



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/458822/2015
EMA/HMPC/M/H/169
Committee on Herbal Medicinal Products (HMPC)

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

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., *aetheroleum* 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/278814/2010)

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.

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:

The proposed use of a bath additive preparation for use in the proposed indication is not considered acceptable.

Indication

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.

Linda Anderson, HMPC member from the United Kingdom

London, 7 July 2015