



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Panax ginseng* C.A.Mey., radix

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 24 out of 27 votes a revised European Union herbal monograph on *Panax ginseng* C.A.Mey., radix which is set out in Annex I.

The divergent positions are appended to this opinion.

This opinion is forwarded to Member States and Norway, together with its Annex I and appendix.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 25 March 2014.

Amsterdam, 29 May 2024.

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**Annex I: European Union herbal monograph
(EMA/HMPC/27744/2023)**

Appendix I: Assessment report (EMA/HMPC/27745/2023)

Appendix II: Divergent positions

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

Ireland does not support the proposed EU herbal monograph for *Panax ginseng* C.A. Meyer, radix. 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.

Jackie Masterson, HMPC member from Ireland.

Amsterdam, 29 May 2024.

The Netherlands does not support the revised EU herbal monograph on *Panax ginseng* C.A. Meyer, radix, because the use in Dutch of "asthenia" in the indication is not in accordance with the requirements mentioned in art. 16a (1) c of Directive 2001/83/EC, because it is not 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. The Netherlands would endorse the following 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."

Burt Kroes, HMPC member from Netherlands.

Amsterdam, 29 May 2024.

Poland refrained from voting in favour the package on Ginseng radix because the whole scientific data on animal pharmacology of constituents contained in the herbal substance and the current knowledge, which was gathered over the former assessment and review period, are richer than the indications, which are based only on the old European tradition and do not fit now to the contemporary scientific data. Both parts of the assessment seem mismatched in the assessment and were not explained enough.

Wojciech Dymowski, HMPC member from Poland.

Amsterdam, 29 May 2024.