



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 July 2022  
EMA/HMPC/637772/2022  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Draft Agenda for the meeting on 18-20 July 2022

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

18 July 2022, 13:00 – 18:00, room 1D / virtual meeting

19 July 2022, 09:00 – 18:00, room 1D / virtual meeting

20 July 2022, 09:00 – 16:00, room 1D / virtual meeting

#### 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 18-20 July 2022. See July 2022 HMPC minutes (to be published post September 2022 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 18-20 July 2022.

### 1.3. Adoption of the minutes

HMPC minutes for 16-18 May 2022.

## 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 July 2022

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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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None

### 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 *Foeniculi amari fructus* and supporting documents

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**Action:** For adoption

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

#### 2.3.2. Public statement on *Foeniculi amari fructus aetheroleum* and supporting documents

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**Action:** For adoption

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

### 2.3.3. Monograph on *Foeniculi dulcis fructus* and supporting documents

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**Action:** For adoption

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

### 2.3.4. Monograph on *Fumariae herba* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance

### 2.3.5. Monograph on *Juniperi pseudo-fructus* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Presentation

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

### 2.4.1. Monograph on *Camelliae sinensis non fermentatum folium* and supporting documents

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**Action:** For adoption

Document tabled: Review report

### 2.4.2. Monograph on *Curcumae xanthorrhizae rhizoma* and supporting documents

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**Action:** For adoption

Documents tabled: Review report

### 2.4.3. Monograph on *Ginseng radix* and supporting documents

---

**Action:** For adoption

Documents tabled: Review report

### 2.4.4. Monograph on *Juglandis folium* and supporting documents

---

**Action:** For adoption

Documents tabled: Review report

### 2.4.5. Monograph on *Paullinae semen* and supporting documents - Postponed

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### 2.4.6. Monograph on *Tiliae flos* and supporting documents - Postponed

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## **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**

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 Assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007)**

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**Action:** For adoption

Document tabled: Concept paper on the revision of the guideline

#### **4.2. Quality**

None

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

##### **4.3.1. Procedure for the review and revision of EU herbal monographs and EU list entries**

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**Action:** For discussion

Document tabled: Draft revised procedure (Rev. 3), Draft revised template

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

##### **4.4.1. Quality DG**

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None

##### **4.4.2. ORGAM DG**

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None

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

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Report: HMPC Chair, Nicoleta Carmen Purdel; Expert: Kristine Hvolby

**Action:** For information

Document tabled: Ad-hoc Quality Group Minutes June 2022

## 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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- French Presidency HMPC SRLM follow up plan - status July 2022  
Report: HMPC Vice Chair  
**Action:** For information  
Document tabled: Follow up plan
- Czech Presidency meeting – 10-11 November 2022 (Hosted by Malta)  
Report: Marketa Prihodova, Everaldo Attard  
**Action:** For information

#### 5.1.2. HMPC membership

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Membership update

Report: HMPC Chair

**Action:** For information

#### 5.1.3. EMA records management system – update on Sharepoint migration

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**Action:** For discussion

Document tabled: Presentation

#### 5.1.4. Hybrid meetings Q3-Q4 2022

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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

Documents tabled: Agenda 27 June 2022



#### 5.2.2. [Coordination with QRD and CMDh – Update on Herbal specifics for QRD template \(CMDh/349/2016, Rev.0 - EMA/HMPC/770889/2014\)](#)

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**Action:** For adoption

Documents tabled: Addendum to the QRD templates, Readers Guidance

#### 5.2.3. [Coordination with CMDh - List of estragole-containing plants](#)

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**Action:** For discussion

Documents tabled: List of potential plants containing estragole with a HMPC monograph

#### 5.2.4. [Outcome PSUSA/00010707/202110 soybean phospholipids \(oral use\)](#)

---

**Action:** For discussion

Documents tabled: [Report from the CMDh meeting held on 21-22 June 2022](#)

### 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, Bruno Spieldenner

**Action:** For information

Document tabled: SoD

- EDQM TCM expert group meeting  
Report: Melanie Bald, Bruno Spieldenner

**Action:** For information

Document tabled: SoD

#### 5.4.2. [Coordination with the European Commission](#)

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Collaboration with EC on the feasibility to establish an EU herbal monograph for Cannabis flos

Report: HMPC Chair

**Action:** For discussion

Documents tabled: Draft Questions & Answers

See also: 7.2.4.

## **5.5. Cooperation with International Regulators**

### **5.5.1. India – EC/EMA Joint Technical Working Group Ayurveda**

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Report: HMPC Chair

**Action:** For information

## **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 18 May 2022**

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Post-hearing discussion / follow-up

Report: HMPC Chair

**Action:** For adoption

Documents tabled: Report on the AESGP hearing at HMPC meeting, May 2022

## **5.7. Work plan and related activities**

### **5.7.1. HMPC work plan 2022**

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Report: HMPC Chair

**Action:** For information

Document tabled: HMPC Work plan, Annex 1, Annex 2 – status July 2022

### **5.7.2. Evaluation of data from paediatric clinical practice for the safe use of herbal substances in children - Postponed**

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Report: Miroslava Petriková; Experts: Peter Voitl, Jacqueline Wiesner, Peter Šišovský, Maria Helena Pinto Ferreira

## **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 Hyperici herba and supporting documents

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**Action:** For 11<sup>th</sup> discussion

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

### 6.2. Revision of EU herbal monographs and list entries in preparation for public consultation

#### 6.2.1. Monograph on Hippocastani cortex and supporting documents

---

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

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

#### 6.2.2. Monograph on Lavandulae aetheroleum and supporting documents

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

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

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

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

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

#### 6.2.4. Monograph on Plantaginis lanceolatae folium and supporting documents - Postponed

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

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

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

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

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

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

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

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

Document 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 Agrimoniae herba and supporting documents**

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

Document tabled: Review report

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

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

Document tabled: Review report, Reader's Guidance, Reference

#### **6.3.3. Monograph on Eschscholziae herba and supporting documents**

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

Document tabled: Review report

#### **6.3.4. Monograph on Sisymbrii officinalis herba and supporting documents**

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

Document tabled: Review report

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

#### **6.4.1. Monograph on Vaccinii macrocarpi fructus and supporting documents**

---

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

Documents tabled: OoC, Reader's Guidance

### **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 - Postponed**

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#### **6.5.2. Monograph on Cnici benedicti herba and supporting documents**

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

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

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

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

Documents tabled: Presentation

## **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 16-18 May 2022

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)**

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None

#### **7.2.3. EU herbal monographs, list entries and public statements – on hold**

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None

#### **7.2.4. Other**

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- EDQM certification of suitability (CEP) procedure – actions taken on CEP/CEP applications
- [Cannabidiol novel food evaluations on hold pending new data](#)
- DRAFT Agenda - PCWP and HCPWP meeting - 22 September 2022
- Meeting minutes - PCWP and HCPWP meeting – 1-2 June 2022