



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 January 2026  
EMA/HMPC/388321/2025  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC) Draft Agenda for the meeting on 19-21 January 2026

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

19 January 2026, 13:00 – 18:00, room 2C

20 January 2026, 09:00 – 18:00, room 2C

21 January 2026, 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 19-21 January 2026. See January 2026 HMPC minutes (to be published post March 2026 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 19-21 January 2026.

### 1.3. Adoption of the minutes

HMPC minutes for 17-19 November 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 January 2026

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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 2026-2027

Report: HMPC Chair

**Action:** For discussion

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

#### 2.1.3. Re-evaluation of Public Statements

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Overview of THMPs on EU market

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

#### 2.2.1. Monograph on Arnicae flos and supporting documents

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**Action:** For adoption

Documents tabled: AR, MO, LoR, OoC, References 0/0

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

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

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**Action:** For adoption

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

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

### **2.4.1. Monograph on Betulae folium and supporting documents**

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**Action:** For adoption

Documents tabled: Review report, Reader's guidance

### **2.4.2. Monograph on Hamamelidis cortex and supporting documents**

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**Action:** For adoption

Document tabled: Review report

### **2.4.3. Monograph on Hamamelidis folium and supporting documents**

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**Action:** For adoption

Document tabled: Review report

### **2.4.4. Monograph on Hamamelidis folium et cortex aut ramunculus destillatum 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 Hyperici herba/Cimicifugae rhizoma and supporting documents**

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**Action:** For adoption

Documents tabled: AR, MO, LoR, OoC

## **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

#### 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 declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/CHMP/CVMP/287539/2005)

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Report: Carmen Purdel

**Action:** For discussion

Document tabled: Draft revised guideline on declarations

### 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 December meeting  
Report: Carmen Purdel  
**Action:** For information  
Document tabled: Minutes December 2025
- QDG 3-year work-plan  
Report: Carmen Purdel  
**Action:** For discussion

## 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 2026

Report: HMPC Chair

**Action:** For information

- Cypriot Presidency meeting June 2026

Report: Christina Sylvia Chrysostomou

**Action:** For information

#### 5.1.2. HMPC membership

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Report: HMPC Chair

**Action:** For information

#### 5.1.3. Election of HMPC Chair

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**Action:** For discussion

Documents tabled: Call for expression of interest, Presentation, [HMPC RoP](#), Candidatures

#### 5.1.4. HMPC Vice-Chairperson - upcoming election March 2026

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**Action:** For discussion

Document tabled: Presentation

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

#### 5.2.1. HMPC/PRAC collaboration on signal detection: safety-assessment for herbal medicinal products

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Report: HMPC (Vice-)Chair(s)

**Action:** For discussion

Documents tabled: Draft "Mandate, Objectives and Rules of Procedure of the HMPC Safety Drafting Group"



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

#### 5.3.1. HMPC/Translational Science Office collaboration: requirements for studying the interaction potential of herbal medicinal products

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Report: HMPC Vice-Chair

**Action:** For information

#### 5.3.2. Patient experience data (PED) reflection paper

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Report: HMPC (Vice-)Chair(s)

**Action:** For discussion

Document tabled: [Reflection Paper on Patient Experience Data \(PED\)](#)

### 5.4. Cooperation within the EU regulatory network

#### 5.4.1. European Pharmacopoeia

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None

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

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**Action:** For information

Documents tabled: Draft opinions on berberine-containing plant preparations and on hydroxycitric-acid-containing plant preparations

### 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

#### 5.6.1. Association of the European Self-Medication Industry (AESGP)

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- AESGP hearing 2025

Report: HMPC Chair

**Action:** For adoption

Document tabled: Hearing report 2025

### 5.7. Work plan and related activities

#### 5.7.1. Follow-up on HMPC work plan 2025

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Report: HMPC Chair

**Action:** For information

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

- (1.3.1) Establish principles for the role of real-world data in supporting European Union herbal monographs

**Action:** For discussion

Document tabled: Email

- (1.3.2) Development of 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

Documents tabled: Draft RP, OoC

- (2.1.1) HMPC position on the role of EU herbal monographs and assessment reports in relationship to borderline issues

**Action:** For discussion

Documents tabled: Draft Reflection paper, OoC, Reader's Guidance

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

**Action:** For adoption

Document tabled: Presentation

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

**Action:** For information

Documents tabled: Herbal Curriculum Training Planning 2026-2027, HMPC training curriculum priorities January 2026, Overview internal HMPC training on AR and MO templates

## 5.7.2. [HMPC work plan 2026](#)

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Report: HMPC (Vice-) Chairs

**Action:** For adoption

Document tabled: HMPC work plan 2026

## 5.8. **Planning and reporting**

### 5.8.1. [EMA/FDA Workshop on herbal medicines development](#)

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Draft program

## 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 Liquiritiae radix and supporting documents

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Action: For 1st discussion

Documents tabled: Draft AR, MO, LoR, OoC

## 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 - postponed

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## 6.3. Review of EU herbal monographs and list entries in preparation for decision on revision

### 6.3.1. Monograph on Anisi aetheroleum and supporting documents - postponed

### 6.3.2. Monograph on Anisi fructus and supporting documents - postponed

### 6.3.3. Monograph on Centaurii herba and supporting documents

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Action: For 1st discussion

Document tabled: Review report

### 6.3.4. Monograph on Eleutherococci radix and supporting documents

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

Document tabled: Presentation

### 6.3.5. Monograph on Myrrha and supporting documents

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

Document tabled: Review report

### 6.3.6. Monograph on Plantaginis ovatae semen and supporting documents

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

Document tabled: Review report

### 6.3.7. Monograph on Plantaginis ovatae seminis tegumentum and supporting documents

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

Document tabled: Review report

### 6.3.8. Monograph on Psyllii semen and supporting documents

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

Document tabled: Review report

### 6.3.9. Monograph on Rusci rhizoma and supporting documents

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

Document tabled: Review report

### 6.3.10. Monograph on Salicis cortex and supporting documents

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

Documents tabled: Review report, Reader's guidance

### 6.3.11. Monograph on Salviae officinalis folium and supporting documents

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

Document tabled: Review report

### 6.3.12. Monograph on Thymi herba and supporting documents

**Action:** For 9<sup>th</sup> discussion

Documents tabled: Review report, Reader's guidance, Annex 1, Annex 2, Annex 3

## **6.4. EU herbal monographs and list entries in preparation for adoption after public consultation**

### 6.4.1. Monograph on Cannabis flos and supporting documents

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

Document tabled: OoC

## **6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation**

### 6.5.1. Monograph on Valerianae radix/Passiflorae herba and supporting documents

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

Documents tabled: Draft MO, AR, LoR

## **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 19-21 November 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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None

#### **7.2.3. Other**

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- Invitation European Herbal Health Products Summit 2026 (email)