



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 November 2016
EMA/HMPC/758101/2016
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 21-22 November 2016

Chair: vacant

21 November 2016, 14:00 – 19:00, 2F

22 November 2016, 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).



Table of contents

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

4.4.2.	ORGAM DG	8
4.4.3.	Proposal for the revision process of the EU monographs/List entries	8
4.4.4.	Disclaimer for EU herbal monographs.....	8
4.4.5.	Mandate and membership of ORGAM DG	8
4.4.6.	ORGAM work plan 2017	9

5. Organisational, regulatory and methodological matters 9

5.1.	Mandate and organisation of the HMPC	9
5.1.1.	Election of HMPC Chair	9
5.1.2.	Election of MLWP Vice-Chair.....	9
5.1.3.	Strategic Review and Learning Meetings	9
5.1.4.	Procedural guidance – revised SOP on MO & LE establishment	9
5.1.5.	Updated policy on handling competing interests for scientific committees’ members and experts.....	9
5.2.	Coordination with EMA Scientific Committees or CMDh-v	10
5.2.1.	Scientific Coordination Board Meeting.....	10
5.2.2.	Coordination with PDCO- Public workshop on extrapolation of efficacy and safety	10
5.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	10
5.3.1.	Coordination with Safety Working Party – Assessment of estragole.....	10
5.3.2.	Joint CVMP/CHMP ad hoc expert group meeting on 3Rs (JEG 3Rs = Replacement, Reduction, Refinement).....	10
5.4.	Cooperation within the EU regulatory network	10
5.4.1.	European Pharmacopeia	10
5.4.2.	Pharmacovigilance - Signal detection for herbal medicinal products – Postponed	11
5.4.3.	Pharmacovigilance – Eudravigilance database and Art.16a registered products.....	11
5.4.4.	EMA survey on uptake of TUR scheme in EU Member States	11
5.5.	Cooperation with International Regulators.....	11
5.5.1.	3 rd Complementary and Herbal Medicines workshop at the 11 th Summit of Heads of Medicines Regulatory Agencies, Interlaken, Switzerland, 10 October 2016.....	11
5.5.2.	9 th Annual Meeting of IRCH to be held in New Delhi, India, 8-10 November 2016	11
5.6.	Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee	11
5.6.1.	EUCOPE.....	11
5.6.2.	Organisation of hearings with Interested Parties in 2017	11
5.7.	HMPC work plan	12
5.7.1.	Projects on the HMPC work plan 2016	12
5.7.2.	HMPC work plan 2017	12
5.8.	Planning and reporting	12
5.9.	Legislation and regulatory affairs	12
5.9.1.	Evidence on the period of traditional use	12

6.	Any other business	12
6.1.	Topics for discussion	12
6.1.1.	ARSP	12
6.1.2.	Update on Management Board data gathering exercise	13
6.1.3.	Follow up on Public Statement on Pyrrolizidine alkaloid contaminations/Update of activities in Member States	13
6.2.	Documents for information	13
6.2.1.	HMPC	13
6.2.2.	MLWP	13
6.2.3.	Other	13

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 21-22 November 2016. See November 2016 HMPC minutes (to be published post January 2017 HMPC meeting).

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

1.2. Adoption of agenda

HMPC agenda for 21-22 November 2016

Time schedule for 21-22 November 2016

1.3. Adoption of the minutes

HMPC minutes for 19-20 September 2016

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP September 2016 meeting

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

- 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

2.1.3. Appointment of Rapporteurs and Peer-reviewers

- Changes of Rapporteur or Peer-reviewers

2.1.4. MLWP work plan 2017

Report: MLWP Chair

Action: for adoption

Document: Draft work plan 2017

2.1.5. Change in membership of MLWP

Report: MLWP Chair

Action: for discussion

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

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

2.2.1. Monograph on Aloe and supporting documents

Action: for adoption

Documents: MO, AR, LoR, References: 102/171

2.2.2. Monograph on Boldi folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR, References: xx/xx

2.2.3. Monograph on Pelargonii radix and supporting documents

Action: for adoption

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

2.2.4. Monograph on Salicis cortex and supporting documents

Action: for adoption

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

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

2.3.2. Monograph on Meliloti herba and supporting documents

Action: for adoption

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

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

Action: for adoption

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

2.3.4. Monograph on Menthae piperitae folium and supporting documents

Action: for discussion

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

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

Action: for discussion

Documents: LE, MO, AR, LoR, References: xx/xx

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

2.5.2. Public statement on Piperis methystici rhizoma and supporting documents

Action: for adoption

Documents: PS, AR, LoR

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

Action: for adoption

Documents: LE, MO, AR, LoR; Email communication; Presentation

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

4.3. Regulatory

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair

- Meeting report from Q DG meeting held on 5 Oct 2016
Action: for adoption
Document: Meeting report
- Draft agenda for the Q DG meeting to be held on 7 Dec 2016
Action: for information
Document: Draft agenda
- Q DG work plan 2017
Action: for adoption
Document: Draft work plan 2017

4.4.2. ORGAM DG

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 xxx Dec 2016

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

Report: ORGAM DG Chair, A. P. Martins

Action: for discussion

Documents: Presentation; Draft procedure; Template example

4.4.4. Disclaimer for EU herbal monographs

Report: M. Delbò, E. Svedlund

Action: for discussion

Documents: Presentation; Disclaimer for EU herbal monographs

4.4.5. Mandate and membership of ORGAM DG

Report: ORGAM DG Chair

Action: for discussion

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

4.4.6. [ORGAM work plan 2017](#)

Report: ORGAM DG Chair

Action: for adoption

Document: Draft work plan 2017

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. [Election of HMPC Chair](#)

Action: for adoption

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

5.1.2. [Election of MLWP Vice-Chair](#)

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

5.1.3. [Strategic Review and Learning Meetings](#)

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

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

Action: for information

5.1.4. [Procedural guidance – revised SOP on MO & LE establishment](#)

Action: for information

Documents: [SOP](#), Presentation

5.1.5. [Updated policy on handling competing interests for scientific committees' members and experts](#)

Action: for information

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

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Action: for information

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

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

Action: for information

Document: Presentation

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

5.3.1. Coordination with Safety Working Party – Assessment of estragole

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

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

Report: G. Laekeman

Action: for discussion

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

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- 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
- Request for establishment of analytical method for pyrrolizidine alkaloids
EDQM: M. Bald; HMPC: L. Anderson
Action: for discussion

Document: Letter from EDQM, 22 Sep 2016

- 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

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

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

Action: for adoption

Documents: Timetable; List of questions

5.5. Cooperation with International Regulators

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

Action: for information

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

5.5.2. 9th Annual Meeting of IRCH to be held in New Delhi, India, 8-10 November 2016

Action: for information

Document: Agenda

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

5.6.1. EUCOPE

Report: HMPC Chair

Action: for discussion

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

5.6.2. Organisation of hearings with Interested Parties in 2017

Report: MLWP Chair

Action: for discussion

Document: Proposal by MLWP Chair, 14 Nov 2016

5.7. HMPC work plan

5.7.1. Projects on the HMPC work plan 2016

Action: for discussion

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

- Involvement of patient representatives in HMPC

Action: for discussion

Document: Patient involvement

5.7.2. HMPC work plan 2017

Report: HMPC Chair

Action: for adoption

Document: Draft work plan

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

5.9.1. Evidence on the period of traditional use

Report: E. v. Galen

Action: for discussion

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

Presentation

6. Any other business

6.1. Topics for discussion

6.1.1. ARSP

- 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
- Procedure of the ARSP translations, Document: Presentation

6.1.2. Update on Management Board data gathering exercise

Action: for discussion

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

Report: HMPC Chair

Action: for discussion

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

6.2. Documents for information

6.2.1. HMPC

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

- 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

- 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)