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SCIENCE MEDICINES HEALTH

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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., oleum raffinatum

### 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 28 out of 29 votes a European Union herbal monograph on *Glycine max* (L.) Merr., oleum raffinatum 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/338914/2016)**

## **Appendix I: Assessment report (EMA/HMPC/338915/2016)**

## Appendix II: Divergent position

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

Concerning the EU Herbal monograph for *Glycine max*, oleum raffinatum (Soiae oleum raffinatum), the indication should be restricted to "Traditional herbal medicinal product used for the symptomatic relief of dry skin conditions, exclusively based on long-term experience."

Taking into account that this Herbal monograph is covering the use as food additive, the extension of the indication to "associated with mild recurrent eczema" is not considered justified.

Emiel van Galen, HMPC member from The Netherlands

London, 31 January 2017