



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 *Cnicus benedictus* L., herba

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 24 out of 25 votes a European Union herbal monograph on *Cnicus benedictus* L., herba which is set out in Annex I.

The divergent position is appended to this opinion.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States 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.

Amsterdam, 20 September 2023.

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Annex I: European Union herbal monograph (EMA/HMPC/32402/2022)

Appendix I: Assessment report (EMA/HMPC/648162/2022)

Appendix II: Divergent position

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

We do not support the proposed European Union Monograph for *Cnicus benedictus* L., herba. We have concerns regarding the potential safe use of this herbal substance "for the temporary loss of appetite", therefore, in our view, this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24/EC.

Sarah Kellaghan, HMPC member from Ireland

Amsterdam, 20 September 2023.