



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 November 2017
EMA/HMPC/757234/2017
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Draft agenda for the meeting on 20-21 November 2017

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

20 November 2017, 14:00 – 19:00, 2F

21 November 2017, 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).



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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 20-21 November 2017. See November 2017 HMPC minutes (to be published post January 2018 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 20-21 November 2017

Time schedule for 20-21 November 2017

1.3. Adoption of the minutes

HMPC minutes for 18-19 September 2017

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP September 2017 meeting

- Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on 19-21 September 2017
- Work plan 2018
Action: for discussion
Documents: MLWP work plan 2018, list of monographs due for review, request for HMPC rapporteurs

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 Meliloti herba and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 88/94

2.2.2. Monograph on Pelargonii radix and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC MO, OoC AR; References: 93/93

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

2.3.1. Monograph on Curcumae longae rhizoma and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 0/142

2.3.2. Monograph on Hederae heliis folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 0/294

2.3.3. Monograph on Valerianae radix/Lupuli flos and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 04/48

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

2.4.1. Monograph on Glycini semen and supporting documents – postponed for March 2018

2.4.2. Public statement on Piperis methystici rhizome and supporting documents

Action: for adoption

Documents: PS, AR, LoR, OoC on PS; References: 160/160

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 to Jan 2018

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

None

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 adoption
Document: OoC
- **Action:** for information
Documents: Presentation; Reflection paper; QDG discussion paper on follow up

4.2. Quality

None

4.3. Regulatory

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: QDG Chair

- Meeting report from Q DG virtual meeting held on 19 Oct 2017
Action: for adoption
Document: Meeting report
- Draft agenda for the Q DG virtual meeting to be held on 07 Dec 2017
Action: for information
Document: Draft agenda
- Work Plan 2018
Action: for discussion
Documents: Draft work plan; QDG 2018 meeting dates

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report
Action: for adoption
Document: Meeting report from ORGAM DG meeting held on 17 Oct 2017
- Agenda
Action: for information
Document: Draft agenda for the ORGAM DG meeting to be held on 05 Dec 2017
- Work Plan 2018
Action: for discussion
Documents: Draft work plan; ORGAM 2018 meeting dates

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

Report: ORGAM DG Chair

Action: for adoption

Document: Draft template

4.4.4. Disclaimer for EU herbal monographs

Report: ORGAM DG Chair

Action: for discussion

Document: Draft Q&A

4.4.5. Feedback from EU procedures and pharmacovigilance (see also 5.7.1. – Project 1.3.5.)

Report: ORGAM DG Chair

Action: for discussion

Document: Draft proposal

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
Estonia Presidency meeting – Bucharest, 11-12 Oct 2017 – follow up
Action: for discussion
Documents: Presentations
- Report: R. Laenger
Austria Presidency meeting – Vienna, 15-17 Oct 2018
Action: for information
Document: SRLM meeting dates

5.1.2. Election of Co-opted members

Report: HMPC Chair

Action: for adoption

Documents: Expertise of HMPC members; Preparation for election of MLWP Chair, Candidatures

General and Family Medicine

Paediatric medicine

Experimental/Non-clinical pharmacology

5.1.3. Preparation for election of MLWP Chair

Report: HMPC Chair

Action: for discussion

Document: [Mandate](#)

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: 11 Dec 2017; Minutes: 21 Sep 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: SWP response, PS, OoC, Presentation

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM 13B expert group meeting held on 20-21 Sep 2017
Action: for information
Document: SoD
- EDQM TCM expert group meeting held on 19-20 Sep 2017
Action: for information
Document: SoD

5.4.2. Coordination with EFSA

- Safety assessment of hydroxyanthracene derivatives - update
Action: for discussion
Document: Response from EFSA

5.5. Cooperation with International Regulators

5.5.1. EU – India/AYUSH communication

Information on 8th EU India Joint WG, Delhi 13-14 July 2017

Action: for discussion

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. 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 discussion
Document: Proposal for assessment received from IPs and NCAs; Summary products 2016 vs. available monographs
- Project 1.3.5. European collaboration (see also 4.4.5)
Action: for adoption
Documents: Presentation; Questionnaire template
- Project 2.1.1. Patients involvement in assessment work
Action: for discussion
- Project 2.1.2. Coordination on safety assessments of herbal constituents
Action: for discussion
- Project 2.1.3. Cooperation with Academia
Report: MLWP Chair
Action: for discussion

5.7.2. HMPC work plan 2018

- Report: HMPC Chair
Action: for discussion
Documents: Draft Work plan 2018, Presentation, Proposals received

5.8. Planning and reporting

5.8.1. HMPC 2017 assessors training

Report: QDG Chair
Action: for discussion
Documents: Draft agenda; Participants list

5.9. Legislation and regulatory affairs

None

6. Any other business

6.1. Topics for discussion

6.1.1. Questions from NCAs on Public Statement on Pyrrolizidine alkaloid contaminations

Report: HMPC Chair
Action: for discussion
Documents: Response to questions; Literature

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

Action: for discussion

Documents:

Preparedness for UK's withdrawal from the EU – Postponed

6.1.3. User manual on CxMP/EMA external representation

Action: for discussion

Documents: Presentation; User manual

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 18-19 September 2017

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 18-19 September 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 21-23 Nov 2017

6.2.3. Other

- PCWP/HCPWP meetings:
 - Minutes of the PCWP/HCPWP joint meeting held on 27-28 June 2017 (EMA/355452/2017): for information
 - Minutes of the PCWP/HCPWP joint meeting held on 20 September 2017 (EMA/626905/2017): for information
 - Report of the Information session on antimicrobial resistance held on 19 Sep 2017: for information
 - Draft Agenda - Training session for patients, consumers and healthcare professionals interested in EMA activities (21 Nov) - (EMA/662990/2017): for information
 - Agenda of the PCWP meeting with all eligible organisations (22 Nov) (EMA/663268/2017): for information

- WHO-IRCH new draft Terms of References: for information
- AESGP proposal on the simplification of variations specific to herbal medicinal products: for information
- EU herbal monographs, list entries and public statements post adoption: for information
 - Publication delays 2016/2017 updates
 - Remaining publication delays:
 - *Allii sativi bulbus*
 - *Pistacia lentiscus* (mastix)