



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/216956/2012
EMA/HMPC/M/H/0114
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a Community herbal monograph on *Zingiber officinale* Roscoe, rhizoma

Opinion

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 24 out of 29 votes a Community herbal monograph on *Zingiber officinale* Roscoe, rhizoma 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, 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, 27 March 2012

On behalf of the HMPC

Dr Werner Knöss, Chair



Annex I: Community herbal monograph (EMA/HMPC/749154/2010)

Appendix I: Assessment report (EMA/HMPC/577856/2010)

Appendix II: Divergent positions

Four members of the HMPC did not agree with the HMPC's opinion on *Zingiber officinale* Roscoe, rhizoma for the following reason:

The data provided is insufficient to support a well-established use indication for *Zingiber officinale* Roscoe as a "Herbal medicinal product for the prevention of nausea and vomiting in motion sickness".

The clinical trials presented are of inadequate quality and *Zingiber officinale* Roscoe has not been scientifically proven to have recognised efficacy in accordance with the requirements of Article 10a and Annex 1 of Directive 2001/83/EC, as amended.

27 March 2012

One member of the HMPC did not agree with the HMPC's opinion on *Zingiber officinale* Roscoe, rhizoma for the following reason:

Ginger is used as food without any restrictions. Additionally there are results of tests on reproductive toxicity and results of clinical trials including pregnant women published which support the safe use during pregnancy. Therefore the restriction for the use during pregnancy is not justified. Moreover the results of the clinical trials for pregnancy induced vomiting are of such a quality that well-established use could be established for *Zingiberis rhizoma*.

27 March 2012