



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/66450/2017
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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Glycine max* (L.) Merr., lecithinum

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 23 out of 24 votes a European Union herbal monograph on *Glycine max* (L.) Merr., lecithinum 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 European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 31 January 2017



Annex I: European Union herbal monograph (EMA/HMPC/220599/2016)

Appendix I: Assessment report (EMA/HMPC/220598/2016)

Appendix II : Divergent position

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

We have concerns regarding the potential safe use of this herbal preparation "for the relief of temporary fatigue and sensation of weakness". In our view this indication is not acceptable for a traditional herbal medicinal product in line with Direction 2004/24/EC.

Rachel Cox, HMPC member from Ireland

London, 31 January 2017