28 February 2014
EMA/128744/2014
Veterinary Medicines

EMEA/V/A/089

Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for all veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys

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 18 October 2012, the United Kingdom presented to the Agency a referral notification under Article 35 of Directive 2001/82/EC, regarding all veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys. The CVMP was requested to consider the indications, dosage regimens and withdrawal periods for chickens and turkeys in order to ensure consumer safety, efficacious treatment in chickens and turkeys, as well as lower the risk of development of antimicrobial resistance to enrofloxacin.

The referral started on 7 November 2012. The Committee appointed H. Jukes as rapporteur and E-M. Vestergaard as co-rapporteur. Written explanations were provided by the applicants and marketing authorisation holders on 15 February 2013 and on 9 September 2013.

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 and conditions of the marketing authorisations. Therefore on 7 November 2013 the Committee adopted by consensus a positive opinion, recommending variations to the terms of the marketing authorisations for all veterinary medicinal products containing enrofloxacin to be administered via drinking water to chickens and/or turkeys.

[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 condition on the marketing authorisations is in Annex IV.

The final opinion was converted into a Decision by the European Commission on 28 February 2014.