

EMEA/HMPC/583001/2009EN EMEA/HMPC/M/H/0059

This document was valid from 12 November 2009 until September 2016. It is now superseded by a <u>new version</u> adopted by the HMPC on 20 September 2016 and published on the EMA website.

## **Opinion**

1. 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 26 out of 28 votes a Community 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 Community herbal monograph and assessment report will be published on the EMEA website.

London, 12 November 2009

On behalf of the HMPC Prof. I. Chinou, Vice-Chair ANNEX I: COMMUNITY HERBAL MONOGRAPH (EMEA/HMPC/331653/2008)

APPENDIX I: ASSESSMENT REPORT (EMEA/HMPC/330383/2008)

APPENDIX II: DIVERGENT POSITIONS

Two members of the HMPC did not agree with the HMPC's opinion for the following reason:

I do not support the proposed Community Monograph for Salvia officinalis L., folium based on the consideration reported below.

The following preparation cannot be considered as medicinal products because it does not differ from common alcoholic beverages, freely sold in wine shops;

- liquid extract (1:7.2) extraction solvent: liquor wine:ethanol 96 % V/V (38.25:61.75 m/m)

This could be misleading for the patients/consumers.

London 12 November 2009