



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a Community herbal monograph on *Humulus lupulus* 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 25 out of 27 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 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 Community herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 8 May 2008.

London, 6 May 2014

On behalf of the HMPC

Prof. Dr Werner Knöss, Chair



# **Annex I: Community herbal monograph (EMA/HMPC/682384/2013)**

## Appendix I: Assessment report (EMA/HMPC/682385/2013)

## Appendix II: Divergent positions

Two members of the HMPC did not agree with the HMPC's opinion on *Humulus lupulus* L., flos for the reason presented below:

In reference to the claimed traditional use for "relief of mild symptoms of mental stress and to aid sleep", we consider that the risk-benefit profile is unclear with respect to the plausibility of the pharmacological effects and efficacy compared to a poor definition of the safety issues, taking into account that there is currently no sufficient information on the level of doses of hop extracts not exerting estrogenic activity.

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

This could be misleading for the patients/consumers.

Marisa Delbó, HMPC member from Italy

Gioacchino Calapai, Co-Opted HMPC member

London, 6 May 2014