European Medicines Agency
Veterinary Medicines and Inspections

London, 18 February 2008
EMEA/48261/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

OPINION FOLLOWING AN ARTICLE 33[1] REFERRAL FOR

Ecomectin 18.7 mg/g Oral Paste for Horses and its associated names

International Non-Proprietary Name (INN): Ivermectin

BACKGROUND INFORMATION

Ecomectin 18.7 mg/g Oral Paste for Horses is a white homogenous paste containing ivermectin. Ivermectin is a member of the macrocyclic lactone class of endectocides. Ecomectin 18.7 mg/g Oral Paste for Horses is intended to be used in horses for the treatment of nematode or arthropod infections caused by *Strongylus vulgaris*, *Strongylus edentatus, Strongylus equinus,* Small strongyles (including benzimidazole resistant strains): *Cyathostomum spp, Cylicocyclus spp*., *Cylicodontophorus spp*., *Cylicostephanus spp*., *Gyalocephalus spp*., Ascarids: *Parascaris equorum*, Pinworms: *Oxyuris equi*m, Neck threadworms: *Onchocerca spp*, Stomach bots: *Gasterophilus spp*

A marketing authorisation for Ecomectin 18.7 mg/g Oral Paste for Horses was previously granted to Eco Animal Health Ltd in Ireland on 10 November 2006.

A mutual recognition procedure was started on 1 February 2007. The Reference Member State was Ireland and the Concerned Member States were Belgium, Cyprus, Czech Republic, Germany, Denmark, Greece, Spain, Finland, France, Hungary, Italy, the Netherlands, Norway, Portugal, Sweden and the United Kingdom. The product was accepted by the Belgium, Cyprus, Czech Republic, Denmark, Greece, Spain, Finland, France, Hungary, Italy, the Netherlands, Norway, Portugal, Sweden and the United Kingdom. Concerns were raised by Germany regarding that this veterinary medicinal product may present a potential serious risk to public health on the following grounds:

- An environmental risk was detected during the risk assessment Phase II Tier A for dung fauna organisms;
- No adequate data for Tier B were provided by the applicant to assess the long-term effects on dung fauna organisms caused by the use of the product.

On 4 July 2007, Ireland notified EMEA that the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMD(v)) failed to reach an agreement regarding Ecomectin 18.7 mg/g Oral Paste for Horses and its associated names. Pursuant to Article 33(4) of Council Directive 2001/82/EC, as amended, the matter has been referred to the CVMP.

The scope of the referral was to whether the environmental risk detected during the risk assessment Phase II Tier A for dung fauna organisms would present a potential serious risk to public health.

[1] Article 33 of Directive 2001/82/EC, as amended

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The arbitration procedure started on 11 July 2007 with the adoption of list of questions. The rapporteur was Dr. B. Urbain and the co-rapporteur was Prof. S. Srčič. The Marketing Authorisation Holder provided written explanations on 12 September 2007. Oral explanations were presented on 10 October 2007 by the Marketing Authorisation Holder to the Committee.

During its 6-8 November 2007 meeting, the CVMP, in light of the overall data submitted and the scientific discussion within the Committee, adopted by consensus an opinion that since the product is intended for use in a minor species (horses) that is reared and treated similarly to a major species, the conclusions on the Environmental Risk Assessment of the major species apply, and therefore the product should be exempt from providing a Phase II assessment and no risk mitigation measures should be included in the SPC of the product.

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 January 2008.