



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 September 2025
EMA/HMPC/285954/2025
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 22-24 September 2025

Chair: Emiel Van Galen, Vice-Chair: Karin Erika Svedlund

22 September 2025, 13:00 – 18:00, room 2C

23 September 2025, 09:00 – 18:00, room 2C

24 September 2025, 09:00 – 16:00, room 2C

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this agenda is a working document primarily designed for HMPC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the [Agency policy on access to documents](#) (EMA/729522/2016).



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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the HMPC plenary session to be held on 22-24 September 2025. See September 2025 HMPC minutes (to be published post November 2025 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 22-24 September 2025.

1.3. Adoption of the minutes

HMPC minutes for 7-9 July 2025.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC activities

2.1.1. Overview of HMPC assessment work including the Rapporteurship distribution – Status in September 2025

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Periodic reviews to start in 2025-2026

Report: HMPC Chair

Action: For discussion

Document tabled: Overview document to sign-up as Rapporteur/Peer-reviewer

2.1.3. Re-evaluation of Public Statements

Report: HMPC Chair

Action: For discussion

Document tabled: Proposal for a possible review of established Public Statements, Annex, Presentation

2.2. Revised EU herbal monographs and list entries for final adoption

None

2.3. Revised EU herbal monographs and list entries for public consultation

2.3.1. Monograph on *Matricariae aetheroleum* and supporting documents - postponed

2.4. Reviewed EU herbal monographs and list entries for decision on revision

2.4.1. Monograph on *Cimicifugae rhizoma* and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/00

2.4.2. Monograph on *Primulae flos* and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/00

2.4.3. Monograph on *Primulae radix* and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/00

2.5. EU herbal monographs, list entries and public statements for final adoption

None

2.6. EU herbal monographs, list entries and public statements for adoption for release for public consultation

2.6.1. Monograph on *Maydis stigma* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Reader's guidance, References 87/92

2.7. EU herbal monographs, list entries and public statements - post finalisation

None

3. Referral procedures

None

4. Guidelines and guidance documents

4.1. Non-clinical/clinical safety and efficacy and multidisciplinary

- 4.1.1. Guideline on the assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007) - postponed
-

4.2. Quality

None

4.3. Regulatory / Procedural

- 4.3.1. Assessment report summary for the public (ARSP)
-

Action: For adoption

Document tabled: Revised template

4.4. Report on HMPC Drafting Groups activities

- 4.4.1. ORGAM DG
-

None

- 4.4.2. Quality DG
-

- QDG September meeting
Report: Carmen Purdel
Action: For information
Document tabled: Minutes September 2025
- Questionnaire on comparability between herbal preparations
Report: Carmen Purdel
Action: For information
Document tabled: Questionnaire
- QDG membership
Report: Carmen Purdel
Action: For information

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

- 5.1.1. Strategic Review and Learning Meetings (SRLM)
-

- HMPC SRLM Follow up plan - status September 2025

Report: HMPC Vice-Chair

Action: For information

Document tabled: Follow-up plan

- Danish Presidency meeting 8-10 October

Report: Nanna Lundgaard Rasmussen

Action: For information

Document tabled: Draft agenda

5.1.2. [HMPC membership](#)

Report: HMPC Chair

Action: For information

5.1.3. [HMPC Chairperson - upcoming election 2026](#)

Report: HMPC Chair

Action: For discussion

5.2. [EMA Scientific Committees or CMDh-v](#)

5.2.1. [HMPC/PRAC collaboration on signal detection: safety-assessment for herbal medicinal products](#)

Report: HMPC Vice-Chair

Action: For discussion

Document tabled: Draft Reflection paper

5.2.2. [HMPC/Translational Science Office collaboration: requirements for studying the interaction potential of herbal medicinal products](#)

Report: HMPC Vice-Chair

Action: For information

Document tabled: [ICH M12 guideline on drug interaction studies](#)

5.2.3. [Scientific Coordination Board Meeting](#)

Report: HMPC Chair

Action: For information

Document tabled: Agenda 19 September 2025

5.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

5.3.1. Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP)

- Nomination of a representative (and alternate)

Report: HMPC Chair

Action: For adoption

Document tabled: Email PCWP/HCPWP

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

None

5.4.2. European Food Safety Authority (EFSA)

- Exchange on safety topics of common interest

Action: For information

5.5. Cooperation with International Regulators

5.5.1. WHO International Regulatory Co-operation for Herbal Medicines (IRCH)

- WHO-IRCH workshops WG 1 (Safety and Regulation of Herbal Medicines) & WG 3 (Efficacy and Intended use of Herbal Medicines) – 6-8 August 2025, Delhi - India

Report: HMPC Chair

Action: For information

Documents tabled: Safety dossier, WHO-IRCH workshop presentation

5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

5.6.1. Association of the European Self-Medication Industry (AESGP)

- AESGP hearing 2025

Report: HMPC Chair

Action: For information

Document tabled: Email AESGP

5.7. Work plan and related activities

5.7.1. HMPC work plan 2025

Report: HMPC Chair

Action: For information

Documents tabled: [HMPC work plan 2025](#), Progress report

- (1.3.1) Establish principles for the role of real-world data in supporting European Union herbal monographs

Action: For discussion

- (1.3.2) Development of guidance on particulars for signal detection for (traditional) herbal medicinal products

Action: For discussion

Document tabled: Draft Reflection paper, presentation

- (1.3.3) Improved evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

Action: For information

- (2.1.1) HMPC position on the role of EU herbal monographs and assessment reports in relationship to borderline issues

Action: For discussion

Documents tabled: Draft Reflection paper, OoC, Presentation

- (2.2.1) HMPC communication of information on (traditional) herbal medicinal products to the public and stakeholders

Action: For discussion

Document tabled: ARSP examples

- (2.3.1) Improve work-sharing in HMPC assessment tasks, supported by new herbal curriculum training courses for assessors

Action: For information

Documents tabled: Overview internal HMPC training on AR and MO templates, Herbal Curriculum Training Planning 2024-2025, Training 'Assessment report template chapter 3 and corresponding sections in the monograph template (including revisions)'

5.7.2. HMPC work plan 2026 - cross-committee topics

Report: HMPC Chair

Action: For information

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation

6.1.1. Monograph on Arnicae flos and supporting documents

Action: For 1st discussion

Documents tabled: Draft AR, MO, LoR, OoC

6.2. Revision of EU herbal monographs and list entries in preparation for public consultation

6.2.1. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 21st discussion

Documents tabled: Draft AR, MO, LoR, Reader's Guidance

6.2.2. Monograph on Lecithinum ex soya and supporting documents

Action: For 2nd discussion

Documents tabled: Draft AR, MO, LoR, Reader's Guidance

6.2.3. Monograph on Matricariae flos and supporting documents

Action: For 1st discussion

Document tabled: Reader's Guidance

6.2.4. Monograph on Ribis nigri folium and supporting documents

Action: For 1st discussion

Documents tabled: Draft AR, MO, LoR

6.3. Review of EU herbal monographs and list entries in preparation for decision on revision

6.3.1. Monograph on Althaeae radix and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.2. Monograph on Carvi aetheroleum and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.3. Monograph on Carvi fructus and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.4. Monograph on Curcumae longae rhizome and supporting documents

Action: For 4th discussion

Document tabled: Review report

6.3.5. Monograph on Echinaceae angustifoliae radix and supporting documents

Action: For 3rd discussion

Document tabled: Review report, references, presentation

6.3.6. Monograph on Echinaceae pallidae radix and supporting documents

Action: For 4th discussion

Document tabled: Review report, references, presentation

6.3.7. Monograph on Equiseti herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.8. Monograph on Myrrha and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.9. Monograph on Oenotherae oleum and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.10. Monograph on Psyllii semen and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.11. Monograph on *Rusci rhizoma* and supporting documents

Action: For 3rd discussion

Document tabled: Review report, Reader's Guidance

6.3.12. Monograph on *Salicis cortex* and supporting documents

Action: For 1st discussion

Document tabled: Review report, Reader's Guidance

6.3.13. Monograph on *Salviae officinalis folium* and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.14. Monograph on *Thymi herba* and supporting documents

Action: For 8th discussion

Document tabled: Review report, Reader's Guidance

6.4. EU herbal monographs and list entries in preparation for adoption after public consultation

6.4.1. Monograph on *Hyperici herba*/*Cimicifugae rhizoma* and supporting documents

Action: For 2nd discussion

Documents tabled: Draft AR, MO, OoC

6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation

None

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 7-9 July 2025

Overview of expertise of members HMPC and subgroups

[Inventory of herbal substances for assessment work](#)

[List of abbreviations used in EMA human medicines scientific committees & CMDh documents and in relation to EMA's regulatory activities](#)

Common names of herbal substances in all languages

Final Monograph Overview

Best practice guide on using HMPC plenary time efficiently (with annexed Reader's Guidance template)

7.2.2. Assessment Report Summary for the Public (ARSP)

On hold

7.2.3. Other

- New EMA Code of Conduct to be tabled to scientific committees meetings