COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

TURNERA DIFFUSA

SUMMARY REPORT

1. *Turnera diffusa* Willd (synonym: *Damiana*) is an aromatically smelling bush of the family *Turneraceae* distributed in tropical and subtropical regions of America and Africa. The homeopathic mother tincture is prepared by ethanolic extraction of the dried leaves of *Turnera diffusa* according to homeopathic pharmacopoeias.

Constituents of *Turnera diffusa* are essential oils (0.2% to 0.9%) with about 20 components, predominantly pinene, cineol, p-cymol and sesquiterpenes. Further constituents are resins (6.5%) bitter components (7%), tannins (3.5%), gum resins (13.5%), proteins (15%), carbohydrates, starch (6%) and traces of arbutin, sitosterol and traces of cyanogenic glycosides.

2. In veterinary homeopathy the mother tincture and dilutions thereof are 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.

*Turnera diffusa* is also used in human homeopathy as the mother tincture as well as in lower concentrations. In traditional medicine a tea prepared of the leaves of *Turnera diffusa* is used by native Americans of Middle- and South America. Leaves and stems are used for flavouring and as infusions.

3. The plant is reported to have nervous stimulant, diuretic and aphrodisiac properties. Intoxications of humans or toxic effects of *Turnera diffusa* have not been reported in the literature.

4. In a preliminary risk evaluation procedure by the Committee for Veterinary Medicinal Products, considering all defended old substances used in veterinary homeopathy in concentrations greater than 1:10 000, the use of *Turnera diffusa* and its individual constituents was considered as not giving rise to specific health concerns. Further information made available and extensive search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Turnera diffusa* 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:

- *Turnera diffusa* 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,
- the substance and constituents thereof do not give rise to specific consumer health concerns which may result from veterinary homeopathic uses in food producing animals;

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

<table>
<thead>
<tr>
<th>Pharmacologically active substance(s)</th>
<th>Animal species</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Turnera diffusa</em></td>
<td>All food producing species</td>
<td>For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only</td>
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