15 January 2020
EMA/HMPC/22236/2020
EMA/HMPC/M/H/0236
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Mentha x piperita* L., aetheroleum

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC and as set out in the appended assessment report, establishes, by a majority of 24 out of 26 votes a revised European Union herbal monograph on *Mentha x piperita* L., aetheroleum which is set out in Annex I.

The divergent positions are appended to this opinion.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States and Norway, together with its Annex I and appendices.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 31 October 2007.

Amsterdam, 15 January 2020

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Annex I: European Union herbal monograph (EMA/HMPC/522410/2013)

Appendix I: Assessment report (EMA/HMPC/522409/2013)

Appendix II: Divergent positions

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

I do not support *Mentha x piperita* L. aetheroleum (peppermint oil) as having well-established medicinal use and recognised efficacy for the symptomatic relief of tension type headache as required by Article 10a of Directive 2001/83/EC. The number of studies and their methodological quality and subject numbers are considered insufficient to support this well-established use indication.

Sheena Kennedy, HMPC Member from Ireland

Amsterdam, 15 January 2020

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

I do not support the well-established cutaneous use indication "Herbal medicinal product for the symptomatic relief of mild tension headache" for *Mentha x piperita* L. aetheroleum as there are no new clinical data available since the date of publication of the first version of the monograph. The clinical and pharmacological data presented for this indication are weak, unclear, and considered insufficient to fulfil the requirements for well-established use and recognised efficacy in accordance with annex I of the Directive 2001/83/EC.

Alessandro Assisi, HMPC Member from Italy
Amsterdam, 15 January 2020