



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/176672/2014
EMA/HMPC/M/H/144
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a Community herbal monograph on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., 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 21 out of 30 votes a Community herbal monograph on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix L., folium 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, 25 March 2014

On behalf of the HMPC

Prof. Dr Werner Knöss, Chair



Annex I: Community herbal monograph (EMA/HMPC/680618/2013)

Appendix I: Assessment report (EMA/HMPC/680615/2013)

Appendix II : Divergent positions

One member of the HMPC did not agree with the HMPC's opinion on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix for the reason presented below:

Due no new data has been published concerning the indications mentioned in the Monograph I express my divergent position on Community herbal monograph of on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix.

Ivan Kosalec, HMPC member from Croatia

25 March 2014

One member of the HMPC did not agree with the HMPC's opinion on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix for the reason presented below:

Adopted wording for the indication refers to a symptom (asthenia) close to the indication adopted for caffeine-containing plants and does not distinguish the different traditional use for Eleuterococci radix.

Zsuzsanna Biróné Dr Sándor, HMPC member from Hungary

25 March 2014

One member of the HMPC did not agree with the HMPC's opinion on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix for the reason presented below:

We have concerns regarding the potential safe use of this herbal substance "for symptoms of asthenia such as fatigue and weakness". In our view this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24/EC.

Anna Cunney, HMPC member from Ireland

25 March 2014

Three members of the HMPC did not agree with the HMPC's opinion on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix for the reason presented below:

Adopted wording for the indication refers to a symptom (asthenia) close to the indication adopted for caffeine-containing plants and do not distinguish the different traditional use of Eleuterococci radix .

The following preparations cannot be considered as medicinal products because it does not differ from common alcoholic beverages, freely sold in wine shops;

J) Liquid extract (DER 1:11-13.6), extraction solvent liquor wine

This could be misleading for the patients/consumers.

Marisa Delbó, HMPC member from Italy

25 March 2014

Eeva Sofia Leinonen, HMPC member from Finland

25 March 2014

Milan Nagy, HMPC member from Slovakia

25 March 2014

One member of the HMPC did not agree with the HMPC's opinion on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix for the reason presented below:

Cannot be adopted, because the use of the word "asthenia", for a Dutch indication, does not fall under the requirement as mentioned in art. 16a (1) c of Directive 2001/83/EC, in a way that is can be understood by a patient or consumer. Asthenia as medical term is rather obsolete and should not be used as part of an indication for traditional herbal medicinal products.

For both, the Netherlands could endorse the indication: "Traditional herbal medicinal product for the relief of fatigue and sensation of weakness.

The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use."

Emiel van Galen, HMPC member from the Netherlands

25 March 2014

One member of the HMPC did not agree with the HMPC's opinion on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix for the reason presented below:

Based mainly on different indication we mainly accepted during discussions in MLWP. I could accept only the indication nr 2, which was proposed as a result of discussion during MLWP session. By analogy to current scientific assessment and view on Ginseng radix documentation I can't support introducing of the substance and preparations on the list.

Wojciech Dymwoski, HMPC member from Polen

25 March 2014

One member of the HMPC did not agree with the HMPC's opinion on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix for the reason presented below:

Because the list entry was accepted in the past based on an (currently) insufficient Ames test before the adoption of the respective HMPC guideline, I did not oppose its acceptance in this revision. My divergent opinion against the list entry status of *Eleutherococcus* is based on a view that in this situation the national assessment is preferential, i.e. list entry would preclude national assessment.

Olavi Pelkonen, HMPC member from Co-opted member Toxicology

25 March 2014