



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2021
EMA/HMPC/747402/2021
EMA/HMPC/M/H/0250
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Taraxacum officinale* F.H. Wigg., 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 majority of 25 out of 26 votes a European Union herbal monograph on *Taraxacum officinale* F.H. Wigg., radix which is set out in Annex I.

The divergent position is appended to this opinion.

The Norwegian HMPC delegate 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, 24 November 2021.



Annex I: European Union herbal monograph (EMA/HMPC/475726/2020)

Appendix I: Assessment report (EMA/HMPC/475725/2020)

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 Monograph for *Taraxaci officinalis radix*. We have concerns regarding the potential safe use of this herbal substance in the following indications "Traditional herbal medicinal product for temporary loss of appetite" and "Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints." In our view these indications are not acceptable for a traditional herbal medicinal product in line with Directive 2004/24/EC. In addition we do not support the proposed dosing in children and adolescents above 12 years of age.

Sarah Kellaghan, HMPC member from Ireland

Amsterdam, 24 November 2021.