



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 September 2017
EMA/HMPC/610004/2017
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 18-19 September 2017

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

18 September 2017, 14:00 – 19:00, 3E

19 September 2017, 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 18-19 September 2017. See September 2017 HMPC minutes (to be published post November 2017 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 18-19 September 2017

Time schedule for 18-19 September 2017

1.3. Adoption of the minutes

HMPC minutes for 17-18 July 2017

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP July 2017 meeting

Report: MLWP Chair

Action: for information

Document: Draft minutes for the MLWP meeting on 18-21 July 2017

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Changes of Rapporteurs for Monograph revision

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

2.2.1. Monograph on Ribis nigri folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 44/44

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

None

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

None

2.6. EU herbal monographs, list entries and public statements - post finalisation

2.6.1. Monograph on Pistacia lentiscus (mastix) 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. Reflection paper on Polycyclic aromatic hydrocarbons in HMP/THMP

Action: for discussion

Documents: Presentation; [Reflection paper](#); QDG Draft Discussion Paper on follow up

4.1.2. Revision of Guideline on assessment of clinical safety and efficacy (EMA/HMPC/104613/2005) Rev.1

Action: for adoption

Documents: Revised guideline for final adoption, OoC

4.2. Quality

4.2.1. Concept paper on the development of a Reflection Paper on new analytical methods/technologies in the quality control of herbal substances, herbal preparations and (traditional) herbal medicinal products (EMA/HMPC/541422/2017)

Action: for adoption

Document: Concept Paper

4.3. Regulatory

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

- Meeting report from Q DG virtual meeting held on 07 Sep 2017

Action: for adoption

Documents: Meeting report; Presentation on outcome survey on Markers

- Draft agenda for the Q DG meeting to be held on 19 Oct 2017

Action: for information

Document: Draft agenda

4.4.2. **ORGAM DG**

Report: ORGAM DG Chair

- Meeting report

Action: for adoption

Document: Meeting report from ORGAM DG meeting held on 05 Sep 2017

- Agenda

Action: for information

Document: Draft agenda for the ORGAM DG meeting to be held on 17 Oct 2017

4.4.3. **Procedure for the review and revision of European Union herbal monographs and/or European Union list entries (EMA/HMPC/326440/2007)**

Report: ORGAM DG Chair

Action: for adoption

Documents: Draft procedure for public consultation; Annex 1 - review template; Addendum – template; Presentation

4.4.4. **Template update – Template on HMPC opinion on list entry or revision of a list entry**

Report: ORGAM DG Chair

Action: for discussion

Documents: Draft template; Presentation

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. **Strategic Review and Learning Meetings**

Report: HMPC Chair, HMPC Vice-chair, C. Purdel

Estonia Presidency meeting – Bucharest, 11-12 Oct 2017

Action: for discussion

Documents: Draft Agenda; Discussion paper for the SRLM in Bucharest

5.1.2. **Preparation for election of Co-opted members**

Report: HMPC Chair

Action: for discussion

Documents: Expertise of HMPC members

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information

Documents: Agenda: 21 Sep 2017; Minutes: 24 Apr 2017

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

5.3.1. Coordination with Safety Working Party – Assessment of estragole

Action: for information

Documents: PS; OoC; Presentation at CHMP; CHMP questions to SWP

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM 13B expert group meeting held on 20-21 Sep 2017
Report: M. Bald (EDQM)
Action: for information
Document: Agenda
- EDQM TCM expert group meeting held on 27 Apr 2017
Report: M. Bald (EDQM)
Action: for information
Document: SoD
- EDQM TCM expert group meeting held on 19-20 Sep 2017
Report: M. Bald (EDQM)
Action: for information
Document: Agenda
- EDQM Working Group on PA analysis
Report: M. Bald, J. Sanz-Biset (EDQM)
Action: for information
Document: Agenda

5.4.2. Coordination with EFSA

- Safety assessment of hydroxyanthracene derivatives - update
Action: for discussion
Documents: Response from EFSA, 10 Mar 2017; Email correspondence
- EFSA new draft statement on PA (see also 6.1.2.)
Action: for discussion
Document: Draft statement for consultation

5.5. Cooperation with International Regulators

5.5.1. WHO – IRCH meetings

- Annual IRCH meeting, 11-13 Sep 2017; TradReg symposium, 14-15 Sep 2017 - Bonn, Germany
Report: HMPC Chair; HMPC Vice-Chair
Action: for discussion
Document: [Draft programme](#)
- WHO meeting on Herbal Quality Guidance - Hong Kong, China, 4-6 Sep 2017
Action: for discussion
Documents: Invitation; Annex 1 guidance on Markers
- WHO draft technical document on clinical research in traditional and complementary medicine
Action: for discussion
Documents: Draft technical document; Table for comments

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

5.6.1. EUROCAM request to become HMPC interested party

Report: HMPC Chair

Action: for adoption

Documents: Presentation by EUROCAM, 13 Feb 2017; Letter of application to HMPC, 05 Jul 2017; EUROCAM status; [List of interested parties to the HMPC](#)

5.7. HMPC work plan

5.7.1. HMPC work plan 2017

- Report: HMPC Chair
Action: for discussion
Document: Work plan 2017 – current status
- Project 1.3.1. Forward planning and prioritisation
Report: HMPC Chair; ORGAM Chair
Action: for adoption
Documents: Presentation; Draft template on proposals for assessment to HMPC
- Project 1.3.5. European collaboration
Action: for discussion
Document: Presentation
- Project 2.1.3. Cooperation with Academia
Report: MLWP Chair
Action: for discussion
Documents: Presentation; Proposal

5.7.2. HMPC work plan 2018

- Report: HMPC Chair
Action: for discussion
Document: Draft Work plan 2018

5.8. Planning and reporting

5.8.1. HMPC 2017 assessors training on quality

Action: for discussion
Document: Draft agenda

5.9. Legislation and regulatory affairs

None

6. Any other business

6.1. Topics for discussion

6.1.1. Question concerning the adjustment of product to HMPC monographs

Report: HMPC Chair
Action: for discussion
Documents: Email correspondence 11 May 2017; Draft response

6.1.2. European Union herbal monograph on *Saccharomyces cerevisiae* CBS 5926

Action: for discussion
Document: Draft letter

6.1.3. Preparedness for UK's withdrawal from the EU

Action: for discussion
Document: Presentation

6.1.4. Additional information on data gathering exercise

Action: for discussion
Document: Report on new data gathering

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 17-18 July 2017

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 17-18 July 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

- Overview of status of HMPC/MLWP assessment work
- Draft agenda of MLWP meeting to be held on 19-21 Sep 2017

6.2.3. ARSP

- English template
- English summaries for publication:
 - *Allii sativi* bulbus

6.2.4. Other

- PCWP/HCPWP meetings:
 - Personalised medicines workshop report – 14 March (EMA/185440/2017): For information
 - Draft Agenda AMR workshop - 19 Sept (EMA/765134/2016): For information
 - Draft agenda PCWP-HCPWP - 20 Sept (EMA/370525/2017): For information
- [Vaccinii macrocarpi fructus – EC Decision](#)
- Invitation to Conference on Cannabis in Vienna