



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 *Plantago lanceolata* L., folium

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 revised European Union herbal monograph on *Plantago lanceolata* L., folium 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.

The opinion is forwarded to Member States and Norway, together with its Annex I and appendices.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 22 November 2011.

Amsterdam, 09 July 2025.

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Annex I: European Union herbal monograph (EMA/HMPC/887979/2022)

Appendix I: Assessment report (EMA/HMPC/887981/2022)

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 European Union Monograph for *Plantaginis lanceolate folium*. We do not support the inclusion of children under 12 years of age for indications 1 and 3 as this is not appropriate for self-medication in this population. This is in line with our nationally approved THMPs.

Jackie Masterson, HMPC member from Ireland.

Amsterdam, 09 July 2025.