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).
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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 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

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**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

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**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)

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**7.2.2. Assessment Report Summary for the Public (ARSP)**

On hold

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**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)