



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

15 November 2019  
EMA/HMPC/621895/2019  
Inspections, Human Medicines Pharmacovigilance & Committees Division

## Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 18-20 November 2019

Chair: Marisa Delbò Vice-Chair: Emiel van Galen

18 November 2019, 14:00 – 19:00, 1C

19 November 2019, 09:00 – 19:00, 1C

*(AESGP hearing: 19 November 2019, 14.00 – 16.00, 1C)*

20 November 2019, 09:00 – 16:00, 1C

*(HMPC Chair elections: 20 November 2019, 15.15 – 16.00, 1C)*

### 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 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).

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## 1. Introduction

### 1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the HMPC plenary session to be held on 18-20 November 2019. See November 2019 HMPC minutes (to be published post January 2020 HMPC meeting).

New nomination membership:

- MT, Matthew Camilleri (alternate) as of 11 October 2019

End of membership:

- MT, Andre Mangani (alternate) as of 10 October 2019

### 1.2. Adoption of agenda

HMPC agenda for 18-20 November 2019

Time schedule for 18-20 November 2019

### 1.3. Adoption of the minutes

HMPC minutes for 23-25 September 2019

## 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 2019

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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

Documents: Call for Rapporteurs/Peer Reviewers, List B with volunteers

### 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 Millefolii herba and supporting documents

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**Action:** for adoption

Documents: MO, LE, AR, LoR; References: 00/69

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

### **2.4.1. Monograph on Arctii radix and supporting documents**

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**Action:** for adoption  
Document: Review report; References: 59/33

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

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**Action:** for adoption  
Document: Review report; References: 05/04

### **2.4.3. Monograph on Taraxaci folium and supporting documents**

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**Action:** for adoption  
Document: Review report; References: 17/16

### **2.4.4. Monograph on Taraxaci radix cum herba and supporting documents**

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**Action:** for adoption  
Document: Review report; References: 39/14

### **2.4.5. Monograph on Quercus cortex and supporting documents**

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**Action:** for adoption  
Document: Review report; References: 18/10

## **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 Calendulae herba and supporting documents**

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**Action:** for discussion  
Documents: PS, AR, LoR, discussion letter, discussion material; References: 15/16

### **2.6.2. Monograph on Herniariae herba and supporting documents**

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**Action:** for discussion  
Documents: MO, AR, LoR, Readers guidance; References: 35/22

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

None

### 3. Referral procedures

None

### 4. Guidelines and guidance documents

#### 4.1. Non-clinical/clinical safety and efficacy and multidisciplinary

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

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**Action:** for discussion

Documents: Draft revised PS; OoC; Questions for finalisation,

##### 4.1.2. Public statement on the contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)

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**Action:** for discussion

Documents: Presentation (see also 4.1.3.); [PS](#)

##### 4.1.3. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011)

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**Action:** for discussion

Documents: Presentation (see also 4.1.2.); [PS](#)

#### 4.2. Quality

None

#### 4.3. Regulatory / Procedural

##### 4.3.1. Update on procedures for monograph and list entry establishment - postponed

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#### 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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Finnish Presidency meeting – Czech Republic, Prague – 5-6 November 2019

**Action:** for discussion

Documents: Presentations, Summary of discussions groups

### 5.1.2. Election of HMPC Chair

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**Action:** for adoption

Documents: Call for candidates, [HMPC RoP](#), Candidatures

### 5.1.3. Preparation of upcoming elections

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**Action:** for discussion

Document: Presentation

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

### 5.2.1. Scientific Coordination Board Meeting

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Report: HMPC Chair

**Action:** for information

Document: Draft Minutes dated 25 September 2019

### 5.2.2. Coordination with PDCO/PRAC

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Discussion paper of age limitation of use of cough and cold herbal medicinal products in children

**Action:** for discussion

Documents: Draft discussion paper, OoC, Summary of age limitations, Table of products for children

## 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 meetings  
**Action:** for information
- EDQM 13B expert group meetings  
**Action:** for information
- EDQM TCM expert group meetings  
**Action:** for information
- EDQM PA expert group meetings  
**Action:** for information
- Certification procedure - Steering Committee interaction with HMPC  
**Action:** for information  
Documents: email communication



#### 5.4.2. Herbal EU NTC curriculum: Draft principles and priorities for training

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**Action:** for adoption

Documents: Draft Herbal EU NTC curriculum, Draft curriculum priorities

Documents for information: Draft curriculum principles, Presentation

### 5.5. Cooperation with International Regulators

#### 5.5.1. 11<sup>th</sup> WHO IRCH meeting in Budapest 5-7 December

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**Action:** for information

Document: Draft programme

### 5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

#### 5.6.1. AESGP – hearing

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Report: HMPC Chair

**Action:** for discussion

Documents: Draft Agenda, List of participants

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

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Report: HMPC Chair

**Action:** for discussion

Document: [Procedure for EU guidelines \(EMA/P/24143/2004 Rev. 1 corr\)](#)

### 5.7. Work plan

#### 5.7.1. HMPC work plan 2019

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Report: HMPC Chair

**Action:** for discussion

Documents: Work plan 2019, Annex 1, Annex 2 – current status November 2019

#### 5.7.2. Draft HMPC work plan 2020

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Report: HMPC Chair

**Action:** for discussion

Documents: Draft Work plan 2020, Annex 1, Annex 2

### 5.8. Planning and reporting

#### 5.8.1. Move to EMA building – timelines and practical arrangements

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**Action:** for discussion

Document: Presentation

#### 5.8.2. EMA future proofing

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**Action:** for discussion

Document: Presentation

## 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 Hippocastani semen and supporting documents

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**Action:** for discussion

Documents: MO, AR, LoR; References: 75/72

### 6.1.2. Monograph on Hyperici herba and supporting documents - postponed

### 6.1.3. Monograph on Menthae piperitae aetheroleum and supporting documents (see also 7.2.3.)

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**Action:** for discussion

Documents: LE, MO, AR, LoR (document for information: Menthae piperitae folium – MO);  
References: 109/205

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

### 6.2.1. Monograph on Trigonellae foenugraeci semen and supporting documents - postponed

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

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### 6.3.1. Monograph on Filipendulae ulmariae herba and supporting documents

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

Document: Review report; References: 15/15

### 6.3.2. Monograph on Juniperi aetheroleum and supporting documents - postponed

### 6.3.3. Monograph on Juniperi pseudo-fructus and supporting documents - postponed

### 6.3.4. Monograph on Sabalis serrulatae fructus and supporting documents – request for unscheduled revision

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

Document: Review report; References: 05/05

6.3.5. Monograph on Rosmarini aetheroleum and supporting documents - postponed

6.3.6. Monograph on Rosmarini folium and supporting documents - postponed

6.3.7. Monograph on Solidaginis virgaureae herba and supporting documents

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

Document: Review report; References: 21/19

6.3.8. Monograph on Zingiberis rhizoma and supporting documents – request for unscheduled revision

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

Documents: Review report; Readers guidance, References: 137/25

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

None

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

6.5.1. Monograph on Cisti cretici folium and supporting documents - postponed

6.5.2. Monograph on Menyanthes trifoliata folium and supporting documents

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

Documents: Draft MO, AR, LoR; References: 69/73

6.5.3. Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents

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**Action:** for 7<sup>th</sup> discussion

Documents: Draft MO, Draft LE, Draft AR, Draft LoR, References: 02/188

6.5.4. Monograph on Salviae mitiorrhizae radix et rhizoma and supporting documents

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

Documents: Draft MO, AR, LoR, Additional information NL; References: 00/32

6.5.5. Monograph on Species amarae and supporting documents

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

Documents: Draft MO, AR, LoR; References: 00/16

6.5.6. Monograph on Species sedativae and supporting documents - postponed

6.5.7. Monograph on Vaccinii macrocarpi fructus and supporting documents

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**Action:** for 5<sup>th</sup> discussion

Documents: Draft MO, AR, LoR; References: 00/18

- 6.5.8. Monograph on *Verbenae citriodorae folium* and supporting documents - postponed
- 6.5.9. Monograph on *Andrographidis paniculatae folium* and supporting documents - postponed
- 6.5.10. Monograph on *Centellae asiaticae herba* and supporting documents - postponed

## 7. Any other business

### 7.1. Topics for discussion

#### 7.1.1. Develop a strategy for use of PhV data/tools in HMPC assessment

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**Action:** for discussion  
Document: Presentation

#### 7.1.2. PSUSA procedure for *Pelargonii radix*

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**Action:** for discussion  
Documents: MO, Presentation

### 7.2. Documents for information

#### 7.2.1. HMPC

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Table of Decisions from HMPC meeting held on 23-25 September 2019

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 23-25 July 2019](#)

[Overview of status of HMPC assessment work – priority list](#)

[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

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- English template
- English summaries for publication
  - Frangula bark
  - Valerian root and hop strobile

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

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- Monograph on *Allii sativi bulbus* and supporting documents – unsolved post-adoption issues
- Monograph on *Foeniculi amari fructus* and supporting documents – awaiting Estragole PS finalisation
- Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents – awaiting Estragole PS finalisation

- Monograph on *Foeniculi dulcis fructus* and supporting documents – awaiting Estragole PS finalisation
- Monograph on *Species digestivae* or *species stomachicae* and supporting documents - awaiting Estragole PS finalisation
- Monograph on *Menthae piperitae folium* and supporting documents - awaiting *Menthae piperitae aetheroleum* finalisation

#### 7.2.4. Other

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- PCWP/HCPWP meetings:
  - Meeting Summary PCWP Plenary Meeting 24 September 2019
  - Meeting Summary HCPWP Plenary Meeting 24 September 2019
  - Meeting Summary PCWP/HCPWP Joint Meeting 25 September 2019
  - Draft Agenda for the Annual PCWP/HCPWP meeting with all eligible organisations, 20 November 2019
- Traditional Chinese Medicine: A Statement by EASAC and FEAM