



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 March 2024
EMA/HMPC/86409/2024
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 18-20 March 2024

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

18 March 2024, 10:00 – 17:00, virtual meeting

19 March 2024, 09:00 – 17:00, virtual meeting

20 March 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

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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 18-20 March 2024. See March 2024 HMPC minutes (to be published post May 2024 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 18-20 March 2024.

1.3. Adoption of the minutes

HMPC minutes for 29-31 January 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 January 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

- New Rapporteurs (re-appointments according to Austrian membership change)

Rhodiolae roseae rhizoma et radix (revision pre-final)

Species diureticae (Revision Draft)

- New Peer-reviewer

Crataegi folium cum flore (revision draft)

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

2.2.1. Monograph on Rhodiolae roseae rhizoma et radix and supporting documents

Action: For adoption

Documents tabled: MO, AR, OoC, LoR, References 30/122

2.2.2. Monograph on Rosmarini aetheroleum and supporting documents

Action: For discussion

Documents tabled: Draft MO, AR, OoC, LoR, References 15/92

2.2.3. Monograph on Rosmarini folium and supporting documents

Action: For discussion

Documents tabled: Draft MO, AR, LoR, References 15/92

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

2.3.1. Monograph on Eucalypti aetheroleum and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

2.3.2. Monograph on Pilosellae herba cum radice and supporting documents

Action: For adoption

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

2.3.3. Monograph on Urticae herba and supporting documents

Action: For adoption

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

2.3.4. Monograph on Urticae radix and supporting documents

Action: For adoption

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

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

2.4.1. Monograph on Malvae sylvestris flos and supporting documents

Action: For adoption

Documents tabled: Review report

2.4.2. Monograph on Malvae folium and supporting documents

Action: For adoption

Documents 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 Prunus avium peduncle 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

4.1.1. Guideline on the assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007)

Action: For discussion

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 information

Document tabled: Draft revised GACP guideline

4.3. Regulatory / Procedural

4.3.1. Template for Assessment report for the development of EU herbal monographs and EU list entries (EMA/HMPC/418902/2005)

Action: For adoption

Document tabled: Draft revised AR template

4.3.2. Template for a European Union herbal monograph (EMA/HMPC/107436/2005)

Action: For adoption

Documents tabled: Draft revised MO template, Addendum to QRD templates

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

Action: For adoption

Document tabled: Draft reflection paper

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

Action: For discussion

Document tabled: Draft revised HMPC best practice guide

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 March 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

Document tabled: Draft Agenda

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

5.1.3. HMPC Co-opted members

- Appointment of expert: Paediatrics - Paediatric medicine

Report: HMPC Chair

Action: For discussion

Documents tabled: Call for nominations dated 11 December 2023, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members

- Call for nomination of experts: Clinical Pharmacology

Report: HMPC Chair

Action: For discussion

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

5.1.4. Assessment Report Summary for the Public (ARSP)

Report: HMPC Chair

Action: For discussion

Document tabled: Presentation

5.2. EMA Scientific Committees or CMDh-v

None

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

5.3.1. EMA/CMDh Drafting Group on the revision of the Variations Framework

Action: For information

Document tabled: Presentation

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

Action: For information

Document tabled: Presentation

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13A expert group meeting

Report: Melanie Bald

Action: For information

Document tabled: SoD

- 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

5.4.2. Coordination with European Commission

- Technical comments on proposals for revision of pharmaceutical legislation

Report: HMPC Chair/Vice-Chair

Action: For information

Document: Herbal issues of technical nature identified in the Revision proposals for Regulation and Directive

5.4.3. Coordination with European Food Safety Authority (EFSA)

- HMPC observer to EFSA

Report: HMPC Chair/Vice-Chair

Action: For information

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 2024

Report: HMPC Chair

Action: For information

Document tabled: [HMPC work plan 2024 \(europa.eu\)](https://europea.eu)

- (2.1.1) HMPC position on the role of EU herbal monographs and assessment reports in relationship to borderline issues

Action: For discussion

Document tabled: Draft "The role of MO and AR in relationship to borderline issues"

- (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

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

Action: For discussion

Documents tabled: Course description EU NTC LMS Contaminants and impurities, Herbal curriculum – contaminants and residues, Herbal curriculum priorities, Draft presentation on Contaminants and residues in Herbal Medicinal Products

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

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**

6.1.1. Monograph on Foeniculi amari fructus aetheroleum and supporting documents

Action: For 3rd discussion

Documents tabled: Draft PS, AR, LoR, OoC, Reader's Guidance

6.1.2. Monograph on Ginseng radix and supporting documents

Action: For 1st discussion

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

6.1.3. Monograph on Pelargonii radix and supporting documents

Action: For 1st discussion

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

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 1st discussion

Document tabled: AR

6.2.2. Monograph on *Fragariae folium* and supporting documents

Action: For 2nd discussion

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

6.2.3. Monograph on *Lavandulae aetheroleum* and supporting documents

Action: For 14th discussion

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

6.2.4. Monograph on *Liquiritiae radix* and supporting documents

Action: For 1st discussion

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

6.2.5. Monograph on *Ononidis radix* and supporting documents

Action: For 2nd discussion

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

6.2.6. Monograph on *Zingiberis rhizoma* and supporting documents

Action: For 10th 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 Mastic (*Mastix, Pistaciae lentisci resina*) and supporting documents

Action: For 3rd discussion

Documents tabled: Review report, Reader's Guidance

6.3.2. Monograph on *Thymi herba* and supporting documents

Action: For 1st discussion

Documents tabled: Review report, references

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 2nd discussion

Document tabled: Presentation

6.5.2. Monograph on Cisti cretici herba and supporting documents

Action: For 18th discussion

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

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

Action: For 8th discussion

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

6.5.4. Monograph on Maydis stigma and supporting documents

Action: For 1st discussion

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

6.5.5. Monograph on Tribuli terrestris herba and supporting documents

Action: For 6th discussion

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

7. Any other business

7.1. Topics for discussion

7.1.1. EU NTC Engagement Event, 5 December 2023

Action: For information

7.1.2. Proxy vote – training

Action: For information

Document tabled: Presentation

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 29-31 January 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

- PCWP/HCPWP, 27 - 28 February 2024 (Draft agenda)
- PCWP/HCPWP, 14-15 November 2023 (Meeting summary)
- Draft guidance on scientific principles and data requirements for the safety and relative bioavailability assessment of substances proposed as new micronutrient sources ([LINK](#))
- Draft guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 ([LINK](#))
- Draft guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 ([LINK](#))
- Tetra-national congress Phytotherapy 2024 ([LINK](#))
- Society of Medicinal Plant and Natural Product Research GA – European Herbal Health Products Summit, 20 February 2024, Brussels (Final program; Presentation)
- RIVM Risk assessment of herbal preparations containing Withania somnifera (Ashwagandha) (Report; [LINK](#))
- Enhancing security of EMA Webex meetings
- Pharmaceuticals – changes to marketing authorisations (review of EU rules) ([LINK](#))
- SNSA Webinar for NCA representatives