied to the concerned products for each target species.

The referral started on 15 May 2013. The Committee appointed C. Muñoz Madero as rapporteur and M. Holzhauser-Alberti as co-rapporteur. Written explanations were provided by some of the applicants and marketing authorisation holders by 30 September 2013 and 3 February 2014.

Based on the evaluation of the currently available data, the CVMP considered that the overall benefit-risk profile for these products remains positive subject to amendments in the product information. Therefore, on 9 April 2014 the Committee adopted by majority a positive opinion, recommending variations to the terms of the marketing authorisations for Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products.

[1] Article 35 of Directive 2001/82/EC, as amended

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The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amendments in the summaries of product characteristics, labelling and package leaflets in Annex III.

The final opinion was converted into a Decision by the European Commission on 1 September 2014.