



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Vaccinium myrtillus* L., fructus siccus

### 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 25 out of 27 votes a European Union herbal monograph on *Vaccinium myrtillus* L., fructus siccus which is set out in Annex I.

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

London, 29 September 2015



## **Annex I: European Union herbal monograph (EMA/HMPC/678995/2013)**

**Appendix I: Assessment report (EMA/HMPC/555161/2013)**

## Appendix II : Divergent position

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

I do not fully endorse the indication established in the monograph. From a Dutch point of view, the indication "Traditional herbal medicinal product for symptomatic treatment of mild irritations in mouth or throat, exclusively based upon long-standing use" would be preferable, instead of "mild inflammations"

Emiel van Galen, HMPC member

London, 29 September 2015

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

We do not support the use of *Myrtilli fructus siccus* in pregnancy and lactation. In our opinion, insufficient data has been presented in the assessment report to justify a recommendation for use in this special population.

Una Mockler, HMPC member

London, 29 September 2015