European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

OPINION FOLLOWING AN ARTICLE 33 (4) REFERRAL

FOR EQUIMECTIN 12MG/G ORAL GEL FOR HORSES

BACKGROUND INFORMATION

Equimectin 12mg/g oral gel for horses contains ivermectin. The product is indicated for the treatment of endo- and ectoparasitic infections in horses, particularly gastrointestinal nematodes, dermal nematodes, lung nematodes and bots.

A Mutual Recognition Procedure (MRP) was started based on the Marketing Authorisation granted by the Netherlands with fourteen Concerned Member States.

The Member States who raised concerns regarding the potential risk to animal health were Belgium, Denmark, France, Germany, Ireland, Italy, Portugal and Spain.

The ground for the referral was the substantiation of the bioavailability/bioequivalence of Equimectin in comparison to Eqvalan.

The CVMP during its meeting of May 2006 started a referral procedure under Article 33(4) of Directive 2001/82/EC as amended. The Marketing Authorisation Holder was requested to substantiate the bioavailability/bioequivalence of the product, justifying the efficacy of the product.

The documentation submitted with this application consisted of literature referring to the use of the originator product Eqvalan, a comparative pharmacokinetic study using Equimectin and Eqvalan, and a supplementary clinical field study. During the referral procedure, it was established that the submitted bioequivalence study was inadequate to demonstrate bioequivalence (as defined in current guidance EMEA/CVMP/016/00-corr- FINAL); however, from the comparative pharmacokinetic data it is possible that the test product is systemically less bioavailable than the reference product. Therefore, the relevance of the bibliographical data regarding Eqvalan to the test product cannot be confirmed. The residue data provided was inadequate and the withdrawal period is therefore inadequately supported.

The Committee, having considered the matter, concluded that on the basis of the available data for Equimectin, bioequivalence with the reference product had not been shown. The efficacy of the product for the treatment of endo- and ectoparasitic infections has not been demonstrated. The amended indication for the treatment of gastrointestinal endoparasitic infections in horses had not been demonstrated by the data provided.

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The CVMP recommended the refusal of the granting of the Marketing Authorisation and the suspension of the Marketing Authorisation for Equimectin where appropriate.

The CVMP Opinion was adopted on 17 January 2007 and the subsequent Commission Decision on 2 April 2007.
