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

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 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
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


**Action:** For discussion

Document tabled: Concept paper

4.2. Quality


**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 bulbus 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 2\(^{nd}\) 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 7\(^{th}\) discussion
Documents tabled: Draft MO, AR, Reader’s Guidance, LoR, presentation

6.5.4. Monograph on Maydis stigma and supporting documents

**Action:** For 1\(^{st}\) discussion
Document tabled: Draft MO, AR, Reader’s Guidance, LoR

6.5.5. Monograph on Pruni cerasi stipites and supporting documents

**Action:** For 2\(^{nd}\) discussion
Documents tabled: Draft MO, AR, LoR

6.5.6. Monograph on Species pectoralis and supporting documents

**Action:** For 1\(^{st}\) 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