

EUROPEAN MEDICINES AGENCY

EMA/HMPC/393172/2014 EMA/HMPC/M/H/153 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.

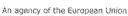
The Community herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 1 July 2014

WKB

On behalf of the HMPC Prof. Dr Werner Knöss, Chair

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

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

## **Appendix II: Divergent positions**

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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