14 July 2017
EMA/HMPC/452670/2017 – rev.3
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 17-18 July 2017

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

17 July 2017, 14:00 – 19:00, 3F

18 July 2017, 09:00 – 13:00, 3F

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 17-18 July 2017. See July 2017 HMPC minutes (to be published post September 2017 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 17-18 July 2017

Time schedule for 17-18 July 2017

1.3. Adoption of the minutes

HMPC minutes for 29-30 May 2017

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP May 2017 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on 30 Mar-01 Jun 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 Pelargonii radix and supporting documents

Action: for discussion
Documents: MO, AR, LoR, OoC MO, OoC AR; References: 98/98

2.2.2. Monograph on Cimicifugae rhizoma and supporting documents

Action: for adoption
Documents: MO, AR, LoR, references: xx/159

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

2.3.1. Monograph on Menthae piperitae aetheroleum and supporting documents

Action: for adoption

Documents: MO, AR, LE, LoR, references: 104/205

2.3.2. Monograph on Sennae folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR, references: 173/224

2.3.3. Monograph on Sennae fructus and supporting documents

Action: for adoption

Documents: MO, AR, LoR, references: 173/224

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

2.4.1. Monograph on Allii sativi bulbus and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC; References: 52/244

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

Action: for discussion

Documents: MO, AR, LoR; References: 65/65

2.6.2. Monograph on Pruni africanae cortex and supporting documents

Action: for discussion

Documents: MO, AR, LoR, OoC, Opinion; References: 70/61

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: Reflection paper; Presentation

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
Documents: Draft revised guideline for public consultation

4.1.3. 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
Documents: Revised guideline for final adoption, OoC

4.2. Quality

4.2.1. Guideline on Manufacture of the Finished Dosage Forms

Report: Q DG Chair
Action: for adoption
Document: QWP guideline

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 virtual meeting held on 28 Jun 2017
  Action: for adoption
  Document: Meeting report
- Draft agenda for the Q DG meeting to be held on 07 Sep 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 27 Jun 2017
- Agenda
  Action: for information
  Document: Draft agenda for the ORGAM DG meeting to be held on 05 Sep 2017

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

Report: ORGAM DG Chair
Action: for discussion
Document: Draft procedures

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, E. Attard, C. Purdel

- Malta Presidency meeting – Malta, 26-28 Apr 2017 – follow up
  Action: for discussion
  Documents: Discussion paper on follow-up and need for improvement; Presentation on need for improvement; Additional presentations from Malta meeting
- Estonia Presidency meeting – Bucharest, 11-12 Oct 2017
  Action: for information
  Documents: Email correspondence from 6 July 2017; Email correspondence from 26 June 2017

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting - postponed

Report: HMPC Chair

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

5.3.1. Coordination with Safety Working Party – Assessment of estragole

Action: for discussion
Documents: PS; OoC; Presentation at CHMP; CHMP questions to SWP

5.4. Cooperation within the EU regulatory network

5.4.1. European Commission - postponed

- Update on List Entries
  Action: for information
  Document: List of herbal substances, preparations and combinations thereof for use in THMP

5.4.2. European Pharmacopoeia

- EDQM 13A expert group meeting held on 13-14 Jun 2017
  Report: M. Bald (EDQM)
  Action: for information
  Documents: Agenda; SoD
- EDQM 13B expert group meeting held on 10-11 May 2017
  Report: M. Bald (EDQM)
  Action: for information
  Documents: Agenda; SoD

5.4.3. Coordination with EFSA

- Safety assessment of hydroxyanthracene derivatives - update
  Report: J. Wiesner
  Action: for discussion
  Documents: Response from EFSA, 10 Mar 2017; Email correspondence

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
  Documents: Draft programme; Invitation
- WHO meeting on Herbal Quality Guidance - Hong Kong, China, 4-6 Sep 2017
  Report: HMPC Chair; QD G Chair
  Action: for discussion
  Documents: Invitation; 2nd Draft guideline on Good Herbal Processing Practice

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

5.6.1. EUROCAM request

Report: HMPC Chair
Action: for information

Documents: Letter to HMPC Chair, 13 Feb 2017; Presentation by EUROCAM, 13 Feb 2017; Letter of application to HMPC, 05 Jul 2017; EUROCAM statuses; 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 discussion
  Documents: Presentation; Draft template on proposals for assessment to HMPC
- Project 2.1.3. Cooperation with Academia
  Report: MLWP Chair
  Action: for discussion
  Documents: Presentation; Proposal

5.8. Planning and reporting

5.8.1. HMPC 2017 assessors training on quality

Report: Q DG Chair
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

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

6.1.2. Follow up on Public Statement on Pyrrolizidine alkaloid contaminations

Action: for discussion
Documents: Herbal Board questions on PA public statement; questions on PA; Meeting report from breakout session May 2017; additional question July 2017; Draft response

6.1.3. DG SANTE study on Regulation (EC) No 1924/2006 with regard to health claims made on plants and their preparations and the general regulatory framework for their use in foods

Report: HMPC Chair
Action: for discussion
Documents: Letter of introduction; Email correspondence; List of questions

6.1.4. European Union herbal monograph on Saccharomyces cerevisiae CBS 5926

Action: for discussion
Documents: Amended draft letter; Presentation

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 29-30 May 2017

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 29-30 May 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 18-20 Jul 2017

6.2.3. ARSP

- English template
- English summaries for publication:
  - Wormword herb
  - Purple coneflower root
  - Grapevine leaf

6.2.4. Other

- PCWP/HCPWP meetings:
  - Draft Agenda of the PCWP/HCPWP joint meeting – 27/28 June (EMA/213892/2017): For information
  - Minutes PCWP/HCPWP joint meeting – 15 March (EMA/182189/2017): For information
- Pharmacovigilance – EudraVigilance database and Art.16a registered products

- WHO - IRCH focal point
- Notification to the CMDh Chair, Referral under Article 29(1) of Directive 2001/83