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Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 33[1] referral for Cobactan IV 4.5% powder and solvent for solution for injection and its associated names

International non-proprietary name (INN): cefquinome

Background information

Cobactan IV 4.5% and its associated names are a powder and solvent for solution for injection. Cobactan IV 4.5% contains cefquinome as an active substance at 45 mg per ml. Cefquinome is a fourth-generation cephalosporin. The veterinary medicinal product is intended for use in horses as an intravenous or an intramuscular injection for the treatment of respiratory diseases caused by *Streptococcus equi* subsp. *zooepidemicus* and severe bacterial infections with a high risk of septicaemia in foals in which *Escherichia coli* is involved.

The marketing authorisation holder, Intervet International B.V., submitted an application for a mutual recognition procedure for Cobactan IV 4.5%. The reference Member State is Germany. The concerned Member States are Austria, Belgium, Denmark, Greece, France, Hungary, Ireland, Italy, Luxembourg, The Netherlands, Poland, Portugal, Spain and United Kingdom.

The mutual recognition procedure started on 22 September 2005. Potential serious risks were identified during the mutual recognition procedure by United Kingdom regarding the safety of the product.

On 2 March 2006, in view of the remaining unsolved issues, Germany submitted a referral notification under Article 33 of Directive 2001/82/EC to the CVMP.

The referral procedure started on 15 March 2006. The Committee appointed C. Friis as rapporteur and H. Hoogland as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 23 March 2006.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

Based on the evaluation of the available data, the CVMP considered that the objections raised by the United Kingdom during the mutual recognition procedure should not prevent the granting of a marketing authorisation for Cobactan IV 4.5% and its associated names. Therefore, the CVMP adopted a positive opinion on 17 May 2006 recommending the granting of the marketing authorisation for the above-mentioned product.

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

The opinion was converted into a Decision by the European Commission on 21 August 2006.