



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

29 January 2024  
EMA/HMPC/572004/2023  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Draft Agenda for the meeting on 29-31 January 2024

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

29 January 2024, 13:00 – 18:00, room 2C

30 January 2024, 09:00 – 18:00, room 2C

31 January 2024, 09:00 – 16:00, room 2C

#### Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the 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 on-going 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 29-31 January 2024. See January 2024 HMPC minutes (to be published post March 2024 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 29-31 January 2024.

**Action:** For adoption

### 1.3. Adoption of the minutes

HMPC minutes for 20-22 November 2023.

**Action:** For adoption

## 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

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Overview

#### 2.1.2. Appointment of Rapporteurs and Peer-reviewers

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Periodic reviews to start in 2024-2025 – Proposal to Sign-up

Report: HMPC Chair

**Action:** For discussion

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

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**Action:** For adoption

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

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

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**Action:** For adoption

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

#### 2.2.3. Monograph on *Rosmarini aetheroleum* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR, LoR, OoC

#### 2.2.4. Monograph on *Rosmarini folium* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR, LoR

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

#### 2.3.1. Monograph on *Urticae herba* and supporting documents

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**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

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

#### 2.4.1. Monograph on *Allii sativi bulbus* and supporting documents

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**Action:** For adoption

Documents tabled: Review report; References 00/00

#### 2.4.2. Monograph on *Matricariae aetheroleum* and supporting documents

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**Action:** For adoption

Documents tabled: Review report; References 00/03

#### 2.4.3. Monograph on *Silybi mariani fructus* and supporting documents

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**Action:** For adoption

Documents tabled: Review report; References 00/05

#### 2.4.4. Monograph on Species diureticae and supporting documents

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**Action:** For adoption

Documents tabled: Review report; References 0/0

#### 2.4.5. Monograph on Symphyti radix and supporting documents

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**Action:** For adoption

Documents tabled: Review report; References 00/04

### 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

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**Action:** For adoption

Documents tabled: MO, 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

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

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**Action:** For discussion

Document tabled: Draft revised guideline

### 4.2. Quality

#### 4.2.1. Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin (EMA/HMPC/246816/2005)

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**Action:** For discussion

Document tabled: Draft revised guideline

4.2.2. [Concept paper on the development of a Reflection Paper on modern manufacturing techniques used for herbal preparations \(EMA/HMPC/885124/2022\)](#)

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**Action:** For discussion

Document tabled: OoC received during public consultation

### 4.3. **Regulatory / Procedural**

4.3.1. [Procedure for the preparation of Monographs/List Entries \(EMA/HMPC/887331/2022\)](#)

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**Action:** For adoption

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

4.3.2. [Template for Assessment report for the development of EU herbal monographs and EU list entries \(EMA/HMPC/418902/2005\)](#)

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**Action:** For discussion

Document tabled: Draft revised AR template

4.3.3. [Template for a European Union herbal monograph \(EMA/HMPC/107436/2005\)](#)

---

**Action:** For discussion

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

4.3.4. [Reflection paper on data recommendations for \(T\)HMPs used in children and adolescents](#)

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**Action:** For adoption

Document tabled: Draft reflection paper

### 4.4. **Report on HMPC Drafting Groups activities**

4.4.1. [ORGAM DG](#)

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None

4.4.2. [Quality DG - report](#)

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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)

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- HMPC SRLM Follow up plan - status January 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

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Report: HMPC Chair

**Action:** For information

#### 5.1.3. HMPC Co-opted members

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- Appointment of expert: Clinical – Clinical trials methodology and statistics

Report: HMPC Chair

**Action:** For discussion

Documents 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, Expertise of HMPC 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](#), Candidatures, 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

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Report: HMPC Chair

**Action:** For information

Documents tabled: Feasibility assessment requests

### 5.4. Cooperation within the EU regulatory network

#### 5.4.1. Coordination with European Pharmacopoeia

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None

#### 5.4.2. Coordination with European Commission

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None

#### 5.4.3. Coordination with European Food Safety Authority (EFSA)

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- HMPC observer to EFSA

Report: HMPC Vice Chair

**Action:** For discussion

Documents tabled: 6<sup>th</sup> WG Draft Agenda 2024-01-26, Invitation letter

### 5.5. Cooperation with International Regulators

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

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- Swissmedic observer to HMPC

Report: HMPC Chair

**Action:** For information

Documents 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 on November 2023

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- AESGP hearing

Report: HMPC Chair

**Action:** For adoption

Document tabled: Draft hearing report

## 5.7. Work plan and related activities

### 5.7.1. HMPC work plan 2024

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Report: HMPC Chair

**Action:** For adoption

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

### 5.7.2. Follow up on HMPC work plan 2023

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

**Action:** For discussion

Documents tabled: Report of ad hoc meeting

- (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”

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

**Action:** For discussion

Documents tabled: Draft presentation on contaminants training (EU-NTC), Herbal curriculum – contaminants and residues, Herbal curriculum priorities

## 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 – postponed

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

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**Action:** For 2<sup>nd</sup> discussion

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

## 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

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**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Draft MO, AR, LoR

### 6.2.2. Monograph on *Fragariae folium* and supporting documents

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**Action:** For 1<sup>st</sup> discussion

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

### 6.2.3. Monograph on *Lavandulae aetheroleum* and supporting documents

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**Action:** For 14<sup>th</sup> discussion

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

### 6.2.4. Monograph on *Ononidis radix* and supporting documents

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**Action:** For 1<sup>st</sup> discussion

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

### 6.2.5. Monograph on *Pilosellae herba cum radice* and supporting documents

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**Action:** For 2<sup>nd</sup> discussion

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

### 6.2.6. Monograph on *Zingiberis rhizoma* and supporting documents

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**Action:** For 9<sup>th</sup> 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 *Malvae sylvestris* flos and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Document tabled: Review report

### 6.3.2. Monograph on Malvae folium and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Document tabled: Review report

### 6.3.3. Monograph on Mastic (Mastix, Pistaciae lentisci resina) and supporting documents

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**Action:** For 2<sup>nd</sup> discussion

Document 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 Cisti cretici herba and supporting documents

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**Action:** For 17<sup>th</sup> discussion

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

### 6.5.2. Monograph on Maydis stigma and supporting documents

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**Action:** For 1<sup>st</sup> discussion

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

## 7. Any other business

### 7.1. Topics for discussion

#### 7.1.1. EU NTC Engagement Event, 5 December 2023

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**Action:** For discussion

Documents tabled: Agenda, Presentations

### 7.2. Documents for information

#### 7.2.1. HMPC

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Table of Decisions from HMPC meeting held on 20-22 November 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)

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On hold

### 7.2.3. Other

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- HMA/EMA Big Data Stakeholder Forum 04 December 2023, program
- The new Ph. Eur. Cannabis flower monograph (3028) - presentation
- Report on the implementation of Regulation on nutrition and health claims made on foods [TA \(europa.eu\)](https://ec.europa.eu/food/food/nutrition/ta)
- Society of Medicinal Plant and Natural Product Research GA – European Herbal Health Products Summit, 20 February 2024, Brussels – draft program, invitation