



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 November 2018  
EMA/HMPC/801864/2018  
Inspections, Human Medicines Pharmacovigilance & Committees Division

## Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 19-20 November 2018

Chair: Marisa Delbò Vice-Chair: Emiel van Galen

19 November 2018, 14:00 – 19:00, 2F

20 November 2018, 09:00 – 13:00, 2F

### 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

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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 19-20 November 2018. See November 2018 HMPC minutes (to be published post January 2019 HMPC meeting).

Swap of roles membership (IE): Una Mockler (alternate) as of 09 October 2018

End of membership (BE): Wim Huygh (alternate); End of mandate: 17 October 2018

### 1.2. Adoption of agenda

HMPC agenda for 19-20 November 2018

Time schedule for 19-20 November 2018

### 1.3. Adoption of the minutes

HMPC minutes for 24-25 September 2018

## 2. European Union herbal monographs and list entries

### 2.1. Report on MLWP activities

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

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Report: HMPC Chair

**Action:** for discussion

#### **Preparation for Rapporteur transfer - for adoption in January 2019**

(Agrimoniae herba)

(Boldi folium)

Calendulae herba

Frangulae cortex

Rhamni purshianae cortex

Rhei radix

Thymi aetheroleum

Mentha folium/aetheroleum

#### **Preparation for Peer-Reviewer transfer - for adoption in January 2019**

Bursae pastoris herba

(Colae semen)

(Lupuli flos)  
(Melissae folium)  
Rosmarini aetheroleum  
Rosmarini folium  
(Sabalis serrulatae fructus)  
(Thymi herba)  
Violae tricoloris herba

#### 2.1.2. Report from the MLWP September 2018 meeting

Report: MLWP Chair/MLWP Vice-Chair

**Action:** for information

Document: Draft minutes for the MLWP meeting on 25-27 September 2018

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

#### 2.2.1. Monograph on Gentianae radix and supporting documents

**Action:** for adoption

Documents: MO, AR, LoR; References: 44/46

#### 2.2.2. Monograph on Rusci aculeati rhizoma and supporting documents

**Action:** for adoption

Documents: MO, AR, LoR, OoC; References: 39/62

### **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 Echinaceae angustifoliae radix and supporting documents

**Action:** for adoption

Documents: Review report, Presentation; References: 00/09

#### 2.4.2. Monograph on Millefolii flos and supporting documents (postponed)

#### 2.4.3. Monograph on Millefolii herba and supporting documents (postponed)

## 2.5. EU herbal monographs, list entries and public statements for final adoption

### 2.5.1. Monograph on *Fragariae folium* and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR, OoC; References: 106/119

### 2.5.2. Monograph on *Malvae sylvestris flos* and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 164/115

### 2.5.3. Monograph on *Malvae folium* and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 164/115

## 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 *Cynarae folium* and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; Email correspondence dated 5 September 2018

## 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 adoption

Documents: Draft revised PS, OoC; SWP subgroup comments; Presentation

#### 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: [PS](#); Presentation; Information received from AESGP

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: [PS](#); Expert report; [Statement by EFSA CONTAM panel on Risks for human health related to the presence of pyrrolizidine alkaloids in food](#)

## 4.2. Quality

4.2.1. Q&A on elemental impurities - evaluation in herbal medicinal products

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Report: ODG Chair, HMPC Chair

**Action:** for adoption

Documents: Draft Q&A; Outcome written procedure; Replies from members; Comments received

## 4.3. Regulatory / Procedural

4.3.1. Procedure on management of proposals submitted by interested parties for EU List Entries or EU Herbal Monographs (EMA/HMPC/328575/2007 Rev.2)

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Report: ORGAM DG Chair

**Action:** for adoption

Document: Draft revised procedure

## 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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Austria Presidency meeting – Vienna, 15-17 Oct 2018

**Action:** for discussion

Documents: Presentations; Minutes

## 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 10 September 2018; Draft Agenda 22 November 2018

### 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 the European Commission

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- Clarification of classification on *Saccharomyces cerevisiae* CBS 5926  
Report: HMPC Chair  
**Action:** for discussion  
Documents: EMA letter to EC, EC response, Draft MO, draft LE, draft AR, draft LOR

#### 5.4.2. Coordination with European Pharmacopoeia

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- EDQM expert group meetings  
**Action:** for information  
Document: Agenda 13B

### 5.5. Cooperation with International Regulators

#### 5.5.1. 9<sup>th</sup> EU-India Joint Working Group on Pharmaceuticals, Biotechnology and Medical Devices

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**Action:** for information

Document: Presentation - feedback from 9th EU-India Joint WG on Pharmaceuticals, Biotechnology and Medical Devices, Brussels 27-28 September

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

#### 5.6.1. AESGP – hearing at MLWP September 2018

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Report: MLWP Chair

**Action:** for adoption

Documents: Draft hearing report; Presentation on Pyrrolizidine Alkaloids

### 5.7. Work plan

#### 5.7.1. HMPC work plan 2018

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Report: HMPC Chair

**Action:** for information

Document: Work plan 2018 – current status November 2018

- 1.3.1. Activity area: Implementation of a modified review/revision procedure for EU herbal monographs



Report: HMPC Chair

- 1.3.2. Activity area: Forward planning and prioritisation
- 1.3.3. Activity area: Coordination on safety assessments of herbal constituents

**Action:** for discussion

Documents: Presentation

- 1.3.4. Activity area: European collaboration
- 2.1.1. Activity area: Patients involvement in assessment work

#### 5.7.2. HMPC work plan 2019

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Report: HMPC Chair

**Action:** for adoption

Documents: Draft work plan 2019 including Annex 1 (monographs) and Annex 2 (guidelines); Comments received from members

### 5.8. Planning and reporting

None

### 5.9. Legislation and regulatory affairs

#### 5.9.1. WEU/Bibliographic application regarding Art. 10a Dir. 2001/83/EC for HMPs – Reference to other products

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Report: HMPC Chair

**Action:** for discussion

Documents: [Guideline on the assessment of clinical safety and efficacy](#); [Regulatory Q&A](#)

## 6. Any other business

### 6.1. Topics for discussion

#### 6.1.1. Workshop on Pyrrolizidine Alkaloids (PAs) – see also 4.1.2. & 4.1.3.

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**Action:** for discussion

Documents: Agenda; Presentation

#### 6.1.2. Management of references for the review and revision of EU herbal monographs and EU list entries

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**Action:** for discussion

Documents: Draft MLWP September 2018 minutes; Best practice guide for revision of MO and LE

## 6.2. Documents for information

### 6.2.1. HMPC

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Table of Decisions from HMPC meeting held on 24-25 September 2018

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 24-25 September 2018](#)

[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

### 6.2.2. MLWP

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- Overview of status of HMPC/MLWP assessment work

### 6.2.3. ARSP

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- English template
- English summaries for publication:
  - Turmeric
  - Milkthistle
  - Senna leaf
  - Senna pods

### 6.2.4. Other

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- PCWP/HCPWP meetings:
  - PCWP - Agenda PCWP meeting 25 Sep 2018
  - PCWP/HCPWP - Agenda Joint PCWP/HCPWP meeting 25 Sep 2018
  - HCPWP - Agenda HCPWP meeting 26 Sep 2018
- EU herbal monographs, list entries and public statements post adoption
  - Allii sativi bulbus: Scientific literature compilation and open questions; post adoption delays (MO, AR, LoR, OoC)
  - Pistacia lentiscus, resinum (mastic) (MO, AR, LoR)
- HMPC meeting dates 2019

### 6.2.5. Feedback on national experiences with HMPC monographs and guidelines

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- draft template
- summary feedback