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

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 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
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)

- (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 (SNSA) 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