



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 November 2025
EMA/HMPC/336818/2025
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 17-19 November 2025

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

17 November 2025, 13:00 – 18:00, room 2C

18 November 2025, 09:00 – 18:00, room 2C

19 November 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 17-19 November 2025. See November 2025 HMPC minutes (to be published post January 2026 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 17-19 November 2025.

1.3. Adoption of the minutes

HMPC minutes for 22-24 September 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 November 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: Overview of THMPs on EU market

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

2.2.1. Monograph on Arnicae flos and supporting documents - postponed

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

None

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

2.4.1. Monograph on Althaeae radix and supporting documents

Action: For adoption

Documents tabled: Review report, References 04/04

2.4.2. Monograph on Carvi aetheroleum and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/00

2.4.3. Monograph on Carvi fructus and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/00

2.4.4. Monograph on Cimicifugae rhizoma and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's Guidance, References 00/07

2.4.5. Monograph on Curcumae longae rhizome and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/15

2.4.6. Monograph on Equiseti herba and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/02

2.4.7. Monograph on Oenotherae oleum and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/02

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

None

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

4.2.1. Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products(EMA/HMPC/CHMP/CVMP/287539/2005)

Report: Carmen Purdel

Action: For discussion

Documents tabled: Guideline on Declarations outcome QDG meeting, Proposals for revision of HMPC declaration

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

- QDG October meeting

Report: Carmen Purdel

Action: For information

Document tabled: Minutes October 2025

- QDG membership – appointment of member(s)

Report: HMPC Chair; Carmen Purdel

Action: For adoption

Documents tabled: [Mandate HMPC DG](#), Call, Nominations

Document tabled: Draft revised guideline

- QDG 3-year work-plan

Report: Carmen Purdel

Action: For discussion

Document tabled: Draft work-plan 2026-28

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 November 2025

Report: HMPC Chair

Action: For information

- Danish Presidency meeting 8-10 October 2025

Report: Nanna Lundgaard Rasmussen

Action: For information

Documents tabled: 'Danish carousel' outcome, Presentations

- Cypriot Presidency meeting June 2026

Report: Christina Sylvia Chrysostomou

Action: For information

Document tabled: Presentation

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

Document tabled: Presentation

5.1.4. Fight against disinformation

Action: For information

Document tabled: Presentation

5.1.5. Code of conduct of the European Medicines Agency – provisions for members and experts of scientific committees

Action: For information

Document tabled: Presentation

5.1.6. Meeting with civil society representatives in EMA scientific committees and management board

Report: HMPC Chair

Action: For information

Document tabled: Report

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(s)

Action: For discussion

Document tabled: Draft "Mandate, Objectives and Rules of Procedure of the HMPC Safety Drafting Group"

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

5.3.1. HMPC/Translational Science Office collaboration: requirements for studying the interaction potential of herbal medicinal products

Report: HMPC Vice-Chair

Action: For discussion

Document tabled: Draft Reflection paper

5.3.2. HMA Substance Validation Group (SVG)

Action: For information

Document tabled: Presentation

5.3.3. Patient experience data (PED) reflection paper

Action: For information

Documents tabled: Presentation; [Reflection Paper on Patient Experience Data \(PED\)](#)

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM 13A expert group meeting

Report: Melanie Bald

Action: For information

Document tabled: SoD

- EDQM 13B expert group meeting

Report: Melanie Bald

Action: For information

Document tabled: SoD

- EDQM TCM expert group meeting

Report: Melanie Bald

Action: For information

Document tabled: SoD

5.4.2. European Food Safety Authority (EFSA)

EFSA botanicals database

Action: For information

Document tabled: Presentation

5.5. Cooperation with International Regulators

None

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; AESGP: Angela Müller, Bernd Röther, Christelle Anquez-Traxler, Nico Symma

Action: For discussion

Documents tabled: Preparatory paper; Presentations

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

Document tabled: Last meeting email

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

Action: For information

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

Action: For discussion

Documents tabled: Draft Reflection paper, Extrapolation in WEU herbal products, OoC

- (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

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

Action: For adoption

Document tabled: ARSPs for Cnici benedicti herba; Ginseng radix; Pilosellae herba cum radice; Rosmarini aetheroleum; Rosmarini folium; Taraxaci officinalis radix; Trigonellae foenugraeci semen; Valerianae radix; Zingiberis rhizoma

- (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 chapters 4-5-6

5.7.2. HMPC work plan 2026

Report: HMPC (Vice-)Chairs

Action: For discussion

Document tabled: Draft workplan

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

None

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 22nd discussion

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

6.2.2. Monograph on Lecithinum ex soya and supporting documents

Action: For adoption

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

6.2.3. Monograph on Matricariae flos and supporting documents – postponed

6.2.4. Monograph on Ribis nigri folium and supporting documents

Action: For 2nd discussion

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

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

6.3.1. Monograph on Anisi aetheroleum and supporting documents

Action: For 1st discussion

Document tabled: Presentation

6.3.2. Monograph on Anisi fructus and supporting documents

Action: For 1st discussion

Document tabled: Presentation

6.3.3. Monograph on *Betulae folium* and supporting documents

Action: For 1st discussion

Documents tabled: Review report, presentation

6.3.4. Monograph on *Echinaceae angustifoliae radix* and supporting documents

Action: For 4th discussion

Document tabled: Review report

6.3.5. Monograph on *Echinaceae pallidae radix* and supporting documents

Action: For 5th discussion

Document tabled: Review report

6.3.6. Monograph on *Hamamelidis cortex* and supporting documents

Action: For 1st discussion

Documents tabled: Review report, References 01/01

6.3.7. Monograph on *Hamamelidis folium* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.8. Monograph on *Hamamelidis folium et cortex aut ramunculus destillatum* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.9. Monograph on *Myrrha* and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.10. Monograph on *Passiflorae herba* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.11. Monograph on *Plantaginis ovatae semen* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.12. Monograph on Plantaginis ovatae seminis tegumentum and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.13. Monograph on Psyllii semen and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.14. Monograph on Rusci rhizoma and supporting documents

Action: For 4th discussion

Document tabled: Review report

6.3.15. Monograph on Salicis cortex and supporting documents

Action: For 2nd discussion

Documents tabled: Review report, Reader's guidance

6.3.16. Monograph on Salviae officinalis folium and supporting documents

Action: For 3rd discussion

Document tabled: Review report

6.3.17. Monograph on Thymi herba and supporting documents - postponed

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, LoR, OoC

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

6.5.1. Monograph on Valerianae radix/Passiflorae herba and supporting documents

Action: For 1st discussion

Document tabled: Draft MO

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 22-24 September 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)

- Cnici benedicti herba
- Ginseng radix
- Pilosellae herba cum radice
- Rosmarini aetheroleum
- Rosmarini folium
- Taraxaci officinalis radix
- Trigonellae foenugraeci semen
- Valerianae radix
- Zingiberis rhizoma

7.2.3. Other

- Invitation to Participate and Publicize the WHO Health Heritage Innovations Open Call (H2I)
- [Mandate, objectives and rules of procedure for EMA working parties under the domains published](#)
- WHO Global Traditional Medicine Strategy for 2025-2034
- Fact sheet on reference limits for contaminants in HMs