



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 March 2025  
EMA/HMPC/71602/2025  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 17-19 March 2025

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

17 March 2025, 10:00 – 17:00, virtual meeting

18 March 2025, 09:00 – 17:00, virtual meeting

19 March 2025, 09:00 – 16:00, virtual meeting

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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 17-19 March 2025. See March 2025 HMPC minutes (to be published post May 2025 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 17-19 March 2025.

### 1.3. Adoption of the minutes

HMPC minutes for 20-22 January 2025.

## 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 March 2025

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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 2025-2026

Report: HMPC Chair

**Action:** For discussion

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

#### 2.1.3. New assessment 2025 - Valeriana + Passiflora

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**Action:** For adoption

Document tabled: Validated proposal for assessment, Updated table with market overview

### 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 *Allii sativi* bulbus and supporting documents**

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**Action:** For adoption

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

### **2.3.2. Monograph on *Arnicae* flos and supporting documents**

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**Action:** For adoption

Documents tabled: Draft MO, AR, LoR

### **2.3.3. Monograph on *Crataegi folium cum flore* and supporting documents**

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**Action:** For adoption

Documents tabled: Draft MO, AR, LoR

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

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**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 *Gentianae radix* and supporting documents**

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**Action:** For adoption

Document tabled: Review report

### **2.4.2. Monograph on *Lupuli* flos and supporting documents**

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**Action:** For adoption

Document tabled: Review report

### **2.4.3. Monograph on *Meliloti herba* and supporting documents**

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**Action:** For adoption

Document tabled: Review report

### **2.4.4. Monograph on *Uvae ursi folium* and supporting documents**

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**Action:** For adoption

Document tabled: Review report

## **2.5. EU herbal monographs, list entries and public statements for final adoption**

### **2.5.1. Monograph on Cisti cretici herba and supporting documents**

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**Action:** For adoption

Documents tabled: Draft MO, AR, LoR, OoC

## **2.6. EU herbal monographs, list entries and public statements for adoption for release for public consultation**

### **2.6.1. Monograph on Maydis stigma and supporting documents**

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**Action:** For adoption

Documents tabled: Draft 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: OoC, Draft revised guideline

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

None

## 4.4. Report on HMPC Drafting Groups activities

### 4.4.1. ORGAM DG

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None

### 4.4.2. Quality DG

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- QDG February meeting  
Report: Carmen Purdel  
**Action:** For information  
Document tabled: Minutes February 2025

## 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 2025  
Report: HMPC Vice-Chair  
**Action:** For information  
Document tabled: Follow-up plan
- Polish Presidency meeting 13-14 May  
Report: Wojciech Dymowski  
**Action:** For information  
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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- Calls for a Co-opted member:  
Report: HMPC Chair  
**Action:** For information  
Document tabled: [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#); Call for Co-opted members to HMPC\_2025-Mar

#### 5.1.4. Committee meeting dates 2027-2028

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- Proposed committee meeting dates for the period of 2027-2028



**Action:** For information

Document tabled: Draft - Committee meeting dates - 2027-2028

#### 5.1.5. Implementation of revised policy 0044 on handling of competing interests

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**Action:** For information

### 5.2. EMA Scientific Committees or CMDh-v

None

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

#### 5.3.1. Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP)

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- Mandates and Rules of Procedure for PCWP and HCPWP

**Action:** For adoption

Documents tabled: EMA HCPWP Mandate and composition update proposal Feb 2025, EMA PCWP and HCPWP Rules of procedure update proposal Feb 2025, EMA PCWP Mandate and composition\_update proposal Feb 2025, Proposal for PCWP and HCPWP membership enlargement

### 5.4. Cooperation within the EU regulatory network

#### 5.4.1. European Pharmacopoeia

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- EDQM 13A, 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

#### 5.4.2. European Food Safety Authority (EFSA)

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**Action:** For information

Document tabled: 19th WG Draft Agenda 2025-03-03, Draft opinion fennel Art 8(2)

### 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 2025

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Report: HMPC Chair

**Action:** For information

Document tabled: [HMPC work plan 2025](#)

- (1.3.2) Development of further guidance on particulars for signal detection for (traditional) herbal medicinal products

**Action:** For information

- (1.3.3) Improved evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

**Action:** For discussion

Document tabled: draft RP on data recommendations for THMPs used in children and adolescents

- (2.2.1) HMPC communication of information on (traditional) herbal medicinal products to the public and stakeholders

**Action:** For discussion

Documents tabled: Draft revised ARSP template, Herbal summaries, Presentation

- (2.3.1) Improve worksharing in HMPC assessment tasks, supported by new herbal curriculum training courses for assessors

Report: HMPC Chair

**Action:** For information

## 5.8. Planning and reporting

### 5.8.1. EU NTC LMS domain for International regulators

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Report: HMPC Vice-Chair

**Action:** For information

Document tabled: Request to include training on contaminants/residues in HMPs (email)

### 5.8.2. HMPC scientific conference

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Report: HMPC Chair/Vice-Chair

**Action:** For information

## 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 Zingiberis rhizoma and supporting documents

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**Action:** For 3<sup>rd</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 Lavandulae aetheroleum and supporting documents

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

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

### 6.2.2. Monograph on Liquiritiae radix and supporting documents

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**Action:** For 4<sup>th</sup> discussion

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

### 6.2.3. Monograph on Ononidis radix and supporting documents

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

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

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

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**Action:** For 1<sup>st</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 Cimicifugae rhizoma and supporting documents

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

Document tabled: Review report, Reader's Guidance

#### **6.3.2. Monograph on *Curcumae longae* rhizome and supporting documents**

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

Documents tabled: Presentation, Review report

#### **6.3.3. Monograph on *Echinaceae angustifoliae* radix and supporting documents - postponed**

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#### **6.3.4. Monograph on *Echinaceae pallidae* radix and supporting documents**

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

Document tabled: Review report

#### **6.3.5. Monograph on *Melissae folium* and supporting documents**

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

Document tabled: Review report

#### **6.3.6. Monograph on *Ribis nigri folium* and supporting documents**

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

Document tabled: Review report, Reader's guidance

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

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**Action:** For 5<sup>th</sup> discussion

Document tabled: Review report

#### **6.3.8. Monograph on *Vitis viniferae folium* and supporting documents**

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**Action:** For 4<sup>th</sup> discussion

Documents tabled: Review report, Reader's guidance

### **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 6<sup>th</sup> discussion

Documents tabled: Draft PS, Reader's Guidance, [Call for data with Annex](#)

## **7. Any other business**

### **7.1. Topics for discussion**

None

### **7.2. Documents for information**

#### **7.2.1. HMPC**

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Table of Decisions from HMPC meeting held on 20-22 January 2025

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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- Meeting Summary PCWP-HCPWP 20 Nov 2024
- DRAFT Agenda - PCWP-HCPWP meeting - 1-2 April 2025\_1