European Medicines Agency
Veterinary Medicines and Inspections

5 May 2009
EMEA/215198/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

OPINION FOLLOWING AN ARTICLE 33 (4) REFERRAL FOR

UNISOL 10% ORAL SOLUTION

International Non-Proprietary Name (INN): Enrofloxacin

BACKGROUND INFORMATION

Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinoline group of antibiotics.

The applicant, Universal Farma S.L., submitted an application for a decentralised procedure for Unisol 10% Oral Solution, indicated for chickens and turkeys and for oral administration via the drinking water. The application was submitted in the framework of Article 32 of Directive 2001/82/EC, as amended, where the Reference Member State was Ireland and the Concerned Member States were Belgium, Czech Republic, Germany and Poland. The Decentralised Procedure IE/V/0200/001/DC started on 19 January 2007.

On 29 April 2008 Ireland, referred the matter to the EMEA under Article 33 (4) of Directive 2001/82/EC, due to concerns, raised by Germany, that enrofloxacin may present a potential serious risk to the environment (risk to blue-green algae and to terrestrial plants).

The referral procedure started on 14 May 2008. The Rapporteur and Co-Rapporteur appointed were: Dr Anja Holm (Denmark) and Dr Boris Kolar (Slovenia), respectively. Written explanations were provided by the Applicant on 17 November 2008.

On the basis of the grounds for referral, the points considered by the CVMP were:

- Adequacy of the data available in respect to the environmental risk assessment for blue-green algae and terrestrial plants;
- Identification of a potential serious risks to blue-green algae and terrestrial plants arising from the use of Unisol 10% Oral solution.

During its 13-15 January 2009 meeting, the CVMP, in light of the overall data submitted and the scientific discussion within the Committee, adopted by consensus an opinion that the use of the product as recommended does not constitute a risk for the environment and therefore the points of disagreement raised by Germany should not prevent the granting of a Marketing Authorisation.

The Committee limited its considerations to the data presented by the Applicant in the dossier for this product in line with the restrictions in legislation with respect to data on environmental risk. No consideration was given nor conclusion drawn regarding the applicability of the conclusions to other licensed products containing the same active ingredient.

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 5 May 2009.

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