



OPINION OF THE COMMITTEE ON HERBAL MEDICINAL PRODUCTS ON A
COMMUNITY HERBAL MONOGRAPH ON
HUMULUS LUPULUS L., FLOS

**This document was valid from May 2008 until May 2014.
It is now superseded by a [new version](#) adopted by the HMPC on
6 May 2014 and published on the EMA website.**

1. 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 24 votes, a Community herbal monograph on *Humulus lupulus L.*, flos which is set out in Annex I.

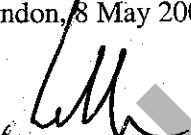
The divergent position is appended to this opinion.

The Icelandic and the Norwegian HMPC members agree 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 Community herbal monograph and assessment report will be published on the EMEA website.

London, 8 May 2008


On behalf of the HMPC
Dr Konstantin Keller, Chair

ANNEX I: COMMUNITY HERBAL MONOGRAPH (EMEA/HMPC/513617/2006)

APPENDIX I: ASSESSMENT REPORT (EMEA/HMPC/513618/2006)

Superseded

APPENDIX II: DIVERGENT POSITION

Superseded

One member of the HMPC did not agree with the HMPC's opinion based on the considerations reported below.

In reference to the claimed traditional use for "relief of mild symptoms of mental stress and to aid sleep", I consider that the risk-benefit profile is unclear as the available preclinical studies show contradictory results on the sedative effect of hop extracts and their constituents. Clinical studies were performed with combinations of hops, valerian, passion flower and lemon balm. Furthermore, studies in human subjects treated with 250 mg/day of a lipophilic hop extract for 5 days showed a lack of a clear sedative effect (Stocker, 1967).

On the other hand, there are pharmacological studies that substantiate the empirical use of hop extracts for the treatment of a variety of gynaecological disorders. Furthermore, the hop constituents responsible of the estrogenic properties have been identified, their pharmacokinetics described and are currently under study for a possible medicinal use as phytoestrogens. However, there is currently no sufficient information on the doses of hop extracts exerting estrogenic activity. Due to this lack of information, patients using hop for its presumed sedative activity could be exposed to unwanted estrogenic effects. This could be worsened by the patient's tendency to assume increasing quantities of hop-containing products as a consequence of not obtaining the expected sedative effect.

Therefore, I deem that the risk is not acceptable compared to the eventual minor benefit, easy achievable with other medications, taking into consideration that the indication is very close to health claims.

Finally, the "Liquid extract (1:10) prepared with sweet wine" cannot be considered as a medicinal product because it does not differ from a common alcoholic beverage, freely sold in wine shops. This could be misleading for the patients/consumers.

London, 1 July 2008