



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 July 2024
EMA/HMPC/308012/2024

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 22-24 July 2024

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

22 July 2024, 10:00 – 17:00, virtual meeting

23 July 2024, 09:00 – 17:00, virtual meeting

24 July 2024, 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).

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	5
1.1.	Welcome and declarations of interest of members, alternates and experts.....	5
1.2.	Adoption of agenda.....	5
1.3.	Adoption of the minutes	5
2.	EU herbal monographs and list entries for adoption	5
2.1.	Status of HMPC activities.....	5
2.1.1.	Overview of HMPC assessment work including the Rapporteurship distribution – Status in July 2024	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers	5
2.2.	Revised EU herbal monographs and list entries for final adoption	5
2.3.	Revised EU herbal monographs and list entries for public consultation	5
2.3.1.	Monograph on Ononidis radix and supporting documents.....	5
2.3.2.	Monograph on Plantaginis lanceolatae folium and supporting documents	6
2.4.	Reviewed EU herbal monographs and list entries for decision on revision.....	6
2.4.1.	Monograph on Mastic (Mastix, Pistaciae lentisci resina) and supporting documents	6
2.4.2.	Monograph on Lecithinum ex soya and supporting documents.....	6
2.4.3.	Monograph on Soiae oleum raffinatum and supporting documents	6
2.5.	EU herbal monographs, list entries and public statements for final adoption	6
2.6.	EU herbal monographs, list entries and public statements for adoption for release for public consultation.....	6
2.6.1.	Monograph on Cisti cretici herba and supporting documents	6
2.7.	EU herbal monographs, list entries and public statements - post finalisation.....	6
3.	Referral procedures	6
4.	Guidelines and guidance documents	7
4.1.	Non-clinical/clinical safety and efficacy and multidisciplinary.....	7
4.2.	Quality.....	7
4.3.	Regulatory / Procedural	7
4.3.1.	Reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues.....	7
4.4.	Report on HMPC Drafting Groups activities.....	7
4.4.1.	ORGAM DG	7
4.4.2.	Quality DG.....	7
5.	Organisational, regulatory and methodological matters	7
5.1.	Mandate and organisation of the HMPC	7
5.1.1.	Strategic Review and Learning Meetings (SRLM).....	7
5.1.2.	HMPC membership.....	8
5.1.3.	Regular summary on MRP-DCP for herbal medicinal products	8

5.2.	EMA Scientific Committees or CMDh-v	8
5.2.1.	Joint resolution regarding scientific committees' principles of conduct	8
5.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	8
5.3.1.	RWD/RWE pilot projects for HMPC	8
5.3.2.	European Substance Registration System (EU-SRS)	8
5.4.	Cooperation within the EU regulatory network	8
5.4.1.	Coordination with European Pharmacopoeia	8
5.5.	Cooperation with International Regulators.....	9
5.5.1.	EU/India Technical Working Group on Ayurveda	9
5.6.	Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee	9
5.6.1.	Association of the European Self-Medication Industry (AESGP)	9
5.7.	Work plan and related activities	9
5.7.1.	HMPC work plan 2024	9
5.7.2.	Follow up on HMPC work plan 2023.....	9
5.8.	Planning and reporting	10
5.9.	Legislation and regulatory affairs	10
5.10.	Questions from members.....	10
5.10.1.	Query from Finnish NCA (Fimea) - Evidence of medicinal use in the EU for THMPs	10
6.	EU herbal monographs and list entries in preparation	10
6.1.	Revision of EU herbal monographs and list entries in preparation for adoption after public consultation	10
6.2.	Revision of EU herbal monographs and list entries in preparation for public consultation.....	10
6.2.1.	Monograph on Allii sativi bulbus and supporting documents	10
6.2.2.	Monograph on Crataegi folium cum flore and supporting documents	10
6.2.3.	Monograph on Fragariae folium and supporting documents	10
6.2.4.	Monograph on Lavandulae aetheroleum and supporting documents	10
6.2.5.	Monograph on Liquiritiae radix and supporting documents	11
6.3.	Review of EU herbal monographs and list entries in preparation for decision on revision	11
6.3.1.	Monograph on Boldi folium and supporting documents	11
6.3.2.	Monograph on Thymi herba and supporting documents	11
6.3.3.	Monograph on Uvae ursi folium and supporting documents	11
6.4.	EU herbal monographs and list entries in preparation for adoption after public consultation.....	11
6.5.	EU herbal monographs and list entries in preparation for adoption for release for public consultation	11
6.5.1.	Monograph on Cannabis flos and supporting documents	11
6.5.2.	Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents.....	11

6.5.3.	Monograph on <i>Maydis stigma</i> and supporting documents.....	11
6.5.4.	Monograph on <i>Species pectorales</i> and supporting documents.....	12
7.	Any other business	12
7.1.	Topics for discussion	12
7.1.1.	EU NTC 10-year anniversary event, 30 May 2024	12
7.1.2.	Workshop "Real-world data to document the use of phytopharmaceuticals in children" – Kraków, 14 July 2024.....	12
7.2.	Documents for information	12
7.2.1.	HMPC.....	12
7.2.2.	Assessment Report Summary for the Public (ARSP)	12
7.2.3.	Other	12

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 July 2024. See July 2024 HMPC minutes (to be published post September 2024 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 22-24 July 2024.

1.3. Adoption of the minutes

HMPC minutes for 27-29 May 2024.

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 2024

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

- Periodic reviews to start in 2024-2025

Report: HMPC Chair

Action: For information

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

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

None

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

2.3.1. Monograph on Ononidis radix and supporting documents

Action: For adoption

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

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

Action: For adoption

Documents tabled: MO, AR, LoR

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

2.4.1. Monograph on Mastic (*Mastix, Pistaciae lentisci resina*) and supporting documents

Action: For adoption

Document tabled: Review report, Reader's Guidance

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

Action: For adoption

Document tabled: Review report

2.4.3. Monograph on *Soiae oleum raffinatum* and supporting documents

Action: For adoption

Document tabled: Review report

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 *Cisti cretici herba* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

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

None

4.2. Quality

None

4.3. Regulatory / Procedural

4.3.1. Reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues

Report: HMPC Vice-Chair

Action: For discussion

Documents tabled: Draft reflection paper, Reader's Guidance

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

- Report: Nicoleta Carmen Purdel

Action: For information

Document tabled: Minutes

- Call for a new QDG member

Report: Nicoleta Carmen Purdel

Action: For information

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 2024

Report: HMPC Vice-Chair

Action: For information

Document tabled: Follow-up plan

- Hungarian Presidency meeting – 02-04 December 2024

Report: Julia Pallos, Rita Nemeth

Action: For information

Document tabled: Presentation

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

5.1.3. Regular summary on MRP-DCP for herbal medicinal products

Report: HMPC Chair

Action: For information

Documents tabled: Summary feedback, Questionnaire

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Joint resolution regarding scientific committees' principles of conduct

Report: HMPC Chair

Action: For information

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

5.3.1. RWD/RWE pilot projects for HMPC

Report: HMPC Chair

Action: For information

Document tabled: Presentation

5.3.2. European Substance Registration System (EU-SRS)

Report: HMPC Chair/Vice-Chair

Action: For information

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13A expert group meeting

Report: TBC

Action: For information

Document tabled: SoD

- EDQM 60 years celebration

Report: HMPC Chair

Action: For information

Document tabled: Programme

5.5. Cooperation with International Regulators

5.5.1. EU/India Technical Working Group on Ayurveda

Report: HMPC Chair

Action: For information

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 2024

Report: HMPC Chair

Action: For discussion

5.7. Work plan and related activities

5.7.1. HMPC work plan 2024

Report: HMPC Chair

Action: For information

Document tabled: HMPC work plan 2024 with annexes (current status - June)

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

Report: HMPC Chair

Action: For discussion

Document tabled: Draft reflection paper

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

Action: For discussion

Document tabled: Draft guidance

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

Action: For discussion

Document tabled: Draft revised ARSP template

5.7.2. Follow up on HMPC work plan 2023

- (1.3.2) Harmonise the approach for the use of EU herbal monographs in the assessment of combination products

Action: For discussion

Document tabled: List of proposed combinations

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

5.10.1. Query from Finnish NCA (Fimea) - Evidence of medicinal use in the EU for THMPs

Action: For discussion

Document tabled: Presentation

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 *Allii sativi bulbus* and supporting documents

Action: For discussion

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

6.2.2. Monograph on *Crataegi folium cum flore* and supporting documents

Action: For 3rd discussion

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

6.2.3. Monograph on *Fragariae folium* and supporting documents

Action: For 4th discussion

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

6.2.4. Monograph on *Lavandulae aetheroleum* and supporting documents

Action: For 15th discussion

Documents tabled: Draft AR, Reader's Guidance

6.2.5. Monograph on Liquiritiae radix and supporting documents

Action: For 2nd discussion

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

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

6.3.1. Monograph on Boldi folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.2. Monograph on Thymi herba and supporting documents

Action: For 2nd discussion

Documents tabled: Review report, Reader's Guidance

6.3.3. Monograph on Uvae ursi folium and supporting documents

Action: For 1st discussion

Documents tabled: Review report, Summary

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

6.5.1. Monograph on Cannabis flos and supporting documents

Action: For 3rd discussion

Document tabled: Presentation

6.5.2. Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents

Action: For 9th discussion

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

6.5.3. Monograph on Maydis stigma and supporting documents

Action: For 3rd discussion

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

6.5.4. Monograph on Species pectorales and supporting documents

Action: For 3rd discussion

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

7. Any other business

7.1. Topics for discussion

7.1.1. EU NTC 10-year anniversary event, 30 May 2024

Report: HMPC Vice-Chair

Action: For discussion

Document tabled: Programme

7.1.2. Workshop "Real-world data to document the use of phytopharmaceuticals in children" – Kraków, 14 July 2024

Report: HMPC Chair

Action: For discussion

Documents tabled: Programme, Presentations

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 27-29 May 2024

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

- Joint HMA/EMA multistakeholder workshop on Patient Registries
- [EMA/CMDh joint paper for EC on the revision of the Variations Guidelines](#)

- Consolidated advice pilots: information and training webinar
- [ICH progresses on harmonisation to integrate RWE into regulatory decision-making across the world](#)
- Invitation to register for the webinar on Regulation (EU)