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 EQUIBACTIN VET.

BACKGROUND INFORMATION

Equibactin vet. is a paste for oral use containing trimethoprim and sulfadiazine as active ingredients and is indicated for treatment of infections in horses caused by bacteria sensitive to the combination of trimethoprim and sulfadiazine, particularly:

- Respiratory tract infections associated with *Streptococcus* spp. and *Staphylococcus aureus*;
- Gastrointestinal infections associated with *E. coli*;
- Urogenital infections associated with beta-hemolytic streptococci;
- Wound infections and open or drained abscesses associated with *Streptococcus* spp. and *Staphylococcus aureus.*

Equibactin vet. is a generic product.

In August 2006 a decentralised procedure started with The Netherlands as Reference Member State and 17 Concerned Member States.

France could not agree to the granting of a marketing authorisation as it considered there were potential serious risks to animal health. The matter was referred to the Co-ordination Group for Mutual Recognition and Decentralised Procedures CMD(v) and subsequently to the CVMP.

France considered that the dosing regime of the product is not correct. It considered this may lead to lack of efficacy and furthering resistance development in target pathogens, which could possibly lead to risks to human health where zoonotic bacteria are concerned.

The CVMP started the referral procedure during its meeting of 6-8 November 2007. The Marketing Authorisation Holder was requested to provide a copy of the dossier and, in view of the concerns raised by France, to indicate and to substantiate where necessary, any differences between Equibactin vet. and the reference product Tribrissen Oral Paste that could justify different conclusions on the safety or efficacy.

In response to the questions, the applicant submitted the dossier and argued on the basis of a comparison of compositions and pharmacokinetic data, that there are no differences between Equibactin vet. and the reference product that would justify different conclusions on the safety and efficacy for the two products.

CVMP agreed that Equibactin vet. proved to be essentially similar to reference product Tribrissen Oral Paste. Therefore the same conclusions on efficacy and safety apply equally to both products and the objections raised by France should not prevent the granting of a marketing authorisation.

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Being aware of a referral ongoing at the time under Article 35 of Directive 2001/82/EC, as amended, for reference product Tribrissen Oral Paste, CVMP recommended that the outcome of that referral procedure (EMEA/V/023) should apply to the marketing authorisation of Equibactin vet.

The CVMP Opinion was adopted on 12 December 2007 and the subsequent Commission Decision on 3 March 2008.
