



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 September 2021  
EMA/HMPC/519371/2021  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 20-22 September 2021

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

20 September 2021, 10:00 – 17:00, virtual meeting

21 September 2021, 09:00 – 17:00, virtual meeting

22 September 2021, 09:00 – 16:00, virtual meeting

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Of note, this agenda is a working document primarily designed for HMPC members and the work the Committee undertakes.

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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 20-22 September 2021. See September 2021 HMPC minutes (to be published post November 2021 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 20-22 September 2021.

### 1.3. Adoption of the minutes

HMPC minutes for 05-07 July 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 September 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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None

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

#### 2.2.1. Monograph on *Orthosiphonis folium* and supporting documents

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**Action:** For adoption

Documents tabled: MO, AR, LoR, OoC; References: 37/46

### 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 *Solidaginis virgaureae herba* and supporting documents**

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**Action:** For adoption

Document tabled: Review report; References 04/04

### **2.4.2. Monograph on *Urticae folium* and supporting documents - postponed**

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### **2.4.3. Monograph on *Urticae herba* and supporting documents - postponed**

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

### **2.5.1. Public statement on *Salviae mitiorrhizae radix et rhizoma* and supporting documents - postponed**

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

### **2.6.1. Monograph on *Centellae asiaticae herba* and supporting documents**

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**Action:** For adoption

Documents tabled: MO, AR, LoR; References: 13/142

### **2.6.2. Monograph on *Cisti cretici herba* and supporting documents - postponed**

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## **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 adoption

Documents tabled: Final revised PS, OoC, Questions to SWP, Response from SWP, Comments regarding SWP remarks

### 4.2. Quality

#### 4.2.1. Guideline on quality of herbal medicinal products/traditional herbal medicinal products

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**Action:** For adoption

Documents tabled: Revised Guideline, OoC

#### 4.2.2. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products

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**Action:** For adoption

Documents tabled: Revised Guideline, OoC

#### 4.2.3. Nitrosamines and Herbal MPs

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Report: HMPC Chair

**Action:** For adoption

Documents tabled: CMDh practical guidance for Marketing Authorisation Holders, [Questions and answers for marketing authorisation holders/applicants](#)

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

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**Action:** For discussion

Document tabled: Concept paper on the revision of GACP GL 2021

### 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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Slovenia Presidency virtual meeting – 08-09 December 2021

**Action:** for discussion

Document tabled: Draft agenda

#### 5.1.2. HMPC membership

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Report: HMPC Chair

**Action:** For information

#### 5.1.3. Pilot – Relaunch of face to face Scientific Committee Meetings

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**Action:** For discussion

Document tabled: Presentation

#### 5.1.4. HMPC Rules of procedure - revision

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**Action:** For adoption

Document tabled: HMPC Rules of Procedure

### 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 29 June 2021, Agenda 03 September 2021

### 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 expert group meetings



**Action:** For information

#### 5.4.2. Coordination with the European Commission

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Cannabis for medicinal use

Report: HMPC Chair

**Action:** For adoption

### 5.5. Cooperation with International Regulators

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

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**Action:** For discussion

Documents tabled: Agreed ToR, Presentation

### 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) proposal on combinations of traditionally used herbal extracts based on monographs

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Report: HMPC Chair

**Action:** For discussion

### 5.7. Work plan

#### 5.7.1. HMPC work plan 2021

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Report: HMPC Chair, HMPC Vice Chair

**Action:** For information

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

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

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Report: Carmen Purdel

**Action:** For discussion

Documents tabled: Presentation, Report template

#### 5.7.3. Working methodology adaptations for herbal MO and GL establishment and maintenance (1-3-1)

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Report: HMPC Chair

**Action:** For discussion

#### 5.7.4. PhV data and experiences in national assessments (1-3-2)

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Report: HMPC Vice Chair

**Action:** For discussion

#### 5.7.5. Use of real-world data and requirements for the safe use of herbal substances in children (1-3-3)

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Report: Maria Helena Pinto Ferreira

**Action:** For discussion

Document tabled: Presentation

#### 5.7.6. Forward planning and prioritisation (1-3-4)

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Report: HMPC Chair, HMPC Vice Chair

**Action:** For discussion

#### 5.7.7. Training on assessment of applications for herbal medicinal products (2-1-2)

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Report: HMPC Vice Chair

**Action:** For discussion

Documents tabled: Presentation

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

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Report: HMPC Chair

**Action:** For discussion

Documents tabled: Template, HMPC 2021 WP report

### 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 *Trigonellae foenugraeci semen* and supporting documents

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**Action:** For discussion

Documents tabled: Draft MO, AR, LoR; References: 68/128

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

### **6.2.1. Monograph on *Foeniculi amari fructus* and supporting documents**

---

**Action:** For discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance, Comments from PL; References: 136/199

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

---

**Action:** For discussion

Documents tabled: Draft PS, AR, LoR, Reader's Guidance, Comments from PL; References: 136/199

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

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**Action:** For discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance, Comments from PL; References: 136/199

### **6.2.4. 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

### **6.2.5. Monograph on *Lavandulae aetheroleum* and supporting documents - postponed**

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

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**Action:** For discussion

Document tabled: Draft MO; References: 11/00

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

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**Action:** For discussion

Document tabled: Draft MO; References: 11/00

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

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**Action:** for discussion

Documents: Readers Guidance; References: 00/00

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

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

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**Action:** For discussion

Document tabled: Review report; References 04/04

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

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**Action:** For discussion

Document tabled: Presentation; References 00/00

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

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**Action:** For discussion

Document tabled: Review report; References 06/06

#### **6.3.4. Monograph on Eucalypti aetheroleum and supporting documents - postponed**

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#### **6.3.5. Monograph on Eucalypti folium and supporting documents - postponed**

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

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**Action:** For discussion

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

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

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**Action:** For discussion

Documents tabled: Review report, Readers Guidance; References 14/15

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

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**Action:** For discussion

Document tabled: Presentation; References 00/00

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

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**Action:** For discussion

Document tabled: Review report; References 09/12

#### 6.3.10. Monograph on Lichen islandicus and supporting documents

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**Action:** For discussion

Document tabled: Review report; References 16/16

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

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**Action:** For discussion

Document tabled: Review report; References 00/02

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

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**Action:** For discussion

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

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

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

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**Action:** For discussion

Documents tabled: Draft PS, AR, LoR; References: 02/214

#### 6.4.2. Monograph on Taraxaci officinalis radix and supporting documents

---

**Action:** For discussion

Documents tabled: Draft MO, AR, LoR; References: 78/85

#### 6.4.3. Monograph on Vaccinii macrocarpi fructus and supporting documents - postponed

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

#### 6.5.1. Monograph on Cnici benedicti herba and supporting documents

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**Action:** For discussion

Document tabled: Presentation; References: 07/04

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

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**Action:** For discussion

Document 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. Changes to the Meeting Report format

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**Action:** For discussion

Document tabled: Presentation

### 7.2. Documents for information

#### 7.2.1. HMPC

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Table of Decisions from HMPC meeting held on 05-07 July 2021

Overview of expertise of members HMPC and subgroups

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

[Abbreviations in HMPC agendas/minutes](#)

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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#### 7.2.3. EU herbal monographs, list entries and public statements

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None

#### 7.2.4. Other

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- Baden-Württemberg BPI programme - Panel discussion on the regulation on health claims
- Draft Agenda for the PCWP/HCPWP Joint meeting on the 21-22 September 2021
- Meeting Summary PCWP-HCPWP meeting 1-2 June 2021
- CxMP/EMA external representation: Revision of user manual: EMA/462963/2016; Template Request for meeting outside EMA premises: EMA/382651/2017