



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 *Rhodiola rosea* L., rhizoma et radix

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 Community herbal monograph on *Rhodiola rosea* L., rhizoma et radix 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/232091/2011)

Appendix I: Assessment report (EMA/HMPC/232100/2011)

Appendix II: Divergent positions

One member of the HMPC did not agree with the HMPC's opinion on *Rhodiola rosea* L., rhizoma et radix for the following reason:

We do not support the proposed Community Monograph for *Rhodiolae rosea* L. We have concerns regarding the potential safe use of this herbal substance "relief of symptoms of stress, such as fatigue and sensation of weakness", therefore, in our view this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24/EC.

27 March 2012

One member of the HMPC did not agree with the HMPC's opinion on *Rhodiola rosea* L., rhizoma et radix for the following reason:

Having considered the traditional use of *Rhodiola rosea*, radix and preparations and the basis of presented pharmacological data, I cannot support the use of the herbal substance and the herbal preparations in the 'relief of symptoms of stress such as fatigue and sensations of weakness.'

27 March 2012