05 May 2025
EMA/HMPC/122977/2025
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 5-7 May 2025

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

5 May 2025, 13:00 – 18:00, room 1C

6 May 2025, 09:00 – 18:00, room 1C

7 May 2025, 09:00 – 16:00, room 1C

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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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 5-7 May 2025. See May 2025 HMPC minutes (to be published post July 2025 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 5-7 May 2025.

1.3. Adoption of the minutes

HMPC minutes for 17-19 March 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 May 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

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

2.2.1. Monograph on Zingiberis rhizoma and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, LoR, OoC, 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 Ononidis radix and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, LoR

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

2.4.1. Monograph on Melissae folium and supporting documents

Action: For adoption

Document tabled: Review report

2.4.2. Monograph on Ribis nigri folium and supporting documents

Action: For adoption

Document tabled: Review report

2.4.3. Monograph on Vitis viniferae folium and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's guidance

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: 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 (EMEA/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 (internal consultation)

Document tabled: Draft revised guideline, OoC

4.3. Regulatory / Procedural

4.3.1. Reflection paper on data recommendations for traditional herbal medicinal products and herbal medicinal products used in children and adolescents (EMA/HMPC/122977/2025)

Action: For adoption (public consultation)

Document tabled: Draft RP on data recommendations for THMP used in children/adolescents

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

- QDG April meeting

  Report: Carmen Purdel

  Action: For information

  Document tabled: Minutes April 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 May 2025

  Report: HMPC Vice-Chair

  Action: For information

  Document tabled: Follow-up plan

- Polish Presidency meeting 13-14 May

  Report: Wojciech Dymowski

  Action: For information

  Document tabled: Draft agenda

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

5.1.3. HMPC Co-opted members

- Appointment of Co-opted member:

  Report: HMPC Chair

  Action: For adoption

  Document tabled: Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC; Appointment of Co-opted member to HMPC_2025May

5.1.4. Health & Safety induction

Action: For information

Document tabled: Video link

5.2. EMA Scientific Committees or CMDh-v

5.2.1. HMPC/PRAC collaboration on signal detection for herbal medicinal products

Action: For information

Document tabled: Presentation 'EudraVigilance and safety signal management process'

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

None

5.4.2. European Food Safety Authority (EFSA)

Action: For information

Document tabled: Draft opinion fennel Art 8(2); HMPC comments on the EFSA draft opinion

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

Action: For discussion

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

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

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

  Report: HMPC Chair

  Action: For discussion

  Documents tabled: Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence for regulatory purposes; Email 'Participation of HMPC delegates on the 73rd International Congress and Annual Meeting of the Society for Medicinal Plants and Natural Product Research (GA)'

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

  Action: For information

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

  Action: For information

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

  Report: HMPC Chair

  Action: For information

  Document tabled: 'Assessment report template chapters 1 and 2 and corresponding sections in the monograph template (including revisions)'

5.8. Planning and reporting

5.8.1. EU-NTC LMS domain for International regulators

Report: HMPC Vice-Chair

Action: For discussion

Document tabled: Presentation

5.8.2. EU-NTC LMS 'welcome pack' for new committee members

Action: For information

Documents tabled: Enhancing the Onboarding Experience, HMPC-specific presentation

5.8.3. HMPC scientific conference

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

6.1.1. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: For 2nd discussion

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

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 19th discussion

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

6.2.2. Monograph on Liquiritiae radix and supporting documents

Action: For 5th discussion

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

6.2.3. Monograph on Matricariae aetheroleum and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR, LoR

6.2.4. Monograph on Species diureticae and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR, 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 Calendulae flos and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.2. Monograph on Cimicifugae rhizoma and supporting documents

Action: For 2nd discussion

Document tabled: Review report, Reader's Guidance

6.3.3. Monograph on Curcumae longae rhizome and supporting documents

Action: For 3rd discussion

Documents tabled: Review report

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

Action: For 2nd discussion

Document tabled: Review report

6.3.5. Monograph on Echinaceae pallidae radix and supporting documents

Action: For 3rd discussion

Document tabled: Review report

6.3.6. Monograph on Plantaginis ovatae semen and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.7. Monograph on Plantaginis ovatae seminis tegumentum and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.8. Monograph on Rusci rhizoma and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.9. Monograph on Thymi herba and supporting documents

Action: For 6th 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 Species pectorales and supporting documents

Action: For 1st discussion

Documents tabled: Draft AR, LoR, MO

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

6.5.1. Monograph on Cannabis flos and supporting documents

Action: For 7th discussion

Document tabled: Draft PS

7. Any other business

7.1. Topics for discussion

7.1.1. New HMPC guideline on the requirements to study the interaction potential of herbal medicinal products

Rapporteur: HMPC Vice-Chair

Action: For discussion

Documents tabled: ICH M12 Guideline on drug interaction studies; EU guideline on the investigation of drug interactions

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 17-19 March 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

- EFSA Evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 of a powder obtained from cranberries, and defence against bacterial pathogens in the lower urinary tract