



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

18 March 2024  
EMA/HMPC/86409/2024  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 18-20 March 2024

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

18 March 2024, 10:00 – 17:00, virtual meeting

19 March 2024, 09:00 – 17:00, virtual meeting

20 March 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 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 18-20 March 2024. See March 2024 HMPC minutes (to be published post May 2024 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 18-20 March 2024.

### 1.3. Adoption of the minutes

HMPC minutes for 29-31 January 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 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

Report: HMPC Chair

**Action:** For information

Document tabled: Overview document to sign-up as Rapporteur/Peer-reviewer

- New Rapporteurs (re-appointments according to Austrian membership change)

Rhodiolae roseae rhizoma et radix (revision pre-final)

Species diureticae (Revision Draft)

- New Peer-reviewer

Crataegi folium cum flore (revision draft)

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

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

---

**Action:** For adoption

Documents tabled: MO, AR, OoC, LoR, References 30/122

### 2.2.2. Monograph on Rosmarini aetheroleum and supporting documents

**Action:** For discussion

Documents tabled: Draft MO, AR, OoC, LoR, References 15/92

### 2.2.3. Monograph on Rosmarini folium and supporting documents

**Action:** For discussion

Documents tabled: Draft MO, AR, LoR, References 15/92

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

### 2.3.1. Monograph on Eucalypti aetheroleum and supporting documents

**Action:** For adoption

Documents tabled: MO, AR, LoR

### 2.3.2. Monograph on Pilosellae herba cum radice and supporting documents

**Action:** For adoption

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

### 2.3.3. Monograph on Urticae herba and supporting documents

**Action:** For adoption

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

### 2.3.4. Monograph on Urticae radix and supporting documents

**Action:** For adoption

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

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

### 2.4.1. Monograph on Malvae sylvestris flos and supporting documents

**Action:** For adoption

Documents tabled: Review report

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

**Action:** For adoption

Documents 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 Prunus avium peduncle and supporting documents

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**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

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

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**Action:** For discussion

### 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 information

Document tabled: Draft revised GACP guideline

### 4.3. Regulatory / Procedural

#### 4.3.1. 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 adoption

Document tabled: Draft revised AR template

#### 4.3.2. Template for a European Union herbal monograph (EMA/HMPC/107436/2005)

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**Action:** For adoption

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

#### 4.3.3. Reflection paper on data recommendations for (T)HMPs used in children and adolescents (EMA/HMPC/71333/2023)

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**Action:** For adoption

Document tabled: Draft reflection paper

#### 4.3.4. Best practice guide on using HMPC plenary time efficiently (EMA/HMPC/601160/2020)

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**Action:** For discussion

Document tabled: Draft revised HMPC best practice guide

### 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 March 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: 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](#), Expertise of HMPC members

- Call for nomination of experts: Clinical Pharmacology

Report: HMPC Chair

**Action:** For discussion

Documents tabled: [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members, presentation

### 5.1.4. Assessment Report Summary for the Public (ARSP)

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Presentation

## 5.2. EMA Scientific Committees or CMDh-v

None

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

### 5.3.1. EMA/CMDh Drafting Group on the revision of the Variations Framework

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**Action:** For information

Document tabled: Presentation

### 5.3.2. Call for nominations for the Biological and Chemical Quality European Specialised Expert Community (ESEC)

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**Action:** For information

Document tabled: Presentation

## 5.4. Cooperation within the EU regulatory network

### 5.4.1. Coordination with European Pharmacopoeia

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- 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

#### 5.4.2. Coordination with European Commission

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- Technical comments on proposals for revision of pharmaceutical legislation

Report: HMPC Chair/Vice-Chair

**Action:** For information

Document: Herbal issues of technical nature identified in the Revision proposals for Regulation and Directive

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

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- HMPC observer to EFSA

Report: HMPC Chair/Vice-Chair

**Action:** For information

### 5.5. Cooperation with International Regulators

None

### 5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

None

### 5.7. Work plan and related activities

#### 5.7.1. HMPC work plan 2024

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Report: HMPC Chair

**Action:** For information

Document tabled: [HMPC work plan 2024 \(europa.eu\)](https://europea.eu)

- (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 issues"

- (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

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

**Action:** For discussion

Documents tabled: Course description EU NTC LMS Contaminants and impurities, Herbal curriculum – contaminants and residues, Herbal curriculum priorities, Draft presentation on Contaminants and residues in Herbal Medicinal Products

### 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

## 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

**Action:** For 3<sup>rd</sup> discussion

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

### 6.1.2. Monograph on Ginseng radix and supporting documents

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

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

### 6.1.3. Monograph on Pelargonii radix and supporting documents

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

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

## 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

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

Document tabled: AR

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

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

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

### 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 *Liquiritiae radix* and supporting documents

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

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

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

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

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

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

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**Action:** For 10<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 Mastic (*Mastix, Pistaciae lentisci resina*) and supporting documents

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**Action:** For 3<sup>rd</sup> discussion

Documents tabled: Review report, Reader's Guidance

### 6.3.2. Monograph on *Thymi herba* and supporting documents

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

Documents 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 Cannabis flos and supporting documents

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

Document tabled: Presentation

### 6.5.2. Monograph on Cisti cretici herba and supporting documents

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**Action:** For 18<sup>th</sup> discussion

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

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

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**Action:** For 8<sup>th</sup> discussion

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

### 6.5.4. 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

### 6.5.5. Monograph on Tribuli terrestris herba and supporting documents

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**Action:** For 6<sup>th</sup> discussion

Documents tabled: Draft PS, 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 information

#### 7.1.2. Proxy vote – training

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**Action:** For information

Document tabled: Presentation

## 7.2. Documents for information

### 7.2.1. HMPC

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Table of Decisions from HMPC meeting held on 29-31 January 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)

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

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On hold

### 7.2.3. Other

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- PCWP/HCPWP, 27 - 28 February 2024 (Draft agenda)
- PCWP/HCPWP, 14-15 November 2023 (Meeting summary)
- Draft guidance on scientific principles and data requirements for the safety and relative bioavailability assessment of substances proposed as new micronutrient sources ([LINK](#))
- Draft guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 ([LINK](#))
- Draft guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 ([LINK](#))
- Tetra-national congress Phytotherapy 2024 ([LINK](#))
- Society of Medicinal Plant and Natural Product Research GA – European Herbal Health Products Summit, 20 February 2024, Brussels (Final program; Presentation)
- RIVM Risk assessment of herbal preparations containing Withania somnifera (Ashwagandha) (Report; [LINK](#))
- Enhancing security of EMA Webex meetings
- Pharmaceuticals – changes to marketing authorisations (review of EU rules) ([LINK](#))
- SNSA Webinar for NCA representatives