



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 January 2020  
EMA/HMPC/13533/2020  
Inspections, Human Medicines Pharmacovigilance & Committees Division

## Committee on Herbal Medicinal Products (HMPC)

### Draft Agenda for the meeting on 13-15 January 2020

Chair: vacant Vice-Chair: Emiel van Galen

13 January 2020, 12:00 – 19:00, 1C

*(HMPC Chair elections: 13 January 2020, 16.00 – 17.00, 1C)*

14 January 2020, 09:00 – 18:00, 1C

15 January 2020, 09:00 – 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 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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## 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 13-15 January 2020. See January 2020 HMPC minutes (to be published post March 2020 HMPC meeting).

New nomination membership:

- DE, Susanne Flemisch (alternate) as of 19 December 2019
- FR, Michele Brum (alternate) as of 01 January 2020

End of membership:

- DE, Birgit Merz (alternate) as of 18 December 2019

### 1.2. Adoption of agenda

HMPC agenda for 13-15 January 2020

Time schedule for 13-15 January 2020

### 1.3. Adoption of the minutes

HMPC minutes for 18-20 November 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 January 2020

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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 discussion

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

*New assessments to start in 2020*

- Taraxaci radix

*Periodic reviews to be started in 2020*

- Agropyri repentis rhizoma
- Caryophyllii floris aetheroleum
- Carvi aetheroleum
- Carvi fructus
- Chamomillae romanae flos
- Cinnamomi cortex
- Cinnamomi corticis aetheroleum
- Colae semen
- Fucus vesiculosus
- Fumariae herba
- Lavandulae aetheroleum
- Lavandulae flos
- Mate folium
- Plantaginis lanceolatae folium
- Solani dulcamarae stipites
- Urticae herba
- Urticae folium
- Viola tricoloris herba

### 2.1.3. Absinthii herba and supporting documents - request for unscheduled monograph revision

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**Action:** for discussion

Documents: Request from AESGP, Review Report

### 2.1.4. Taraxaci radix and supporting documents - possible monograph development

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**Action:** for discussion

Documents: Proposal for assessment; see also 5.7.1.

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

### 2.2.1. Monograph on Hippocastani semen and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR, Reader's guidance; References: 75/72

### 2.2.2. Monograph on Menthae piperitae aetheroleum and supporting documents

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**Action:** for adoption

Documents: LE, MO, AR, LoR ; References: 109/205

### 2.2.3. Monograph on Menthae piperitae folium and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 109/205

## 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 Arctii radix and supporting documents

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**Action:** for adoption

Document: Review report; References: 58/33

## 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

None

## 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 contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)

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**Action:** for discussion

Document: Draft revised [PS](#)

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

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### 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

Document: Summary of group discussions

#### 5.1.2. Election of HMPC Chair

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**Action:** for adoption

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

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

#### 5.2.1. Coordination with PDCO/PRAC

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

**Action:** for discussion

Documents: Draft discussion paper, Annex to draft discussion paper

### 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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Report: M Bald

**Action:** for discussion

Document: [Draft method for determination of Pyrrolizidine Alkaloids published in Pharmedica](#)



## 5.5. Cooperation with International Regulators

### 5.5.1. 11th WHO IRCH meeting in Budapest 5-7 December

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Report: HMPC Vice-Chair

**Action:** for information

Document: Report from Vice-Chair

## 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 adoption

Document: Draft report

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

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Report: HMPC Chair/Vice Chair

## 5.7. Work plan

### 5.7.1. Draft HMPC work plan 2020

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Report: HMPC Chair/Vice Chair

**Action:** for adoption

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

## 5.8. Planning and reporting

### 5.8.1. EMA building – Health & Safety induction (compulsory for all members)

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**Action:** for information

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 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 *Orthosiphonis folium* and supporting documents - postponed

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6.2.2. Monograph on *Trigonellae foenugraeci semen* and supporting documents - postponed

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

6.3.1. Monograph on *Filipendulae ulmariae flos* and supporting documents - postponed

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6.3.2. Monograph on *Filipendulae ulmariae herba* and supporting documents

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**Action:** for discussion

Documents: Review report; References: 15/15

6.3.3. Monograph on *Juniperi aetheroleum* and supporting documents

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**Action:** for discussion

Documents: Review report; References: 00/58

6.3.4. Monograph on *Juniperi pseudo-fructus* and supporting documents

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**Action:** for discussion

Documents: Review report; References: 00/38

6.3.5. Monograph on *Pelargonii radix* and supporting documents - request for unscheduled monograph revision

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**Action:** for discussion

Documents: Review report, MO; References: 00/07

6.3.6. Monograph on *Rosmarini aetheroleum* and supporting documents - postponed

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6.3.7. Monograph on *Rosmarini folium* and supporting documents - postponed

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6.3.8. Monograph on *Sabalidis serrulatae fructus* and supporting documents – request for unscheduled revision

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**Action:** for discussion

Documents: Review report; References: 05/05

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

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**Action:** for discussion

Document: 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 *Menyanthes trifoliata* folium and supporting documents

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**Action:** for discussion

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

6.5.2. Monograph on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

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**Action:** for discussion

Documents: Draft MO, Draft LE, Draft AR, Draft LoR, EMA letter to EC, EC response;  
References: 02/188

6.5.3. Monograph on *Species amarae* and supporting documents

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**Action:** for discussion

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

6.5.4. Monograph on *Species sedativae* and supporting documents - postponed

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6.5.5. Monograph on *Vaccinii macrocarpi* fructus and supporting documents

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**Action:** for discussion

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

6.5.6. Monograph on *Verbenae citriodora* folium and supporting documents - postponed

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6.5.7. Monograph on *Andrographidis paniculatae* folium and supporting documents - postponed

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6.5.8. Monograph on *Centellae asiaticae* herba and supporting documents - postponed

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

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**Action:** for discussion

## 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

### 7.2. Documents for information

#### 7.2.1. HMPC

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Table of Decisions from HMPC meeting held on 18-20 November 2019

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 18-20 November 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

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

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- Monograph on *Allii sativi bulbosus* 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

#### 7.2.4. Other

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None