17 December 2012
EMA/789897/2012
Veterinary Medicines and Product Data Management

EMEA/V/A/079

Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for HIPRALONA ENRO-S and its generics indicated for use in rabbits

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.

HIPRALONA ENRO-S and its generics are veterinary medicinal products which contain enrofloxacin as active substance, and are indicated in rabbits for the treatment of respiratory infections caused by *Pasteurella multocida*. The pharmaceutical form is an oral solution administered via the drinking water. The dosage is 10 mg enrofloxacin per kg bodyweight during 5 days.

On 30 September 2011, France initiated a referral procedure under Article 35 of Directive 2001/82/EC, as amended, for the veterinary medicinal product HIPRALONA ENRO-S and its generics indicated for use in rabbits, due to concerns that the use of the products in rabbit production would increase *Escherichia coli* and *Staphylococcus aureus* resistance to enrofloxacin.

The referral procedure started on 12 October 2011. The Committee appointed Dr M. Holzhauser-Alberti as rapporteur and Dr C. Muñoz Madero as co-rapporteur. Supplementary information was provided in writing by an applicant and marketing authorisation holders on 16 January 2012.

Based on the evaluation of the available data, on 11 April 2012, the CVMP adopted by majority an opinion recommending the maintenance of the marketing authorisations for the veterinary medicinal product HIPRALONA ENRO-S and its generics in accordance with the previously approved product information.

On 14 May 2012, the European Commission requested the CVMP to review its opinion, mainly to clarify some aspects related to antimicrobial resistance and the prudent use of antimicrobials in veterinary medicine.

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

On 13 September 2012, the CVMP adopted by majority a revised opinion confirming the recommendation, included in its opinion of 11 April 2012, that the marketing authorisations for the veterinary medicinal product HIPRALONA ENRO-S and its generics should be maintained in accordance with the previously approved product information.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 17 December 2012.