



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 *Panax ginseng* C.A.Meyer, radix

**This document was valid from 25 March 2014 until May 2024.
It is now superseded by a [new version](#) adopted by the HMPC on
29 May 2024 and published on the EMA website.**

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 29 votes a Community herbal monograph on *Panax ginseng* C.A.Meyer, radix 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.

London, 25 March 2014

On behalf of the HMPC

Prof. Dr Werner Knöss, Chair



**Annex I: Community herbal monograph
(EMA/HMPC/321233/2012)**

Superseded

Appendix I: Assessment report (EMA/HMPC/321232/2012)

Superseded

Appendix II: Divergent positions

Superseded

One member of the HMPC did not agree with the HMPC's opinion on *Panax ginseng* C.A.Meyer, 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

London, 25 March 2014

Superseded

Three members of the HMPC did not agree with the HMPC's opinion on *Panax ginseng* C.A.Meyer, 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 Ginseng 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

Gioacchino Calapai, Co-Opted HMPC member

Silvia Girotto, Co-Opted HMPC member

London, 25 March 2014

One member of the HMPC did not agree with the HMPC's opinion on *Panax ginseng* C.A.Meyer, 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 Ginseng radix.

Zsuzsanna Biróné Dr Sándor, HMPC member from Hungary

London, 25 March 2014

Superseded

One member of the HMPC did not agree with the HMPC's opinion on *Panax ginseng* C.A.Meyer, 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

London, 25 March 2014

One member of the HMPC did not agree with the HMPC's opinion on *Panax ginseng* C.A.Meyer, radix for the reason presented below:

Cannot be adopted, because the use of the word "asthenia", for a Dutch indication, does not fall under Adopted wording is almost the same as for caffeine-containing plants. Caffeine acts mainly through adenosine receptors in human body. Opposite, Ginseng and related plants /Eleutherococcus,.../ develop their "adaptogenic" action by quite different mechanisms: influencing the hypothalamic-pituitary-adrenal axis and the regulation of key mediators of stress response, such as molecular chaperons (e.g., HSP70), stress-activated c-Jun N-terminal protein kinase 1 JNK1), Forkhead box O (FOXO) transcription factor DAF-16, cortisol...

Thus I preferred the wording, which would contain "stress" as a source of fatigue.

Milan Nagy, HMPC member from Slovakia

London, 25 March 2014