



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 May 2018  
EMA/HMPC/370139/2018  
Inspections, Human Medicines Pharmacovigilance & Committees Division

## Committee on Herbal Medicinal Products (HMPC)

### Agenda for the meeting on 04-05 June 2018

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

04 June 2018, 14:00 – 19:00, 2F

05 June 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

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 04-05 June 2018. See June 2018 HMPC minutes (to be published post July 2018 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 04-05 June 2018

Time schedule for 04-05 June 2018

### 1.3. Adoption of the minutes

HMPC minutes for 26-27 March 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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Changes of Rapporteurs for PS review

Adhatoda vasica folium

Andrographidis paniculatae folium

Angelicae sinensis radix

Centellae asiaticae herba

Withaniae somniferae radix

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

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Report: MLWP Chair/MLWP Vice-Chair

**Action:** for information

Document: Draft minutes for the MLWP meeting on 28-29 March 2018

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

#### 2.2.1. Monograph on Curcumae longae rhizoma and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 00/132

#### 2.2.2. Monograph on Echinaceae pallidae radix and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 59/62

### 2.2.3. Monograph on Oenotherae biennis oleum and supporting documents

**Action:** for adoption

Documents: MO, AR, LoR; References: 61/106

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

**Action:** for adoption

Documents: MO, AR, LoR, OoC MO, OoC AR; References: 99/96; New references

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

None

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

### 2.4.1. Public statement on Glycini semen and supporting documents

**Action:** for adoption

Documents: PS, AR, LoR; References: 52/49

### 2.4.2. Monograph on Silybi mariani fructus and supporting documents

**Action:** for discussion

Documents: MO, AR, LoR, OoC, Presentation

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

### 2.5.1. Monograph on Malvae folium and supporting documents

**Action:** for adoption

Documents: MO, AR, LoR, OoC; References: 149/119

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

**Action:** for adoption

Documents: MO, AR, LoR, OoC; References: 149/119

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

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

**Action:** for adoption

Document: Review outcome; References: 07/08

## 2.6.2. Monograph on Polypodii rhizoma and supporting documents

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**Action:** for adoption

Document: Review outcome; References: 00/00

## 3. Referral procedures

None

## 4. Guidelines and guidance documents

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

#### 4.1.1. Guideline on non-clinical documentation in applications for marketing authorisation/registration of well- established and traditional herbal medicinal products (EMA/HMPC/32116/2005 Rev.1)

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**Action:** for adoption

Documents: Guideline, OoC

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

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**Action:** for discussion

Documents: Draft revised PS, OoC

### 4.2. Quality

#### 4.2.1. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3)

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Report: Q DG Chair

**Action:** for adoption

Documents: Draft revised Guideline

#### 4.2.2. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)

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Report: Q DG Chair

**Action:** for adoption

Documents: Draft revised Guideline

### 4.3. Regulatory / Procedural

#### 4.3.1. Procedure for the review and revision of European Union herbal monographs and European Union list entries (EMA/HMPC/124695/2011 Rev.2)

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**Action:** for adoption

Documents: Draft procedure; Review template; Addendum template

## 4.4. Report on HMPC Drafting Groups activities

### 4.4.1. Quality DG

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Report: Q DG Chair

- Meeting report from Q DG virtual meeting held on 19 Apr 2018  
**Action:** for adoption  
Document: Meeting report
- Draft agenda for the Q DG virtual meeting to be held 21 Jun 2018  
**Action:** for information  
Document: Draft agenda

### 4.4.2. ORGAM DG

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Report: ORGAM DG Chair

- Meeting report from ORGAM DG virtual meeting held on 23 Apr 2018  
**Action:** for adoption  
Document: Meeting report
- Agenda ORGAM DG meeting to be held on 19 Jun 2018  
**Action:** for information  
Document: Draft agenda
- Appointment for new member at ORGAM DG  
**Action:** for adoption  
[ORGAM mandate](#); Candidature

## 5. Organisational, regulatory and methodological matters

### 5.1. Mandate and organisation of the HMPC

#### 5.1.1. Relocation Preparedness to CxMPs – cancelled

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#### 5.1.2. Update on the EMA relocation

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**Action:** for information  
Document: Presentation

#### 5.1.3. Strategic Review and Learning Meetings

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Austria Presidency meeting – Vienna, 15-17 Oct 2018  
**Action:** for discussion  
Document: Revised Agenda

## 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

Documents: Minutes 12 March 2018; Agenda 3 May 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  
**Action:** for discussion
- AESGP proposal on the simplification of variations specific to herbal medicinal product  
**Action:** for discussion  
Document: QDG proposal

### 5.4.2. 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 working party  
**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

### 5.6.1. Question on HMPC assessment and national monograph use

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Report: HMPC Chair

**Action:** for adoption

## 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 June 2018

## 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

## 6. Any other business

### 6.1. Topics for discussion

#### 6.1.1. Questions from NCAs on Public statement on pyrrolizidine alkaloid contaminations

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**Action:** for adoption

Documents: Summarised responses to questions from BE & NL; Literature

### 6.2. Documents for information

#### 6.2.1. HMPC

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Table of Decisions from HMPC meeting held on 26-27 March 2018

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 27-28 March 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
- Draft agenda of MLWP meeting to be held on 05-07 June 2018

#### 6.2.3. ARSP

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- English template
- English summaries for publication:
  - Black cohosh
  - Agnus castus

- Calendula
- Elder flower
- Mullein flower

#### 6.2.4. Other

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- EU herbal monographs, list entries and public statements post adoption
  - Remaining publication delays:
    - Allii sativi bulbus
    - Pistacia lentiscus (mastix)
    - Cynarae folium
- Conference on 6 June: Reducing the need for antibiotics – The contribution of Complementary and Alternative Medicine

#### 6.2.5. Guideline on quality of water for pharmaceutical use (EMA/150605/2018)

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Documents: Guideline; [Concept paper](#), HMPC comments provided 26 April 2018

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

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- draft template
- summary feedback, examples feedback received

#### 6.2.7. EU – India/AYUSH communication

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#### 6.2.8. Request from NL regarding products on the EU market containing *Erythrina mulungu* Mart. Ex Benth (*Erythrina verna* Vell)

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Document: NL questions to all HMPC members