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EMA/HMPC/599993/2014
Committee on Herbal Medicinal Products (HMPC)

Public statement on *Salvia fruticosa* Mill., folium

Final

Discussion in Working Party on European Union Monographs and List (MLWP)	November 2014 May 2015 July 2015
Adoption by Committee on Herbal Medicinal Products (HMPC)	24 November 2015
Start of public consultation	9 December 2015
End of consultation (deadline for comments) ¹	15 March 2016
Re-discussion in MLWP	April 2016
Adoption by HMPC	31 May 2016

Keywords	Herbal medicinal products; HMPC; Public statements; <i>Salvia fruticosa</i> Mill., folium; <i>Salviae fruticosae folium</i> ; Three-lobed sage leaf
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¹ No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.



Public statement on *Salvia fruticosa* Mill., folium

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a European Union herbal monograph on *Salvia fruticosa* Mill., folium as announced in the 2014 MLWP work programme. A call for the submission of scientific data was published on the EMA website with a submission period from 15 February 2014 until 15 May 2014.

A comprehensive literature search was conducted and available data, including information on products on the market in the European Union, were assessed in relation to the requirements laid down in Directive 2001/83/EC and its Annex I, in particular Article 1, Article 10a and Chapter 2a.

The HMPC/MLWP concluded that the following requirements for the establishment of a European Union herbal monograph on traditional herbal medicinal products containing *Salvia fruticosa* Mill., folium are not fulfilled:

- the requirement laid down in Article 10a of Directive 2001/83/EC that the active substance has a recognised efficacy and an acceptable level of safety and that the period of well-established medicinal use has elapsed
- the requirement laid down in Article 16a(1)(d) of Directive 2001/83/EC that “the period of traditional use as laid down on Article 16c(1)(c) has elapsed”
- the requirement laid down in Article 16a(1)(e) of Directive 2001/83/EC that “the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience”

The HMPC/MLWP recognises the use of *Salvia fruticosa*, as medicinal plant, in several EU member states, however documented specific and unequivocal historical information is insufficient to verify the necessary conditions of a long-standing traditional use.

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a European Union herbal monograph on *Salvia fruticosa* Mill., folium cannot be established at present, unless new data are provided.

To read more about the assessment carried out, a link is provided to the page where to access the assessment report on *Salvia fruticosa* Mill., folium and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000205.jsp&mid=WC0b01ac058001fa1d