EMA/HMPC/74082/2016
EMA/HMPC/M/H/179
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Valeriana officinalis* L., radix

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 22 out of 27 votes a European Union herbal monograph on *Valeriana officinalis* L., radix which is set out in Annex I.

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 European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 13 July 2006.

London, 2 February 2016

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Annex I: European Union herbal monograph (EMA/HMPC/150848/2015)

Appendix I: Assessment report (EMA/HMPC/150846/2015)

Appendix II: Divergent positions

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

There are no data to support the Well Established Use in adolescents

Silvia Girotto, Co-opted member of the HMPC

London 2 February 2016

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

Ireland does not support the proposed European Union herbal monograph for *Valeriana officinalis* L., radix for the well-established use indication for the relief of mild nervous tension and sleep disorders

In our view the data provided do not fulfil the requirements for well-established medicinal use in accordance with Annex 1 of 2001/83/EC, as amended. The efficacy of *Valeriana officinalis* L., radix has not been sufficiently and consistently proven.

Una Mockler, HMPC member from the Ireland

London 2 February 2016

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

Well Established Use

In my view data provided for Valerian extracts do not fulfil the requirements for well-established medicinal use in accordance with Annex 1 of 2001/83/EC, as amended. and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

In our view the data provided do not fulfil the requirements for well-established medicinal use The efficacy of *Valeriana officinalis* L., radix has not been sufficiently and consistently proven.

Furthermore, with regard to use as a traditional herbal medicinal product the proposed use for relief of mild symptoms of mental stress and to aid sleep in adolescents, 12 – 18 years, is not considered acceptable.

The data to support the proposed use in this age group are insufficient and it is considered that treatment should be under medical supervision.

The proposed indications for well-established use are not has not been sufficiently and consistently proven byconclusive or well-designed clinical trials.

With regard to the use in "*relief of mild nervous tension*", 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. Moreover "*mild nervous tension"* does not correspond to any medical diagnosis and therefore the indication can be considered suitable for traditional use only.

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 use of *Valeriana officinalis* L.*,* radix preparations as traditional herbal medicinal products for relief of mild symptoms of mental stress and to aid sleep in adolescents, 12 – 18 years, is not considered acceptable. There are insufficient data to support the proposed use in this age group and treatment should be under medical supervision.

Furthermore, the following preparation cannot be considered as medicinal products because sweet wine with no further specification cannot be accepted as extraction solvent and the herbal preparation does not differ from common alcoholic beverages, freely sold in wine shops:

Liquid extract (DER 1:7-9), extraction solvent: sweet wine

Marisa Delbò, HMPC member from Italy

London 2 February 2016

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

Well Established Use

In my view 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 conclusive or well-designed clinical trials, which may only support the plausibility of traditional use indications.

With regard to the use in *"relief of mild nervous tension*", 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. Moreover *"mild nervous tension"* does not correspond to any medical diagnosis and therefore the indication can be considered suitable for traditional use only.

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 use of *Valeriana officinalis* L., radix preparations as a traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep in adolescents, 12 – 18 years, is not considered acceptable. There are no data to support the proposed use in this age group and treatment should be under medical supervision.

Gioacchino Calapai, Co-opted member of the HMPC

London 2 February 2016

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

The UK does not support the proposed European Union herbal monograph for *Valeriana officinalis* L., radix for the well-established use indication for the relief of mild nervous tension and sleep disorders.

In our view the data provided do not fulfil the requirements for well-established medicinal use in accordance with Annex 1 of 2001/83/EC, as amended. The efficacy of *Valeriana officinalis* L., radix has not been sufficiently and consistently proven.

Furthermore, with regard to use as a traditional herbal medicinal product the proposed use for relief of mild symptoms of mental stress and to aid sleep in adolescents, 12 – 18 years, is not considered acceptable.

The data to support the proposed use in this age group are insufficient and it is considered that treatment should be under medical supervision.

Linda Anderson, HMPC member from the United Kingdom

London 2 February 2016