ANNEX I

NAME, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCT, ANIMAL SPECIES, ROUTES OF ADMINISTRATION, AND MARKETING AUTHORISATION HOLDER

Applicant or Marketing Authorisation Holder	Product invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration	Recommended dose
Le Vet B.V. Willeskop 212 3421 GW Oudewater The Netherlands	Equibactin vet. (333 mg/g + 67 mg/g) Oral Paste for Horses.	paste	333.3 mg/g sulfadiazine and 66.7 mg/g trimethoprim.	horse	oral	5 mg trimethoprim and 25 mg sulfadiazine per kg body weight per day to a maximum of 5 days.

ANNEX II

SCIENTIFIC CONCLUSIONS

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1. Introduction and background

The Netherlands, reference member state in the decentralised procedure, notified the EMEA on 24 September 2007 that the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMD(v)) failed to reach an agreement for Equibactin vet. (333 mg/g + 67 mg/g) Oral Paste for Horses. Pursuant to Article 33(4) of Council Directive 2001/82/EC, as amended, the matter was referred to the CVMP.

France considers that the dosing regime of the product is not correct. 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.

CVMP noted that Equibactin vet. (333 mg/g + 67 mg/g) Oral Paste for Horses is a generic of Tribrissen oral paste (authorised in the Netherlands) and that the concerns raised by France can only be addressed in the framework of this procedure, in case any differences between both products would justify different conclusions on the safety or efficacy.

CVMP started the procedure on 6 November 2007. A list of questions was adopted on 8 November 2007 and sent to the marketing authorisations holders (MAH), by which the procedure clock was stopped. On 16 November 2007 responses to the questions were received from MAH and the clock restarted.

The aim of the assessment is to establish whether marketing authorisations of veterinary medicinal products included in the referral procedure should be maintained, suspended, varied or revoked with view to the grounds for referral.

2. Discussion

The applicant was requested to provide the following information:

1. A copy of the dossier of Equibactin vet. (333 mg/g + 67 mg/g) Oral Paste for Horses and any supplementary data added to it, up to day 60 of the referral procedure in CM(v).
2. In view of the concerns raised by France, to indicate and to substantiate where necessary any differences between Equibactin vet. (333 mg/g + 67 mg/g) Oral Paste for Horses and the reference product Tribrissen Oral Paste (authorised in the Netherlands) that could justify different conclusions on the safety or efficacy for the two products.

In response to question 1, the applicant provided a copy of the original dossier as submitted in support of the application of a decentralised procedure, and any supplementary data submitted during the decentralised procedure in response to the phase I and phase II assessment and the referral procedure in CMD(v) thereafter.

In a GLP single dose bioequivalence study in horses, performed in accordance with appropriate guidelines, Equibactin vet. Oral Paste for Horses proved to be bioequivalent to the reference products Tribrissen (REG NL 5055 in the Netherlands) and Tribissen (Vm 0201/4064 in the UK). The original reference product "Tribrissen Oral Paste" was authorised in the Netherlands in 1992.

Under these conditions the applicant is exempted from submitting further preclinical or clinical data on efficacy of the proposed product, and can claim the same indications for use and the same precautionary warnings to ensure safe use for the product as for the reference product Tribrissen Oral Paste.

In response to question 2, the applicant pointed out that there are no differences at all that would justify different conclusions on the safety and efficacy for the two products. Moreover, there are only

similarities proving equal safety and efficacy of Equibactin vet. Oral Paste for Horses with the reference product Tribrissen Oral Paste (authorised in the Netherlands under REG NL 5055).

Based on the identical composition with respect to active ingredients, Trimethoprim and Sulfadiazine, the same pharmaceutical form, and proven bioequivalence between Equibactin vet. Oral Paste and Tribrissen oral paste for trimethoprim as well as for sulfadiazine, the products are regarded to be essentially similar. Consequently, the conclusions on efficacy and safety for the reference product, Tribrissen oral paste, can be extended to the generic product, Equibactin vet. Oral Paste.

The applicant agreed to submit a request for variation of Equibactin vet. Oral Paste, in accordance with the outcome of referral procedure EMEA/V/023 under Article 35 of Directive 2001/82/EC as amended, for the reference medicinal product Tribrissen Oral Paste authorised in The Netherlands.

3. Conclusions and Recommendations

Equibactin vet Oral Paste proved to be essentially similar to the reference product, Tribrissen Oral Paste. Consequently, the same conclusions on efficacy and safety apply to both products. The objections raised by France should not prevent the granting of a marketing authorisation for Equibactin vet. Oral Paste.

It is recommended to vary Equibactin vet. Oral Paste in accordance with the outcome of referral procedure EMEA/V/023 under Article 35 of Directive 2001/82/EC as amended, for the reference medicinal product Tribrissen Oral Paste authorised in The Netherlands.

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE INSERT

The valid Summary of Product Characteristics, labelling and package leaflet are the versions agreed by the Reference Member State and Concerned Member States (except France) at day 210 of the decentralised procedure.