



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Matricaria recutita* L., flos

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC, as amended, and as set out in the appended assessment report, establishes by a majority of 26 out of 28 votes a European Union herbal monograph on *Matricaria recutita* L., flos which is set out in Annex I.

The divergent positions are appended to this opinion.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States, to Iceland and Norway, together with its Annex I and appendices.

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 7 July 2015



**Annex I: European Union herbal monograph
(EMA/HMPC/55843/2011)**

Appendix I: Assessment report (EMA/HMPC/55837/2011)

Appendix II : Divergent positions

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

Traditional herbal medicinal product used for adjuvant therapy of irritations of skin and mucosae in the anal and genital region, after serious conditions have been excluded by a medical doctor. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use. The application as a bath additive in relation to this indication is not considered suitable for use in self-care.

Furthermore, from a Dutch point of view, for indication 3: "Traditional herbal medicinal product for symptomatic treatment of mild irritations in the mouth or throat. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use", would be preferable.

And for indication 5, restriction of the indication to: "Traditional herbal medicinal product used in case of superficial wounds. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use" would be considered, preferable.

Emiel van Galen, HMPC member from the Netherlands

London, 7 July 2015

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

1. The proposed use of a bath additive preparation for use in **indication 4** is not considered acceptable.
2. The data to support use in children below 12 years of age is not sufficient to demonstrate safe use.

Indication 1)

Traditional herbal medicinal product used for the symptomatic treatment of minor gastro-intestinal complaints such as bloating and minor spasms

There are concerns about the use of the comminuted herbal substance in boiling water as a herbal infusion in children from 6 months to 12 years.

Indication 2)

Traditional herbal medicinal product used for the relief of symptoms of common cold.

There are concerns about the use in children from 6 to 12 years.

Indication 3)

Traditional herbal medicinal product for the treatment of minor ulcers and inflammations of the mouth and throat.

There are concerns about the use in children from 6 to 12 years.

Indication 4)

Traditional herbal medicinal product used for adjuvant therapy of irritations of skin and mucosae in the anal and genital region, after serious conditions have been excluded by a medical doctor.

There are concerns about the use in children from 4 weeks to 12 years.

Indication 5)

Traditional herbal medicinal product used for the treatment of minor inflammation of the skin (sunburn) and superficial wounds and small boils (furuncles).

There are concerns about the use in children from 4 weeks to 12 years.

Linda Anderson, HMPC member from the United Kingdom

London, 7 July 2015