



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 September 2026
EMA/HMPC/169828/2026
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 22-24 September 2026

Chair: Carmen Purdel, Vice-Chair: Olga Palomino

22 September 2026, 13:00 – 18:00, room 1A

23 September 2026, 09:00 – 18:00, room 1A

24 September 2026, 09:00 – 16:00, room 1A

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 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 22-24 September 2026. See September 2026 HMPC minutes (to be published post November 2026 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 22-24 September 2026.

1.3. Adoption of the minutes

HMPC minutes for 06-08 July 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 September 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

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

2.2.1. Monograph on Ribis nigri folium and supporting documents

Action: For adoption

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

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

2.3.1. Monograph on Betulae folium and supporting documents

Action: For adoption

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

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

2.4.1. Monograph on Myrrha and supporting documents

Action: For adoption

Document tabled: Review report

2.4.2. Monograph on Passiflorae herba and supporting documents

Action: For adoption

Document tabled: Review report

2.4.3. Monograph on Plantaginis ovatae semen and supporting documents

Action: For adoption

Documents tabled: Review report; FI email

2.4.4. Monograph on Plantaginis ovatae seminis tegumentum and supporting documents

Action: For adoption

Documents tabled: Review report; FI email

2.4.5. Monograph on Thymi herba and supporting documents

Action: For adoption

Document tabled: Review report

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

2.5.1. Monograph on Cannabis flos and supporting documents

Action: For adoption

Document tabled: OoC

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

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

Action: For adoption

Documents tabled: AR, LoR, Presentation

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, Reader's Guidance

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

None

4.3. Regulatory/Procedural

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

Action: For adoption

Documents tabled: Draft Reflection paper, OoC, Reader's Guidance

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

- QDG September meeting
Report: Astrid Obmann
Action: For information
Document tabled: Presentation
- Query on *Vaccinium myrtillus* L., fructus recens monograph
Action: For information
Document tabled: Email
- Pharmeuropa
Action: For information
Document tabled: *Pharmeuropa* issue 38.3

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 2026
Report: HMPC (Vice-)Chairs
Action: For information
Document tabled: Follow up plan
- Irish Presidency meeting 24 November 2026
Action: For information
Document tabled: Draft agenda

5.1.2. HMPC membership

Report: HMPC Chair
Action: For information

5.1.3. Call for nomination of co-opted member

Report: HMPC Chair
Action: For information
Document tabled: Email

5.1.4. Call for nomination of NCA experts for the Pharmacovigilance group

Report: HMPC Chair
Action: For discussion

Documents tabled: Email, Nominations

5.1.5. NPL Topic of Annex II

Action: For information

Document tabled: Email

5.1.6. Medical Literature Monitoring service: medical literature databases

Report: HMPC Chair

Action: For discussion

Document tabled: Emails

5.1.7. Data protection notice for Committees, Working Parties (WPs), Scientific Advisory Groups (SAGs) and Ad-Hoc Expert Groups (AHEGs)

Action: For information

Document tabled: Email

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Request for PRAC advice on Echinacea and the annexed assessment report

Action: For adoption

Documents tabled: PRAC advice on Echinacea, HMPC AR on Echinacea and DILI, Reader's Guidance

5.2.2. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Document tabled: Agenda 18 September 2026

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

Report: HMPC Chair

Action: For information

Document tabled: Agenda

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 adoption

Documents tabled: Draft Reflection paper, Reader's guidance

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

None

5.5. Cooperation with International Regulators

5.5.1. Health Canada summary safety review on Ashwagandha hepatotoxicity

Report: HMPC Chair

Action: For information

Document tabled: Email

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

WHO-IRCH workshop WG 2 (Quality control, standardization and sustainability of herbal medicines), 23 September 2026

Action: For information

Document tabled: Email

5.5.3. NMPA Invitation to World Conference on Traditional Medicine - October 2026

Report: HMPC Chair

Action: For information

Document tabled: Email

5.5.4. NMPB Proposal for Quality-Assured Medicinal Plants, GACP and Export Readiness Programme – Request for Review and Collaborative Action

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) – preparation for the hearing in November 2026

Report: HMPC Chair

Action: For discussion

Document tabled: Email

5.7. Work plan and related activities

5.7.1. HMPC work plan 2026 - follow-up

Report: HMPC Chair

Action: For information

Document tabled: [HMPC work plan 2026](#); HMPC mid-year report

- 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 information

- 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 information

- 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 information

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

5.7.2. HMPC work plan 2027 - cross-committee topics

Report: HMPC Chair

Action: For information

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; [Webpage](#)

5.8.2. Questionnaire on (T)HMPs in the EU market 2026

Action: For discussion

Document tabled: Questionnaire (template)

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 *Lecithinum ex soya* and supporting documents

Action: For 1st discussion

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

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

6.2.1. Monograph on *Matricariae flos* and supporting documents

Action: For 1st discussion

Document tabled: Draft AR

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

6.3.1. Monograph on *Absinthii herba* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.2. Monograph on *Echinaceae purpureae herba* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.3. Monograph on *Echinaceae purpureae radix* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.4. Monograph on Eleutherococci radix and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.5. Monograph on Filipendulae ulmariae flos and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.6. Monograph on Filipendulae ulmariae herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.7. Monograph on Herniariae herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.8. Monograph on Leonuri cardiaca herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.9. Monograph on Millefolii flos herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.10. Monograph on Millefolii herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.11. Monograph on Phaseoli fructus (sine semine) and supporting documents

Action: For 1st discussion

Document tabled: Presentation

6.3.12. Monograph on Psyllii semen and supporting documents

Action: For 4th discussion

Document tabled: Review report

6.3.13. Monograph on Quercus cortex and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.14. Monograph on Tanacetii parthenii herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.15. Monograph on Taraxaci folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.16. Monograph on Taraxaci radix cum herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.17. Monograph on Tormentillae rhizoma and supporting documents

Action: For 1st discussion

Document tabled: Review report

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

None

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. 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 06-08 July 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

- PMDA-ATC Herbal Medicine Seminar 2026
- Botanical Safety Consortium (BSC) - Annual Meeting 2026