



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 May 2010
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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a Community herbal monograph

This document was valid from 6 May 2010 until September 2019. It is now superseded by a [new version](#) adopted by the HMPC on 25 September 2019 and published on the EMA website.

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 23 out of 28 votes a Community herbal monograph on *Valeriana officinalis* L., radix and *Humulus lupulus* L., flos which is set out in Annex I.

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

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

London/ 6 May 2010

On behalf of the HMPC

Dr Konstantin Keller, Chair



**Annex I: Community herbal monograph
(EMA/HMPC/585558/2007)**

Superseded

Appendix I: Assessment report (EMA/HMPC/215214/2008)

Superseded

Appendix II: Divergent positions

Superseded

Five members of the HMPC did not agree with the HMPC's opinion on the Community herbal monograph on the Well-established use and Traditional use for *Valeriana officinalis* L., radix and *Humulus lupulus* L., flos for the following reason:

The evidence does not support the position of combinations of Valerian and Hops as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

Results of the studies presented as evidence for the indication of relief of sleep disorders are contradictory and there is significant inconsistency between trials in terms of subjects, experimental design and procedures and methodological quality.

The evidence in support of this indication and the proposed posology is considered inadequate.

6 May 2010