



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a Community herbal monograph on *Leonurus cardiaca* L., herba

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 25 out of 27 votes a Community herbal monograph on *Leonurus cardiaca* L., herba which is set out in Annex I.

The Norwegian divergent position is appended to this opinion.

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, 16 September 2010

On behalf of the HMPC

Dr Konstantin Keller, Chair



Annex I: Community herbal monograph (EMA/HMPC/127428/2010)

Appendix I: Assessment report (EMA/HMPC/127430/2010)

Appendix II: Divergent positions

Three of the members of the HMPC did not agree with the HMPC's opinion on the Community herbal monograph on *Leonurus cardiaca* L., herba for the following reason:

We have concerns regarding the potential safe use of this herbal substance for self-medication "to relieve symptoms of nervous cardiac complaints such as palpitations, after serious conditions have been excluded by a medical doctor" as outlined in the second indication, therefore, in our view this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24 EC

16 September 2010