



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 January 2022  
EMA/HMPC/32469/2022  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 24-26 January 2022

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

24 January 2022, 10:00 – 17:00, virtual meeting

25 January 2022, 09:00 – 17:00, virtual meeting

26 January 2022, 09:00 – 16:00, virtual 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 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>
<b>2.1.</b>	<b>Status of HMPC/MLWP activities .....</b>	<b>5</b>
2.1.1.	Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in November 2021 .....	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers .....	5
2.1.3.	New substances for assessment .....	6
<b>2.2.</b>	<b>Revised EU herbal monographs and list entries for final adoption .....</b>	<b>6</b>
2.2.1.	Monograph on Agropyri repentis rhizoma and supporting documents .....	6
<b>2.3.</b>	<b>Revised EU herbal monographs and list entries for public consultation .....</b>	<b>6</b>
2.3.1.	Monograph on Fumariae herba and supporting documents.....	6
2.3.2.	Monograph on Juniperi pseudo-fructus and supporting documents.....	7
<b>2.4.</b>	<b>Reviewed EU herbal monographs and list entries for decision on revision.....</b>	<b>7</b>
2.4.1.	Monograph on Aloes folii succus siccatus and supporting documents .....	7
2.4.2.	Monograph on Arnicae flos and supporting documents - Postponed.....	7
2.4.3.	Monograph on Cichorii intybi radix and supporting documents.....	7
2.4.4.	Monograph on Eucalypti aetheroleum and supporting documents.....	7
2.4.5.	Monograph on Eucalypti folium and supporting documents .....	7
2.4.6.	Monograph on Fraxini folium and supporting documents.....	7
2.4.7.	Monograph on Fucus vesiculosus and supporting documents .....	7
2.4.8.	Monograph on Hippocastani cortex and supporting documents .....	7
2.4.9.	Monograph on Marrubii herba and supporting documents .....	8
2.4.10.	Monograph on Origani dictamni herba and supporting documents.....	8
2.4.11.	Monograph on Paullinae semen and supporting documents - Postponed.....	8
2.4.12.	Monograph on Rhodiolae roseae rhizoma et radix and supporting documents .....	8
2.4.13.	Monograph on Sennae folium and supporting documents.....	8
2.4.14.	Monograph on Sennae fructus and supporting documents.....	8
2.4.15.	Monograph on Urticae folium and supporting documents .....	8
<b>2.5.</b>	<b>EU herbal monographs, list entries and public statements for final adoption .....</b>	<b>8</b>
2.5.1.	Public statement on Salviae mitiorrhizae radix et rhizoma and supporting documents .....	8
2.5.2.	Monograph on Species digestivae and supporting documents .....	8
<b>2.6.</b>	<b>EU herbal monographs, list entries and public statements for adoption for release for public consultation .....</b>	<b>9</b>
<b>2.7.</b>	<b>EU herbal monographs, list entries and public statements - post finalisation.....</b>	<b>9</b>
2.7.1.	Monograph on Taraxaci officinalis radix and supporting documents .....	9

<b>3.</b>	<b>Referral procedures</b>	<b>9</b>
<b>4.</b>	<b>Guidelines and guidance documents</b>	<b>9</b>
<b>4.1.</b>	<b>Non-clinical/clinical safety and efficacy and multidisciplinary</b>	<b>9</b>
4.1.1.	Guideline on Assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007)	9
<b>4.2.</b>	<b>Quality</b>	<b>9</b>
4.2.1.	Guideline on Good Agricultural and Collection Practice (GACP) of starting materials of herbal origin - Postponed	9
<b>4.3.</b>	<b>Regulatory / Procedural</b>	<b>9</b>
<b>4.4.</b>	<b>Report on HMPC Drafting Groups activities</b>	<b>9</b>
4.4.1.	Quality DG	9
4.4.2.	ORGAM DG	9
<b>5.</b>	<b>Organisational, regulatory and methodological matters</b>	<b>10</b>
<b>5.1.</b>	<b>Mandate and organisation of the HMPC</b>	<b>10</b>
5.1.1.	Strategic Review and Learning Meetings	10
5.1.2.	HMPC membership	10
<b>5.2.</b>	<b>EMA Scientific Committees or CMDh-v</b>	<b>10</b>
5.2.1.	Scientific Coordination Board Meeting	10
5.2.2.	Coordination with QRD and CMDh – Update on Herbal specifics for QRD template (CMDh/349/2016, Rev.0 - EMA/HMPC/770889/2014) - Postponed	10
<b>5.3.</b>	<b>Coordination with EMA Working Parties/Working Groups/Drafting Groups</b>	<b>10</b>
<b>5.4.</b>	<b>Cooperation within the EU regulatory network</b>	<b>10</b>
5.4.1.	Coordination with European Pharmacopoeia	10
<b>5.5.</b>	<b>Cooperation with International Regulators</b>	<b>11</b>
5.5.1.	IRCH – WHO 13th annual virtual meeting	11
<b>5.6.</b>	<b>Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee</b>	<b>11</b>
5.6.1.	Association of the European Self-Medication Industry (AESGP) – hearing in March 2022	11
<b>5.7.</b>	<b>Work plan</b>	<b>11</b>
5.7.1.	HMPC work plan 2022	11
5.7.2.	Review of Working parties and Drafting groups	11
5.7.3.	Quality domain governance and draft multiannual work plan	11
<b>5.8.</b>	<b>Planning and reporting</b>	<b>11</b>
<b>5.9.</b>	<b>Legislation and regulatory affairs</b>	<b>12</b>
<b>5.10.</b>	<b>Questions from members</b>	<b>12</b>
<b>6.</b>	<b>EU herbal monographs and list entries in preparation</b>	<b>12</b>
<b>6.1.</b>	<b>Revision of EU herbal monographs and list entries in preparation for adoption after public consultation</b>	<b>12</b>
6.1.1.	Monograph on Hyperici herba and supporting documents	12

<b>6.2.</b>	<b>Revision of EU herbal monographs and list entries in preparation for public consultation.....</b>	<b>12</b>
6.2.1.	Monograph on Foeniculi amari fructus and supporting documents .....	12
6.2.2.	Monograph on Foeniculi amari fructus aetheroleum and supporting documents .....	12
6.2.3.	Monograph on Foeniculi dulcis fructus and supporting documents .....	12
6.2.4.	Monograph on Lavandulae aetheroleum and supporting documents .....	12
6.2.5.	Monograph on Pelargonii radix and supporting documents - Postponed .....	12
6.2.6.	Monograph on Plantaginis lanceolatae folium and supporting documents - Postponed.....	12
6.2.7.	Monograph on Rosmarini aetheroleum and supporting documents .....	13
6.2.8.	Monograph on Rosmarini folium and supporting documents .....	13
<b>6.3.</b>	<b>Review of EU herbal monographs and list entries in preparation for decision on revision .....</b>	<b>13</b>
6.3.1.	Monograph on Camelliae sinensis non fermentatum folium and supporting documents .....	13
6.3.2.	Monograph on Curcumae xanthorrhizae rhizoma and supporting documents - Postponed..	13
6.3.3.	Monograph on Ginseng radix and supporting documents.....	13
6.3.4.	Monograph on Juglandis folium and supporting documents .....	13
6.3.5.	Monograph on Liquiritiae radix and supporting documents .....	13
6.3.6.	Monograph on Tiliae flos and supporting documents – Postponed .....	13
6.3.7.	Monograph on Urticae radix and supporting documents.....	14
<b>6.4.</b>	<b>EU herbal monographs and list entries in preparation for adoption after public consultation.....</b>	<b>14</b>
6.4.1.	Monograph on Vaccinii macrocarpi fructus and supporting documents - Postponed.....	14
<b>6.5.</b>	<b>EU herbal monographs and list entries in preparation for adoption for release for public consultation .....</b>	<b>14</b>
6.5.1.	Monograph on Cisti cretici herba and supporting documents - Postponed.....	14
6.5.2.	Monograph on Cnici benedicti herba and supporting documents.....	14
6.5.3.	Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents - Postponed .....	14
6.5.4.	Monograph on Tribuli terrestris herba and supporting documents .....	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.	Assessment Report Summary for the Public (ARSP) .....	15
7.2.3.	EU herbal monographs, list entries and public statements – on hold.....	15
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 24-26 January 2022. See January 2022 HMPC minutes (to be published post March 2022 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 24-26 January 2022.

### 1.3. Adoption of the minutes

HMPC minutes for 22-24 November 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

---

Report: HMPC Chair

**Action:** For discussion

Document tabled: Overview

#### 2.1.2. Appointment of Rapporteurs and Peer-reviewers

---

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

Unscheduled reviews to consider specific new data:

##### **2<sup>nd</sup> step – (planned adoption March 2022)**

- Frangulae cortex
- Rhamni purshianae cortex
- Rhei radix

Periodic reviews to start in 2022:

##### **Monographs/LEs adopted in 2014**

- Melaleucae aetheroleum
- Ononidis radix
- Rosae flos
- Rubi idaei folium
- Sisymbrii officinalis herba

### **Monographs/LEs adopted in 2015**

- Agrimoniae herba
- Capsici fructus
- Epilobii herba
- Eschscholziae herba
- Ginkgo folium
- Matricariae flos
- Myrtilli fructus siccus
- Myrtilli fructus recens
- Pilosellae herba cum radice
- Symphyti radix

### **Monographs/LEs adopted in 2016**

- Crataegi folium cum flore
- Helichrysi flos
- Origani majoranae herba
- Polygoni avicularis herba
- Pruni africanae cortex
- Ricini oleum
- Sideritis herba

#### **2.1.3. New substances for assessment**

---

Report: HMPC Chair

**Action:** For discussion

Documents tabled: Email communication, Template for new proposals

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

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

---

**Action:** For adoption

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

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

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

---

**Action:** For adoption

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

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

**Action:** For adoption

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

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

### 2.4.1. Monograph on Aloes folii succus siccatus and supporting documents

**Action:** For adoption

Document tabled: Review report; References 03/04

### 2.4.2. Monograph on Arnicae flos and supporting documents - Postponed

### 2.4.3. Monograph on Cichorii intybi radix and supporting documents

**Action:** For adoption

Document tabled: Review report; References 00/00

### 2.4.4. Monograph on Eucalypti aetheroleum and supporting documents

**Action:** For adoption

Document tabled: Review report; References 19/19

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

**Action:** For adoption

Document tabled: Review report; References 06/06

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

**Action:** For adoption

Document tabled: Review report; References 05/05

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

**Action:** For adoption

Documents tabled: Review report; References 12/13

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

**Action:** For adoption

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

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

---

**Action:** For adoption

Document tabled: Review report; References 02/02

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

---

**Action:** For adoption

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

#### 2.4.11. Monograph on Paullinae semen and supporting documents - Postponed

---

**Action:** For adoption

Document tabled: Review report; References 00/17

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

---

**Action:** For adoption

Documents tabled: Review report; References 14/14

#### 2.4.13. Monograph on Sennae folium and supporting documents

---

**Action:** For adoption

Document tabled: Review report; References 02/02

#### 2.4.14. Monograph on Sennae fructus and supporting documents

---

**Action:** For adoption

Document tabled: Review report; References 02/02

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

---

**Action:** For adoption

Document tabled: Review report; References 04/04

### 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

---

**Action:** For adoption

Documents tabled: PS, AR, LoR; References: 67/89

#### 2.5.2. Monograph on Species digestivae and supporting documents

---

**Action:** For adoption



Documents tabled: MO, AR, LoR, Combinations table; References: 37/42

## **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**

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

---

**Action:** For adoption

Documents tabled: MO, AR; References: 91/84

## **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)**

---

**Action:** For discussion

Document tabled: Draft concept paper

### **4.2. Quality**

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

---

- Slovenian Presidency virtual meeting – 08-09 December 2021

**Action:** For information

Documents tabled: Agenda, Presentations, Follow-up plan

- French Presidency virtual meeting – 14 April 2022

**Action:** For information

Document tabled: Draft agenda

#### 5.1.2. HMPC membership

---

Report: HMPC Chair

**Action:** For information

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

#### 5.2.1. Scientific Coordination Board Meeting

---

Report: HMPC Chair

**Action:** For information

Documents tabled: Minutes 03 December 2021, Agenda 31 January 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](#)) - Postponed

---

### 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

---

- EDQM 13B expert group meeting

Report: Melanie Bald

**Action:** For information

Document tabled: SoD

- New assay method for Rhei radix

Report: Melanie Bald

**Action:** For discussion

Document tabled: Email communication

## 5.5. Cooperation with International Regulators

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

---

Report: HMPC Chair

**Action:** For information

Documents tabled: Agenda

## 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 in March 2022

---

Report: HMPC Chair

**Action:** For discussion

Documents tabled: Proposal on combinations of traditionally used herbal extracts based on monographs

## 5.7. Work plan

### 5.7.1. HMPC work plan 2022

---

Report: HMPC Chair

**Action:** For adoption

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

### 5.7.2. Review of Working parties and Drafting groups

---

Report: HMPC Chair

**Action:** For discussion

Documents tabled: Presentation

### 5.7.3. Quality domain governance and draft multiannual work plan

---

Report: Carmen Purdel, HMPC Chair

**Action:** For discussion

Documents tabled: Consolidated 3-year work plan, Proposal from the HMPC Chair

## 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

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

## 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; References: 136/199

### 6.2.2. Monograph on Foeniculi amari fructus aetheroleum and supporting documents

---

**Action:** For discussion

Documents tabled: Draft PS, Presentation, Reader's Guidance; References: 136/199

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

---

**Action:** For discussion

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

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

---

**Action:** For discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance; References: 92/129

### 6.2.5. Monograph on Pelargonii radix and supporting documents - Postponed

---

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

---

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

---

**Action:** For discussion

Documents tabled: Draft MO, AR; References: 13/00

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

---

**Action:** For discussion

Documents tabled: Draft MO, AR; References: 13/00

### 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

---

**Action:** For discussion

Documents tabled: Review report, Readers Guidance; References 13/26

#### 6.3.2. Monograph on Curcumae xanthorrhizae rhizoma and supporting documents - Postponed

---

**Action:** For discussion

Document tabled: Review report; References 00/00

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

---

**Action:** For discussion

Document tabled: Readers Guidance; References 00/00

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

---

**Action:** For discussion

Document tabled: Review report; References 00/00

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

---

**Action:** For discussion

Documents tabled: Review report, Readers Guidance; References 00/29

#### 6.3.6. Monograph on Tiliae flos and supporting documents – Postponed

---

**Action:** For discussion

Document tabled: Review report; References 00/00

### 6.3.7. 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 *Vaccinii macrocarpi fructus* and supporting documents - Postponed

---

## 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

---

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

---

**Action:** For discussion

Documents tabled: Draft MO, LoR, Presentation; References: 07/16

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

---

### 6.5.4. Monograph on *Tribuli terrestris herba* and supporting documents

---

**Action:** For discussion

Document tabled: Presentation; References: 00/00

## 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 22-24 November 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)

---

None

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

---

None

#### 7.2.4. Other

---

- Compilation terms and definitions for cannabis derived MPs; EC comments and response
- PA Database evaluation 2021
- Schrenk *et al.* Novel Insights into Pyrrolizidine Alkaloid Toxicity and Implications for Risk Assessment: Occurrence, Genotoxicity, Toxicokinetics, Risk Assessment–A Workshop Report. *Planta Medica* 2021
- Update on BAH PA database received by Barbara Steinhoff