



EMEA/HMPC/453712/2007EN
EMEA/HMPC/M/H/0024

**OPINION OF THE COMMITTEE ON HERBAL MEDICINAL PRODUCTS ON A
COMMUNITY HERBAL MONOGRAPH ON *MENTHA X PIPERITA* L., AETHEROLEUM**

**This document was valid from 31 October 2007 until January 2020.
It is now superseded by a [new version](#) adopted by the HMPC on
15 January 2020 and published on the EMA website.**

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 25 out of 28 votes a Community herbal monograph on *Mentha x piperita* L., aetheroleum which is set out in Annex I.

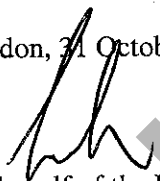
The divergent positions are appended to this opinion.

The Icelandic and the Norwegian HMPC members do agree with the above mentioned recommendation of the HMPC.

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, 31 October 2007


On behalf of the HMPC
Dr Konstantin Keller, Chairman

ANNEX I: COMMUNITY HERBAL MONOGRAPH EMEA/HMPC/349466/2006

APPENDIX I: ASSESSMENT REPORT EMEA/HMPC/349465/2006

Superseded

APPENDIX II: DIVERGENT POSITION

Superseded

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

We do not support the well-established cutaneous use indication for *Mentha x piperita* L., aetheroleum:

“Herbal medicinal product for the symptomatic relief of mild tension type headache.”

In our view the data provided to support this indication do not fulfil the requirements for well-established use and recognised efficacy in accordance with Annex 1 of 2001/83/EC, as amended. Specifically, the clinical and pharmacological data presented for this indication are weak, unclear, and considered insufficient to support the proposed well-established use indication.

London, 31 October 2007

Superseded