



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 November 2021  
EMA/HMPC/692111/2021  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Draft Agenda for the meeting on 22-24 November 2021

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

22 November 2021, 10:00 – 17:00, virtual meeting

23 November 2021, 09:00 – 17:00, virtual meeting

24 November 2021, 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.

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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/127362/2006).

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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 22-24 November 2021. See November 2021 HMPC minutes (to be published post January 2022 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 22-24 November 2021.

### 1.3. Adoption of the minutes

HMPC minutes for 20-22 September 2021.

## 2. EU herbal monographs and list entries for adoption

### 2.1. Status of HMPC/MLWP activities

#### 2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in November 2021

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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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##### **New Rapporteur-New Peer Reviewer**

Unscheduled reviews to start in 2021

- Aloes folii succus siccatus
- Frangulae cortex
- Rhamni purshianae cortex
- Rhei radix
- Sennae folium
- Sennae fructus

##### **Change of rapporteurship:**

Revision (started in 2020)

- Pelargonii radix

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

### **2.2.1. Monograph on *Trigonellae foenugraeci semen* and supporting documents**

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**Action:** For adoption

Documents tabled: MO, AR, LoR; References: 67/130

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

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

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance; References: 20/66

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

### **2.4.1. Monograph on *Arnicae flos* and supporting documents - Postponed**

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### **2.4.2. Monograph on *Cucurbitae semen* and supporting documents**

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**Action:** For adoption

Document tabled: Review report; References 06/06

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

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**Action:** For adoption

Document tabled: Review report; References 07/07

### **2.4.4. Monograph on *Hippocastani cortex* and supporting documents**

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**Action:** For adoption

Document tabled: Review report; References 15/12

### **2.4.5. Monograph on *Levistici radix* and supporting documents**

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**Action:** For adoption

Document tabled: Review report; References 09/11

### **2.4.6. Monograph on *Lichen islandicus* and supporting documents**

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**Action:** For adoption

Document tabled: Review report, Reference for discussion; References 17/16

#### 2.4.7. Monograph on *Urticae folium* and supporting documents

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**Action:** For adoption

Document tabled: Review report; References 04/04

#### 2.4.8. Monograph on *Urticae herba* and supporting documents

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**Action:** For adoption

Document tabled: Review report; References 05/05

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

---

**Action:** For adoption

Documents tabled: Review report, Readers Guidance; References: 10/10

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

#### 2.5.1. Public statement on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

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**Action:** For adoption

Documents tabled: PS, AR, LoR; References: 04/214

#### 2.5.2. Public statement on *Salviae mitiorrhizae radix et rhizoma* and supporting documents

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**Action:** For adoption

Documents tabled: PS, AR, LoR; References:00/90

#### 2.5.3. Monograph on *Taraxaci officinalis radix* and supporting documents

---

**Action:** For adoption

Documents tabled: MO, AR, LoR; References: 78/84

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

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

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance, Comments from Peer Review; References: 03/66

### 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. Public statement on the use of herbal medicinal products containing estragole

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**Action:** for discussion

Documents tabled: Final revised PS, OoC, Question to SWP, Response from SWP, CMDh feedback

##### 4.1.2. Guideline on Assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007)

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**Action:** For discussion

Document tabled: Email communication

#### 4.2. Quality

##### 4.2.1. Nitrosamines and Herbal MPs

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##### 4.2.2. Guideline on Good Agricultural and Collection Practice (GACP) of starting materials of herbal origin

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**Action:** For adoption

Document tabled: Concept paper on the revision, comments from SE

##### 4.2.3. Q&A on Elemental impurities - evaluation in herbal medicinal products

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Draft Q&A on Elemental impurities for addition to [Herbal Quality Q&A](#)

#### 4.3. Regulatory / Procedural

None

#### 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

## 5. Organisational, regulatory and methodological matters

### 5.1. Mandate and organisation of the HMPC

#### 5.1.1. Strategic Review and Learning Meetings

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- Slovenian Presidency virtual meeting – 08-09 December 2021

**Action:** For information

Document tabled: Draft agenda

- Czech Republic Presidency meeting 2022 - cancelled

**Action:** For information

Document tabled: Email correspondence

#### 5.1.2. HMPC membership

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Report: HMPC Chair

**Action:** For information

### 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: Minutes 03 September 2021, Minutes 18 October 2021, Agenda 03 December 2021, email communication

#### 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 discussion

Documents tabled: Discussion paper, Email communication

### 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

None

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

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

**Action:** For discussion

Documents tabled: Terms of references, Presentation

#### 5.5.2. IRCH – WHO 13th annual virtual meeting

Report: HMPC Chair

**Action:** For information

Documents tabled: Communication EMA/HMPC representation, Draft Agenda

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

None

### 5.7. **Work plan**

#### 5.7.1. HMPC work plan 2021

Report: HMPC Chair, HMPC Vice Chair

**Action:** For discussion

Documents tabled: Work plan 2021, Annex 1, Annex 2

- Update the HMPC Review and Revision Best Practice Guides, HMPC Assessment Report and Review Report templates (Annex 2, 2-3)

Report: Nicoleta Carmen Purdel

- Working methodology adaptations for herbal MO and GL establishment and maintenance (1-3-1)  
Report: HMPC Chair
- PhV data and experiences in national assessments (1-3-2)  
Report: HMPC Vice Chair
- Use of real-world data and requirements for the safe use of herbal substances in children (1-3-3)  
Report: Maria Helena Pinto Ferreira
- Forward planning and prioritisation (1-3-4)  
Report: HMPC Chair

#### 5.7.2. Preparation of HMPC work plan 2022

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Report: HMPC Chair

**Action:** For discussion

Documents tabled: Draft Work plan 2022, Draft Annex 1, Draft Annex 2

#### 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 *Agropyri repentis rhizoma* and supporting documents

---

**Action:** For discussion

Documents tabled: Draft MO, AR, LoR; References: 77/84

##### 6.1.2. Monograph on *Hyperici herba* and supporting documents

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**Action:** For discussion

Documents tabled: Draft MO, AR, LoR, OoC, Reader's Guidance; References: 238/823

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

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

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**Action:** For discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance; References: 47/69

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

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**Action:** For discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance; References: 83/126

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

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### 6.2.4. Monograph on *Rosmarini aetheroleum* and supporting documents

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**Action:** For discussion

Documents tabled: Draft MO, AR; References: 11/00

### 6.2.5. Monograph on *Rosmarini folium* and supporting documents

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**Action:** For discussion

Documents tabled: Draft MO, AR; References: 11/00

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

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

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**Action:** For discussion

Document tabled: Presentation; References 01/04

### 6.3.2. Monograph on *Cichorii intybi radix* and supporting documents

---

**Action:** For discussion

Document tabled: Review report; References 00/00

### 6.3.3. Monograph on *Eucalypti aetheroleum* and supporting documents

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**Action:** For discussion

Document tabled: Review report; References 00/19

#### 6.3.4. Monograph on Eucalypti folium and supporting documents

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**Action:** For discussion

Document tabled: Review report; References 00/06

#### 6.3.5. Monograph on Fraxini folium and supporting documents

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**Action:** For discussion

Document tabled: Review report; References 08/04

#### 6.3.6. Monograph on Fucus vesiculosus and supporting documents

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**Action:** For discussion

Documents tabled: Review report, Presentation; References 00/00

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

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**Action:** For discussion

Document tabled: Readers Guidance; References 00/00

#### 6.3.8. Monograph on Juglandis folium and supporting documents

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**Action:** For discussion

Document tabled: Review report; References 00/00

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

---

**Action:** For discussion

Document tabled: Review report; References 00/64

#### 6.3.10. Monograph on Marrubii herba and supporting documents

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**Action:** For discussion

Document tabled: Review report; References 00/02

#### 6.3.11. Monograph on Origani dictamni herba and supporting documents

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**Action:** For discussion

Document tabled: Review report, Presentation; References 00/10

#### 6.3.12. Monograph on Paullinae semen and supporting documents

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**Action:** For discussion

Document tabled: Review report; References 00/17

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

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**Action:** For discussion

Document tabled: Review report, Readers Guidance; References 13/14

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

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### 6.3.15. Monograph on *Urticae radix* and supporting documents

---

**Action:** For discussion

Document tabled: Review report; References 04/04

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

### 6.4.1. Monograph on *Species digestivae* and supporting documents

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**Action:** For discussion

Documents tabled: Draft MO, AR, LoR; References: 42/42

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

---

**Action:** For discussion

Documents tabled: Readers Guidance, OoC; References: 197/00

## 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 discussion

Documents tabled: Presentation; References: 07/00

## 7. Any other business

### 7.1. Topics for discussion

#### 7.1.1. Working methodology of monograph establishment

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**Action:** For discussion

Document tabled: Presentation

7.1.2. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs - post finalisation

---

**Action:** For discussion

Document tabled: PS, email communication from AT

## 7.2. Documents for information

### 7.2.1. HMPC

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Table of Decisions from HMPC meeting held on 20-22 September 2021

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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- Meeting Summary PCWP-HCPWP joint meeting on 21 and 22 September 2021
- Agenda Meeting with civil society representatives in EMA scientific committees 01 October 2021
- Draft Agenda - Annual PCWP-HCPWP joint meeting with all Eligible Organisations on 24 November 2021