



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2016
EMA/HMPC/616784/2016
Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 19-20 September 2016

Chair: Werner Knöss – Vice-Chair: Marisa Delbò

19 September 2016, 14:00 – 19:00, 2F

20 September 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 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

1.	Introduction	4
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
2.	European Union herbal monographs and list entries	4
2.1.	Report on MLWP activities	4
2.1.1.	Report from the MLWP July 2016 meeting.....	4
2.1.2.	Appointment of Rapporteurs and Peer-reviewers	4
2.1.3.	MLWP membership	5
2.2.	Revised EU herbal monographs and list entries for final adoption	5
2.2.1.	Monograph on Pelargonii radix and supporting documents – postponed	5
2.2.2.	Monograph on Salviae officinalis folium and supporting documents	5
2.3.	Revised EU herbal monographs and list entries for public consultation	5
2.4.	EU herbal monographs, list entries and public statements for final adoption	5
2.4.1.	Monograph on Origani majoranae herba	5
2.4.2.	Monograph on Silybi mariani fructus	5
2.5.	EU herbal monographs, list entries and public statements for adoption for release for public consultation	6
2.5.1.	List Entry and Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents.....	6
2.5.2.	Monograph on Species diureticae and supporting documents	6
3.	Referral procedures	6
4.	Guidelines and guidance documents	6
4.1.	Non-clinical/clinical safety and efficacy and multidisciplinary.....	6
4.2.	Quality.....	6
4.3.	Regulatory	6
4.3.1.	Patient Leaflet template concerning advice on preparations of herbal teas by end-users	6
4.3.2.	Revised regulatory questions and answers - EMA/HMPC/345132/2010	6
4.4.	Report on HMPC Drafting Groups activities.....	6
4.4.1.	Quality DG.....	6
4.4.2.	ORGAM DG	7
5.	Organisational, regulatory and methodological matters	7
5.1.	Mandate and organisation of the HMPC	7
5.1.1.	Preparation for election of HMPC Chair and Vice-Chair	7
5.1.2.	Assessors Training 3-4 November 2016	7
5.1.3.	Strategic Review and Learning Meetings	8
5.1.4.	Procedural guidance – revised SOP on MO & LE establishment – postponed	8

5.2.	Coordination with EMA Scientific Committees or CMDh-v	8
5.2.1.	Coordination with CHMP: drafting group on excipients: ethanol as an excipient	8
5.2.2.	Coordination with CMDh – Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual recognition and Decentralised procedures for (T)HMPs	8
5.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	8
5.3.1.	Coordination with Innovation Task Force and CHMP	8
5.4.	Cooperation within the EU regulatory network	8
5.4.1.	European Pharmacopeia	8
5.5.	Cooperation with International Regulators.....	9
5.5.1.	HMPC – International representation and cooperation	9
5.5.2.	EU-India joint working group July 2016	9
5.5.3.	Announcement of the 3 rd Complementary and Herbal Medicines workshop at the 11 th Summit of Heads of Medicines Regulatory Agencies, Interlaken, Switzerland, 10 October 2016	9
5.5.4.	Announcement of the 9th Annual Meeting of IRCH to be held in New Delhi, India, 8-10 November 2016.....	9
5.6.	Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee	9
5.6.1.	EUCOPE.....	9
5.7.	HMPC work plan	9
5.7.1.	Projects on the HMPC work plan 2016	9
5.7.2.	Preparation of HMPC work plan 2017.....	10
5.8.	Planning and reporting	10
5.9.	Legislation and regulatory affairs	10
6.	Any other business	10
6.1.	Topics for discussion	10
6.1.1.	ARSP.....	10
6.1.2.	Update on Management Board data gathering exercise.....	10
6.1.3.	Information on EMA internal organisational adjustments.....	10
6.1.4.	Follow up on Public Statement on Pyrrolizidine alkaloid contaminations/Update of activities in Member States	10
6.1.5.	Evidence on the period of traditional use	11
6.2.	Documents for information.....	11
6.2.1.	HMPC.....	11
6.2.2.	MLWP.....	11
6.2.3.	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 19-20 September 2016. See September 2016 HMPC minutes (to be published post November 2016 HMPC meeting).

Mandate of member and alternate of Estonia is vacant, informed by NCA. Expiry date for both mandates: 22 September 2016.

End of mandate:

- Annamarie O'Sullivan (Ireland) alternate resigned. Her membership in HMPC ended on 16 August 2016
- Tina-Soon Engraff (European Commission) resigned. Her mandate ended 29 July 2016

1.2. Adoption of agenda

HMPC agenda for 19-20 September 2016

Time schedule for 19-20 September 2016

1.3. Adoption of the minutes

HMPC minutes for 11-12 July 2016

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP July 2016 meeting

Report: MLWP Chair

Action: for information

Document: Draft minutes for the MLWP meeting on the 12-14 July 2016

2.1.2. Appointment of Rapporteurs and Peer-reviewers

- Changes of Rapporteur or Peer-reviewers for Monograph revision
 - Absinthii herba
 - Anisi aetheroleum
 - Anisi fructus
 - Arctii radix

2.1.3. MLWP membership

- Call for nominations for **position 1** (medical doctor with expertise in paediatrics)
Report: HMPC Chair
Action: for discussion
Documents: Mandate of MLWP; Email, 29 April 2016; Correspondence with PDCO and HCPWG; DE & IT nominations
- Call for nominations for **position 2** (clinical/non-clinical assessor)
Report: HMPC Chair
Action: for discussion
Documents: Email, 28 July 2016; DE & IT nominations

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

2.2.1. Monograph on *Pelargonii radix* and supporting documents – postponed

2.2.2. Monograph on *Salviae officinalis folium* and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC, References: 61/68

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

None

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

2.4.1. Monograph on *Origani majoranae herba*

Rapporteur: C. Cavaleiro; Peer-reviewer: M. Heroutová
Action: for adoption
Documents: MO, AR, LoR, References: 34/38

2.4.2. Monograph on *Silybi mariani fructus*

Rapporteur: O. Palomino; Peer-reviewer: W. Knöss
Action: for adoption
Documents: MO, AR, LoR, OoC, References: 114/196

Action: for information

Document: Draft agenda for the Q DG meeting to be held on 5 October 2016

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report
Action: for adoption
Document: Meeting report from ORGAM DG meeting held on 6 September 2016
- Agenda
Action: for information
Document: Draft agenda for the ORGAM DG meeting to be held on 6 October 2016
- Draft revised template for EU herbal monographs
Action: for discussion
Document: Presentation
- Proposal for the revision process of the EU monographs/List entries
Action: for discussion
Document: Presentation
- Resignation of M. Delbó as ORGAM member effective from 10 July 2016
Action: for discussion
Documents: Resignation letter; IT nomination
- Mandate and membership of ORGAM DG
Action: for discussion
Documents: Presentation; [Current mandate](#); [Possible future mandate](#)

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Preparation for election of HMPC Chair and Vice-Chair

Action: for discussion

Document: Procedure for the election of HMPC Chair and Vice-Chair

5.1.2. Assessors Training 3-4 November 2016

Report: S. Bager

Action: for adoption

Document: Draft Agenda

5.1.3. Strategic Review and Learning Meetings

Report: HMPC Chair; E. van Galen

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

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

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Coordination with CHMP: drafting group on excipients: ethanol as an excipient

Rapporteurs: J. Wiesner, S. Girotto

Action: for information

Documents: Presentation, Q&A on ethanol

5.2.2. Coordination with CMDh – Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual recognition and Decentralised procedures for (T)HMPs

Report: ORGAM Chair

Action: for information

Documents: Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures specific for (T)HMPs (EMA/HMPC/770889/2014; [CMDh/349/2016](#)); [QRD template](#); [Press release](#)

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

5.3.1. Coordination with Innovation Task Force and CHMP

Rapporteur: R. Länger, E. Svedlund

Action: for information

Documents: Request for a scientific opinion on the principal mode of action of proanthocyanidins intended to be used for prevention and treatment of urinary tract infections; Report

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13B expert group meeting held on 13-14 September 2016
EDQM: M. Bald; HMPC Observer: H. Neef
Action: for information
Document: Draft Agenda

- EDQM TCM expert group meeting to be held on 20-21 September 2016
EDQM: M. Bald; HMPC Observer: R. Länger
Action: for information
Document: Draft Agenda

5.5. Cooperation with International Regulators

5.5.1. HMPC – International representation and cooperation

Report: HMPC Chair

Action: for discussion

Document: Draft proposal HMPC international cooperation

5.5.2. EU-India joint working group July 2016

Action: for discussion

Document: Report

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

Report: HMPC Chair

Action: for information

Document: Agenda

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

Report: HMPC Chair

Action: for information

Document: Draft 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 July 2016; Respond from HMPC, September 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

- Harmonisation of assessment practice for herbal substances of non-European origin
Report: E. van Galen
Action: for adoption
Documents: Draft letter to Indian authorities (AYUSH); Inventory list of Ayurveda Herbs, July 2016

5.7.2. Preparation of HMPC work plan 2017

Report: HMPC Chair
Action: for discussion
Document: Draft working plan

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

6. Any other business

6.1. Topics for discussion

6.1.1. ARSP

- English summaries for publication
Documents: Aniseed; Anise oil; Bearberry leaf; Hop strobili; Passion flower; Primula flower
Primula root; Thyme
- English template
- Procedural challenges ARSP translations (presentation)

6.1.2. Update on Management Board data gathering exercise

Action: for discussion

6.1.3. Information on EMA internal organisational adjustments

Action: for discussion
Document: Presentation

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

Report: HMPC Chair
Action: for discussion
Document: EDQM response on Pyrrolizidine alkaloids, 3 August 2016

6.1.5. Evidence on the period of traditional use

Report: E. v. Galen

Action: for discussion

Document: Question for clarification, 30 August 2016

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 11-12 July 2016

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 11-12 July 2016](#)

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

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

[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 20-22 September 2016

6.2.3. Other

- Publication on ethanol exposure in children from food, July 2016
- [Update of documents on EU Good Pharmacovigilance Practices \(EU-GVP\)](#)
- PCWP/HCPWP meetings:
 - Report of a joint EMA workshop with patient and healthcare professional representatives about communication on medicines - 8 March 2016 (EMA/194543/2016)
 - Minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting - 9 March 2016 (EMA/183905/2016)
 - Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – Workshop on social media – 19 September 2016 (EMA/825257/2015)
 - Draft Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – 20 September 2016 (EMA/428004/2016)
- PCWP meeting:
 - Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) meeting – 14 June 2016 (EMA/274681/2016)
 - Minutes - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) meeting – 14 June 2016 (EMA/419205/2016)

- Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) 10th Anniversary meeting – 14 June 2016 (EMA/392315/2016)
- HCPWP meeting:
 - Agenda - EMA Human Scientific Committees' Working Parties with Healthcare Professionals' Organisations (HCPWP) meeting – 15 June (EMA/285607/2016)
 - Minutes - EMA Human Scientific Committees' Working Parties with Healthcare Professionals' Organisations (HCPWP) meeting – 15 June (EMA/418148/2016)