



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/615038/2017  
EMA/HMPC/M/H/0213  
Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Ribes nigrum* L., folium

### 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 24 out of 25 votes a European Union herbal monograph on *Ribes nigrum* L., folium which is set out in Annex I.

The divergent position is appended to this opinion.

The Norwegian HMPC member does agree 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, 19 September 2017



# **Annex I: European Union herbal monograph (EMA/HMPC/745353/2016)**

## **Appendix I: Assessment report (EMA/HMPC/745347/2016)**

## 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 EU Herbal monograph for *Ribes nigri folium*, from a Dutch point of view the indication "Traditional herbal medicinal product used to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.", is preferable.

Without the part "to increase the amount of urine" which is difficult to demonstrate, based on proof exclusively upon long-standing use and experience.

Emiel van Galen, HMPC Member from The Netherlands

London, 19 September 2017