The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

CAMPHORA
(use in veterinary homeopathy)

SUMMARY REPORT

1. Homeopathic preparations of *Camphora* are made from the solid essential oil D-(+)-camphor ((+)-2-bornanone, CAS No 464-49-3), which is obtained from the wood of the evergreen tree *Cinnamonum camphora*, native to Eastern Asia. The contents of D-(+)-camphor in the homeopathic starting material is at least 96%.

2. Camphor is used topically in veterinary medicine as mild analgesic (antipruritic), antiseptic and rubefacient. Camphor is present in topical formulations (e.g. ointments, oils) at concentrations of 3% to up to 20%. The total dose is dependent on the size of the affected skin area. Camphor is also used as expectorant following inhalation, orally or parenteral administration (information on doses not available).

   Camphor has previously been considered by the Committee for Veterinary Medicinal Products (CVMP) and is included in Annex II of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
Camphor	All food producing species	External use only

3. This application relates to the homeopathic mother tincture of *Camphora*, which corresponds to the 1:10 aqueous-ethanolic dilution of the homeopathic starting material, and which is intended for use in all food-producing animals. The use follows the principles of homeopathic therapy where animals are diagnosed on basis of the individual pattern of clinical signs. The recommended maximum parenteral dose for large animals is 10 ml/animal. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

   Camphor is also used in human homeopathy as the mother tincture as well as in lower concentrations. In babies and infants younger than 2 years the use of higher concentrations than the homeopathic 1:10 000 dilution is contraindicated.

   In human medicine the drug has been used topically for treatment of rheumatism and orally or topically in diseases of the respiratory tract or orally for treatment of hypotonic circulatory regulation disorders. External use was reported to be in concentrations in the final products not higher than 25%, reported oral doses are in the range of 15 to 300 mg/person.

4. Though detailed quantitative data on pharmacokinetics were not available, camphor, due to its lipophilic character, is generally considered to be rapidly absorbed in significant amounts through mucous membranes and intact skin. Metabolism is by hydroxylation and conjugation of the substance with glucuronic acid. Camphor and its metabolites are excreted mainly via urine.

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5. Camphor is acutely toxic and the therapeutic range is considered narrow. The reported human lethal dose is 15 to 500 mg/kg bw. Infants are most vulnerable because of lower activity of liver enzymes able to hydroxylate and conjugate camphor with glucuronic acid. Acute camphor ingestion may lead to neonatal toxicity because camphor crosses the placenta. Symptoms of camphor poisoning are hepatotoxicity and neurotoxic effects presenting as confusion, respiratory dysregulation and tonic-clonic convulsions.

6. The above Annex II entry for camphor is considered to also cover the topical use of veterinary homeopathic preparations of *Camphora* in all concentrations including the mother tincture.

   Furthermore it was concluded, that for all other routes of administration homeopathic dilutions of *Camphora* resulting in concentrations in the veterinary medicinal product not exceeding 1 part per 100 may be used, as they can be considered as not giving rise to any specific consumer health concerns and to provide a sufficient margin of safety.

Conclusions and recommendation

Having considered the criteria laid down by the Committee for Veterinary Medicinal Products for the inclusion of substances in Annex II of Council Regulation (EEC) No 2377/90 and in particular that:

- camphor for topical uses in veterinary medicine has already been included in Annex II of Council Regulation (EEC) No 2377/90,
- *Camphora* is used only in a small number of individual animals for non-regular treatments,
- animals are unlikely to be sent for slaughter during or immediately after treatment,
- *Camphora* did not give rise to specific consumer health concerns which may result from intended veterinary homeopathic uses in food producing animals;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for *Camphora* and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
Camphora	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per hundred only