



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

09 March 2023  
EMA/HMPC/68747/2023  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 13-15 March 2023

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

13 March 2023, 13:00 – 18:00, room 1C

14 March 2023, 09:00 – 18:00, room 1C

15 March 2023, 09:00 – 16:00, room 1C

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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 13-15 March 2023. See March 2023 HMPC minutes (to be published post May 2023 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 13-15 March 2023.

### 1.3. Adoption of the minutes

HMPC minutes for 23-25 January 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 March 2023

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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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##### **Systematic Reviews**

- Symphyti radix
- Thymi herba

##### **New assessments started in 2023**

- Pruni cerasi stipites
- Species pectoralis
- Cannabis flos

#### 2.1.3. Maydis stigma – new proposal for assessment

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**Action:** For discussion

Documents: Validated proposal for assessment, references

#### 2.1.4. Pruni cerasi stipites – for information

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**Action:** For information

Documents: Amended proposal for assessment, new references

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

#### 2.2.1. Monograph on Juniperi pseudo-fructus (galbulus) and supporting documents

---

**Action:** For adoption

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

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

None

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

#### 2.4.1. Monograph on Crataegi folium cum flore and supporting documents

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**Action:** For adoption

Document tabled: Review report

#### 2.4.2. Monograph on Helichrysi flos 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 adoption for release for public consultation

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

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**Action:** For adoption

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

### 2.6. 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. Public statement on use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005 Rev 1)
- 

**Action:** For discussion

Document tabled: Public statement – draft correction

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

**Action:** For discussion

Documents tabled: [Concept paper](#), comments received

### 4.2. Quality

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

**Action:** For information

Documents tabled: GACP revision 2023, HMPC Guideline on GACP, Overview of comments

### 4.3. Regulatory / Procedural

None

### 4.4. Report on HMPC Drafting Groups activities

- 4.4.1. Herbal Quality DG – Member re-appointment
- 

Report: HMPC Chair, Nicoleta Carmen Purdel

**Action:** For adoption

Documents tabled: [Mandate ODG](#), Call for expression of interest, Presentation, Re-nominations

- 4.4.2. Herbal Quality DG – Chair election
- 

Report: HMPC Chair, Nicoleta Carmen Purdel

**Action:** For adoption

Documents tabled: [Mandate ODG](#), Call for expression of interest, Presentation, Motivation Letter, Candidature

- 4.4.3. ORGAM DG
- 

None

#### 4.4.4. Ad-hoc Quality drafting group

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Report: Nicoleta Carmen Purdel

**Action:** For information

Document tabled: Minutes February 2023

## 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 2023

Report: HMPC Vice Chair

**Action:** For information

Document tabled: Follow up plan

- Swedish Presidency meeting – 18-19 April 2023

Report: Karin Erika Svedlund

**Action:** For discussion

Document tabled: Draft Agenda, presentation

#### 5.1.2. HMPC membership

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Report: HMPC Chair

**Action:** For information

#### 5.1.3. Election of HMPC Vice-Chair

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**Action:** For adoption

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

#### 5.1.4. Document collaborative platform – Teams integration

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**Action:** For discussion

Document tabled: Presentation

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

#### 5.2.1. Scientific Coordination Board Meeting

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Report: HMPC Chair

**Action:** For information

Document tabled: Draft agenda



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

None

### 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  
Document tabled: SoD

#### 5.4.2. Coordination with the European Commission

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None

### 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 2023

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Report: HMPC Chair

**Action:** For discussion

Documents tabled: Work plan 2023, Annex 1, Annex 2 – current status

- (1.3.1) Evaluation of data from paediatric clinical practice for the safe use of herbal substances in children  
**Action:** For discussion

Documents tabled: Presentation

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

**Action:** For information

Documents tabled: Meeting Summary

- (2.2.1) Prepare a new Communication Initiative for HMPC stakeholders on herbal products

**Action:** For information

Documents tabled: Presentation, Survey

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

**Action:** For discussion

- (2.3.1) Implement new working methodology for HMPC – new main procedure and revised template documents

**Action:** For discussion

Documents tabled: Draft Procedure establishment monographs, Draft revised AR template, Draft revised AR template with comments, Reader's guidance

## 5.8. Planning and reporting

### 5.8.1. HMPC meeting organisation 2023

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Report: HMPC Chair

**Action:** For information

Document tabled: Email communication

### 5.8.2. HMPC meeting dates 2025-2026

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Report: HMPC Chair

**Action:** For information

Document tabled: Draft meeting schedule

## 5.9. Legislation and regulatory affairs

None

### 5.9.1. Request on Article 16c Directive 2001/83/EC

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**Action:** For discussion

Document tabled: Presentation

## 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* and supporting documents – postponed

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6.1.2. Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents – postponed

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6.1.3. Monograph on *Foeniculi dulcis fructus* and supporting documents – postponed

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6.1.4. Monograph on *Fumariae herba* and supporting documents

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

Documents tabled: Draft MO, AR, LoR, 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 – postponed

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6.2.2. Monograph on *Lavandulae aetheroleum* and supporting documents

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

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

6.2.3. Monograph on *Ginseng radix* and supporting documents

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

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

6.2.4. Monograph on *Pelargonii radix* and supporting documents

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

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

6.2.5. Monograph on *Plantaginis lanceolatae folium* and supporting documents

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

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

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

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

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

#### 6.2.7. Monograph on Urticae herba and supporting documents- postponed

#### 6.2.8. Monograph on Urticae radix and supporting documents- postponed

#### 6.2.9. Monograph on Zingiberis rhizoma and supporting documents

**Action:** For 5<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 Capsici fructus and supporting documents

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

Document tabled: Review report

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

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

Document tabled: Review report

#### 6.3.3. Monograph on Matricariae flos and supporting documents

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

Document tabled: Review report

#### 6.3.4. Monograph on Melaleucae aetheroleum and supporting documents

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

Document tabled: Review report

#### 6.3.5. Monograph on Myrtilli fructus siccus and supporting documents

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

Document tabled: Review report

#### 6.3.6. Monograph on Myrtilli fructus recens and supporting documents

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

Document tabled: Review report

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

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

Document tabled: Review report, Reader's guidance

#### 6.3.8. Monograph on Origani majoranae herba and supporting documents

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

Document tabled: Review report

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

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

Document tabled: Presentation

#### 6.3.10. Monograph on Polygoni avicularis herba and supporting documents

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

Document tabled: Review report

#### 6.3.11. Monograph on Pruni africanae cortex and supporting documents - postponed

#### 6.3.12. Monograph on Ricini oleum and supporting documents

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

Document tabled: Review report

#### 6.3.13. Monograph on Rosae flos and supporting documents – postponed

#### 6.3.14. Monograph on Rubi idaei folium and supporting documents

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

Documents tabled: Review report, Reader's guidance

#### 6.3.15. Monograph Sideritis herba and supporting documents – postponed

#### 6.3.16. Monograph on Sisymbrii officinalis herba and supporting documents

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

Documents tabled: Review report, Reader's Guidance

#### 6.3.17. Monograph on Symphyti radix and supporting documents -postponed

### **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 Hyperici herba/Cimicifugae rhizoma and supporting documents

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

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

#### 6.5.2. Monograph on Tribuli terrestris herba and supporting documents - postponed

## **7. Any other business**

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

#### 7.1.1. Availability of ESCOP monographs for HMPC assessment work

**Action:** For discussion

Document tabled: Email communication

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

#### 7.2.1. HMPC

Table of Decisions from HMPC meeting held on 23-25 January 2023

Overview of expertise of members HMPC and subgroups

[Inventory of herbal substances for assessment work](#)

[Abbreviations in HMPC agendas/minutes](#)

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

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- Agenda - Pharmacovigilance herbal MP conference at Kew Gardens, 13-14 April 2023 (presentation)
- Meeting Summary – PCWP-HCPWP meeting with all eligible organisations - 15 Nov November 2022
- Agenda - PCWP-HCPWP Joint meeting – 3 March 2023
- Paediatric uses of herbal medicines (updated document: Jan 2023)