



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 *Valeriana officinalis* 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 25 out of 27 votes a European Union herbal monograph on *Valeriana officinalis* L., aetheroleum which is set out in Annex I.

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. They replace those adopted on 13 July 2006.

London, 2 February 2016



Annex I: European Union herbal monograph (EMA/HMPC/278053/2015)

Appendix I: Assessment report (EMA/HMPC/150846/2015)

Appendix II: Divergent positions

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

Assessment report does not contain data on the traditional use of the oil by adolescents from the age of 12-18. Mental health problems of this age group should be considered carefully, request for advice from an expert (psychologist, physician) before use of such medicinal products is preferable. Furthermore the specific smell of the oil would cause problem for this age group.

Zsuzsanna Biróné Dr Sándor, HMPC member from Hungary

London, 2 February 2016

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

The use of *Valeriana officinalis* L., aetheroleum as a traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep in adolescents, 12 – 18 years, is not considered acceptable.

The data to support the proposed use in this age group are insufficient and it is considered that treatment should be under medical supervision.

Linda Anderson, HMPC member from the United Kingdom

London, 2 February 2016