



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/642019/2015
EMA/HMPC/M/H/173
Committee on Herbal Medicinal Products (HMPC)

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

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 23 out of 27 votes a European Union herbal monograph on *Vaccinium myrtillus* L., fructus recens 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/375808/2014)**

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

Appendix II : Divergent position

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

The EU monograph on *Vaccinium myrtillus* L., fructus recens was adopted with the following therapeutic indication (indication 2):

Traditional herbal medicinal product to relieve symptoms of cutaneous capillary fragility.

This indication is not sufficiently clear to be accepted for a traditional herbal medicinal product intended for use without the supervision of a physician. It is unclear which symptoms that are alluded to. In the absence of such important information, the patient will not be able to use the product in a safe way.

The rest of the monograph and the safety of *Vaccinium myrtillus* L., fructus recens as such are considered acceptable. The divergent opinion is only concerning the acceptability of indication 2 of the monograph.

Per Claeson, HMPC member

Eeva Sofia Leinonen, HMPC member

Emiel van Galen, HMPC member

Steffen Bager, HMPC member

London, 29 September 2015