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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., radix and *Humulus lupulus* L., flos

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC and as set out in the appended assessment report, establishes, by a majority of 20 out of 23 votes a revised European Union herbal monograph on *Valeriana officinalis* L., radix and *Humulus lupulus* L., flos 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 Norway, together with its Annex I and appendices.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 06 May 2010.

Amsterdam, 25 September 2019

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Annex I: European Union herbal monograph (EMA/HMPC/327107/2017)

Appendix I: Assessment report (EMA/HMPC/441766/2017)

Appendix II: Divergent positions

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

I do not agree with the HMPC's opinion on Community herbal monograph on the well-established use for *Valeriana officinalis* L., radix and *Humulus lupulus* L., flos for the following reason:

No new clinical studies to substantiate efficacy of the herbal preparations were found during the revision of the monograph, therefore the previous divergent opinion is maintained. Indeed, the evidence does not support the position of combinations of Valerian and Hop 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.

Alessandro Assisi, HMPC Member from Italy

Amsterdam, 25 September 2019

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

The evidence does not support the position of the combination *Valeriana radix/Lupuli flos* as having well-established medicinal use and recognised efficacy as a herbal medicinal product for the relief of sleep disorders as required by Article 10a of Directive 2001/83/EC. The data are considered insufficient to support a well-established use indication for this combination, in accordance with Annex 1 of 2001/83/EC.

The efficacy of the combination *Valeriana radix/Lupuli flos* has not been sufficiently and consistently proven

Emiel van Galen, HMPC Member from The Netherlands

Amsterdam, 25 September 2019

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

The evidence presented in the assessment report does not support the position of combinations of valerian and hops as having well-established use and efficacy as per Article 10a of Directive 2001/83/EC with regard to an indication for the relief of sleep disorders. In this revision of the monograph, no new clinical studies were found which substantiated efficacy of these herbal preparations and it is acknowledged in the assessment report that the methodological quality and clinical outcome of the studies presented are weak, with low subject numbers and lack of statistically significant results limiting any evidence which may be used to support this indication and proposed posology.

Sheena Kennedy, HMPC Member from Ireland

Amsterdam, 25 September 2019