EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Opinion of the HMPC on a Community herbal monograph on *Vitis vinifera* L., folium

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 19 out of 25 votes a Community herbal monograph on *Vitis vinifera* L., folium 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, 15 July 2010

On behalf of the HMPC

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Annex I: Community herbal monograph (EMA/HMPC/16635/2009))

Appendix I: Assessment report (EMA/HMPC/16633/2009)

Appendix II: Divergent positions

Six members of the HMPC did not agree with the HMPC's opinion on Community herbal monograph on Well-established use and Traditional use for *Vitis vinifera* L., folium for the following reason:

The evidence does not support the position of Vitis viniferae folium as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

Results of the studies presented as evidence for the indication of *treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves* are contradictory and there is significant inconsistency between trials in terms of subjects, experimental design and procedures and methodological quality.

The evidence in support of this indication and the proposed posology is considered inadequate.

15 July 2010