



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 July 2016
EMA/HMPC/474350/2016
Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 11-12 July 2016

Chair: Werner Knöss – Vice-Chair: Marisa Delbò

11 July 2016, 14:00 – 19:00, 3E

12 July 2016, 09:00 – 13:00, 3E

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

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

Of note, this agenda is a working document primarily designed for HMPC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).



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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the HMPC plenary session to be held on 11-12 July 2016. See July 2016 HMPC minutes (to be published post Sept 2016 HMPC meeting).

Swap of roles in Slovenia. New member is Samo Kreft and alternate Barbara Razingar; Starting date of mandate: 29 June 2016.

End of mandate: Kapka Kaneva (Bulgaria) alternate retired, her membership in HMPC terminated on 21 June 2016.

1.2. Adoption of agenda

HMPC agenda for 11-12 July 2016

Time schedule for 11-12 July 2016

1.3. Adoption of the minutes

HMPC minutes for 30-31 May 2016

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP April 2016 meeting

Report: MLWP Chair

Action: for information

Document: Draft minutes for the MLWP meeting on the 1-2 June 2016

2.1.2. Appointment of Rapporteurs and Peer-reviewers

- Changes of Rapporteur and Peer-reviewers for Monograph revision
Grindeliae herba – Peer-reviewer: B Kroes
Hippocastani cortex – Rapporteur: W. Dymowski, Peer reviewer: C. Purdel

2.1.3. MLWP membership

- Nomination of new MLWP member (medical doctor with expertise in paediatrics)
Report: HMPC Chair
Action: for discussion
Documents: Mandate of MLWP; "Call for nominations", 29 April 2016; DE nomination;
Correspondence with PDCO & HCPWG

- Resignation of M. Delbó as MLWP member
Report: HMPC Chair, MLWP Chair, M. Delbó
Action: for discussion
Documents: Resignation letter, 1 July 2016; IT nomination

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

2.2.1. Monograph on *Althaeae radix* and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC, References: 71/71

2.2.2. Monograph on *Harpagophyti radix* and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC, OoC 2, References: 57/109

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 *Origanum majoranae herba*

Rapporteur: C. Cavaleiro; Peer-reviewer: M. Heroutová
Action: for adoption
Documents: MO, AR, LoR, References: xx/109

2.4.2. Monograph on *Prunella africana cortex*

Rapporteur: I. Chinou; Peer-reviewer: G. Calapai
Action: for adoption
Documents: MO, AR, LoR, OoC, References: xx/58

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

2.5.1. Monograph on *Allium sativum bulb* and supporting documents

Action: for adoption
Documents: MO, AR, LoR

2.5.2. Monograph on *Cistus creticus folium* and supporting documents – postponed

2.5.3. Monograph on Lecithinum ex soya and supporting documents

Action: for adoption

Documents: MO, AR, LoR, Presentation

2.5.4. Monograph on Soiae oleum raffinatum and supporting documents

Action: for adoption

Documents: MO, AR, LoR

2.5.5. List Entry and Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents – postponed

3. Referral procedures

None

4. Guidelines and guidance documents

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

4.1.1. Revision of 'Guideline on assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs/entries to the Community list for traditional herbal medicinal products/substances/preparations (EMA/HMPC/104613/2005)

Action: for adoption

Document: Draft revised guideline for release for public consultation

4.1.2. Revision of 'Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration' ([EMEA/HMPC/32116/2005](#))

Action: for adoption

Document: Concept paper

4.2. Quality

None

4.3. Regulatory

4.3.1. Patient Leaflet template concerning advice on preparations of herbal teas by end-users

Action: for discussion

Document: Template

4.3.2. Revised regulatory questions and answers - [EMA/HMPC/345132/2010](#)

Report: ORGAM Chair

Action: for adoption

Documents: Revised Q&A; Clarification from EC, 8 June 2010

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair

Action: for adoption

Document: Meeting report from Q DG meeting held on 28 June 2016

Action: for information

Document: Draft agenda for the Q DG meeting to be held on 7 September 2016

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report

Action: for adoption

Document: Meeting report from ORGAM DG meeting held on 30 June 2016

- Agenda

Action: for information

Document: Draft agenda for the ORGAM DG meeting to be held on 6 September 2016

- Resignation of M. Delbó as ORGAM member effective from 10 July 2016

Action: for discussion

Documents: Resignation letter; IT nomination

- Draft revised template for EU herbal monographs

Action: for discussion

Documents: Draft revised MO template; Proposal from E. Svedlund, 13 June 2016

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Mandate of Quality DG and expression of interest for members/observers

Action: for adoption

Documents: Overview of QDG member interests; New mandate; New nominations; Presentation

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

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

Action: for adoption

Documents: Revised SOP on MO & LE establishment; Presentation

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting held on 10 June 2016

Report: HMPC Vice-Chair

Action: for discussion

Document: Agenda

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

Rapporteur: J. Wiesner, HMPC Chair

Action: for discussion

Documents: PS; OoC; CHMP Safety Working Party response to HMPC/CHMP questions on Pulegone and Menthofuran; HMPC letter to EDQM on pulegone menthofuran, 24 June 2016; Annex

5.2.3. 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 adoption

Document: Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual recognition and Decentralised procedures for (T)HMPs (EMA/HMPC/770889/2014)

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

5.3.1. Coordination with PCWP/HCPWP

Observer: S. Bager

- EMA PCWP/HCPWP session on communication and information on medicines, 8 March 2016

Action: for information

Document: Report

- EMA PCWP/HCPWP joint meeting, 9 March 2016
Action: for information
Document: Minutes

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13A expert group meeting held on 8-10 June 2016
EDQM: M. Bald; HMPC Observer: I. Chinou
Action: for information
Document: Summary of discussion

5.4.2. Survey on uptake of the traditional use registration and implementation of Directive 2004/24/EC in EU Member States, 2015

Action: for discussion
Documents: Presentation; [EMA/HMPC/322570/2011 Rev. 6](#)

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

Report: HMPC Chair, HMPC Vice-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

None

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 discussion
Documents: Comparative List for Ayurveda Herbs; Discussion paper

5.7.2. Preparation of HMPC work plan 2017

Action: for information
Document: Presentation

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

6.1.2. [New EMA website “regulatory herbal”](#)

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 30-31 May 2016

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 30-31 May 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 12-14 July 2016

6.2.3. Other

- Updated Welcome Packs uploaded in MMD (MMD/HMPC/General)
- Article 57, Documents: Dashboard report to EMA Committees; [EVDAS User Guide](#)