



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 May 2026
EMA/HMPC/86201/2026
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC) Draft Agenda for the meeting on 04-06 May 2026

Chair: Carmen Purdel, Vice-Chair: Olga Maria Palomino

04 May 2026, 10:00 – 17:00, virtual meeting

05 May 2026, 09:00 – 17:00, virtual meeting

06 May 2026, 09:00 – 16:00, virtual meeting

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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 04-06 May 2026. See May 2026 HMPC minutes (to be published post July 2026 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 04-06 May 2026.

1.3. Adoption of the minutes

HMPC minutes for 02-04 March 2026.

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 2026

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Periodic reviews to start in 2026-2027

Report: HMPC Chair

Action: For discussion

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

2.1.3. Unscheduled reviews - Primulae radix and combination Primulae radix/Thymi herba

Report: HMPC Chair

Action: For discussion

Document tabled: Draft revised Ph.Eur. monograph on Primula root

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

2.2.1. Monograph on Arnicae flos and supporting documents - postponed

2.2.2. Monograph on Fragariae folium and supporting documents

Action: For adoption

Documents tabled: AR, MO, LoR, Reader's Guidance, References 0/101

2.2.3. Monograph on *Species diureticae* and supporting documents - postponed

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

2.3.1. Monograph on *Lecithinum ex soya* and supporting documents

Action: For adoption

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

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

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

None

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

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

Action: For adoption

Documents tabled: AR, MO, LoR, OoC

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

4.2. Quality

None

4.3. Regulatory/Procedural

- 4.3.1. Reflection paper on data recommendations for herbal medicinal products and traditional herbal medicinal products used in paediatric patients (EMA/HMPC/71333/2023)
-

Action: For adoption

Documents tabled: Final Reflection paper, OoC

- 4.3.2. Reflection paper on the use of information in European Union herbal monographs and assessment reports for borderline issues (EMA/HMPC/224438/2024)
-

Action: For discussion

Documents tabled: Draft Reflection paper, OoC

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

ORGAM in between the plenary meetings

Report: HMPC (Vice)-Chairs

Action: For discussion

4.4.2. Quality DG

- QDG April meeting
Report: Carmen Purdel
Action: For information
Document tabled: Minutes April 2026
- Draft Agenda for 22 September meeting
Report: Carmen Purdel
Action: For information
Document tabled: Draft agenda
- Invitation to EDQM's workshop: Companies' data for CEP applications
Report: HMPC Vice-Chair
Action: For information
Document tabled: Email
- QDG Chair election
Report: HMPC Chair

Action: For adoption

Documents tabled: [Mandate QDG](#), Call, Candidatures

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 2026

Report: HMPC (Vice-)Chairs

Action: For information

- Cypriot Presidency meeting June 2026

Report: Christina Sylvia Chrysostomou

Action: For information

Document tabled: SRLM agenda

- Irish Presidency meeting second half 2026

Report: Jacqueline Masterson

Action: For information

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

5.1.3. HMPC Face-to-Face Meeting Dates for 2027

Action: For information

Document tabled: Draft F2F - HMPC meeting schedule 2027

5.1.4. HMPC 22-24 September 2026

Report: HMPC (Vice-)Chairs

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

Action: For discussion

Document tabled: Draft Reflection paper

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

Action: For discussion

Document tabled: Draft Reflection paper

5.3.2. EU Substance Registration System (EU-SRS)

Action: For information

Document tabled: Email

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM TCM expert group meeting

Report: Melanie Bald

Action: For information

Document tabled: SoD

- Feedback on Ginkgo request

Report: Melanie Bald

Action: For discussion

Document tabled: Letter

5.4.2. European Food Safety Authority (EFSA)

Draft opinions on berberine-containing and hydroxycitric acid-containing plant preparations

Action: For discussion

Documents tabled: Email, presentations

5.5. Cooperation with International Regulators

5.5.1. EU/India Technical Working Group on Ayurveda

Report: HMPC Chair

Action: For discussion

Document tabled: Email

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) – request for a hearing in November 2026

Report: HMPC Chair

Action: For information

5.7. Work plan and related activities

5.7.1. Follow-up on HMPC work plan 2026

Report: HMPC Chair

Action: For information

Document tabled: [HMPC work plan 2026](#)

- 1) Explore new initiatives for the use of real-world data (RWD) and opportunities to use digitalisation and artificial intelligence (AI) in support of decisions

Action: For discussion

Document tabled: Presentation

- 2) HMPC position on the role of European Union herbal monographs and assessment reports in relationship to borderline issues

Action: For information

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

Action: For adoption

Document tabled: Presentation

- 4) Improve the evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

Action: For information

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

Action: For information

- 6) Improve work-sharing in HMPC activities aiming at sustainability of the European medicines agencies network (EMRN)

Action: For discussion

Documents tabled: Herbal Curriculum Training Planning 2026-2027, HMPC training curriculum priorities January 2026

5.8. Planning and reporting

5.8.1. EMA/FDA Workshop on herbal medicines development

Report: HMPC Chair

Action: For discussion

Document tabled: Draft programme

5.8.2. Summary on MRP/DCP for herbal medicinal products

Action: For discussion

Document tabled: List EU herbal procedures in CTS

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 *Betulae folium* and supporting documents

Action: For 1st discussion

Documents tabled: Draft AR, MO, LoR

6.2.2. Monograph on *Matricariae flos* and supporting documents - postponed

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 3rd discussion

Documents tabled: Review report, Reader's Guidance

6.3.2. Monograph on *Anisi fructus* and supporting documents

Action: For 3rd discussion

Documents tabled: Review report, Reader's Guidance

6.3.3. Monograph on *Echinaceae angustifoliae radix* and supporting documents - postponed

6.3.4. Monograph on *Echinaceae pallidae radix* and supporting documents - postponed

6.3.5. Monograph on *Eleutherococci radix* and supporting documents - postponed

6.3.6. Monograph on *Myrrha* and supporting documents

Action: For 4th discussion

Document tabled: Review report

6.3.7. Monograph on *Passiflorae herba* and supporting documents -postponed

6.3.8. Monograph on *Plantaginis ovatae semen* and supporting documents - postponed

6.3.9. Monograph on *Plantaginis ovatae seminis tegumentum* and supporting documents - postponed

6.3.10. Monograph on *Psyllii semen* and supporting documents - postponed

6.3.11. Monograph on *Salicis cortex* and supporting documents

Action: For 5th discussion

Document tabled: Review report

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

Action: For 6th discussion

Document tabled: Review report

6.3.13. Monograph on *Thymi herba* and supporting documents

Action: For 11th discussion

Document tabled: Review report

6.3.14. Monograph on *Valerianae aetheroleum* and supporting documents - postponed

6.3.15. Monograph on *Valerianae radix* and supporting documents - postponed

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

6.4.1. Monograph on *Cannabis flos* and supporting documents

Action: For 3rd discussion

Document tabled: OoC

6.4.2. Monograph on Maydis stigma and supporting documents

Action: For 1st discussion

Document tabled: Draft MO, AR, LoR

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 4th discussion

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

7. Any other business

7.1. Topics for discussion

7.1.1. Pilot – transition to IRIS/SharePoint

Action: For information

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 04-06 March 2026

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)

None

7.2.3. Other

- Updated EMA-HMA workplan on data and AI in medicines regulation 2026 to 2028