



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

2 July 2021  
EMA/HMPC/297871/2021  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Draft Agenda for the meeting on 5-7 July 2021

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

5 July 2021, 10:00 – 17:00, virtual meeting

6 July 2021, 09:00 – 17:00, virtual meeting

7 July 2021, 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 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/127362/2006).

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## 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 May 2021 .....	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers .....	5
2.1.3.	Cancellation of assessment for Andrographidis paniculatae folium and supporting documents .....	6
<b>2.2.</b>	<b>Revised EU herbal monographs and list entries for final adoption .....</b>	<b>6</b>
<b>2.3.</b>	<b>Revised EU herbal monographs and list entries for public consultation .....</b>	<b>6</b>
2.3.1.	Monograph on Agropyri repentis rhizoma and supporting documents .....	6
<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 Rosmarini aetheroleum and supporting documents .....	7
2.4.2.	Monograph on Rosmarini folium and supporting documents .....	7
2.4.3.	Monograph on Sabalis serrulatae fructus and supporting documents .....	7
2.4.4.	Monograph on Urticae folium and supporting documents - postponed.....	7
2.4.5.	Monograph on Urticae herba and supporting documents - postponed .....	7
<b>2.5.</b>	<b>EU herbal monographs, list entries and public statements for final adoption .....</b>	<b>7</b>
<b>2.6.</b>	<b>EU herbal monographs, list entries and public statements for adoption for release for public consultation .....</b>	<b>7</b>
2.6.1.	Monograph on Species digestivae and supporting documents .....	7
<b>2.7.</b>	<b>EU herbal monographs, list entries and public statements - post finalisation .....</b>	<b>7</b>
2.7.1.	Monograph on Verbenae citriodoraе folium and supporting documents .....	7
<b>3.</b>	<b>Referral procedures</b>	<b>8</b>
<b>4.</b>	<b>Guidelines and guidance documents</b>	<b>8</b>
<b>4.1.</b>	<b>Non-clinical/clinical safety and efficacy and multidisciplinary .....</b>	<b>8</b>
4.1.1.	Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs .	8
4.1.2.	Public statement on the use of herbal medicinal products containing estragole .....	8
<b>4.2.</b>	<b>Quality .....</b>	<b>8</b>
4.2.1.	Guideline on quality of herbal medicinal products/traditional herbal medicinal products .....	8
4.2.2.	Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products ....	8
4.2.3.	Nitrosamines and Herbal MPs .....	8
4.2.4.	Change of assay methods in Ph. Eur. monographs .....	8

<b>4.3.</b>	<b>Regulatory / Procedural .....</b>	<b>8</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>9</b>
<b>5.1.</b>	<b>Mandate and organisation of the HMPC .....</b>	<b>9</b>
5.1.1.	Strategic Review and Learning Meetings .....	9
5.1.2.	HMPC membership.....	9
<b>5.2.</b>	<b>EMA Scientific Committees or CMDh-v .....</b>	<b>9</b>
5.2.1.	Scientific Coordination Board Meeting.....	9
<b>5.3.</b>	<b>Coordination with EMA Working Parties/Working Groups/Drafting Groups .....</b>	<b>9</b>
<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 .....	10
<b>5.5.</b>	<b>Cooperation with International Regulators.....</b>	<b>10</b>
<b>5.6.</b>	<b>Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee .....</b>	<b>10</b>
<b>5.7.</b>	<b>Work plan .....</b>	<b>10</b>
5.7.1.	HMPC work plan 2021 .....	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>11</b>
<b>6.1.</b>	<b>Revision of EU herbal monographs and list entries in preparation for adoption after public consultation .....</b>	<b>11</b>
6.1.1.	Monograph on Orthosiphonis folium and supporting documents.....	11
<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 Foeniculi amari fructus and supporting documents .....	11
6.2.2.	Monograph on Foeniculi amari fructus aetheroleum and supporting documents .....	11
6.2.3.	Monograph on Foeniculi dulcis fructus and supporting documents .....	11
6.2.4.	Monograph on Fumariae herba and supporting documents.....	11
6.2.5.	Monograph on Juniperi pseudo-fructus and supporting documents.....	11
6.2.6.	Monograph on Lavandulae aetheroleum 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>12</b>
6.3.1.	Monograph on Arnicae flos and supporting documents - postponed.....	12
6.3.2.	Monograph on Camelliae sinensis non fermentatum folium and supporting documents - postponed .....	12
6.3.3.	Monograph on Cichorii intybi radix and supporting documents - postponed .....	12

6.3.4.	Monograph on Cucurbitae semen and supporting documents.....	12
6.3.5.	Monograph on Curcumae xanthorrhizae rhizoma and supporting documents - postponed .	12
6.3.6.	Monograph on Fucus vesiculosus and supporting documents - postponed .....	12
6.3.7.	Monograph on Hippocastani cortex and supporting documents .....	12
6.3.8.	Monograph on Solidaginis virgaureae herba and supporting documents .....	12
6.3.9.	Monograph on Zingiberis rhizoma and supporting documents.....	12
<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 Salviae mitiorrhizae radix et rhizoma 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 Centellae asiaticae herba and supporting documents.....	13
6.5.2.	Monograph on Cisti cretici folium and supporting documents.....	13
<b>7.</b>	<b>Any other business</b>	<b>13</b>
<b>7.1.</b>	<b>Topics for discussion .....</b>	<b>13</b>
<b>7.2.</b>	<b>Documents for information.....</b>	<b>13</b>
7.2.1.	HMPC.....	13
7.2.2.	Assessment Report Summary for the Public (ARSP) .....	13
7.2.3.	EU herbal monographs, list entries and public statements – on hold.....	13
7.2.4.	Other .....	14

## 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 5-7 July 2021. See July 2021 HMPC minutes (to be published post September 2021 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 5-7 July 2021.

### 1.3. Adoption of the minutes

HMPC minutes for 3-5 May 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 May 2021

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Report: HMPC Chair

**Action:** for discussion

Document: Overview

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

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Report: HMPC Chair

**Action:** for adoption

##### **New Peer-Reviewer:**

New assessments started in 2021

- Tribulus terrestris herba

Periodic reviews started in 2021

- Arnicae flos
- Camelliae sinensis non fermentatum folium
- Cichorii intybi radix
- Cucurbitae semen
- Curcumae xanthorrhizae rhizoma
- Eucalypti aetheroleum

- Eucalypti folium
- Fraxini folium
- Ginseng radix
- Grindeliae herba
- Hippocastani cortex
- Juglandis folium
- Levistici radix
- Lichen islandicus
- Liquiritiae radix
- Marrubii herba
- Origani dictamni herba
- Paullinae semen
- Rhodiolae roseae rhizoma et radix
- Tiliae flos
- Urticae radix

**Change of rapporteurship:**

Periodic reviews started in 2020

- Fucus vesiculosus

2.1.3. **Cancelation of assessment for Andrographidis paniculatae folium and supporting documents**

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**Action:** for adoption

Documents: Review reports, email communication, presentation, [PS](#); References: 24/13

**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 Agropyri repentis rhizoma and supporting documents**

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**Action:** for adoption

Documents: MO, AR, LoR; References: 77/86

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

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

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**Action:** for adoption

Documents: Review report; References: 05/05

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

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**Action:** for adoption

Documents: Review report; References: 08/08

### **2.4.3. Monograph on Sabalis serrulatae fructus and supporting documents**

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**Action:** for adoption

Document: Review report, Readers guidance; References: 16/16

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

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### **2.4.5. 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**

None

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

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

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**Action:** for adoption

Documents: MO, AR, LoR; References: 41/43

## **2.7. EU herbal monographs, list entries and public statements - post finalisation**

### **2.7.1. Monograph on Verbenae citriodoraе folium and supporting documents**

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**Action:** for adoption

Documents: MO, Presentation; References: 31/35

### 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 toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs

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**Action:** for adoption

Documents: Draft PS, OoC, Comments from SWP

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

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**Action:** for discussion

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

#### 4.2. Quality

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

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**Action:** for discussion

Documents: Draft revised Guideline, OoC, Presentation

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 discussion

Documents: Draft revised Guideline, OoC, Presentation

4.2.3. Nitrosamines and Herbal MPs

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**Action:** for discussion

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

4.2.4. Change of assay methods in Ph. Eur. monographs

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**Action:** for discussion

#### 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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None

#### 5.1.2. HMPC membership

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New membership:

- Portugal, Maria da Graça Ribeiro Campos (co-opted member) as of 5 July 2021

End of membership:

- Luxembourg, Clemence Varret (member) as of 1<sup>st</sup> July 2021
- Poland, Ewa Balkowiec Iskra (co-opted member) as of 3 July 2021

### 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: Agenda 29 June 2021, Minutes 28 April 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 13A expert group meeting

Report: M Bald

**Action:** for information

Document: SoD

#### 5.4.2. Coordination with the European Commission

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- Cannabis for medicinal use

Report: HMPC Chair

**Action:** for information

#### 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

None

#### 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: Work plan 2021, Annex 1, Annex 2

- PhV data and experiences in national assessments

Report: HMPC Vice Chair

**Action:** for information

- Development of training on assessment of applications for herbal medicinal products

Report: HMPC Vice Chair, J Wiesner

**Action:** for information

Document: EU NTC June 2021 newsletter, Presentations

#### 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 Orthosiphonis folium and supporting documents

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**Action:** for discussion

Documents: Draft MO, AR, LoR, OoC; References: 40/46

### 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

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**Action:** for discussion

Documents: Draft MO, AR, Reader's Guidance; References: 00/00

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

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**Action:** for discussion

Documents: Draft MO, AR, Reader's Guidance; References: 00/00

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

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**Action:** for discussion

Documents: Draft MO, AR, Reader's Guidance; References: 00/00

#### 6.2.4. Monograph on Fumariae herba and supporting documents

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**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 33/69

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

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**Action:** for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 18/64

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

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**Action:** for discussion

Documents: Reader's Guidance; References: 08/08

### **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 - postponed

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6.3.2. Monograph on Camelliae sinensis non fermentatum folium and supporting documents - postponed

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6.3.3. Monograph on Cichorii intybi radix and supporting documents - postponed

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6.3.4. Monograph on Cucurbitae semen and supporting documents

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**Action:** for discussion

Document: Review report, Presentation; References 00/00

6.3.5. Monograph on Curcumae xanthorrhizae rhizoma and supporting documents - postponed

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6.3.6. Monograph on Fucus vesiculosus and supporting documents - postponed

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6.3.7. Monograph on Hippocastani cortex and supporting documents

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**Action:** for discussion

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

6.3.8. Monograph on Solidaginis virgaureae herba and supporting documents

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**Action:** for discussion

Document: Review report; References 14/14

6.3.9. Monograph on Zingiberis rhizoma and supporting documents

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**Action:** for discussion

Document: Review report, Readers Guidance; References: 137/100

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

### 6.4.1. Monograph on *Salviae mitiorrhizae radix et rhizoma* and supporting documents

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**Action:** for discussion

Documents: Draft PS, AR, LoR; References: 00/89

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

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

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**Action:** for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 00/140

### 6.5.2. Monograph on *Cisti cretici folium* and supporting documents

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**Action:** for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 00/67

## 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 3-5 May 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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#### 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 meeting 3-4 March 2021
- Agenda - PCWP-HCPWP Joint meeting 1-2 June 2021
- GPT Position Statement Extrapolation Phytomedicine 2017