



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 *Rubus idaeus* L., folium

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 28 out of 29 votes a Community herbal monograph on *Rubus idaeus* 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.

London, 28 January 2014

On behalf of the HMPC

Prof. Dr. Werner Knöss, Chair



Annex I: Community herbal monograph (EMA/HMPC/44211/2012)

Appendix I: Assessment report (EMA/HMPC/44209/2012)

Appendix II: Divergent positions

One member of the HMPC did not agree with the HMPC's opinion on *Rubus idaeus* L., folium for the reason presented below:

The Netherlands would prefer the following wording for the second part of the indication:

Traditional herbal medicinal product for the symptomatic relief of mild irritation of the mouth or throat
Because the anti-inflammatory effect based on traditional use, is not sufficiently demonstrated.

The Netherlands would prefer the following wording for the third part of the indication:

Traditional herbal medicinal product that can be used in case of mild diarrhoea when causal treatment is not possible.

Because this is a better indication, under which the traditional herbal medicinal product will be used safely for this specific indication.

Emiel van Galen, HMPC member from the Netherlands

28 January 2014