



OPINION OF THE COMMITTEE ON HERBAL MEDICINAL PRODUCTS ON A
COMMUNITY HERBAL MONOGRAPH ON

Valeriana officinalis L., radix

This document was valid from 13 July 2006 until February 2016. It is now superseded by a [new version](#) adopted by the HMPC on 2 February 2016 and published on the EMA website.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 votes out of 27 votes a Community herbal monograph on *Valeriana officinalis* L., radix which is set out in Annex I.

The divergent positions are 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, 13 July 2006


On behalf of the HMPC
Dr Konstantin Keller, Chairman

ANNEX I: COMMUNITY HERBAL MONOGRAPH (EMEA/HMPC/340719/2005)

Superseded

APPENDIX I: ASSESSMENT REPORT (EMEA/HMPC/167391/2006)

Superseded

APPENDIX II: DIVERGENT POSITIONS

One member of the HMPC did not agree with the HMPC's opinion for the following reasons:

It is considered that the evidence does not support the position of Valerian 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 *sleep disorders* are contradictory and there is significant inconsistency between trials in terms of subjects, experimental design and procedures and methodological quality.

With regard to the indication of *relief of mild nervous tension*, this is not a recognised clinical term. Furthermore, the evidence in support of this indication and the proposed posology is considered inadequate.

The proposed well established use for *sleep disorders* and the traditional use, at a lower dosage, to *aid sleep* are considered confusing.

The terms *relief of mild nervous tension* and *relief of mild symptoms of mental stress* are not recognised clinical terms and are not sufficiently distinct to warrant the use of different posology/preparations.

London, 12 September 2006

One member of the HMPC did not agree with the HMPC's opinion for the following reasons:

Qualitative and quantitative composition

The qualitative and quantitative compositions of the extractive herbal preparations for traditional use are not specified at least as a range.

Indications

Well Established Use

It is considered that the evidence does not support the position of Valerian extracts as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

The proposed indications for well-established use are not supported by data coming from conclusive or well designed clinical trials, which may only give ground for the plausibility of traditional use indications.

With regard to the use in "*relief of mild nervous tension*", that is not a recognised clinical term, the evidence in the proposed indication and the proposed posology is considered inadequate for clinical methodology, number of subjects investigated, recognised potential bias in the experimental design and inconsistency of the valerian preparations used.

Relating to the indication in "*sleep disorders*" the data are contradictory and there is significant inconsistency between trials in terms of subjects, experimental design, procedures and methodological quality. Most of the trials were performed by assessing the efficacy of treatments through secondary endpoints such as subjective impressions of patients with no placebo comparison or confirmatory statistical evaluations. The answers of patient were rated using not fully relevant or validated questionnaires and are affected by methodological bias. Clinical trials vs. placebo do not show significant superiority of valerian root extract in insomnia.

Traditional use

The proposed indications for traditional use are not sufficiently distinct from the food supplement claims. Compared to the proposed indications for well-established use, the indications for traditional use are furthermore misleading, particularly for non-prescription medicinal products.

London, 15 September 2006

One member of the HMPC did not agree with the HMPC's opinion for the following reasons:

The data provided do not fulfil the requirements for well-established use in accordance with Annex I of 2001/83/EC, as amended and the distinction between well-established use and traditional use based solely on product type is considered to be inappropriate. In addition, the proposed indications for well-established and traditional use are considered to be the same and this approach is potentially misleading from a patient/consumer perspective.

Specifically, the data presented are considered insufficient to support the proposed well-established indications as follows:

a.) Relief of mild nervous tension

Only one of the clinical studies presented investigated the indication proposed, the results of which are unclear and of unknown clinical significance.

b.) Sleep disorders

The studies relating to sleep disorders are inconsistent in terms of subjects investigated; some were healthy volunteers while others had diagnosed sleep disorders. In addition, the outcome measures [subjective and objective] and doses of Valerian used varied from one study to the next. Overall, the totality of the data does not support the indication for treatment of sleep disorders.

Finally, the product types included under well-established use should be included under traditional use in order for the traditional use section to be considered acceptable.

London, 12 September 2006

One member of the HMPC did not agree with the HMPC's opinion for the following reasons:

The content of VALERIANA RADIX meets the quality acquired. The only reason why I voted against is the formulation of the indication '... and to aid sleep...'. As to my opinion this formulation is too close to a health claim. Although it may already been used for registered drugs, it can be easily adapted. 'Aide sleep' cannot be considered as a therapeutic activity. My proposal would have been: '... relief of mild symptoms of mental stress and to aid sleep in these circumstances.'

London, 13 September 2006

Superseded