



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

31 January 2017  
EMA/HMPC/85652/2017  
Inspections, Human Medicines Pharmacovigilance & Committees Division

## Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 21-22 November 2016

Chair: Marisa Delbò

21 November 2016, 14:00 – 19:00, 2F

22 November 2016, 09:00 – 13:00, 2F

### Disclaimers

Some of the information contained in this set of minutes is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this set of minutes 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).



## Table of contents

<b>1.</b>	<b>Introduction</b>	<b>5</b>
1.1.	Welcome and declarations of interest of members, alternates and experts .....	5
1.2.	Adoption of agenda.....	5
1.3.	Adoption of the minutes .....	5
<b>2.</b>	<b>European Union herbal monographs and list entries</b>	<b>6</b>
<b>2.1.</b>	<b>Report on MLWP activities .....</b>	<b>6</b>
2.1.1.	Report from the MLWP September 2016 meeting.....	6
2.1.2.	Prioritisation of substances for assessment .....	6
2.1.3.	Appointment of Rapporteurs and Peer-reviewers .....	6
2.1.4.	MLWP work plan 2017 .....	6
2.1.5.	Change in membership of MLWP.....	7
<b>2.2.</b>	<b>Revised EU herbal monographs and list entries for final adoption .....</b>	<b>7</b>
2.2.1.	Monograph on Aloe and supporting documents.....	7
2.2.2.	Monograph on Boldi folium and supporting documents .....	7
2.2.3.	Monograph on Pelargonii radix and supporting documents .....	7
2.2.4.	Monograph on Salicis cortex and supporting documents .....	8
<b>2.3.</b>	<b>Revised EU herbal monographs and list entries for public consultation .....</b>	<b>8</b>
2.3.1.	Monograph on Echinaceae purpureae radix and supporting documents .....	8
2.3.2.	Monograph on Meliloti herba and supporting documents .....	9
2.3.3.	List Entry and Monograph on Menthae piperitae aetheroleum and supporting documents....	9
2.3.4.	Monograph on Menthae piperitae folium and supporting documents .....	9
2.3.5.	List Entry and Monograph on Vitis viniferae folium and supporting documents.....	9
<b>2.4.</b>	<b>EU herbal monographs, list entries and public statements for final adoption .....</b>	<b>9</b>
<b>2.5.</b>	<b>EU herbal monographs, list entries and public statements for adoption for release for public consultation.....</b>	<b>10</b>
2.5.1.	Monograph on Cisti cretici folium and supporting documents - Postponed .....	10
2.5.2.	Public statement on Piperis methystici rhizoma and supporting documents .....	10
2.5.3.	List Entry and Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents.....	10
<b>3.</b>	<b>Referral procedures</b>	<b>10</b>
<b>4.</b>	<b>Guidelines and guidance documents</b>	<b>10</b>
<b>4.1.</b>	<b>Non-clinical/clinical safety and efficacy and multidisciplinary.....</b>	<b>10</b>
<b>4.2.</b>	<b>Quality.....</b>	<b>11</b>
4.2.1.	Guideline on quality of HMP/THMP – Postponed .....	11
<b>4.3.</b>	<b>Regulatory .....</b>	<b>11</b>
<b>4.4.</b>	<b>Report on HMPC Drafting Groups activities.....</b>	<b>11</b>
4.4.1.	Quality DG.....	11

4.4.2.	ORGAM DG .....	11
4.4.3.	Proposal for the revision process of the EU monographs/List entries .....	12
4.4.4.	Disclaimer for EU herbal monographs.....	12
4.4.5.	Mandate and membership of ORGAM DG .....	12
4.4.6.	ORGAM work plan 2017 .....	12

## **5. Organisational, regulatory and methodological matters 13**

<b>5.1.</b>	<b>Mandate and organisation of the HMPC .....</b>	<b>13</b>
5.1.1.	Election of HMPC Chair .....	13
5.1.2.	Election of MLWP Vice-Chair.....	13
5.1.3.	Strategic Review and Learning Meetings .....	13
5.1.4.	Procedural guidance – revised SOP on MO & LE establishment .....	14
5.1.5.	Updated policy on the handling of competing interests for scientific committees’ members and experts .....	14
<b>5.2.</b>	<b>Coordination with EMA Scientific Committees or CMDh-v .....</b>	<b>14</b>
5.2.1.	Scientific Coordination Board Meeting.....	14
5.2.2.	Coordination with PDCO- Public workshop on extrapolation of efficacy and safety .....	14
<b>5.3.</b>	<b>Coordination with EMA Working Parties/Working Groups/Drafting Groups .....</b>	<b>14</b>
5.3.1.	Coordination with Safety Working Party – Assessment of estragole.....	14
5.3.2.	Joint CVMP/CHMP ad hoc expert group meeting on 3Rs (JEG 3Rs = Replacement, Reduction, Refinement).....	15
<b>5.4.</b>	<b>Cooperation within the EU regulatory network .....</b>	<b>15</b>
5.4.1.	European Pharmacopeia .....	15
5.4.2.	Pharmacovigilance - Signal detection for herbal medicinal products – Postponed .....	16
5.4.3.	Pharmacovigilance – Eudravigilance database and Art.16a registered products.....	16
5.4.4.	EMA survey on uptake of TUR scheme in EU Member States .....	16
<b>5.5.</b>	<b>Cooperation with International Regulators.....</b>	<b>17</b>
5.5.1.	3 <sup>rd</sup> Complementary and Herbal Medicines workshop at the 11 <sup>th</sup> Summit of Heads of Medicines Regulatory Agencies, Interlaken, Switzerland, 10 October 2016.....	17
5.5.2.	9 <sup>th</sup> Annual Meeting of IRCH held in New Delhi, India, 8-10 November 2016.....	17
<b>5.6.</b>	<b>Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee .....</b>	<b>17</b>
5.6.1.	EUCOPE.....	17
5.6.2.	Organisation of hearings with Interested Parties in 2017 .....	17
<b>5.7.</b>	<b>HMPC work plan .....</b>	<b>18</b>
5.7.1.	Projects on the HMPC work plan 2016 .....	18
5.7.2.	HMPC work plan 2017 .....	18
<b>5.8.</b>	<b>Planning and reporting .....</b>	<b>18</b>
<b>5.9.</b>	<b>Legislation and regulatory affairs .....</b>	<b>18</b>
5.9.1.	Evidence on the period of traditional use .....	18

<b>6.</b>	<b>Any other business</b>	<b>19</b>
<b>6.1.</b>	<b>Topics for discussion</b>	<b>19</b>
6.1.1.	Assessment reports summary for the public (ARSPs)	19
6.1.2.	Update on Management Board data gathering exercise	19
6.1.3.	Follow up on Public Statement on Pyrrolizidine alkaloid contaminations/Update of activities in Member States	20
6.1.4.	Information on initiative within the European Commission REFIT consultation	20
<b>6.2.</b>	<b>Documents for information</b>	<b>20</b>
6.2.1.	HMPC	20
6.2.2.	MLWP	20
6.2.3.	Other	21
<b>List of participants</b>		<b>22</b>

## 1. Introduction

### 1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room).

New alternate (Ireland): Rachel Cox; Starting date of mandate: 7 October 2016

End of membership (France): Jacqueline Viguet Poupelloz alternate; End date of mandate: 22 September 2016

### 1.2. Adoption of agenda

HMPC agenda for 21-22 November 2016

Time schedule for 21-22 November 2016

**Outcome:**

The agenda was adopted with a minor change (added point 6.1.4.). The time schedule was endorsed.

It was asked to follow previously agreed deadlines for submission of documents in order to allow all members to prepare for the meeting in particular before adoption of documents. Similar deadlines as agreed for MLWP should be followed in principle.

### 1.3. Adoption of the minutes

HMPC minutes for 19-20 September 2016

**Outcome:**

The minutes were adopted with a minor change in 2.1.3.

## 2. European Union herbal monographs and list entries

### 2.1. Report on MLWP activities

#### 2.1.1. Report from the MLWP September 2016 meeting

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Report: MLWP Chair

**Action:** for information

Document: Draft minutes for the MLWP meeting on the 20-22 Sep 2016

#### 2.1.2. Prioritisation of substances for assessment

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- Three tea combinations (gastrointestinal disorders, mental stress, to aid sleep)

**Action:** for discussion

Documents: [Procedure on management of proposals from interested parties for Community list entries or Community herbal monographs](#), [Guideline on the documentation to be submitted for inclusion into the 'community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'](#)

- Herbal substance name and monograph title for tea combinations

**Action:** for discussion

Documents: [Draft monograph Species diureticae](#); Email communication on translation

**Outcome:**

HMPC agreed in principle to MLWP proposal and Rapporteur appointment for herbal tea combination assessment following the pilot project on Species diureticae.

Difficulties with the substance terminology / monograph title and subsequent translations according to national traditions were explained. Reference was made to the Ph. Eur. monograph 1435.

HMPC noted missing justification for prioritization, specified substance title and scope of the assessment. Clarification is required before allowing addition to the HMPC priority list and publication of a specific call for scientific data.

MLWP to specify and substantiate the proposal. HMPC secretariat to distribute MLWP proposal to all members for consideration of translation and addition to the common name list for final agreement in January 2017.

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

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- Changes of Rapporteur or Peer-reviewers

**Outcome:**

See 2.1.2.

#### 2.1.4. MLWP work plan 2017

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Report: MLWP Chair

**Action:** for adoption

Document: Draft work plan 2017

**Outcome:**

HMPC endorsed draft MLWP work plan requesting final clarifications by MLWP as regards procedural guidance to be revised in coordination with ORGAM DG.

MLWP to discuss final amendments.

Thereafter HMPC secretariat to distribute to all HMPC members for adoption by written procedure until **15 December 2016**.

#### 2.1.5. [Change in membership of MLWP](#)

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Report: MLWP Chair

**Action:** for discussion

Document: Resignation of a MLWP member, A. J. Vlietinck, 24 Nov 2016

**Outcome:**

According to resignation of A. J. Vlietinck membership ceases at the end of the MLWP meeting following the HMPC meeting.

HMPC members and MLWP members to clarify needs for MLWP in January 2017 to allow request for nomination with specified expert profile.

## 2.2. [Revised EU herbal monographs and list entries for final adoption](#)

### 2.2.1. [Monograph on Aloe and supporting documents](#)

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**Action:** for adoption

Documents: MO, AR, LoR, References: 140/171

**Outcome:**

Final revised monograph and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

### 2.2.2. [Monograph on Boldi folium and supporting documents](#)

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**Action:** for adoption

Documents: MO, AR, LoR, References: 53/68

**Outcome:**

Final revised monograph and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

Rapporteur in liaison with HMPC secretariat to check availability and provide references before publication of the finalised documents.

### 2.2.3. [Monograph on Pelargonii radix and supporting documents](#)

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**Action:** for adoption

Documents: MO versions 1-4, AR, LoR, OoC, References: 74/113; Email correspondence; Presentations

**Outcome:**

Adoption postponed and monograph and supporting documents returned to MLWP. In case of remaining open questions on substance-specific and general assessment points, specific list of questions and limited number of solutions to be presented to HMPC for decision.

The Rapporteur presented the main issues during the revision and after public consultation as discussed at MLWP: statistical versus clinical relevance, use in adolescents/children, and equivalence of pharmaceutical forms.

The peer reviewer suggested improvements in presentation of detailed clinical studies in the AR and asked for general clarification on some points before being able to finalise the PR: (1) scope of the review/revision (bronchitis severity score modification only – no systematic review in analogy to Hedera and Primula/Thyme, (2) generic monograph assessment based on publicly available substance data (WEU/TU based on bibliographic data) versus individual product-specific assessment at NCAs.

#### 2.2.4. Monograph on *Salicis cortex* and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR, References: 95/132

**Outcome:**

Adoption postponed and monograph and supporting documents returned to MLWP to discuss and finalise open questions for possible adoption by HMPC in January 2017.

Rapporteur to reflect appropriately final proposal regarding contraindications and warnings in the assessment report.

The committee discussed mainly potential risks related to the salicylate content (e.g. Reye's syndrome) taking into account existing knowledge for acetyl salicylic acid and other salicylate containing herbal substances and their reflection in product/patient information both, for well-established use and traditional use.

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

#### 2.3.1. Monograph on *Echinaceae purpureae radix* and supporting documents

---

**Action:** for adoption

Documents: MO, AR, LoR, References: 32/138

**Outcome:**

Changes introduced in monograph section 4.1. Rapporteur to explain wording of the indication in the draft assessment report before publication.

Draft revised monograph with minor changes and supporting documents adopted by majority vote for 3 months public consultation.

Members discussed mainly the plausibility, meaning and wording of both, the old indication (reworded) and the newly added indication based on information available from the Member States.



### 2.3.2. Monograph on Meliloti herba and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR, References: 88/101

**Outcome:**

Adoption postponed and monograph and supporting documents returned to MLWP for final alignment of assessment report and monograph regarding the preparations included, posology and pharmaceutical form.

### 2.3.3. List Entry and Monograph on Menthae piperitae aetheroleum and supporting documents

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**Action:** for discussion

Documents: LE, MO, AR, LoR, References: 107/205; Presentation

**Outcome:**

Adoption postponed. Final necessary improvements detected during peer review requiring amendment of the documents before adoption for public consultation.

### 2.3.4. Monograph on Menthae piperitae folium and supporting documents

---

**Action:** for discussion

Documents: MO, AR, LoR, References: 107/205

**Outcome:**

Adoption postponed. Final necessary improvements detected during peer review requiring amendment of the documents before adoption for public consultation.

### 2.3.5. List Entry and Monograph on Vitis viniferae folium and supporting documents

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**Action:** for adoption

Documents: LE, MO, AR, LoR, References: 0/130

**Outcome:**

Rapporteur to clean documents (peer reviewer comments) and provide to secretariat for publication.

Draft revised monograph and supporting documents adopted by majority vote for release for public consultation.

HMPC confirmed that there are no relevant new data that would require a revision of the List entry.

The newly introduced qualifier in TU indication 2 was discussed and agreed by a majority. Apart from information on 'no fertility data available', there are no other changes in the revised monograph.

## 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

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**Outcome:**

Adoption postponed to January 2017 meeting.

### 2.5.2. Public statement on *Piperis methystici rhizoma* and supporting documents

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**Action:** for adoption

Documents: PS, AR, LoR

**Outcome:**

Draft public statement and supporting documents adopted by consensus for 3 months public consultation.

### 2.5.3. List Entry and Monograph on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

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**Action:** for adoption

Documents: LE, MO, AR, LoR; Email communication from FI, IE, SI and IT; Presentation

**Outcome:**

Adoption postponed to January 2017 meeting.

No specific questions to CHMP/BWP had been agreed following decision at the HMPC September meeting.

Members with preference for BWP consultation before publication of the draft to provide specific questions to the Rapporteurs by **15 December 2016**. Anticipated HMPC follow-up according to BWP response should be included.

Decision on possible questions to be forwarded to BWP for coordination and/or possible release for public consultation to be taken at the HMPC January 2017 meeting. Members to reflect on classification of the active substance as herbal substance or herbal preparation and Rapporteur to review documents according to the discussion.

## 3. Referral procedures

None

## 4. Guidelines and guidance documents

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

None

## 4.2. Quality

### 4.2.1. Guideline on quality of HMP/THMP – Postponed

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Report: Q DG Chair

## 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 meeting held on 5 October 2016  
**Action:** for adoption  
Document: Meeting report
- Draft agenda for the Q DG meeting to be held on 7 December 2016  
**Action:** for information  
Document: Draft agenda  
**Outcome:**  
Report adopted. No new items were proposed for the Q DG December agenda.
- Q DG work plan 2017  
**Action:** for adoption  
Document: Draft work plan 2017  
**Outcome:**  
Work plan 2017 adopted with minor changes.

HMPC agreed to the review of the marker concept as reflected in the 2008 reflection paper taking into account current definitions and regulatory practice. The work should be started in 2017 under the lead of Q DG and coordinated with MLWP (addition) before HMPC agreement and coordination with EDQM as necessary. At later stage it will be decided which guidance documents may need revision.

### 4.4.2. ORGAM DG

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Report: ORGAM DG Chair

- Meeting report  
**Action:** for adoption  
Document: Meeting report from ORGAM DG meeting held on 6 Oct 2016
- Agenda  
**Action:** for information  
Document: Draft agenda for the ORGAM DG meeting to be held on 6 Dec 2016

**Outcome:**

Report adopted. No new items were proposed for the ORGAM December agenda with main focus on the review/revision procedure.

#### 4.4.3. [Proposal for the revision process of the EU monographs/List entries](#)

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Report: ORGAM DG Chair, A. P. Martins

**Action:** for discussion

Documents: Presentation; Draft procedure; Template example

**Outcome:**

Postponed to January 2017.

#### 4.4.4. [Disclaimer for EU herbal monographs](#)

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Report: M. Delbò, E. Svedlund

**Action:** for discussion

Documents: Presentation; Disclaimer for EU herbal monographs

**Outcome:**

Postponed to January 2017.

#### 4.4.5. [Mandate and membership of ORGAM DG](#)

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Report: ORGAM DG Chair

**Action:** for discussion

Documents: Presentation; [Current mandate](#); [Possible future mandate](#)

**Outcome:**

Postponed. HMPC noted expiry of the ORGAM DG Chair fourth mandate on 26 January 2017.

The election of the new DG Chair and Members will take place following HMPC discussion and decision on future structure of ORGAM DG (including need for DG Chair and changes to mandates) scheduled for January 2017.

HMPC secretariat to send out a call for expression of interest for ORGAM DG membership and Chairmanship to be taken into consideration for the HMPC decision in January.

#### 4.4.6. [ORGAM work plan 2017](#)

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Report: ORGAM DG Chair

**Action:** for adoption

Document: Draft work plan 2017

**Outcome:**

ORGAM work plan 2017 was adopted, pending the finalization of the MLWP work plan for coordination on guidelines to be revised.

## 5. Organisational, regulatory and methodological matters

### 5.1. Mandate and organisation of the HMPC

#### 5.1.1. Election of HMPC Chair

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**Action:** for adoption

Documents: Procedure for the election of HMPC Chair; Email, 29 Sep 2016; [HMPC rules of procedure](#); Candidatures

**Outcome:**

Election for the position of Chair took place on 21 November 2016, in accordance with the 'Procedure for the election of the HMPC Chair and Vice-Chair' (EMA/604262/2016) based on the HMPC rules of procedure (EMA/HMPC/139800/2004 Rev 3).

Marisa Delbò was elected as new HMPC Chair for a three year mandate starting 21 November 2016.

HMPC noted upcoming HMPC Vice-Chair election at the January 2017 meeting according to HMPC decision in September. HMPC secretariat will send out the call for candidatures.

#### 5.1.2. Election of MLWP Vice-Chair

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**Action:** for adoption

Documents: Email, 13 Oct 2016; [Mandate, objectives and rules of procedure for the HMPC WP on Community Monographs and Community List \(MLWP\)](#); Candidatures

**Outcome:**

Election for the position of MLWP Vice-Chair took place on 21 November 2016, in accordance with the MLWP mandate (EMA/HMPC/358825/2005 Rev.3).

B. Kroes was elected as new MLWP Vice-Chair for a three year mandate starting 22 November 2016.

#### 5.1.3. Strategic Review and Learning Meetings

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Report: HMPC Chair; E. van Galen

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

**Action:** for discussion

Documents: Email from HMPC Chair, 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 – breakout sessions

**Outcome:**

Postponed to January 2017.

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

**Action:** for information

Documents: Agenda; Presentation

**Outcome:**

Postponed to January 2017.

#### 5.1.4. Procedural guidance – revised SOP on MO & LE establishment

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**Action:** for information

Documents: [Standard operating procedure \(SOP\)](#); Presentation

**Outcome:**

Postponed to January 2017.

#### 5.1.5. Updated policy on the handling of competing interests for scientific committees' members and experts

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**Action:** for information

Documents: Presentation; [EMA policy on the handling of competing interests of scientific committees' members and experts](#)

**Outcome:**

HMPC members were informed on the updated policy on the handling of competing interests of scientific committees' members and experts, which becomes applicable as from **01 December 2016** (policy 0044). The update stems from an alignment with the policy on the handling of competing interests for Management Board members. Committee members impacted by the updated policy will be contacted by EMA as necessary.

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

#### 5.2.1. Scientific Coordination Board Meeting

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**Action:** for information

Documents: Minutes from meeting held on 10 June 2016; Agenda from the meeting held on 22 Sep 2016

**Outcome:**

Postponed to January 2017.

#### 5.2.2. Coordination with PDCO- Public workshop on extrapolation of efficacy and safety

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**Action:** for information

Document: Presentation

**Outcome:**

Postponed to January 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, M. Andersson (SWP)

**Action:** for discussion

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

**Outcome:**

HMPC welcomed SWP response on questions submitted in September 2015.

Practical implications for marketed medicinal products (estragole in excipients or active substance) and relevant HMPC monographs to be discussed at MLWP January 2017. If necessary new communication to HMPC, CMDh and CHMP to be agreed.

HMPC Rapporteurs to review response and necessary changes in the draft revised public statement EMA/HMPC/137212/2005 Rev 1. Rapporteurs for estragole containing substances to show consequences according to posology and duration of use in HMPC monographs.

The SWP response on 4 questions was discussed in particular regarding applicable model, mechanism, limits of a threshold-based reasoning as well as background exposure via food. While it is currently debated whether an acceptable exposure limit can be based on the limited available toxicological data, the regulatory consequences for medicinal products on the market, i.e. the risk management needs further discussion.

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

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Report: G. Laekeman

**Action:** for discussion

Documents: Meeting report, 18-19 Oct 2016; Presentation

**Outcome:**

Postponed to January 2017.

## 5.4. Cooperation within the EU regulatory network

### 5.4.1. European Pharmacopeia

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- EDQM 13A expert group meeting held on 8-10 Nov 2016  
EDQM: M. Bald; HMPC Observer: I. Chinou  
**Action:** for information  
Document: Agenda
  - EDQM 13B expert group meeting held on 13-14 Sep 2016  
EDQM: M. Bald; HMPC Observer: to be confirmed  
**Action:** for information  
Document: Summary of decisions
  - EDQM TCM expert group meeting held on 20-21 Sep 2016  
EDQM: M. Bald; HMPC Observer: R. Länger  
**Action:** for information  
Document: Summary of decisions
- Outcome:**  
HMPC noted highlighted information from the 3 expert groups including the revision of the hawthorn monographs with regard to distinctive chemical profiles of different species and a proposal to the Ph. Eur. commission to start a pilot for a TCM substance with a different approach regarding assay requirements.

- Request for establishment of analytical method for pyrrolizidine alkaloids  
EDQM: M. Bald; HMPC: L. Anderson  
**Action:** for discussion  
Documents: Letter from EDQM, 22 Sep 2016; Response to EDQM 9 Nov 2016; Response from EDQM 18 Nov 2016

**Outcome:**  
Following recent communication HMPC noted that the decision to develop an official Ph. Eur. assay for pyrrolizidine alkaloids is delayed since a feasibility study is considered necessary before proposing to Ph. Eur. Commission (possibly March 2017). HMPC members regretted the delay since the matter is considered a question of public health, some methods are already available/used and NCAs already ask for data for new and existing products on the market.

HMPC Q DG to further integrate requirements on PA testing into quality guidelines.
- Q DG Observers at EDQM experts group, 13A, 13B, TCM  
Report: Q DG Chair  
**Action:** for adoption  
Documents: Meeting dates in 2017; H. Neef resignation letter, 19 Sep 2016  
*See 4.4.1*

**Outcome:**  
Following resignation by H. Neef and preference by EDQM for quality assessors from NCAs and Q DG members as observers for 2017 were appointed: **13A:** previous observer I. Chinou (HMPC) and M. Brum (Q DG) according to their availability, **13B:** B. Kroes, **TCM:** R. Laenger.

HMPC confirmed the importance of having observers at the three expert groups and their written reports to Q DG and HMPC.

#### 5.4.2. Pharmacovigilance - Signal detection for herbal medicinal products – Postponed

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

**Action:** for discussion  
Document: Presentation

**Outcome:**  
Postponed to January 2017.

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

**Action:** for adoption  
Documents: Timetable; List of questions

**Outcome:**  
Adopted.



## 5.5. Cooperation with International Regulators

### 5.5.1. 3<sup>rd</sup> Complementary and Herbal Medicines workshop at the 11<sup>th</sup> Summit of Heads of Medicines Regulatory Agencies, Interlaken, Switzerland, 10 October 2016

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**Action:** for information

Documents: Report by W. Knöss; Minutes; Presentation by W. Knöss; Attendees list

**Outcome:**

HMPC noted feedback on the workshop by EMA international affairs department and previous HMPC Chair as provided in the meeting documents.

The importance given to herbal medicines regulation was noted. The report highlighted also that (A) The workshop is driven by an ACSS-consortium (Australia, Canada, Singapore, Switzerland) having information exchange and work sharing. Four assessments finalized (e.g. Ginkgo) are potentially of interest regarding methodology and outcome. (B) The summit is a chance to exchange information amongst high management of regulatory authorities, while participation of herbal experts is limited. The relevance of future herbal workshops may be discussed case-by-case. Beside frequent participation of few key persons with special interest, participation will always depend on the host country making it difficult to develop a continued, target-oriented strategy with a defined outcome.

### 5.5.2. 9<sup>th</sup> Annual Meeting of IRCH held in New Delhi, India, 8-10 November 2016

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**Action:** for information

Document: Agenda

**Outcome:**

Postponed to January 2017.

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

### 5.6.1. EUCOPE

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Report: HMPC Chair

**Action:** for discussion

Documents: Letter to HMPC, 25 Jul 2016; Response from HMPC, 12 Oct 2016

**Outcome:**

Postponed to January 2017.

### 5.6.2. Organisation of hearings with Interested Parties in 2017

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Report: MLWP Chair

**Action:** for discussion

Document: Proposal by MLWP Chair, 14 Nov 2016

**Outcome:**

Postponed to January 2017.

## 5.7. HMPC work plan

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

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**Action:** for discussion

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

**Outcome:**

Postponed to January 2017.

- Involvement of patient representatives in HMPC

Report: S. Bager

**Action:** for discussion

Documents: Patient involvement; Presentation

**Outcome:**

HMPC noted list of patient representatives that expressed an interest in herbal medicine, although mostly not from organisations focussed on OTC products and minor diseases. The input into herbal summaries for the public was confirmed as useful.

For training purposes, starting in January 2017, 2 representatives at a time will attend the next HMPC meetings. For any upcoming assessments where patient involvement is considered useful, HMPC members are invited to flag the request to the EMA secretariat and the HMPC member at the PCWP.

### 5.7.2. HMPC work plan 2017

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Report: HMPC Chair

**Action:** for adoption

Document: Draft work plan

**Outcome:**

No proposals (deadline 18 October) had been submitted. Apart from remaining 2 year (2016/2017) projects, the HMPC draft work plan 2017 needs still to be developed regarding activities in 2017, topic leads and members contributing.

HMPC members to provide proposals by **15 December**. HMPC Chair in liaison with secretariat to compile proposals for adoption of the HMPC work plan 2017 by written procedure until **10 January 2017**.

## 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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Report: E. v. Galen

**Action:** for discussion

Documents: Question for clarification, 30 Aug 2016; Response from EC, 11 Oct 2016;

Presentation

**Outcome:**

HMPC noted EMA legal view confirmed by the Eur. Com.. EMA legal department agreed to reconsider justification of response in view of previous interpretations and clarifications given by HMPC members for discussion at the HMPC January 2017 meeting.

The legal view regarding possible consideration of oversea areas and former colonies for requirements of Art. 16a(1)(d) and 16c(1)(c) was discussed taking into account regions, historic developments, existing treaties as well as timing and previous interpretation by EC and HMPC regarding the period of use.

## 6. Any other business

### 6.1. Topics for discussion

#### 6.1.1. Assessment reports summary for the public (ARSPs)

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- English summaries for publication:
  - Marjoram
  - Sage leaf
  - Arnica flower
  - Javanese turmeric
  - Eucalyptus oil
  - Pygeum africanum bark
  - Marshmallow root
  - Devil's claw root
  - Bladderwrack

- English template

**Outcome:**

No specific comments were raised.

- Procedure of the ARSP translations, Document: Presentation

**Outcome:**

Because of pertaining issues with the translations of herbal summaries despite development of several procedural tools over the last 2 years, HMPC agreed to discontinue the translation of ARSPs. No new translations will be generated from November 2016 onwards. Translations initiated before will be finalised and published. Already published translations remain on the EMA website.

The generation and publication of English summaries will continue according to standard procedure including consultation of patient representatives (see also 5.7.1).

Proposals for the improvement of the English template are welcome and should be provided to the secretariat. HMPC members asked for feedback on such proposals in the future.

#### 6.1.2. Update on Management Board data gathering exercise

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**Action:** for discussion

**Outcome:**

Postponed to January 2017.

### 6.1.3. Follow up on Public Statement on Pyrrolizidine alkaloid contaminations/Update of activities in Member States

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Report: HMPC Chair

**Action:** for discussion

Documents: EDQM response on Pyrrolizidine alkaloids, 3 August 2016; List of questions; Presentation

**Outcome:**

HMPC noted report on measures taken in EU member states following the HMPC public statement EMA/HMPC/328782/2016. Still incomplete information on data situation was noted.

It was emphasised that implementation is in Member State responsibility, while the integration of PA testing in HMPC quality guidance is discussed at the HMPC Quality DG. Further communication with EDQM regarding method development was highlighted as important towards a harmonised approach (see also 5.4.1).

The feedback from Member States demonstrated partially different measures across Member States in terms of (most) affected species, communication, possible timelines or availability of batch data. Risks of reduced testing schemes and available analytical resources were discussed. It was also confirmed that testing requests are already discussed during MRP/DCP procedures.

### 6.1.4. Information on initiative within the European Commission REFIT consultation

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Report: Zs. Birone-Sandor

**Action:** for discussion

**Outcome:**

Following email communication to all members an update is scheduled for the HMPC January 2017 meeting.

## 6.2. Documents for information

### 6.2.1. HMPC

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Table of Decisions from HMPC meeting held on 19-20 September 2016

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 19-20 September 2016](#)

[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 22-24 Nov 2016

### 6.2.3. Other

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- Revised regulatory questions and answers - EMA/HMPC/345132/2010, Document: Revised Q&A
- Assessors Training 3-4 Nov 2016; Documents: Presentations
- Monograph on Harpagophyti radix; Documents: MO, AR, Email correspondence
- Ongoing first centralised procedure for herbal medicinal product for veterinary use at CVMP
- PCWP meeting:
  - Minutes - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) meeting – 14 June 2016 (EMA/419205/2016)
  - Agenda - Training session for patients and consumers interested in EMA activities (29 Nov 2016)(EMA/636824/2016)
  - Agenda - PCWP meeting with all eligible organisations (30 Nov 2016) (EMA/668397/2016)

## List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 21-22 November 2016 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Marisa Delbò	Chair	Italy	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Heidi Neef	Member	Belgium	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Elena Mustakerova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Maria Stavrou	Member	Cyprus	No interests declared	
Marie Heroutova	Member	Czech Republic	No interests declared	
Martina Holenkova	Expert	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Sari Koski	Alternate (via TC)	Finland	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Zoi Karampourmpouni	Alternate	Greece	No interests declared	
Zsuzsanna Biróné Dr Sándor	Member	Hungary	No interests declared	
Una Mockler	Member	Ireland	No restrictions applicable to this meeting	
Rachel Cox	Alternate	Ireland	No interests declared	
Gioacchino Calapai	Co-opted member	Italy	No interests declared	
Silvia Giroto	Co-opted member	Italy	No interests declared	
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Baiba Jansone	Alternate	Latvia	No interests declared	
Rugile Pilviniene	Member	Lithuania	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	

Emiel Van Galen	Member	Netherlands	No interests declared	
Steinar Madsen	Member	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Nadia Grigoras	Member	Romania	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Samo Kreft	Member	Slovenia	No restrictions applicable to this meeting	
Adela Nunez Velazquez	Member	Spain	No interests declared	
Cristina Martinez Garcia	Alternate	Spain	No interests declared	
Per Claeson	Member	Sweden	No interests declared	
Erika Svedlund	Alternate	Sweden	No interests declared	
Linda Anderson	Member	United Kingdom	No interests declared	
Melanie Bald	Observer (via TC)	EDQM	No interests declared	