



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 January 2018  
EMA/HMPC/18658/2018  
Inspections, Human Medicines Pharmacovigilance & Committees Division

## Committee on Herbal Medicinal Products (HMPC)

### Agenda for the meeting on 29-30 January 2018

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

29 January 2018, 14:00 – 19:00, 2F

30 January 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 ongoing 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).



## Table of contents

<b>1.</b>	<b>Introduction</b>	<b>4</b>
1.1.	Welcome and declarations of interest of members, alternates and experts .....	4
1.2.	Adoption of agenda.....	4
1.3.	Adoption of the minutes .....	4
<b>2.</b>	<b>European Union herbal monographs and list entries</b>	<b>4</b>
<b>2.1.</b>	<b>Report on MLWP activities .....</b>	<b>4</b>
2.1.1.	MLWP Mandate and Rules of Procedure - revision .....	4
2.1.2.	MLWP work plan 2018 .....	4
2.1.3.	New substances proposed for HMPC assessment.....	4
2.1.4.	Appointment of Rapporteurs and Peer-reviewers .....	5
2.1.5.	Election of MLWP Chair .....	5
2.1.6.	Appointment of new MLWP member .....	5
2.1.7.	Report from the MLWP November 2017 meeting.....	5
<b>2.2.</b>	<b>Revised EU herbal monographs and list entries for final adoption .....</b>	<b>5</b>
2.2.1.	Monograph on Uvae ursi folium .....	5
<b>2.3.</b>	<b>Revised EU herbal monographs and list entries for public consultation .....</b>	<b>5</b>
2.3.1.	Monograph on Rusci aculeati rhizoma and supporting documents .....	5
2.3.2.	Monograph on Hyperici herba and supporting documents.....	5
<b>2.4.</b>	<b>EU herbal monographs, list entries and public statements for final adoption .....</b>	<b>6</b>
<b>2.5.</b>	<b>EU herbal monographs, list entries and public statements for adoption for release for public consultation .....</b>	<b>6</b>
2.5.1.	Monograph on Cisti cretici folium and supporting documents – postponed to March 2018 ...	6
<b>3.</b>	<b>Referral procedures</b>	<b>6</b>
<b>4.</b>	<b>Guidelines and guidance documents</b>	<b>6</b>
<b>4.1.</b>	<b>Non-clinical/clinical safety and efficacy and multidisciplinary .....</b>	<b>6</b>
<b>4.2.</b>	<b>Quality .....</b>	<b>6</b>
<b>4.3.</b>	<b>Regulatory .....</b>	<b>6</b>
<b>4.4.</b>	<b>Report on HMPC Drafting Groups activities.....</b>	<b>6</b>
4.4.1.	Quality DG.....	6
4.4.2.	ORGAM DG .....	7
<b>5.</b>	<b>Organisational, regulatory and methodological matters</b>	<b>7</b>
<b>5.1.</b>	<b>Mandate and organisation of the HMPC .....</b>	<b>7</b>
5.1.1.	Strategic Review and Learning Meetings .....	7
5.1.2.	Election of Co-opted member .....	7
<b>5.2.</b>	<b>Coordination with EMA Scientific Committees or CMDh-v .....</b>	<b>7</b>
5.2.1.	Scientific Coordination Board Meeting.....	7

<b>5.3.</b>	<b>Coordination with EMA Working Parties/Working Groups/Drafting Groups .....</b>	<b>7</b>
5.3.1.	Ethanol used as an excipient in medicinal products for human use .....	7
<b>5.4.</b>	<b>Cooperation within the EU regulatory network .....</b>	<b>8</b>
5.4.1.	Coordination with the European Commission .....	8
5.4.2.	Coordination with European Pharmacopoeia .....	8
5.4.3.	Coordination with EFSA .....	8
<b>5.5.</b>	<b>Cooperation with International Regulators.....</b>	<b>8</b>
<b>5.6.</b>	<b>Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee .....</b>	<b>8</b>
5.6.1.	Requests by Interested Parties .....	8
5.6.2.	Question on HMPC assessment and national monograph use .....	9
<b>5.7.</b>	<b>Work plan .....</b>	<b>9</b>
5.7.1.	HMPC work plan 2017 .....	9
5.7.2.	HMPC work plan 2018 .....	9
<b>5.8.</b>	<b>Planning and reporting .....</b>	<b>9</b>
<b>5.9.</b>	<b>Legislation and regulatory affairs .....</b>	<b>9</b>
5.9.1.	Evidence on the period of traditional use .....	9
5.9.2.	Letter to the HMPC regarding data protection and substance prioritisation .....	9
<b>6.</b>	<b>Any other business</b>	<b>10</b>
6.1.1.	Questions from NCAs on Public statement on pyrrolizidine alkaloid contaminations .....	10
6.1.2.	Follow up on HMPC 2017 assessors training .....	10
6.1.3.	Saccharomyces cerevisiae CBS 5926 .....	10
6.1.4.	User manual on CxMP/EMA external representation .....	10
6.1.5.	Submission and use of confidential data for HMPC assessment work .....	10
6.1.6.	Preparedness for UK's withdrawal from the EU – postponed .....	10
<b>6.2.</b>	<b>Documents for information .....</b>	<b>10</b>
6.2.1.	HMPC .....	10
6.2.2.	MLWP .....	11
6.2.3.	ARSP .....	11
6.2.4.	Feedback on national experiences with HMPC monographs and guidelines .....	11
6.2.5.	New PhV information on herbal substances relevant for HMPC assessment.....	11
6.2.6.	Other .....	11

## 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 29-30 January 2018. See January 2018 HMPC minutes (to be published post March 2018 HMPC meeting).

*End of memberships:*

Gioacchino Calapai (Italy); his membership terminated on 28 November 2017

Per Claeson (Sweden); his membership terminated on 15 January 2018

*New memberships:*

Erika Svedlund, member (Sweden); her membership started on 20 January 2018

Katarzyna Tomaszewska, alternate (Poland); her membership started on 14 December 2017

### 1.2. Adoption of agenda

HMPC agenda for 29-30 January 2018

Time schedule for 29-30 January 2018

### 1.3. Adoption of the minutes

HMPC minutes for 20-21 November 2017

## 2. European Union herbal monographs and list entries

### 2.1. Report on MLWP activities

#### 2.1.1. MLWP Mandate and Rules of Procedure - revision

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**Action:** for adoption

Document: Revised mandate/ RoP Rev. 4

#### 2.1.2. MLWP work plan 2018

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Report: MLWP Chair

Work plan 2018

**Action:** for adoption

Documents: MLWP work plan 2018, list of monographs due for review

#### 2.1.3. New substances proposed for HMPC assessment

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Report: MLWP Chair, E. v. Galen;

**Action:** for discussion

Document: inventory, presentation, proposals for HMPC assessment received: Aloysiae folium (*Lippia citriodora*), Combination: *Rehmannia 6*, Combination: *Species pectorals*, *Ecliptae prostatae herba*, *Herniariae herba* (in combination), *Menyanthes trifoliatae folium* (in combination), *Pueraria lobatae radix*, *Salvia miltiorrhizae rhizoma*, *Siegesbeckia orientalis herba*, *Tribuli terrestris herba*, proposal NL regarding public statements

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

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Changes of Rapporteurs for Monograph revision

#### 2.1.5. Appointment of new Rapporteurs for new substances adopted for start HMPC assessment Election of MLWP Chair

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Report: HMPC Chair;

**Action:** for adoption

Document: Call for candidates from 11 January 2018

#### 2.1.6. Appointment of new MLWP member

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Report: HMPC Chair;

**Action:** for adoption

Document: Call for nominations from 04 January 2018

#### 2.1.7. Report from the MLWP November 2017 meeting

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Report: MLWP Chair;

**Action:** for information

Document: Draft minutes for the MLWP meeting on 20-23 November 2017

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

#### 2.2.1. Monograph on *Uvae ursi folium*

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**Action:** for adoption

Documents: MO, AR, LoR, OoC; References: 111/111

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

#### 2.3.1. Monograph on *Rusci aculeati rhizoma* and supporting documents

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**Action:** for adoption

Documents: Draft MO, AR, LoR; References: 10/57

#### 2.3.2. Monograph on *Hyperici herba* and supporting documents

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**Action:** for adoption

Documents: Draft MO, AR, LoR; References: 236/236

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

None

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

### 2.5.1. Monograph on Cisti cretici folium and supporting documents – postponed to March 2018

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## 3. Referral procedures

None

## 4. Guidelines and guidance documents

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

None

### 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: QDG Chair

- Meeting report from Q DG virtual meeting held on 07 Dec 2017  
**Action:** for adoption  
Document: Meeting report
- Meeting report from Q DG face to face meeting held on 14-15 Dec 2017  
**Action:** for adoption  
Document: Meeting report
- Draft agenda for the Q DG face-to-face meeting to be held 22 Feb 2018  
**Action:** for information  
Document: Draft agenda
- Work Plan 2018  
**Action:** for adoption  
Documents: Draft work plan; QDG 2018 meeting dates

#### 4.4.2. ORGAM DG

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Report: ORGAM DG Chair

- Meeting report from ORGAM virtual meeting held on 05 Dec 2017  
**Action:** for adoption  
Document: Meeting report from ORGAM DG meeting held on 05 Dec 2017
- Draft agenda for the ORGAM DG meeting to be held on 20 Feb 2018  
**Action:** for information  
Document: Draft agenda
- Work Plan 2018  
**Action:** for adoption  
Documents: Draft work plan; ORGAM DG 2018 meeting dates

## 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, HMPC Vice-chair;

Estonia Presidency meeting – Bucharest, 11-12 Oct 2017 – follow up

**Action:** for discussion

Documents: presentations; Follow-up discussion paper

#### 5.1.2. Election of Co-opted member

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Report: HMPC Chair

**Action:** for adoption

Documents: Expertise of HMPC members; Call for nominations from 04 Jan 2018;

### 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: Agenda 11 Dec 2017

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

#### 5.3.1. Ethanol used as an excipient in medicinal products for human use

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**Action:** for discussion

Documents: Ethanol PIL comparison, Q&A, email dated 11 January 2018

## 5.4. Cooperation within the EU regulatory network

### 5.4.1. Coordination with the European Commission

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- Update on List entries  
**Action:** for information
- Update on workshop "[Complementary and alternative therapies for patients today and tomorrow](#)" held at EP, Brussels, 16 October 2017  
**Action:** for information  
Document: summary report, [REFIT Platform Opinion on the submission by businesses on the THMP Directive](#)

### 5.4.2. Coordination with European Pharmacopoeia

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- EDQM 13A expert group meeting to be held on 6-7 March 2018  
**Action:** for information
- EDQM 13B expert group meeting held on 23-24 January 2018  
**Action:** for information  
Document: Draft agenda
- EDQM TCM expert group meeting to be held on 24-25 January 2018  
**Action:** for information  
Document: Draft agenda
- EDQM PA working party

### 5.4.3. Coordination with EFSA

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- Safety assessment of hydroxyanthracene derivatives - update  
**Action:** for discussion  
Document: email communication, comments, EFSA draft opinion
- Safety assessment of green tea - update  
**Action:** for discussion  
Document: email communication, EFSA draft opinion, draft comments

## 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. Requests by Interested Parties

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- Requests for hearing by EUROCAM  
Report: HMPC Chair;  
**Action:** for discussion  
Documents: email communication



- Request for IP status by ECHAMP  
Report: HMPC Chair;  
**Action:** for discussion  
Documents: Request dated 18 Jan 2018

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

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Report: HMPC Chair  
**Action:** for discussion  
Document: Request dated 21 December 2017, Draft HMPC response

### 5.7. Work plan

#### 5.7.1. HMPC work plan 2017

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- Report: HMPC Chair  
**Action:** for discussion  
Document: Work plan 2017 – implementation status
- Project 2.1.1. Patients involvement in assessment work  
**Action:** for discussion  
Documents: Presentation
- Project 2.1.2. Coordination on safety assessments of herbal constituents – postponed
- Project 2.1.3. Cooperation with Academia - postponed  
Report: MLWP Chair;

#### 5.7.2. HMPC work plan 2018

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- Report: HMPC Chair  
**Action:** for adoption  
Documents: Draft Work plan 2018

### 5.8. Planning and reporting

None

### 5.9. Legislation and regulatory affairs

#### 5.9.1. Evidence on the period of traditional use

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**Action:** for discussion

#### 5.9.2. Documents: Request to EC, draft response Jan 2017; presentationsLetter to the HMPC regarding data protection and substance prioritisation

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Report: HMPC Chair  
**Action:** for information  
Document: Letter dated 28 Sept 2017, EMA response dated 22 Jan 2018

## 6. Any other business

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

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**Action:** for discussion

Documents: Response to questions from BE & NL received in May 2017; Literature

### 6.1.2. Follow up on HMPC 2017 assessors training

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Report: ODG Chair

**Action:** for discussion

Documents: agenda, presentations

### 6.1.3. *Saccharomyces cerevisiae* CBS 5926

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**Action:** for discussion

Documents: draft letter dated 22 Jan 2018 rev HMPC Chair; table status in MS

### 6.1.4. User manual on CxMP/EMA external representation

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**Action:** for discussion

Documents: Presentation; User manual

### 6.1.5. Submission and use of confidential data for HMPC assessment work

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**Action:** for discussion

Documents: information received during public consultations

### 6.1.6. Preparedness for UK's withdrawal from the EU – postponed

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## 6.2. Documents for information

### 6.2.1. HMPC

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Table of Decisions from HMPC meeting held on 20-21 November 2017

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 20-21 November 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 30 January-1 February 2018

### 6.2.3. ARSP

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- English template
- English summaries for publication:
  - Hederae heliicis folium
  - Meliloti herba
  - Ribis nigri folium

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

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- draft template
- summary feedback, examples feedback received

### 6.2.5. New PhV information on herbal substances relevant for HMPC assessment

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- summary of available PSURs

### 6.2.6. Other

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- PCWP/HCPWP meetings:
  - Meeting summary of the PCWP meeting with all eligible organisations held on 22 November 2017 (EMA/757232/2017): for information
- Anticipated PMDA/MHLW Recommendations for Regulatory Action
- EU herbal monographs, list entries and public statements post adoption: for information
  - Publication delays 2016/2017 updates
  - Remaining publication delays:
    - Allii sativi bulbus
    - Pistacia lentiscus (mastix)