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Veterinary Medicines and Inspections

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Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 33[1] referral for Orbax

International non-proprietary name (INN): orbifloxacin

Background information

Orbax is a veterinary medicinal product for dogs containing orbifloxacin presented in 6.25 mg, 25 mg and 75 mg film-coated tablets. The active substance orbifloxacin is a synthetic broad spectrum antibacterial agent from the class of fluoroquinolone carboxylic acid derivatives. Orbax is intended for use in dogs for the treatment of uncomplicated bacterial cystitis due to susceptible strains of *E. coli* and *Proteus mirabilis* and treatment of skin and associated soft tissue infections (wounds and abscesses), associated with bacteria susceptible to orbifloxacin.

The marketing authorisation holder, Schering-Plough Limited, submitted an application for a mutual recognition procedure for Orbax on the basis of the marketing authorisation granted by the United Kingdom. This was an extension application to add the above-mentioned indication for treatment of skin and associated soft tissue infections (wounds and abscesses). The reference Member State is United Kingdom. The concerned Member States are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Luxembourg, the Netherlands, Portugal, Spain and Sweden.

The mutual recognition procedure started on 14 June 2002. Potential serious risks were identified during the mutual recognition procedure by Denmark and Spain regarding the efficacy.

On 12 September 2002, in view of the remaining unsolved issues Denmark and Spain submitted a referral notification under Article 33 of Directive 2001/82/EC to the CVMP.

The referral procedure started on 2 October 2002. The Committee appointed J. Luthman as rapporteur and R. Breathnach as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 15 November 2002.

Based on the evaluation of the available data, the CVMP considered that the objections raised by Denmark and Spain during the mutual recognition procedure should not prevent the granting of a

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

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marketing authorisation for Orbax. Therefore, the CVMP adopted a positive opinion on 15 January 2003 recommending the granting of the marketing authorisation the above-mentioned product.

The scientific conclusions are provided in Annex I. The list of product names concerned is given in Annex II, together with the Summaries of Product Characteristics in Annex III.

The opinion was converted into a Decision by the European Commission on 16 April 2003.