



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 *Rosa gallica* L., *Rosa centifolia* L., *Rosa damascena* Mill., flos

### 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 26 out of 27 votes a Community herbal monograph on *Rosa gallica* L., *Rosa centifolia* L., *Rosa damascena* Mill., flos 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 appendix.

The Community herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 1 July 2014

On behalf of the HMPC

Prof. Dr Werner Knöss, Chair



## **Annex I: Community herbal monograph (EMA/HMPC/137299/2013)**

## **Appendix I: Assessment report (EMA/HMPC/137298/2013)**

## Appendix II: Divergent positions

One member of the HMPC did not agree with the HMPC's opinion on *Rosa gallica* L., *Rosa centifolia* L., *Rosa damascena* Mill., flos for the reason presented below:

In both indications, the word "Inflammation(s)" is not supported, because an anti-inflammatory effect is not considered substantiated.

For registration in the Netherlands, the following indications are considered acceptable:

**Indication 1)** Traditional herbal medicinal product used for mild irritations of the oral and pharyngeal mucosa.

**Indication 2)** Traditional herbal medicinal product used for relief of minor skin irritation.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

Emiel van Galen, HMPC member from the Netherlands

1 July 2014