



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/301711/2025
EMA/HMPC/M/H/0279
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Species pectorales*

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 25 out of 26 votes a European Union herbal monograph on *Species pectorales* 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 appendices.

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

Amsterdam, 09 July 2025.

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Annex I: European Union herbal monograph (EMA/HMPC/239465/2024)

Appendix I: Assessment report (EMA/HMPC/189454/2023)

Appendix II: Divergent position

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

Ireland does not support the proposed European Union Monograph for *Species pectorales*. We do not support the inclusion of children under 12 years of age for 'Combinations containing Althaeae radix and Foeniculi amari fructus in children between 4 and 12 years of age' as this is not appropriate for self-medication in this population. This is in line with our nationally approved THMPs.

Jacqueline Masterson, HMPC member from Ireland.

Amsterdam, 09 July 2025.