1 September 2014
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Veterinary Medicines Division

**EMEA/V/A/091**

## Committee for medicinal products for veterinary use (CVMP)

# Opinion following an Article 34[1] referral for Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their 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 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names are solutions for injection containing enrofloxacin at 25 mg/ml, 50 mg/ml and 100 mg/ml respectively.

Due to divergent national decisions taken by Member States with respect to target species, indications, posology and withdrawal periods concerning the authorisations of Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names, on 26 October 2012 France referred the issue to the CVMP under Article 34(1) of Directive 2001/82/EC, in order to resolve the divergence in the product information of nationally authorised products across the European Union.

The referral procedure started on 7 November 2012. The Committee appointed M. Holzhauser-Alberti as rapporteur and C. Muñoz Madero as co-rapporteur. Written explanations were provided by the marketing authorisation holders on 17 June 2013, 10 January 2014 and 12 March 2014.

Based on the evaluation of the currently available data, the CVMP considered that the benefit-risk profile of Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names remains positive, subject to amendments in the product information. The Committee adopted a positive opinion by majority on 9 April 2014.

[1] Article 34 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 amended summary of product characteristics, labelling and package leaflet in Annex III.

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