

EMA/HMPC/756918/2010 EMA/HMPC/M/H/0082 Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a Community herbal monograph on *Cimicifuga racemosa* (L.) Nutt., rhizoma

This document was valid from 25 November 2010 until March 2018. It is now superseded by a <u>new version</u> adopted by the HMPC on 27 March 2018 and published on the EMA website.

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 29 out of 31 votes a Community herbal monograph on *Cimicifuga racemosa* (L.) Nutt., rhizoma 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 European Medicines Agency website.

London, 25 November 2010

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On behalf of the HMPC

Werner Knöss, Chair



Annex I: Community herbal monograph (EMA/HMPC/600717/2007)



Appendix I: Assessment report (EMA/HMPC/3968/2008)



Appendix II: Divergent positions



Two members of the HMPC did not agree with the HMPC's opinion Community herbal monograph on *Cimicifuga racemosa* (L.) Nutt., rhizoma for the following reason:

The published data could only support a traditional use and the scientific data provided are currently insufficient to recognise *Cimicifuga rhizoma* preparations as well established treatment in the relief of menopausal complaints. In particular, there are insufficient genotoxicity data to support well established use.

25 November 2010