



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 March 2017  
EMA/HMPC/201087/2017  
Inspections, Human Medicines Pharmacovigilance & Committees Division

## Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 27-28 March 2017

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

27 March 2017, 14:00 – 19:00, 2F

28 March 2017, 09:00 – 13:00, 2F

(AESGP hearing at MLWP: 28 March 2017, 14.00 – 16.00, Room 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 27-28 March 2017. See March 2016 HMPC minutes (to be published post May 2017 HMPC meeting).

New memberships:

Carmen Purdel (Romania) member; start of mandate: 22 Feb 2017

Raluca Iavorszky (Romania) alternate; start of mandate: 22 Feb 2017

Iliana Ionkova (Bulgaria) alternate; start of mandate: 16 Feb 2017

Evita Skukauska (Latvia) member; start of mandate: 20 Feb 2017

Wim Huygh (Belgium) alternate; start of mandate: 14 Feb 2017

Alessandro Assisi (Italy) member; start of mandate: 9 Mar 2017

End of memberships:

Dace Kalke (Latvia) member; end of mandate: 19 Feb 2017

Nadia Grigoras (Romania) member; end of mandate: 21 Feb 2017

### 1.2. Adoption of agenda

HMPC agenda for 27-28 March 2017

Time schedule for 27-28 March 2017

### 1.3. Adoption of the minutes

HMPC minutes for 30-31 Jan 2017

## 2. European Union herbal monographs and list entries

### 2.1. Report on MLWP activities

#### 2.1.1. Report from the MLWP February 2017 meeting

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Report: MLWP Chair

**Action:** for information

Document: Draft minutes for the MLWP meeting on the 1-2 Feb 2017

### 2.1.2. Change in membership of MLWP

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Report: MLWP Chair

**Action:** for discussion

Documents: Resignation letter from a MLWP member, A. J. Vlietinck, 24 Nov 2016; List of expertise

## 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 Meliloti herba and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 88/94; Presentations; Bibliography assessment

### 2.3.2. Monograph on Sennae folium and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 173/224

### 2.3.3. Monograph on Sennae fructus and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 173/224

### 2.3.4. Monograph on Uvae ursi folium and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 15/113

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

### 2.4.1. Monograph on Allii sativi bulbus and supporting documents – postponed

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### 2.4.2. Monograph on Species diureticae and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR, OoC; References: 4/4

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

None

### 3. Referral procedures

None

### 4. Guidelines and guidance documents

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

##### 4.1.1. Reflection paper on Polycyclic aromatic hydrocarbons in HMP/THMP

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**Action:** for discussion

Documents: [Reflection paper](#); Presentation

#### 4.2. Quality

None

#### 4.3. Regulatory

None

#### 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 (FtF) meeting held on 23-24 Feb 2016

**Action:** for adoption

Document: Meeting report

See also 6.2.4.

- Draft agenda for the Q DG meeting to be held on 20 Apr 2017

**Action:** for information

Document: Draft agenda

- Change in membership of Q DG – appointment of new Q DG member

**Action:** for adoption

Documents: Email on call for interest 7 Mar 2017; Nomination

##### 4.4.2. Mandate and membership of ORGAM DG

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Report: HMPC Chair

**Action:** for discussion

Documents: Presentations; Email on call for interest, 16 Feb 2017; Confirmations of interest expressed for memberships; [Current mandate](#); [Possible future mandate for adoption](#); [Work plan](#)

#### 4.4.3. Election of ORGAM DG Chair

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**Action:** for adoption

Documents: Email on call for interest, 16 Feb 2017; Candidatures

#### 4.4.4. Proposal for the revision process of the EU monographs/List entries

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Report: E. V. Galen, A. P. Martins

**Action:** for discussion

Documents: Draft procedure; Template examples; Presentations

See also 6.1.2

#### 4.4.5. Disclaimer for EU herbal monographs

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Report: M. Delbø

**Action:** for discussion

Documents: Presentation; Disclaimer for EU herbal monographs

## 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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Report: HMPC Chair, E. V. Galen, E. Attard

- Transfer from Utrecht, 12-13 Apr 2016 – follow up

**Action:** for discussion

Documents: Email from W. Knöss, 26 May 2016; Summary in presentation; Summary of Strategic Review meeting in NL 2016; Transfer from Utrecht – follow up; Breakout session groups – follow up; Presentation by EMA – Future of HMPC (breakout sessions)

- Presidency meeting – Malta, 26-28 Apr 2017 – update

**Action:** for information

Documents: Draft Agenda; 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

Documents: Minutes from meeting held on 10 Jun 2016; Agenda for the meetings: 22 Sep 2016, 31 Jan 2017, 24 Apr 2017

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

### 5.3.1. Coordination with Safety Working Party – Assessment of estragole

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Rapporteurs: J. Wiesner, H. Foth

**Action:** for discussion

Documents: PS; OoC; Letter from HMPC Chair to CHMP Chair, 15 Sep 2015; SWP response, 16 Nov 2016; Presentation

### 5.3.2. Joint CVMP/CHMP ad hoc expert group meeting on 3Rs (JEG 3Rs = Replacement, Reduction, Refinement)

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- Joint CVMP/CHMP ad hoc expert group meeting on 3Rs  
Report: G. Laekeman  
**Action:** for information  
Documents: Meeting report, 18-19 Oct 2016; Presentation
- New structure J3RsWG - Joint CVMP/CHMP ad hoc expert group  
**Action:** for information  
Documents: J3RsWG Mandate 2017-2019; J3RsWG Work plan 2017; Email correspondence, 9 Jan 2017; Thank you letter to G. Laekeman

## 5.4. Cooperation within the EU regulatory network

### 5.4.1. European Commission

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- European Union herbal monograph on *Saccharomyces cerevisiae* CBS 5926  
**Action:** for adoption  
Document: Draft letter  
**Action:** for discussion  
Documents: Draft MO, draft AR, draft LoR; draft LE; Pros&Cons by FI
- Update on List Entries  
**Action:** for information  
Document: [List of herbal substances, preparations and combinations thereof for use in THMP](#)

### 5.4.2. European Pharmacopeia

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- EDQM 13A expert group meeting held on 28 Feb - 1 Mar 2017  
Report: M. Bald (EDQM); HMPC/Q DG Observer: M. Brum/I. Chinou  
**Action:** for information  
Documents: Agenda; Summary of decisions; Report by M. Brum
- EDQM 13B expert group meeting to be held on 10-11 May 2017  
Report: M. Bald (EDQM); HMPC/Q DG Observer: B. H. Kroes  
**Action:** for information



- EDQM TCM expert group meeting held on 31 Jan – 1 Feb 2017  
Report: M. Bald (EDQM); HMPC/Q DG Observer: R. Länger  
**Action:** for information  
Document: Summary of decisions
- EDQM TCM expert group meeting to be held on 26-27 Apr 2017  
Report: M. Bald (EDQM); HMPC/Q DG Observer: R. Länger  
**Action:** for information
- HMPC herbal substance proposal for Ph. Eur. monograph establishment  
Report: Q DG Chair  
**Action:** for adoption  
Document: List of herbal substances  
  
See also 5.7.1

#### 5.4.3. Pharmacovigilance – Eudravigilance database and Art.16a registered products

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**Action:** for discussion  
Documents: Email correspondence, 17 Oct 2016; [THMP and simplified registrations for homeopathic medicinal products: PhV requirements and EV access](#)

#### 5.4.4. Coordination with EFSA

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- Safety assessment of hydroxyanthracene derivatives  
**Action:** for discussion  
Document: Response from EFSA, 10 Mar 2017

#### 5.4.5. Survey on uptake of the traditional use registration and implementation of Directive 2004/24/EC in EU Member States, 2016 - Preliminary outcome

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**Action:** for information  
Document: Presentation

### 5.5. Cooperation with International Regulators

#### 5.5.1. 9<sup>th</sup> Annual Meeting of IRCH held in New Delhi, India, 8-10 November 2016

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**Action:** for discussion  
Documents: Agenda; Draft Minutes

### 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

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Report: MLWP Chair  
**Action:** for discussion  
Document: Draft Agenda with List of participants

## 5.6.2. EUROCAM

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Report: HMPC Chair

**Action:** for information

Documents: Letter to HMPC Chair, 13 Feb 2017; The regulation of herbal medicinal products in the EU – by EUROCAM, 13 Feb 2017

## 5.7. HMPC work plan

### 5.7.1. Projects on the HMPC work plan 2016

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- Work plan 2016

**Action:** for discussion

Documents: Work plan 2016 – current status; HMPC work plan tracking tool 2016

- Exchange with EDQM on quality standards as basis for EU herbal monographs– proposal of substances for Ph. Eur. monograph establishment

**Action:** for discussion

See also 5.4.2

### 5.7.2. HMPC work plan 2017

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- Work plan 2017

Report: HMPC Chair

**Action:** for discussion

Document: Work plan 2017 – current status

- Develop a strategy for cooperation with Academia to include HMPC standards in the teaching activities and to stimulate research

Report: HMPC Chair

**Action:** for information

Document: Presentation on 'Framework of collaboration between the EMA and Academia'

## 5.8. Planning and reporting

### 5.8.1. Meeting dates for 2019-2021

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**Action:** for adoption

Document: HMPC/MLWP 2019 to 2021

## 5.9. Legislation and regulatory affairs

### 5.9.1. Comments received on draft PS Piperis methystici rhizoma

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**Action:** for discussion

Documents: Comments 10 Feb 2017; Response, 24 Mar 2017

## 6. Any other business

### 6.1. Topics for discussion

#### 6.1.1. Monographs adopted - not yet published

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- Pistacia lentiscus (mastix); Adopted: 2 Feb 2016
- Pruni africanae; Adopted: 12 Jul 2016
- Salviae officinalis folium; Adopted: 20 Sep 2016
- Aloe; Adopted: 22 Nov 2016

#### 6.1.2. Polypodii rhizoma

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**Action:** for discussion  
Documents: Revision of MO; Annex  
See also 4.4.4

#### 6.1.3. Update on Management Board data gathering exercise – postponed

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#### 6.1.4. Survey to committee's members 2016 – follow up

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**Action:** for discussion  
Document: Presentation

### 6.2. Documents for information

#### 6.2.1. HMPC

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Table of Decisions from HMPC meeting held on 30-31 Jan 2017

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 30-31 Jan 2017](#)

[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 28-30 Mar 2017

### 6.2.3. ARSP

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- English template
- English summaries for publication:
  - Soya-bean lecithin
  - Soya-bean oil
  - Olive leaf
  - Willow bark

### 6.2.4. Other

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- Adulteration warning Singapore herbal remedies Mar 2017, Document: HAS Alert - Anyang herbal blue and red – Final
- WHO guideline on good herbal processing practices (GHPP) – COMPILED comments, Document: Comments on draft technical guidelines
- Correction on templates: [MO](#), [AR](#), [Call for scientific data](#)
- PCWP meeting:
  - Minutes - EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations, 30 Nov 2016
- PCWP/HCPWP meetings:
  - Agenda - EMA Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – Workshop on personalised medicines: role of patients, consumers and healthcare professionals, 14 Mar 2017
  - Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting, 15 Mar 2017