



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/454921/2015  
EMA/HMPC/M/H/167  
Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Carum carvi* L., aetheroleum

### 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 27 out of 28 votes a European Union herbal monograph on *Carum carvi* L., aetheroleum 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, 7 July 2015



# **Annex I: European Union herbal monograph (EMA/HMPC/715094/2013)**

**Appendix I: Assessment report (EMA/HMPC/715093/2013)**

## Appendix II: Divergent position

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

Regarding the European Union herbal monograph for *Carum carvi* L., aetheroleum, I do not support the proposed cutaneous use in infants, children, adolescents, adults and elderly, in relation to the indication: Traditional herbal medicinal product for the symptomatic relief of digestive disorders such as bloating and flatulence, because of the pharmacological effects are not sufficiently made plausible based on long-term marketing and experience.

Emiel van Galen, HMPC member

London, 7 July 2015