



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/148107/2024
EMA/HMPC/M/H/0265
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Rhodiola rosea* L., rhizoma et radix

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC and as set out in the appended assessment report, establishes, by a majority of 23 out of 24 votes a revised European Union herbal monograph on *Rhodiola rosea* L., rhizoma et radix which is set out in Annex I.

The divergent position appended to this opinion.

This opinion is forwarded to Member States and Norway, together with its Annex I and appendix.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 27 March 2012.

Amsterdam, 20 March 2024

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



**Annex I: European Union herbal monograph
(EMA/HMPC/24177/2023)**

Appendix I: Assessment report (EMA/HMPC/24186/2023)

Appendix II: Divergent position

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

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

Jackie Masterson, HMPC member from Ireland

Amsterdam, 20 March 2024