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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Fragaria vesca* L., *Fragaria moschata* Weston, *Fragaria viridis* Weston and *Fragaria x ananassa* (Weston) Duchesne ex Rozier, folium

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC and as set out in the appended assessment report, establishes, by a majority of 23 out of 24 votes a European Union herbal monograph on *Fragaria vesca* L., *Fragaria moschata* Weston, *Fragaria viridis* Weston and *Fragaria x ananassa* (Weston) Duchesne ex Rozier, folium 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 European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 20 November 2018

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Annex I: European Union herbal monograph (EMA/HMPC/432278/2015)

Appendix I: Assessment report (EMA/HMPC/432276/2015)

Appendix II: Divergent position

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

In our view the data provided are insufficient to support a traditional use in accordance with article 16a Directive 2001/83/EC.

From the data provided the continuous use of the posologies described in the monograph cannot be derived.

Jaqueline Wiesner, HMPC Member from Germany

London, 20 November 2018