



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 May 2024
EMA/HMPC/149272/2024
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 27-29 May 2024

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

27 May 2024, 13:00 – 18:00, room 2C

28 May 2024, 09:00 – 18:00, room 2C

29 May 2024, 09:00 – 16:00, room 2C

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Of note, this agenda is a working document primarily designed for HMPC members and the work the Committee undertakes.

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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 27-29 May 2024. See May 2024 HMPC minutes (to be published post July 2024 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 27-29 May 2024.

1.3. Adoption of the minutes

HMPC minutes for 18-20 March 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 May 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

2.2.1. Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents

Action: For adoption

Documents tabled: PS, AR, LoR, OoC, Reader's Guidance, References 11/155

2.2.2. Monograph on *Ginseng radix* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, OoC, Reader's Guidance, References 34/376

2.2.3. Monograph on *Pelargonii radix* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance, References 8/109

2.2.4. Monograph on *Rosmarini aetheroleum* and supporting documents

Action: For adoption

Documents tabled: MO, AR, OoC, LoR, Reader's Guidance, References 6/91

2.2.5. Monograph on *Rosmarini folium* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance, References 15/91

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

2.3.1. Monograph on *Urticae herba* and supporting documents

Action: For adoption

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

2.3.2. Monograph on *Urticae radix* and supporting documents

Action: For adoption

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

2.3.3. Monograph on *Zingiberis rhizoma* and supporting documents

Action: For adoption

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

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

2.6.1. Monograph on *Prunus avium peduncle* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

2.6.2. Monograph on Tribuli terrestris herba and supporting documents

Action: For adoption

Documents tabled: PS, 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

None

4.2. Quality

None

4.3. Regulatory / Procedural

4.3.1. Best practice guide on using HMPC plenary time efficiently (EMA/HMPC/601160/2020)

Action: For adoption

Documents tabled: Draft revised HMPC best practice guide, Reader's Guidance

4.3.2. Reflection paper on data recommendations for (T)HMPs used in children and adolescents (EMA/HMPC/71333/2023)

Report: HMPC Chair

Action: For discussion

Document tabled: Draft reflection paper

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG - report

Report: Nicoleta Carmen Purdel

Action: For information

Document tabled: Minutes

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 2024

Report: HMPC Vice-Chair

Action: For information

Document tabled: Follow-up plan

- Belgian Presidency meeting – 24-25 April 2024

Report: Patricia Bodart

Action: For discussion

Documents tabled: Agenda, Presentations

- Hungarian Presidency meeting

Report: Julia Pallos, Rita Nemeth

Action: For information

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

5.1.3. HMPC Co-opted members

- Appointment: Epidemiology - use of herbal medicinal products in children

Report: HMPC Chair

Action: For discussion

Documents tabled: Call for nominations, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members, Presentation

- Appointment: Clinical Pharmacology

Report: HMPC Chair

Action: For discussion

Documents tabled: Call for nominations, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members, Presentation

5.1.4. Training on the Review procedure including Review Report Template and Peer-reviewer's tasks

Report: HMPC Vice Chair, Nicoleta Carmen Purdel

Action: For information

Document tabled: Presentation

5.1.5. Interim measures for scientific committees and other groups following the Hopveus appellate judgment

Report: HMPC Chair

Action: For information

Documents tabled: Email, Presentation

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair/Vice Chair

Action: For information

Documents tabled: Agenda, Minutes

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

5.3.1. Call for nominations for the Biological and Chemical Quality European Specialised Expert Community (ESEC)

Report: HMPC Chair

Action: For information

5.3.2. Revision of the Pharmaceutical Legislation / Variations Framework

Report: HMPC Chair/Vice Chair

Action: For information

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 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

5.5. 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 report 2023
Report: HMPC Chair
Action: For adoption
Document tabled: Report
- HMPC response to AESGP request on Sennae revision
Report: HMPC Chair
Action: For adoption
Document tabled: Response letter
- 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 \(europa.eu\)](https://european-council.europa.eu/media/en/press-room/pages/press-room.aspx?pid=149272)

- (2.1.1) HMPC position on the role of EU herbal monographs and assessment reports in relationship to borderline issues
Action: For discussion
Documents tabled: Draft paper, Draft paper commented, Reader's Guidance
- (2.2.1) HMPC communication of information on herbal medicinal products to the public and stakeholders
Action: For discussion

Documents tabled: Draft revised ARSP template, Draft valerian root template

- (2.2.2) Training on assessment of applications for herbal medicinal products

Action: For discussion

Document tabled: Herbal curriculum priorities

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

Documents tabled: List of proposed combinations, presentation

5.8. Planning and reporting

None

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 Crataegi folium cum flore and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR, LoR

6.2.2. Monograph on Fragariae folium and supporting documents

Action: For 3rd discussion

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

6.2.3. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 14th discussion

Documents tabled: Draft AR, Reader's Guidance

6.2.4. Monograph on Ononidis radix and supporting documents

Action: For 3rd discussion

Documents tabled: Draft MO, AR, LoR

6.2.5. Monograph on Liquiritiae radix and supporting documents (postponed)

6.2.6. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: For 5th 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 Mastic (Mastix, Pistaciae lentisci resina) and supporting documents

Action: For 4th discussion

Documents tabled: Review report, Reader's Guidance

6.3.2. Monograph on Lecithinum ex soya and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.3. Monograph on Soiae oleum raffinatum and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.4. Monograph on Thymi herba 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

6.5.1. Monograph on Cannabis flos and supporting documents

Action: For 3rd discussion

6.5.2. Monograph on Cisti cretici herba and supporting documents

Action: For 19th discussion

Documents tabled: Draft MO, AR, LoR

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

Action: For 9th discussion

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

6.5.4. Monograph on Maydis stigma and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR

6.5.5. Monograph on Species pectoralis and supporting documents

Action: For 3rd discussion

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

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 18-20 March 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 & CMD 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

- Webex telephone audio to be disabled on Monday 11th of March 2024
- Simultaneous National Scientific Advice (NSA) information and training webinar on 19th of April 2024
- Invitation to participate in EU NTC 10-year Anniversary event
- Joint HMA/EMA Big Data Steering Group Workshop on RWE methods
- [Draft reflection paper on the use of real-world data in non-interventional studies to generate real-world evidence](#)
- A comprehensive review on the hepatotoxicity of herbs used in the Indian (Ayush) systems of alternative medicine