



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/171225/2017
EMA/HMPC/M/H/202
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Species diureticae*

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 28 out of 29 votes a European Union herbal monograph on *Species diureticae* 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, 28 March 2017



Annex I: European Union herbal monograph (EMA/HMPC/224755/2016)

Appendix I: Assessment report (EMA/HMPC/224754/2016)

Appendix II: Divergent position

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

The undersigned member of HMPC prefers as indication for these herbal teas:

Traditional herbal medicinal product 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 exclusively based upon long-standing use.

That the increase of the amount of urine is related to (a combination of) the herbal preparation(s), and not by an increase in fluid intake by the herbal tea, cannot be unequivocally be distinguished from each other.

Emiel Van Galen, HMPC Member from The Netherlands

London, 27 March 2017