



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Capsicum annuum* L. var. *minimum* (Miller) Heiser and small fruited varieties of *Capsicum frutescens* L., fructus

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 27 out of 29 votes a European Union herbal monograph on *Capsicum annuum* L. var. *minimum* (Miller) Heiser and small fruited varieties of *Capsicum frutescens* L., fructus which is set out in Annex I.

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 appendix.

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 5 May 2015



Annex I: European Union herbal monograph (EMA/HMPC/674139/2013)

Appendix I: Assessment report (EMA/HMPC/674138/2013)

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Appendix II : Divergent position

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

In our view the conclusions of the assessment are contradictory and the monograph is not consistent with the conclusions of the assessment report, where it is reported that capsaicinoids are considered to be responsible for the clinical efficacy and therefore the capsici fructus preparations have to be standardized to a certain content of capsaicinoids.

On the contrary even non-standardized preparations of capsici fructus are included in the monograph.

Moreover, the conclusions state that "The clinical efficacy of locally applied capsaicin in medicated plasters depends in a high degree on the excipients used. Therefore a bridging of clinical data from a certain medicinal product to another one without supporting data may not be acceptable from a regulatory point of view." We agree with this statement.

Lastly, complete information on the safe use of plasters containing capsici fructus preparations is missing.

Marisa Delbò HMPC member from Italy

Gioacchino Calapai Co-opted HMPC member

London, 5 May 2015