EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/711682/2014
EMA/HMPC/M/H/0155
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Betula pendula* Roth, *Betula pubescens* Ehrh. as well as hybrids of both species, 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 28 out of 29 votes a European Union herbal monograph on *Betula pendula* Roth, *Betula pubescens* Ehrh. as well as hybrids of both species, folium 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. They replace those added on 8 May 2008.

London, 24 November 2014

On behalf of the HMPC

Prof. Dr Werner Knöss, Chair

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Annex I: European Union herbal monograph (EMA/HMPC/573241/2014)

Appendix I: Assessment report (EMA/HMPC/573240/2014)

Appendix II: Divergent position

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

Based on the fact that an increase in amount of urine cannot be substantiated, while additional fluid intake is also recommended, the following indication would be preferable: "Traditional herbal medicinal product to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use"

Emiel van Galen the HMPC member from Netherlands

London, 24 November 2014