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 COMPAGEL GEL FOR HORSES

BACKGROUND INFORMATION

Compagel Gel for Horses contains heparin sodium, levomenthol and hydroxyethyl salicylates. The gel is applied on the skin and its indications are:

- Haematoma, tendinitis, tendovaginitis, bursitis, capped hock, saddle sore, sprain, torsion, contusion, bruising, inflammation of the joint capsule (synovitis), muscle rupture, after nerve block anaesthesia, after paravenous injection.
- To accelerate the absorption of infiltrates (e.g. postoperative swelling, penile paralysis).
- To treat inflammations of superficial veins (e.g. phlebitis, thrombophlebitis, infusion thrombophlebitis).

Compagel Gel for Horses is a generic product.

In June 2007 a mutual recognition procedure started with Germany as Reference Member State and 5 Concerned Member States.

France and Sweden could not agree to the granting of a marketing authorisation as they 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 and Sweden considered that due to the absence of efficacy documentation it cannot be assumed that the product is efficacious and that this as such presents a potential serious risk to animal health.

The CVMP started the referral procedure during its meeting of 15-17 January 2008. The Marketing Authorisation Holder was requested to provide a copy of the dossier and, in view of the concerns raised by France and Sweden, to indicate and to substantiate where necessary any differences between Compagel Gel for Horses and the reference product that could justify different conclusions on the safety or efficacy for the two products.

In response to the questions, the applicant submitted the dossier and argued on the basis of a comparison of the compositions that there are no differences between Compagel Gel for Horses and the reference product that could justify different conclusions on the safety and efficacy.

Having considered the referral notification and responses of the applicant, the CVMP concluded that all concerned member states in the mutual recognition procedure agreed that Compagel Gel for Horses is essentially similar to Tensolvet 50000. No differences between the two products have been identified that would justify different conclusions on the safety and efficacy. Under these conditions the applicant is exempted from submitting further preclinical or clinical data on efficacy of the

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proposed product and can claim the same indications for use as for the reference product. Therefore, the absence of efficacy documentation does not present a potential serious risk to animal health.
The objections from France and Sweden should not prevent the granting of a marketing authorisation.

The CVMP Opinion was adopted on 13 February 2008 and the subsequent Commission Decision on 2 April 2008.
