



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

BELLIS PERENNIS

SUMMARY REPORT

1. *Bellis perennis* L., (synonym : daisy) is a common of the family *Asteraceae* (*Compositae*) widely distributed on meadows all over Europe. In veterinary homeopathy *Bellis perennis* is used as mother tincture prepared from the entire fresh flowering plant of *Bellis perennis* according to homeopathic pharmacopoeias, and dilutions thereof. Constituents of the *Bellis perennis* are triterpenoic saponins, including the ester triterpenoic bellissaponins 1 and 2. The overground parts of the plant contain about 2.7% triterpenoic saponins, the content in the roots is reported to be higher. Additionally flavonoids have been identified, namely two flavone glycosides of apigenin and three flavonoid aglycones (apigenin, kaempferol and quercetin). Further constituents of *Bellis perennis* are malic acid, acetic acid, oxalic acid, resins, wax, inulin, mucilaginous substances, essential oils and tannins. Glucose, rhamnose and arabinose have been identified among the sugars.
2. *Bellis perennis* 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 is 10 ml/animal. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

Bellis perennis is also used in human homeopathy as the mother tincture as well as in lower concentrations.
3. *Bellis perennis* is a ubiquitous occurring plant in fields and meadows. For grazing animals or via hay it is a regular part of animals diet. There are no reports on intoxication of humans or animals published in the literature.
4. In a preliminary risk evaluation procedure by the Committee for Veterinary Medicinal Products (CVMP) considering all defended old substances used in veterinary homeopathy in concentrations greater than 1:10 000, the use of *Bellis perennis* and its individual constituents was considered as not giving rise to specific health concern. Further information made available and extensive search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Bellis perennis* alerting to specific health risks which may result from residues in food producing animals following the intended uses. Special emphasis was put on identification of any suspicion pointing to genotoxicity or other potential of serious health effects of plant constituents.

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:

- *Bellis perennis* is a normal component of animals diet,
- *Bellis perennis* is used in a small number of individual animals for non-regular treatments,
- animals are unlikely to be sent for slaughter during or immediately after treatment,
- the substance and constituents thereof do not give rise to specific consumer health concern which may result from the use in veterinary homeopathy;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for any constituents of *Bellis perennis* and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 according to the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Bellis perennis</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only