



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 July 2025
EMA/HMPC/200229/2025
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 7-9 July 2025

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

7 July 2025, 10:00 – 17:00, virtual meeting

8 July 2025, 09:00 – 17:00, virtual meeting

9 July 2025, 09:00 – 16:00, virtual 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 ongoing 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 7-9 July 2025. See July 2025 HMPC minutes (to be published post September 2025 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 7-9 July 2025.

1.3. Adoption of the minutes

HMPC minutes for 5-7 May 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 July 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

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

2.2.1. Monograph on *Plantaginis lanceolatae folium* and supporting documents

Action: For adoption

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

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

2.3.1. Monograph on *Fragariae folium* and supporting documents

Action: For adoption

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

2.3.2. Monograph on *Liquiritiae radix* and supporting documents

Action: For adoption

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

2.3.3. Monograph on *Species diureticae* and supporting documents

Action: For adoption

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

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

2.4.1. Monograph on *Calendulae flos* and supporting documents

Action: For adoption

Document tabled: Review report

2.4.2. Monograph on *Cimicifugae rhizoma* and supporting documents - postponed

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

2.5.1. Monograph on *Species pectorales* and supporting documents

Action: For adoption

Documents tabled: Draft AR, LoR, MO

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

2.6.1. Monograph on *Cannabis flos* and supporting documents

Action: For adoption

Document tabled: Draft PS

2.6.2. Monograph on Maydis stigma and supporting documents

Action: For adoption

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

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)

Action: For discussion

Document tabled: Draft revised guideline

4.2. Quality

4.2.1. Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin (EMA/HMPC/246816/2005)

Action: For adoption

Document tabled: Revised guideline, OoC

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 June meeting

Report: Carmen Purdel

Action: For information

Document tabled: Minutes June 2025

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 July 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 meetings in 2026

- Meetings 'in-person' vs 'remotely'

Report: HMPC Chair

Action: For information

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: Presentation

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

Documents tabled: Agenda 27 June 2025

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

None

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM 13A, 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 opinion on fennel Article 8(2)

Action: For information

Document tabled: Draft opinion

- EFSA Compendium of botanicals

Report: HMPC (Vice-)Chairs

Action: For information

Document tabled: [Compendium of botanicals | EFSA](#)

5.4.3. 'Pharma package' - Pharmaceutical Legislation Reform

Report: HMPC Chair

Action: For information

Document tabled: [proposal for revised Regulation](#); [proposal for revised Directive](#)

5.4.4. Exchange of views with European Commission on Pharmaceutical Legislation Reform

EC representatives: Olga Solomon, Florian Schmidt

Action: For discussion

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

Document tabled: Invitation; Concept note; Provisional programme

- WHO Traditional, Complementary and Integrative medicine (TCI)

Report: HMPC Vice-Chair

Action: For information

Document tabled: [Traditional, complementary and integrative medicine \(TCI\)](#); [WHO Traditional Medicine Strategy 2025–2034](#)

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

None

5.7. Work plan and related activities

5.7.1. HMPC work plan 2025

Report: HMPC Chair

Action: For information

Document 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: HMPC RWE Liaison Group Meeting 20_05_2025

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

Action: For discussion

Document tabled: 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 information

Document tabled: Draft Reflection paper, OoO, Reader's guidance

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

Action: For discussion

Document tabled: draft revised ARSP

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

Action: For information

Document tabled: Overview internal HMPC training on AR and MO templates, Herbal Curriculum Training Planning 2024-2025

5.7.2. HMPC work plan 2026 - cross-committee topics

Report: HMPC Chair

Action: For discussion

5.8. Planning and reporting

5.8.1. EMA/HMPC scientific conference/event

- EMA's 30th anniversary scientific conference

Report: HMPC Chair

Action: For information

Document tabled: Agenda

- HMPC scientific event

Report: HMPC Chair

Action: For discussion

Document tabled: Draft programme

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 20th discussion

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

6.2.2. Monograph on Lecithinum ex soya and supporting documents

Action: For 1st discussion

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

6.2.3. Monograph on Matricariae aetheroleum and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR, LoR

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

6.3.1. Monograph on Echinaceae angustifoliae radix and supporting documents - postponed

6.3.2. Monograph on Echinaceae pallidae radix and supporting documents - postponed

6.3.3. Monograph on Plantaginis ovatae semen and supporting documents

Action: For 3rd discussion

Document tabled: Review report

6.3.4. Monograph on Plantaginis ovatae seminis tegumentum and supporting documents

Action: For 3rd discussion

Document tabled: Review report

6.3.5. Monograph on Primulae flos and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.6. Monograph on Primulae radix and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.7. Monograph on Rusci rhizoma and supporting documents

Action: 2nd discussion

Document tabled: Review report

6.3.8. Monograph on Salviae officinalis folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.9. Monograph on Thymi herba and supporting documents

Action: For 7th discussion

Document tabled: Review report

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 1st discussion

Documents tabled: Draft MO, AR, OoC, LoR

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

7.1.1. Study on the use of traditional herbal products to treat animals – stakeholder consultation

Report: HMPC Chair

Action: For discussion

Document tabled: Letter

7.1.2. EMA's Methodology Working Party (MWP) temporary drafting group - Assessment of SmPC section 5.1: A Guide for Assessors of Centralised Applications

Report: HMPC (Vice-)Chairs

Action: For information

Document tabled:  [draft version](#); [Guide on assessment of SmPC section 5.1](#)

7.1.3. GP-TCM Annual Meeting - London 24-27 July 2025

Report: HMPC Chair

Action: For information

Document tabled: Agenda

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 5-7 May 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
