



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/61599/2015  
EMA/HMPC/M/H/160  
Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Agrimonia eupatoria* L., herba

### 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 29 out of 30 votes a European Union herbal monograph on *Agrimonia eupatoria* L., herba which is set out in Annex I.

The divergent positions are 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, 28 January 2015

On behalf of the HMPC

Prof. Dr Werner Knöss, Chair



# Annex I: European Union herbal monograph (EMA/HMPC/680597/2013)

## Appendix I: Assessment report (EMA/HMPC/680595/2013)

## Appendix II : Divergent positions

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

Because in the indication as traditional herbal medicinal products, "inflammation(s)" should be replaced by "irritation(s)", because an anti-inflammatory effect has not been demonstrated.

The relevant parts of the indication are considered acceptable as:

Traditional herbal medicinal products for use as a gargle for the symptomatic relief of minor irritations of the mouth and throat.

Traditional herbal medicinal products for relief of minor skin irritations.

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

Emiel van Galen HMPC member from The Netherlands

London, 28 January 2015