



European Medicines Agency
Evaluation of Medicines for Human Use

EMEA/HMPC/305008/2008EN
EMEA/HMPC/M/H/0040

**OPINION OF THE COMMITTEE ON HERBAL MEDICINAL PRODUCTS ON A
COMMUNITY HERBAL MONOGRAPH ON
AVENA SATIVA L., HERBA**

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 18 out of 25 votes a Community herbal monograph on *Avena sativa L.*, herba which is set out in Annex I.

The divergent positions are appended to this opinion.

The Icelandic and the Norwegian HMPC members 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, 4 September 2008

On behalf of the HMPC
Dr Konstantin Keller, Chair

ANNEX I: COMMUNITY HERBAL MONOGRAPH (EMEA/HMPC/202966/2007)

APPENDIX I: ASSESSMENT REPORT (EMEA/HMPC/202967/2007)

APPENDIX II: DIVERGENT POSITIONS

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

With reference to the claimed traditional use for "relief of mild symptoms of mental stress and to aid sleep", we consider that the pharmacological effects and efficacy are not plausible on the basis of long standing use and experience.

No information on products on the market is provided and the overview of literature data regarding pharmacological activities of *Avena sativa* L. does not include information on any sedative effect for oat herb.

Conclusions on the traditional use as a herbal sedative usually administered as herbal tea, aqueous or ethanolic extracts or expressed juice from the fresh herb are not substantiated in the assessment report for each preparation by data on historical use and posology.

London, 4 September 2008