



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

18 September 2020  
EMA/HMPC/459014/2020  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Draft Agenda for the meeting on 21-23 September 2020

Chair: E. van Galen, Vice-Chair: E. Svedlund

21 September 2020, 10:00 – 17:00, virtual meeting

22 September 2020, 09:00 – 17:00, virtual meeting

23 September 2020, 09:00 – 16:00, 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 set 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 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).

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



## Table of contents

<b>1.</b>	<b>Introduction</b>	<b>5</b>
1.1.	Welcome and declarations of interest of members, alternates and experts	5
1.2.	Adoption of agenda	5
1.3.	Adoption of the minutes	5
<b>2.</b>	<b>EU herbal monographs and list entries for adoption</b>	<b>5</b>
2.1.	Status of HMPC/MLWP activities	5
2.1.1.	Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in September 2020	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers	6
2.2.	Revised EU herbal monographs and list entries for final adoption	6
2.2.1.	Monograph on Millefolii herba and supporting documents	6
2.3.	Revised EU herbal monographs and list entries for public consultation	6
2.4.	Reviewed EU herbal monographs and list entries for decision on revision	6
2.4.1.	Monograph on Juniperi aetheroleum and supporting documents	6
2.4.2.	Monograph on Juniperi pseudo-fructus and supporting documents	6
2.5.	EU herbal monographs, list entries and public statements for final adoption	6
2.6.	EU herbal monographs, list entries and public statements for adoption for release for public consultation	7
2.6.1.	Monograph on Menyanthes trifoliata folium and supporting documents	7
2.6.2.	Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents	7
2.7.	EU herbal monographs, list entries and public statements - post finalisation	7
<b>3.</b>	<b>Referral procedures</b>	<b>7</b>
<b>4.</b>	<b>Guidelines and guidance documents</b>	<b>7</b>
4.1.	Non-clinical/clinical safety and efficacy and multidisciplinary	7
4.1.1.	Public statement on the use of herbal medicinal products containing estragole	7
4.2.	Quality	7
4.2.1.	Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)	7
4.2.2.	Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3) - postponed	7
4.3.	Regulatory / Procedural	7
4.4.	Report on HMPC Drafting Groups activities	8
4.4.1.	Quality DG	8
4.4.2.	ORGAM DG	8
<b>5.</b>	<b>Organisational, regulatory and methodological matters</b>	<b>8</b>
5.1.	Mandate and organisation of the HMPC	8
5.1.1.	Strategic Review and Learning Meetings	8

5.1.2.	Election of Co-opted member (paediatrics) .....	8
5.1.3.	Preparation of election Co-opted members (Experimental/non-clinical pharmacology and General and family medicine) .....	8
5.1.4.	Proxy form for HMPC .....	8
5.1.5.	Organisation of November 2020 HMPC meeting .....	8
5.1.6.	HMPC meeting dates 2022-2024 .....	9
<b>5.2.</b>	<b>EMA Scientific Committees or CMDh-v .....</b>	<b>9</b>
5.2.1.	Scientific Coordination Board Meeting .....	9
5.2.2.	Coordination with PDCO and PRAC .....	9
<b>5.3.</b>	<b>Coordination with EMA Working Parties/Working Groups/Drafting Groups .....</b>	<b>9</b>
5.3.1.	Coordination with SAWP .....	9
<b>5.4.</b>	<b>Cooperation within the EU regulatory network .....</b>	<b>9</b>
5.4.1.	Coordination with European Pharmacopoeia .....	9
5.4.2.	Coordination with the European Commission .....	9
<b>5.5.</b>	<b>Cooperation with International Regulators .....</b>	<b>9</b>
<b>5.6.</b>	<b>Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee .....</b>	<b>9</b>
5.6.1.	Comments on use of HMPC Reflection Papers in National Procedures .....	9
<b>5.7.</b>	<b>Work plan .....</b>	<b>10</b>
5.7.1.	HMPC work plan 2020 .....	10
<b>5.8.</b>	<b>Planning and reporting .....</b>	<b>10</b>
<b>5.9.</b>	<b>Legislation and regulatory affairs .....</b>	<b>10</b>
<b>5.10.</b>	<b>Questions from members .....</b>	<b>10</b>
<b>6.</b>	<b>EU herbal monographs and list entries in preparation</b>	<b>10</b>
<b>6.1.</b>	<b>Revision of EU herbal monographs and list entries in preparation for adoption after public consultation .....</b>	<b>10</b>
6.1.1.	Monograph on Hyperici herba and supporting documents .....	10
<b>6.2.</b>	<b>Revision of EU herbal monographs and list entries in preparation for public consultation .....</b>	<b>11</b>
6.2.1.	Monograph on Orthosiphonis folium and supporting documents .....	11
6.2.2.	Monograph on Trigonellae foenugraeci semen and supporting documents .....	11
<b>6.3.</b>	<b>Review of EU herbal monographs and list entries in preparation for decision on revision .....</b>	<b>11</b>
6.3.1.	Monograph on Agropyri repentis rhizoma and supporting documents .....	11
6.3.2.	Monograph on Carvi aetheroleum and supporting documents .....	11
6.3.3.	Monograph on Carvi fructus and supporting documents .....	11
6.3.4.	Monograph on Caryophylli floris aetheroleum and supporting documents .....	11
6.3.5.	Monograph on Chamomillae romanae flos and supporting documents .....	11
6.3.6.	Monograph on Cinnamomi corticis aetheroleum and supporting documents – postponed ..	11
6.3.7.	Monograph on Cinnamomi cortex and supporting documents – postponed .....	11

6.3.8.	Monograph on Colae semen and supporting documents .....	12
6.3.9.	Monograph on Fucus vesiculosus and supporting documents – postponed .....	12
6.3.10.	Monograph on Fumariae herba and supporting documents – postponed .....	12
6.3.11.	Monograph on Lavandulae aetheroleum and supporting documents .....	12
6.3.12.	Monograph on Lavandulae flos and supporting documents .....	12
6.3.13.	Monograph on Mate folium and supporting documents .....	12
6.3.14.	Monograph on Plantaginis lanceolatae folium and supporting documents – postponed .....	12
6.3.15.	Monograph on Rosmarini aetheroleum and supporting documents – postponed .....	12
6.3.16.	Monograph on Rosmarini folium and supporting documents – postponed .....	12
6.3.17.	Monograph on Solani dulcamarae stipites and supporting documents .....	12
6.3.18.	Monograph on Solidaginis virgaureae herba and supporting documents – postponed .....	12
6.3.19.	Monograph on Urticae folium and supporting documents .....	12
6.3.20.	Monograph on Urticae herba and supporting documents .....	13
6.3.21.	Monograph on Viola tricoloris herba and supporting documents .....	13
<b>6.4.</b>	<b>EU herbal monographs and list entries in preparation for adoption after public consultation .....</b>	<b>13</b>
6.4.1.	Monograph on Aloysiae citriodora folium and supporting documents – postponed .....	13
6.4.2.	Monograph on Species amarae and supporting documents .....	13
6.4.3.	Monograph on Species sedativae and supporting documents .....	13
<b>6.5.</b>	<b>EU herbal monographs and list entries in preparation for adoption for release for public consultation .....</b>	<b>13</b>
6.5.1.	Monograph on Andrographidis paniculatae folium and supporting documents – postponed .....	13
6.5.2.	Monograph on Centellae asiaticae herba and supporting documents .....	13
6.5.3.	Monograph on Salviae miltiorrhizae radix et rhizoma and supporting documents .....	13
6.5.4.	Monograph on Species digestivae or species stomachicae and supporting documents – postponed .....	13
6.5.5.	Monograph on Taraxaci officinalis radix and supporting documents .....	14
6.5.6.	Monograph on Vaccinii macrocarpi fructus and supporting documents .....	14
6.5.7.	Monograph on Hyperici herba and supporting documents .....	14
6.5.8.	Monograph on Cisti cretici folium and supporting documents - postponed .....	14
<b>7.</b>	<b>Any other business</b>	<b>14</b>
<b>7.1.</b>	<b>Topics for discussion .....</b>	<b>14</b>
<b>7.2.</b>	<b>Documents for information .....</b>	<b>14</b>
7.2.1.	HMPC .....	14
7.2.2.	ARSP .....	14
7.2.3.	EU herbal monographs, list entries and public statements – on hold .....	14
7.2.4.	Other .....	15

## 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 21-23 September 2020. See September 2020 HMPC minutes (to be published post November 2020 HMPC meeting).

New membership:

- Italy, Alessandro Assisi (member) as of 13 August 2020
- Greece, Stavroula Mamoucha (alternate) as of 6 September 2020
- Finland, Maria Paile Hyvarinen (member) as of 17 September 2020

End of membership:

- France, Michele Brum (alternate) as of 13 July 2020
- Ireland, Sheena Kennedy (member) as of 21 July 2020
- Denmark, Karoline Holm Felding (alternate) as of 7 August 2020
- Greece, Zoi Karampourpouni (alternate) as of 5 September 2020
- Luxembourg, Marcel Bruch (member) as of 10 September 2020
- Finland, Eeva Sofia Leinonen (member) as of 16 September 2020

### 1.2. Adoption of agenda

HMPC agenda for 21-23 September 2020.

Time schedule for 21-23 September 2020.

### 1.3. Adoption of the minutes

HMPC minutes for 6-8 July 2020.

## 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 2020

---

Report: HMPC Chair

**Action:** for discussion

Document: Overview

## 2.1.2. Appointment of Rapporteurs and Peer-reviewers

---

### **New assessments**

Centellae asiaticae herba - New Peer Reviewer: TBC

Cisti cretici folium - New Rapporteur: TBC

Menyanthes trifoliata folium - New Peer Reviewer: TBC

### **Reviews**

Absinthi herba - New Peer Reviewer: TBC

Cinnamomi corticis aetheroleum - New Peer Reviewer: TBC

Cinnamomi cortex - New Peer Reviewer: TBC

Colae semen - New Peer Reviewer: TBC

Fumariae herba - New Rapporteur: TBC

Plantaginis lanceolatae folium - New Peer Reviewer: TBC

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

### 2.2.1. Monograph on Millefolii herba and supporting documents

---

**Action:** for adoption

Documents: MO, LE, AR, LoR, Reader's guidance; References: 81/94

## 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 Juniperi aetheroleum and supporting documents

---

**Action:** for adoption

Documents: Review report, Reader's guidance; References: 9/0

### 2.4.2. Monograph on Juniperi pseudo-fructus and supporting documents

---

**Action:** for adoption

Documents: Review report, Reader's guidance; References: 10/2

## 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

### 2.6.1. Monograph on *Menyanthes trifoliata* folium and supporting documents

---

**Action:** for adoption

Documents: MO, AR, LoR; References: 77/73

### 2.6.2. Monograph on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

---

**Action:** for discussion

Documents: Draft PS, AR, LoR; References: 2/214

## 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

---

**Action:** for discussion

Documents: [Draft revised PS](#), OoC

### 4.2. Quality

#### 4.2.1. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)

---

**Action:** for information

Documents: Draft 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 (EMA/HMPC/162241/2005 Rev. 3) - postponed

---

### 4.3. Regulatory / Procedural

None

## 4.4. Report on HMPC Drafting Groups activities

### 4.4.1. Quality DG

---

None

### 4.4.2. ORGAM DG

---

None

## 5. Organisational, regulatory and methodological matters

### 5.1. Mandate and organisation of the HMPC

#### 5.1.1. Strategic Review and Learning Meetings

---

Germany Presidency meeting – September 2020

**Action:** for information

Documents: Final agenda, presentations

#### 5.1.2. Election of Co-opted member (paediatrics)

---

Report: HMPC Chair

**Action:** for adoption

Documents: Call for nominations , [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members

#### 5.1.3. Preparation of election Co-opted members (Experimental/non-clinical pharmacology and General and family medicine)

---

Report: HMPC Chair

**Action:** for discussion

Documents: [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members

#### 5.1.4. Proxy form for HMPC

---

**Action:** for information

Documents: Template, presentation, [HMPC rules of procedure](#)

#### 5.1.5. Organisation of November 2020 HMPC meeting

---

**Action:** for information

Document: [Information from EMA website](#)



#### 5.1.6. HMPC meeting dates 2022-2024

---

**Action:** for information  
Document: Meeting dates

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

#### 5.2.1. Scientific Coordination Board Meeting

---

None

#### 5.2.2. Coordination with PDCO and PRAC

---

- PDCO response to HMPC on Hedera Helix  
**Action:** for discussion

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

#### 5.3.1. Coordination with SAWP

---

- Scientific Advice and Protocol Assistance  
**Action:** for information  
Document: Email correspondence

### 5.4. Cooperation within the EU regulatory network

#### 5.4.1. Coordination with European Pharmacopoeia

---

None

#### 5.4.2. Coordination with the European Commission

---

- Cannabis for medicinal use  
Report: HMPC Chair  
**Action:** for discussion  
Document:

### 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. Comments on use of HMPC Reflection Papers in National Procedures

---

Report: HMPC Chair

**Action:** for adoption

Documents: BPI request , Draft HMPC response

## 5.7. Work plan

### 5.7.1. HMPC work plan 2020

---

Report: HMPC Chair, HMPC Vice Chair

**Action:** for discussion

Document: Work plan 2020, Annex 1, Annex 2 – current status September 2020

- Activity area 1-3-1: Implementation of a modified procedure for EU herbal monograph establishment and maintenance  
Report: HMPC Vice Chair, HMPC Chair  
**Action:** for discussion  
Document: Reader's Guidance template
- Activity area 1-3-2: Forward planning and prioritisation  
Report: HMPC Vice Chair, HMPC Chair  
**Action:** for discussion  
Document: Presentation
- Activity area 2-2-1: Development of training on assessment of applications for herbal medicinal products  
Report: HMPC Vice Chair  
**Action:** for discussion  
Document: Presentation

## 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

---

**Action:** for discussion (see also 6.5.7)

Documents: MO-TU, AR, LoR, OoC, Reader's guidance; References: 03/822

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

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

---

**Action:** for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 0/55

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

---

**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 5/99

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

### 6.3.1. Monograph on *Agropyri repentis rhizoma* and supporting documents

---

**Action:** for discussion

Documents: Review report; References: 67/2

### 6.3.2. Monograph on *Carvi aetheroleum* and supporting documents

---

**Action:** for discussion

Documents: Review report, Reader's guidance; References: 17/17

### 6.3.3. Monograph on *Carvi fructus* and supporting documents

---

**Action:** for discussion

Documents: Review report, Reader's guidance; References: 17/17

### 6.3.4. Monograph on *Caryophyllii floris aetheroleum* and supporting documents

---

**Action:** for discussion

Documents: Review report; References: 5/5

### 6.3.5. Monograph on *Chamomillae romanae flos* and supporting documents

---

**Action:** for discussion

Documents: Review report; References: 31/21

### 6.3.6. Monograph on *Cinnamomi corticis aetheroleum* and supporting documents – postponed

---

### 6.3.7. Monograph on *Cinnamomi cortex* and supporting documents – postponed

---

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

---

**Action:** for discussion

Documents: Review report; References: 53/53

#### 6.3.9. Monograph on Fucus vesiculosus and supporting documents – postponed

---

#### 6.3.10. Monograph on Fumariae herba and supporting documents – postponed

---

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

---

**Action:** for discussion

Documents: Review report, Readers guidance; References: 43/197

#### 6.3.12. Monograph on Lavandulae flos and supporting documents

---

**Action:** for discussion

Documents: Review report; References: 0/0

#### 6.3.13. Monograph on Mate folium and supporting documents

---

**Action:** for discussion

Document: Presentation; References: 0/0

#### 6.3.14. Monograph on Plantaginis lanceolatae folium and supporting documents – postponed

---

#### 6.3.15. Monograph on Rosmarini aetheroleum and supporting documents – postponed

---

#### 6.3.16. Monograph on Rosmarini folium and supporting documents – postponed

---

#### 6.3.17. Monograph on Solani dulcamarae stipites and supporting documents

---

**Action:** for discussion

Documents: Review report; References: 0/0

#### 6.3.18. Monograph on Solidaginis virgaureae herba and supporting documents – postponed

---

#### 6.3.19. Monograph on Urticae folium and supporting documents

---

**Action:** for discussion

Documents: Review report; References: 28/28

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

**Action:** for discussion

Documents: Review report; References: 28/28

#### 6.3.21. Monograph on *Violae tricoloris herba* and supporting documents

**Action:** for discussion

Documents: Review report; References: 0/29

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

#### 6.4.1. Monograph on *Aloysiae citriodoraefolium* and supporting documents – postponed

#### 6.4.2. Monograph on *Species amarae* and supporting documents

**Action:** for discussion

Documents: Draft MO, AR, LoR, OoC; References: 10/21

#### 6.4.3. Monograph on *Species sedativae* and supporting documents

**Action:** for discussion

Documents: Draft MO, AR, LoR, OoC; References: 35/23

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

#### 6.5.1. Monograph on *Andrographidis paniculataefolium* and supporting documents – postponed

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

**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 0/216

#### 6.5.3. Monograph on *Salviae miltiorrhizae radix et rhizoma* and supporting documents

**Action:** for discussion

Documents: Draft PS, AR, LoR; References: 0/90

#### 6.5.4. Monograph on *Species digestivae* or *species stomachicae* and supporting documents – postponed

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

---

**Action:** for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 0/99

#### 6.5.6. Monograph on Vaccinii macrocarpi fructus and supporting documents

---

**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 459/260

#### 6.5.7. Monograph on Hyperici herba and supporting documents

---

**Action:** for discussion (see also 6.1.1)

Documents: Draft MO-WEU, comments from FI

#### 6.5.8. Monograph on Cisti cretici folium and supporting documents - postponed

---

## 7. Any other business

### 7.1. Topics for discussion

None

### 7.2. Documents for information

#### 7.2.1. HMPC

---

Table of Decisions from HMPC meeting held on 6-8 July 2020

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

#### 7.2.2. ARSP

---

- English template
- English summaries for publication
  - Herniariae herba
  - Thymi aetheroleum
  - Tanacetii parthenii herba

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

---

None

#### 7.2.4. Other

---

- Meeting report PCWP HCPWP meeting 2 June
- Meeting report PCWP HCPWP meeting (ICH) 3 June
- Meeting report PCWP HCPWP meeting (PhV) 24 June
- Draft Agenda Workshop on the application of the General Data Protection Regulation (GDPR) in the area of health and Secondary Use of Data for Medicines and Public Health Purposes - 23/09/2020
- Draft Agenda Workshop on benefit-risk of medicines used during pregnancy and breastfeeding - 22/09/2020
- Nitrosamines Impurities in medicinal products - CHMP outcome