



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 July 2015  
EMA/HMPC/449990/2015  
Procedure Management and Committees Support Division

## Committee on Herbal Medicinal Products (HMPC)

### Agenda for the meeting on 6-7 July 2015

Vice-Chair: Marisa Delbó, replacing HMPC Chair

6 July 2015 14:00 – 19:00, 2F

7 July 2015, 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 6-7 July 2015. See July 2015 HMPC minutes (to be published post September 2015 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 6-7 July 2015.

### 1.3. Adoption of the minutes

HMPC minutes for 4-5 May 2015.

## 2. European Union herbal monographs and list entries

### 2.1. Report on MLWP activities

#### 2.1.1. Report from the MLWP May meeting

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Report: MLWP Chair

**Action:** for information

Documents: draft minutes for the MLWP meeting on the 5-7 May 2015

draft meeting report of the AESGP/MLWP hearing held on 5 May 2015

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

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Herbal substance: Piper methysticum G. Forst., rhizoma

#### 2.1.3. Cancellation of assessment work for Juniperi communis summitates

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**Action:** for adoption

Document: presentation

### 2.2. Revised EU herbal monographs and list entries for public consultation/final adoption after systematic review/revision

#### 2.2.1. Monograph on Equiseti herba and supporting documents

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**Action:** for adoption for release for public consultation

Documents: draft MO, AR, LoR; references: 92/127

#### 2.2.2. Monograph on Valerianae aetheroleum and supporting documents

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**Action:** for adoption for release for public consultation

Documents: draft MO, AR, LoR; references 88/96

### 2.2.3. List entry and monograph on Valerianae radix and supporting documents

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**Action:** for adoption for release for public consultation  
Documents: draft LE, draft MO, AR, LoR; references 88/96

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

### 2.3.1. Monograph on Pistacia lentiscus (mastix) and supporting documents

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**Action:** for adoption  
Documents: draft MO, AR, LoR

### 2.3.2. Monograph on Ricini oleum and supporting documents

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**Action:** for adoption  
Documents: draft MO, AR, LoR

### 2.3.3. List entry and monograph on Sideritis herba and supporting documents

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**Action:** for adoption  
Documents: draft LE, draft MO, AR, LoR

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

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**Action:** for adoption  
Documents: draft MO, AR, LoR

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

### 2.4.1. Monograph on Carvi aetheroleum and supporting documents

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Rapporteur: P. Claeson; Peer-reviewer: M. Delbó; Expert: E. Svedlund  
**Action:** for adoption  
Documents: MO, AR, LoR; references: 54/55

### 2.4.2. Monograph on Carvi fructus and supporting documents

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Rapporteur: P. Claeson; Peer-reviewer: M. Delbó; Expert: E. Svedlund  
**Action:** for adoption  
Documents: MO, AR, LoR, OoC; references: 54/55

### 2.4.3. Monograph on *Matricariae aetheroleum* and supporting documents

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Rapporteur: W. Knöss; Peer-reviewer: R. Länger; Expert: C. Werner

**Action:** for adoption

Documents: MO, AR, LoR, OoC; references: 115/127

Document for information: email from W. Knöss dated 25/06/2015  
email from W. Dymowski dated 02/07/2015

### 2.4.4. Monograph on *Matricariae flos* and supporting documents

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Rapporteur: W. Knöss; Peer-reviewer: R. Länger; Expert: C. Werner

**Action:** for adoption

Documents: MO, AR, LoR, OoC; references: 115/127

Document for information: email from W. Knöss dated 25/06/2015  
email from W. Dymowski dated 02/07/2015

## 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 pulegone/menthofuran

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**Action:** for information

Documents: PS, OoC, letter from HMPC to CHMP 06/2015, SWP response 11/2014

### 4.2. Quality

None

### 4.3. Regulatory

#### 4.3.1. Public statement on herbal substances containing constituents associated with safety concerns

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Rapporteurs: Marisa Delbò

**Action:** for information

Documents: [Public statement](#)

### 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 meeting held on 21 May 2015

**Action:** for adoption

Draft agenda for the Q DG meeting to be held on 10 September 2015

**Action:** for information

#### 4.4.2. ORGAM DG

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Report: ORGAM DG Chair

Meeting report from the ORGAM DG meeting held on 19 May 2015

**Action:** for adoption

Draft agenda for the ORGAM DG meeting to be held on 8 September 2015

**Action:** for information

## 5. Organisational, regulatory and methodological matters

### 5.1. Mandate and organisation of the HMPC

#### 5.1.1. Strategic Review & Learning Meetings

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Strategic Review & Learning HMPC-Meeting under the Latvian Presidency (co-hosted by BfArM) held on 18-19 June 2015

Report: HMPC Vice-Chair

**Action:** for information

Documents: presentations, agenda

#### 5.1.2. Assessors Training December 2015

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Report: QDG Chair

**Action:** for discussion

Document: draft agenda, draft agenda with breakout session

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

#### 5.2.1. Coordination with CHMP: drafting group on excipients: ethanol as an excipient (after public consultation)

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**Action:** for information

#### 5.2.2. Coordination with CHMP: Public statement on the use of herbal medicinal products containing pulegone/ menthofuran

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*See also 4.1.1*

### 5.2.3. Coordination with PRAC and other Pharmacovigilance topics

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[PhV/EMA literature monitoring for herbal substances](#)

**Action:** for information

### 5.2.4. Coordination with PDCO

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Report from PDCO meeting held on 17-19 June 2015

Observer: S. Girotto

**Action:** for information

### 5.2.5. Scientific Coordination Board Meeting held on 29 June 2015

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Report: HMPC Vice-Chair

**Action:** information

Document: agenda

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

### 5.3.1. Coordination with PCWP/HCPWP

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Report from PCWP/HCPWP joint meetings held on 3-4 June 2015

Observer: S. Bager

**Action:** for information

### 5.3.2. Coordination with SWP

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Report from SWP meetings

Observer: O. Pelkonen

**Action:** for information

### 5.3.3. Coordination with QRD group

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QRD template for THMPs in mutual recognition and decentralised procedures

Report: ORGAM Chair

**Action:** for discussion

Document: draft discussion paper on QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs

## 5.4. Cooperation within the EU regulatory network



#### 5.4.1. European Pharmacopeia

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EDQM 13B expert group meeting held to be held on 22-23 September 2015

EDQM: M. Bald, U. Rose; HMPC Observer: H. Neef

**Action:** for information

EDQM TCM expert group meeting held on 5-6 May 2015

EDQM: M. Bald, U. Rose; HMPC Observer: R. Länger

**Action:** for information

Document: summary of decisions

EDQM 13A expert group meeting held on 2-3 June 2015

EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou

**Action:** for information

Document: summary of decisions

#### 5.4.2. EU survey on uptake of TUR scheme in EU Member States

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**Action:** for information

Documents: Survey - [EMA/HMPC/322570/2011](#)

### 5.5. Cooperation with International Regulators

#### 5.5.1. HMPC – International representation and cooperation - *postponed*

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

None

### 5.7. HMPC work plan

#### 5.7.1. HMPC work plan 2015 and preparation for 2016

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**Action:** for information

Document: [HMPC work plan 2015](#), presentations, tracking tool

### 5.8. Planning and reporting

#### 5.8.1. EMA Annual report 2014

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**Action:** for information

Document: [EMA Annual report 2014](#)

#### 5.8.2. Meeting dates

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**Action:** for information

Documents: HMPC/MLWP 2016-2018, HMPC drafting groups 2016

## 5.9. Legislation and regulatory affairs

### 5.9.1. Comments on draft revised monograph on [Thymi herba/Primulae radix](#)

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Rapporteur: R. Länger

**Action:** for discussion

Document: letter dated 15 May 2015

## 6. Any other business

### 6.1. Topics for discussion

Taiwanese regulatory system for traditional medicinal products

Affiliation: Department of Chinese Medicine and Pharmacy, Ministry of Health and Welfare, Taiwan

**Action:** for discussion

Documents: presentation, CV's of the representatives

### 6.2. Documents for information

#### 6.2.1. HMPC

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Table of Decisions from HMPC meeting held on 4-5 May 2015

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 5-7 May 2015](#)

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

[Inventory of herbal substances for assessment work – alphabetical order](#)

[Abbreviations in HMPC minutes](#)

Articles:

Detection of pyrrolizide alkaloids in German licensed herbal medicinal teas. *Phytomedicine* 2015 22(6):648–656

Herbal hepatotoxicity in traditional and modern medicine: actual key issues and new encouraging steps. *Front Pharmacol* 2015 6:72

Safety assessment of botanicals and botanical preparations used as ingredients in food supplements: testing a European Food Safety Authority-tiered approach. *Mol Nutr Food Res* 2010 54(2):175-185

#### 6.2.2. MLWP

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Overview of status of MLWP assessment work

Common names of herbal substances in all EU official languages

Draft agenda of MLWP meeting to be held on 7-9 July 2015

### 6.2.3. Other

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ARSP:

- MIS restarted the work on ARSP's
- Translations in all EU languages are to be published