



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 *Salvia officinalis* 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 27 votes a European Union herbal monograph on *Salvia officinalis* L., folium which is set out in Annex I.

The divergent positions are appended to this opinion.

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 12 November 2009.

London, 20 September 2016



## **Annex I: European Union herbal monograph (EMA/HMPC/277152/2015)**

## **Appendix I: Assessment report (EMA/HMPC/150801/2015)**

## **Appendix II: Divergent positions**

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 *Salvia officinalis* folium, according to the Dutch view, in indication part 3 and indication part 4, "inflammation" should be established as "irritation". For the reason that an inflammatory action is not sufficiently demonstrated.

Indication 3: Traditional herbal medicinal product for relief of *irritations* in the mouth or the throat.

Indication 4: Traditional herbal medicinal product for relief of minor skin *irritations*.

The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.

Emiel Van Galen, HMPC Member from Netherlands

London, 20 September 2016

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

The explanation why the products containing sage leaf cannot be used by adolescents is not adequate: „The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.”

Adequate data can be found in the Assessment report that there have been products on the market for more than 30 years which can be used by adolescents (see page 10-11). The reasoning for the exclusion of adolescents should be rather the safety of thujone, if any.

The Public statement on the use of herbal medicinal products containing thujone (EMA/HMPC/732886/2010 Rev.1) states that “There are no preclinical or clinical studies which would permit reliable scientific assessment of potential consequences regarding exposure of sensitive groups (i.e. pregnant women, children etc). Thus the use of thujone-containing herbal medicinal products in these groups should be minimised.”, however, there is a safety limit for adults. The Hungarian delegate's opinion is that there is not a meaningful difference between adults and adolescents considering the external use of sage leaf. Hence, the use of *Salviae folium* for this population would be also justified.

Zsuzsanna Birone Dr Sandor, HMPC Member from Hungary

London, 20 September 2016

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 liquor wine with no further specification cannot be accepted as an extraction solvent for a medicinal herbal preparation:

- a) Liquid extract (DER 1:4-6), extraction solvent: liquor wine : ethanol 96% V/V (38.25 : 61.75 m/m)

Marisa Delbò, HMPC Member from Italy

London, 20 September 2016