



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 March 2022  
EMA/HMPC/116513/2022  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Draft Agenda for the meeting on 28-30 March 2022

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

28 March 2022, 10:00 – 17:00, virtual meeting

29 March 2022, 09:00 – 17:00, virtual meeting

30 March 2022, 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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## 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 January 2022.....	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers .....	5
2.1.3.	Cross-monographs harmonisation for EU monographs with information that adequate fluid intake is required during treatment and related warning or contraindication concerning the use in patients under a reduced fluid intake .....	5
2.1.4.	Tracking of number of available references in HMPC agendas & minutes.....	5
<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
2.2.2.	Monograph on Centellae asiaticae herba 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 Foeniculi amari fructus and supporting documents .....	6
2.3.2.	Monograph on Foeniculi dulcis fructus and supporting documents .....	6
2.3.3.	Monograph on Fumariae herba and supporting documents.....	6
2.3.4.	Monograph on Juniperi pseudo-fructus and supporting documents.....	6
<b>2.4.</b>	<b>Reviewed EU herbal monographs and list entries for decision on revision.....</b>	<b>6</b>
2.4.1.	Monograph on Arnicae flos and supporting documents.....	6
2.4.2.	Monograph on Frangulae cortex and supporting documents .....	6
2.4.3.	Monograph on Hippocastani cortex and supporting documents .....	7
2.4.4.	Monograph on Juglandis folium and supporting documents .....	7
2.4.5.	Monograph on Liquiritiae radix and supporting documents .....	7
2.4.6.	Monograph on Paullinae semen and supporting documents .....	7
2.4.7.	Monograph on Rhamni purshianae cortex and supporting documents .....	7
2.4.8.	Monograph on Rhei radix and supporting documents.....	7
2.4.9.	Monograph on Urticae radix 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>
2.5.1.	Public statement on Salviae mitiorrhizae radix et rhizoma and supporting documents .....	7
2.5.2.	Monograph on Species digestivae and supporting documents .....	7
<b>2.6.</b>	<b>EU herbal monographs, list entries and public statements for adoption for release for public consultation .....</b>	<b>8</b>
<b>2.7.</b>	<b>EU herbal monographs, list entries and public statements - post finalisation .....</b>	<b>8</b>
2.7.1.	Monograph on Taraxaci officinalis radix and supporting documents .....	8

<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.	Guideline on Assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007) for public consultation	8
<b>4.2.</b>	<b>Quality</b>	<b>8</b>
4.2.1.	Guideline on Good Agricultural and Collection Practice (GACP) of starting materials of herbal origin	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>8</b>
4.4.1.	Quality DG	8
4.4.2.	ORGAM DG	8
<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
5.1.3.	Pilot – Relaunch of face to face Scientific Committee Meetings	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 QRD and CMDh – Update on Herbal specifics for QRD template (CMDh/349/2016, Rev.0 - EMA/HMPC/770889/2014)	9
5.2.3.	Coordination with CMDh – List of estragole-containing plants	10
<b>5.3.</b>	<b>Coordination with EMA Working Parties/Working Groups/Drafting Groups</b>	<b>10</b>
5.3.1.	Nomination of HMPC representative (and alternate) for Patients and Consumers Working Party (PCWP) and for Healthcare Professionals Working Party (HCPWP)	10
<b>5.4.</b>	<b>Cooperation within the EU regulatory network</b>	<b>10</b>
5.4.1.	Coordination with European Pharmacopoeia	10
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>11</b>
5.6.1.	Association of the European Self-Medication Industry (AESGP) – hearing on 18 May 2022	11
<b>5.7.</b>	<b>Work plan and related activities</b>	<b>11</b>
5.7.1.	HMPC work plan 2022	11
5.7.2.	New EMA model for Working Parties and Drafting Groups	11
5.7.3.	Quality domain governance and draft multiannual work plan	11
5.7.4.	Improved use of data source for HMPC relevant safety assessment	11
5.7.5.	Evaluation of data from paediatric clinical practice for the safe use of herbal substances in children - postponed	12
5.7.6.	Development of training on assessment of applications for herbal medicinal products	12

<b>5.8.</b>	<b>Planning and reporting .....</b>	<b>12</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 - postponed .....	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 aetheroleum and supporting documents .....	12
6.2.2.	Monograph on Lavandulae aetheroleum and supporting documents - postponed.....	12
6.2.3.	Monograph on Pelargonii radix and supporting documents .....	12
6.2.4.	Monograph on Plantaginis lanceolatae folium and supporting documents - postponed.....	13
6.2.5.	Monograph on Rosmarini aetheroleum and supporting documents .....	13
6.2.6.	Monograph on Rosmarini folium and supporting documents .....	13
6.2.7.	Monograph on Zingiberis rhizoma 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 .....	13
6.3.3.	Monograph on Ginseng radix and supporting documents.....	13
6.3.4.	Monograph on Tiliae flos and supporting documents.....	13
<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 .....	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 Hyperici herba/Cimicifugae rhizoma and supporting documents.....	14
6.5.3.	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) .....	14
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 28-30 March 2022. See March 2022 HMPC minutes (to be published post May 2022 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 28-30 March 2022.

### 1.3. Adoption of the minutes

HMPC minutes for 24-26 January 2022.

## 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 January 2022

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Report: HMPC Chair

**Action:** For discussion

Document tabled: Overview (new format)

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

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None

#### 2.1.3. Cross-monographs harmonisation for EU monographs with information that adequate fluid intake is required during treatment and related warning or contraindication concerning the use in patients under a reduced fluid intake

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Report: HMPC Vice-Chair

**Action:** For adoption

Document tabled: Proposal from the rapporteurs; Overview concerned monographs 2022

Related to: 2.2.1, 2.3.4, 2.7.1

#### 2.1.4. Tracking of number of available references in HMPC agendas & minutes

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**Action:** For information

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

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

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance; References: 76/84

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

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**Action:** For adoption

Documents tabled: MO, AR, LoR; References: 100/137

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

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

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance

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

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**Action:** For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance

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

---

**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance

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

---

**Action:** For adoption

Documents tabled: MO, AR, LoR, Readers Guidance, Annex

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

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

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**Action:** For adoption

Document tabled: Review report

### 2.4.2. Monograph on *Frangulae cortex* and supporting documents

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**Action:** For adoption

Document tabled: Review report

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

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**Action:** For adoption

Document tabled: Review report

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

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**Action:** For adoption

Document tabled: Review report

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

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**Action:** For adoption

Document tabled: Review report, Readers Guidance

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

---

**Action:** For adoption

Document tabled: Review report

#### 2.4.7. Monograph on Rhamni purshianae cortex and supporting documents

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**Action:** For adoption

Document tabled: Review report

#### 2.4.8. Monograph on Rhei radix and supporting documents

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**Action:** For adoption

Document tabled: Review report

#### 2.4.9. Monograph on Urticae radix 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

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**Action:** For adoption

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

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

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**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

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**Action:** For adoption

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

## 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) for public consultation

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**Action:** For adoption

Document tabled: Concept paper on the revision of the guideline

### 4.2. Quality

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

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**Action:** For information

Document tabled: [Concept paper on the revision of the Guideline](#)

### 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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- French Presidency virtual meeting – 14 April 2022  
Report: An Le  
**Action:** For information  
Document tabled: Draft agenda
- Slovenian Presidency virtual meeting – 08-09 December 2022  
Report: Barbara Razinger  
**Action:** For information  
Document tabled: Follow up plan

#### 5.1.2. HMPC membership

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- Data protection notice  
**Action:** For information  
Documents tabled: Data protection notice - list of CXMP members alternates contacts in MMD (EMA/67519/2022), Presentation, HMPC contact list
- Revision of the procedure for nomination and appointment of co-opted members  
**Action:** For discussion  
Documents tabled: Revised procedure (EMA/747064/2021), Presentation

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

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**Action:** For information  
Document tabled: Presentation

### 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 31 January 2022, Draft Agenda 25 April 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)

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**Action:** For discussion  
Documents tabled: Addendum to the QRD templates, Readers Guidance

### 5.2.3. Coordination with CMDh – List of estragole-containing plants

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**Action:** For discussion

Documents tabled: List of estragole-containing plants, [Public statement on the use of herbal medicinal products containing estragole](#) (EMA/HMPC/137212/2005 Rev.1) published on 01 March 2022, [Report from the CMDh meeting held on 22-23 February](#)

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

### 5.3.1. Nomination of HMPC representative (and alternate) for Patients and Consumers Working Party (PCWP) and for Healthcare Professionals Working Party (HCPWP)

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Report: HMPC Chair

**Action:** For discussion

Documents tabled: Email correspondence dated 09 March 2022

## 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 TCM expert group meeting

Report: Melanie Bald

**Action:** For information

Document tabled: SoD

### 5.4.2. Coordination with the European Commission

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- Revision of EU pharmaceutical legislation (human)

Report: HMPC Chair

**Action:** For information

- Collaboration with EC on the feasibility to establish an EU herbal monograph for Cannabis flos

Report: HMPC Chair

**Action:** For information

Documents tabled: Email correspondence dated 24 February 2022

## 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. Association of the European Self-Medication Industry (AESGP) – hearing on 18 May 2022

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Report: HMPC Chair

**Action:** For discussion

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

Related to: 5.1.3.

## 5.7. Work plan and related activities

### 5.7.1. HMPC work plan 2022

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Report: HMPC Chair

**Action:** For information

Document tabled: HMPC Work plan, Annex 1, Annex 2

### 5.7.2. New EMA model for Working Parties and Drafting Groups

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- Call for nominations for CHMP working parties

Report: HMPC Chair

**Action:** For discussion

Documents tabled: Email correspondence dated 02 March 2022

- Call for nomination for an expert in non-clinical working party

Report: HMPC Chair

**Action:** For discussion

Documents tabled: Email correspondence dated 15 March 2022

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

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Report: Carmen Purdel, HMPC Chair; Expert: Kristine Hvolby

**Action:** For discussion

Document tabled: Ad-hoc Quality Group Minutes 22 February 2022

### 5.7.4. Improved use of data source for HMPC relevant safety assessment

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- Review report template

Report: HMPC Vice-chair, Carmen Purdel

**Action:** For discussion

Documents tabled: Review report template

- Use of MedDRA terminology and classification system in Assessment Reports  
Report: HMPC Vice-chair  
**Action:** For discussion  
Documents tabled: External query received by EMA on Oenotherae oleum (ASK-99172)

#### 5.7.5. Evaluation of data from paediatric clinical practice for the safe use of herbal substances in children - postponed

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Report: Peter Voitl, Miroslava Petriková

#### 5.7.6. Development of training on assessment of applications for herbal medicinal products

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Report: HMPC Vice-chair, Carmen Purdel, Burt Kroes

**Action:** For discussion

Documents tabled: Course description, 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 - postponed

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

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

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**Action:** For 8<sup>th</sup> discussion

Documents tabled: Draft PS, Presentation, Reader's Guidance

#### 6.2.2. Monograph on Lavandulae aetheroleum and supporting documents - postponed

#### 6.2.3. Monograph on Pelargonii radix and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Reader's Guidance, Presentation

6.2.4. Monograph on *Plantaginis lanceolatae folium* and supporting documents - postponed

6.2.5. Monograph on *Rosmarini aetheroleum* and supporting documents

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**Action:** For 4<sup>th</sup> discussion

Documents tabled: Draft MO, AR, Reader's Guidance

6.2.6. Monograph on *Rosmarini folium* and supporting documents

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**Action:** For 4<sup>th</sup> discussion

Documents tabled: Draft MO, AR

6.2.7. Monograph on *Zingiberis rhizoma* and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Reader's Guidance, References

**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 4<sup>th</sup> discussion

Document tabled: Review report, Readers Guidance

6.3.2. Monograph on *Curcumae xanthorrhizae rhizoma* and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Review report

6.3.3. Monograph on *Ginseng radix* and supporting documents

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**Action:** For 3<sup>rd</sup> discussion

Document tabled: Review report

6.3.4. Monograph on *Tiliae flos* and supporting documents

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**Action:** For 1<sup>st</sup> discussion

Documents tabled: Review report, Presentation

## **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**

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**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Draft MO, AR, LoR

## **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 Hyperici herba/Cimicifugae rhizoma and supporting documents**

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**Action:** For 2<sup>nd</sup> discussion

Documents tabled: Presentation

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

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**Action:** For 1<sup>st</sup> discussion

Document tabled: Presentation

## **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 24-26 January 2022

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 meeting with all eligible organisations - 24 November 2021
- Agenda - PCWP-HCPWP Joint meeting – 02-03 March 2022
- Human Medicines Highlights 2021
- Veterinary Medicines Highlights 2021
- Response to External query received by EMA on TU of *Vitis vinifera* L., folium (ASK-98114)