



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2023
EMA/HMPC/468028/2023
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 20-22 November 2023

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

20 November 2023, 10:00 – 17:00, virtual meeting

21 November 2023, 09:00 – 17:00, virtual meeting

22 November 2023, 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.

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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 20-22 November 2023. See November 2023 HMPC minutes (to be published post January 2024 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 20-22 November 2023.

1.3. Adoption of the minutes

HMPC minutes for 18-20 September 2023.

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 November 2023

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New Rapporteur

Re-appointments according to Belgian membership change for ongoing assessment procedures:

- Lavandulae aetheroleum (Revision Draft)

2.1.3. Request for unscheduled review on Sennae folium and Sennae fructus

Rapporteur: HMPC Chair

Action: For discussion

Documents tabled: Email; Request for revision, Report (EN)

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

2.2.1. Monograph on Hippocastani cortex and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

2.2.2. Monograph on Rosmarini aetheroleum and supporting documents - postponed

2.2.3. Monograph on Rosmarini folium and supporting documents - postponed

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

2.3.1. Monograph on Lavandulae aetheroleum and supporting documents

Action: For adoption

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

2.3.2. Monograph on Urticae herba 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

2.4.1. Monograph on Fragariae folium and supporting documents

Action: For adoption

Document tabled: Review report; References 18/19

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

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

Document tabled: [Concept paper](#)

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 discussion

Documents tabled: Draft revised guideline, OoC

- 4.2.2. Q&A on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010)
-

Action: For adoption

Document tabled: Draft revised Q&A (Rev.7)

4.3. Regulatory / Procedural

- 4.3.1. Procedure for the preparation of Monographs/List Entries (EMA/HMPC/887331/2022)
-

Action: For discussion

Document tabled: Draft Procedure for the preparation of MO and LE, Reader's Guidance

- 4.3.2. Reflection paper on data recommendations for (T)HMPs used in children and adolescents
-

Action: For discussion

Documents tabled: Draft reflection paper; Draft Annex: 'Therapeutic areas for adolescents and children for traditional use (TU)'

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

Action: For discussion

Document tabled: Draft revised AR template, Reader's Guidance

4.3.4. Questions & Answers on the EU framework for (traditional) herbal medicinal products, including those from a 'non-European' tradition (EMA/HMPC/402684/2013)

Report: HMPC Chair

Action: For adoption

Document tabled: Draft revised Q&A (Rev.1)

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, QDG Work plan 2024-2026

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 November 2023
Report: HMPC Vice-Chair
Action: For information
Document tabled: Follow-up plan
- Spanish Presidency meeting – 09-10 October 2023
Report: Olga Palomino
Action: For discussion
Documents tabled: Agenda; Presentations
- Belgian Presidency meeting – 24-25 April 2024
Report: Patricia Bodart
Action: For discussion
Document tabled: Agenda
- Improved collaboration between HMPC and European Pharmacopoeia herbal groups
Report: HMPC Chair
Action: For discussion
Document tabled: SRLM Report on European Pharmacopoeia topic

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

5.1.3. HMPC Co-opted members

- Appointment of experts: 1) Clinical – General medical practice; 2) Clinical – Clinical trials methodology and statistics

Report: HMPC Chair

Action: For adoption

Document tabled: Call for nominations dated 06 October 2023, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Candidatures

- Call for nomination of experts: Paediatrics - Paediatric medicine

Report: HMPC Chair

Action: For discussion

Documents tabled: PV resignation email; Expertise of HMPC members

5.2. EMA Scientific Committees or CMDh-v

None

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

5.3.1. RWD/RWE pilot project for HMPC

Report: HMPC Chair

Action: For discussion

Document tabled: Proposed research questions

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

- EDQM Webinar on the new Ph. Eur. Cannabis flower monograph

Report: HMPC Chair

Action: For information

Document tabled: Email

5.4.2. Coordination with European Commission

- Herbal matters in the new proposals for Regulation and Directive

Report: HMPC Vice Chair

Action: For discussion

Document tabled: Presentation

5.5. **Cooperation with International Regulators**

5.5.1. Coordination with Swiss Agency for Therapeutic Products (Swissmedic)

- Swissmedic observer to HMPC

Report: HMPC Chair

Action: For information

Document tabled: [Confidentiality arrangement with Swissmedic](#); [HMPC Roles of Procedure](#)

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) – hearing in November 2023

- AESGP hearing

Report: AESGP Members

Action: For discussion

Document tabled: Agenda, List of participants, Presentations

- Post hearing discussion

Report: HMPC Chair

Action: For discussion

5.7. Work plan and related activities

5.7.1. HMPC work plan 2023

Report: HMPC Chair

Action: For discussion

Documents tabled: Work plan 2023, Annex 1, Annex 2 – current status

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

Action: For discussion

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

Action: For discussion

Document tabled: Survey results

- (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 issue”

- (2.2.1) Prepare a new Communication Initiative for HMPC stakeholders on herbal products

Action: For discussion

Document tabled: Presentation on survey results

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

Action: For discussion

- (2.3.1) Implement new working methodology for HMPC following reorganisation of EMA WPs/DGs

Action: For discussion

Documents tabled: Template for a European Union herbal monograph, Reader's Guidance

5.7.2. HMPC work plan 2024

Report: HMPC Chair

Action: For discussion

Documents tabled: Draft Work plan 2024, Annex 1, Annex 2

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 and List Entry on *Foeniculi amari fructus* and supporting documents

Action: For 4th discussion

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

6.1.2. Monograph and List Entry on *Foeniculi dulcis fructus* and supporting documents

Action: For 4th discussion

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

6.1.3. Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents - postponed

6.1.4. Monograph on *Rhodiolae roseae rhizoma et radix* and supporting documents

Action: For 1st discussion

Document tabled: OoC

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

6.2.1. Monograph on *Eucalypti aetheroleum* and supporting documents - postponed

6.2.2. Monograph on *Pilosellae herba cum radice* and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR

6.2.3. Monograph on *Urticae radix* and supporting documents

Action: For 2nd discussion

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

6.2.4. Monograph on *Zingiberis rhizoma* and supporting documents

Action: For 8th 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 *Allii sativi bulbos* and supporting documents

Action: For 1st discussion

Documents tabled: Review report, presentation

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

Action: For 1st discussion

Document tabled: Presentation

6.3.3. Monograph on *Malvae sylvestris flos* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.4. Monograph on *Malvae folium* and supporting documents

Action: For 1st discussion

Document tabled: Review report

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

Action: For 1st discussion

Document tabled: Presentation

6.3.6. Monograph on *Matricariae aetheroleum* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.7. Monograph on *Silybi mariani fructus* and supporting documents

Action: For 1st discussion

Documents tabled: Review report, presentation

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

Action: For 1st discussion

Document tabled: Presentation

6.3.9. Monograph on *Species diureticae* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.10. Monograph on Symphyti radix and supporting documents

Action: For 2nd 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 - postponed

6.5.2. Monograph on Cisti cretici herba and supporting documents - postponed

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

Action: For 7th discussion

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

6.5.4. Monograph on Maydis stigma and supporting documents

Action: For 1st discussion

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

6.5.5. Monograph on Pruni cerasi stipites and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR, LoR

6.5.6. Monograph on Species pectoralis and supporting documents

Action: For 1st discussion

Document tabled: Presentation

7. Any other business

7.1. Topics for discussion

7.1.1. Update common names list

Action: For discussion

Document tabled: Presentation

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 18-20 September 2023

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

HMPC plenary Best Practice Guide with annexed Reader's Guidance template

7.2.2. Assessment Report Summary for the Public (ARSP)

On hold

7.2.3. Other

- Draft Agenda – PCWP/HCPWP and all eligible organisations meetings
- EMA corporate website relaunch: what you need to know (email)
- Variation for Kalms Night/Day Film-Coated Tablets (active valerian root) - received in Ireland