



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Equisetum arvense* L., herba

### 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 27 votes a European Union herbal monograph on *Equisetum arvense* L., herba 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 appendices.

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 3 July 2008.

London, 2 February 2016



## **Annex I: European Union herbal monograph (EMA/HMPC/278091/2015)**

**Appendix I: Assessment report (EMA/HMPC/278089/2015)**

## Appendix II: Divergent positions

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

The following preparations cannot be considered as medicinal products because sweet wine with no further specification cannot be accepted as an extraction solvent and the herbal preparations do not differ from common alcoholic beverages, freely sold in wine shops;

Liquid extract (DER 1:5), extraction solvent: ethanol 96% (V/V):water: sweet wine 16.5% (V/V) (16.5:13.5:70) (m/m)

Liquid extract (DER 1:4.5-5.0) extraction solvent: sweet wine 16% (V/V):ethanol 96% (V/V) (91:9) (m/m)

This could be misleading for the patients/consumers.

Marisa Delbò, HMPC member from Italy

London, 2 February 2016

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 *Equiseti herba*, 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.

Because the increase in amount of urine, is not demonstrated based on long-standing use.

Emiel van Galen, HMPC member from the Netherlands

London, 2 February 2016

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

The use of *Equiseti herba* as a traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints, in adolescents, 12 – 18 years, is not considered acceptable.

The data to support the proposed use in this age group are insufficient and it is considered that treatment should be under medical supervision.

Linda Anderson, HMPC member from the United Kingdom

London, 2 February 2016