



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 May 2017
EMA/HMPC/333718/2017
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 29-30 May 2017

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

29 May 2017, 14:00 – 19:00, 2F

30 May 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 29-30 May 2017. See May 2017 HMPC minutes (to be published post July 2017 HMPC meeting).

New memberships:

Malin Söderberg (Sweden) alternate; start of mandate: 13 May 2017

1.2. Adoption of agenda

HMPC agenda for 29-30 May 2017

Time schedule for 29-30 May 2017

1.3. Adoption of the minutes

HMPC minutes for 27-28 Mar 2017

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP March 2017 meeting

Report: MLWP Chair

Action: for information

Document: Draft minutes for the MLWP meeting on 28-30 Mar 2017

2.1.2. Appointment of Rapporteurs and Peer-reviewers

- Changes of Rapporteurs for Monograph revision

2.1.3. MLWP membership

Report: MLWP Chair

Action: for adoption

Documents: Call for nomination; List of expertise

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

2.2.1. Monograph on Absinthii herba and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 100/100

2.2.2. Monograph on Echinaceae purpureae radix and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 32/127

2.2.3. Monograph on Pelargonii radix and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC MO, OoC AR; References: 74/104

2.2.4. Monograph and List Entry on Vitis viniferae folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: none/131

Action: for information

Document: LE

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 Allii sativi bulbus and supporting documents – postponed

2.4.2. Monograph on Silybi mariani fructus and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC; References: 114/196

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

2.5.1. Monograph on Fragariae folium and supporting documents – postponed

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

2.6.1. Monograph on Salicis cortex and supporting documents

Action: for adoption

Documents: MO, AR, LoR; Email correspondence; References: 95/132

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

Action: for adoption

Documents: MO, AR, LoR, OoC; Presentations; References: 61/64

2.6.3. Monograph on *Pistacia lentiscus* (mastix) and supporting documents

Action: for discussion

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

2.6.4. Monograph on *Pruni africanae cortex* and supporting documents

Action: for discussion

Documents: MO, AR, LoR, OoC; Email correspondence; 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" (EMA/HMPC/32116/2005)

Action: for adoption

Document: Draft revised guideline for public consultation

4.2. Quality

4.2.1. Planned revision of reflection paper on markers used for quantitative and qualitative analysis of HMP and THMP

Action: for discussion

Document: [Reflection paper](#); Questionnaire

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 (FtF) meeting held on 20 Apr 2017
Action: for adoption
Documents: Meeting report; Draft reflection paper on the use of new analytical methods
- Draft agenda for the Q DG meeting to be held on 28 Jun 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 4 Apr 2017
- Agenda
Action: for information
Document: Draft agenda for the ORGAM DG meeting to be held on 27 Jun 2017

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

Report: G. Laekeman

- Action:** for discussion
Documents: Draft procedure; Template examples
See also 6.1.2

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, E. V. Galen, E. Attard

- Presidency meeting – Malta, 26-28 Apr 2017 – follow up
Action: for discussion
Documents: Agenda; Presentations (8 out of 15); Breakout session groups HMPC July 2016– follow up; Presentation by EMA – Future of HMPC (breakout sessions)

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information

Documents: Minutes from meeting held on 22 Sep 2016, 31 Jan 2017; Agenda: 24 Apr 2017

See also 6.1.4.

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

5.3.1. Coordination with Safety Working Party – Assessment of estragole

Rapporteurs: J. Wiesner, H. Foth

Action: for discussion

Documents: PS; OoC; Letter from HMPC Chair to CHMP Chair, 15 Sep 2015; SWP response, 16 Nov 2016; Presentation

5.4. Cooperation within the EU regulatory network

5.4.1. European Commission

- European Union herbal monograph on *Saccharomyces cerevisiae* CBS 5926
Action: for adoption
Document: Draft letter
Action: for discussion
Documents: Draft MO, draft AR, draft LoR; draft LE
- 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 to be held on 13-14 Jun 2017
Report: M. Bald (EDQM)
Action: for information
Document: Agenda
- EDQM 13B expert group meeting held on 10-11 May 2017
Report: M. Bald (EDQM)
Action: for information
Documents: Agenda; SoD
- EDQM TCM expert group meeting held on 26-27 Apr 2017
Report: M. Bald (EDQM)
Action: for information
Document: Summary of decisions

- EDQM new Pyrrolizidine Alkaloids Working Party (PA)
Report: M. Bald (EDQM)
Action: for discussion
Documents: Nomination form; DoI

5.4.3. Pharmacovigilance – EudraVigilance database and Art.16a registered products

Action: for discussion
Documents: Email correspondence, 17 Oct 2016; Presentations; [THMP and simplified registrations for homeopathic medicinal products: PhV requirements and EV access](#)

5.4.4. Coordination with EFSA

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

5.5. Cooperation with International Regulators

5.5.1. WHO – IRCH meetings

- New Delhi, India, 8-10 Nov 2016
Report: HMPC Chair
Action: for discussion
Documents: Agenda; Draft Summary Report
- Bonn, Germany, 14-15 Sep 2017
Report: HMPC Chair
Action: for discussion
Documents: Draft programme; Invitation; Email on focal point appointment

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

5.6.1. AESGP – hearing at MLWP March 2017

Report: MLWP Chair
Action: for information
Document: Draft meeting report

5.6.2. EUROCAM request

Report: HMPC Chair
Action: for information
Documents: Letter to HMPC Chair, 13 Feb 2017; The regulation of herbal medicinal products in the EU – by EUROCAM, 13 Feb 2017

5.7. HMPC work plan

5.7.1. HMPC work plan 2017

Report: HMPC Chair

Action: for discussion

Documents: Work plan 2017 – current status; Presentation and proposal I. Chinou on project 2.1.3. Cooperation with Academia

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

5.9.1. Evidence on the period of traditional use

Report: E. V. Galen

Action: for discussion

Documents: Request to EC, 20 Dec 2016; Presentations

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

6.1.2. Polypodii rhizoma

Action: for discussion

Documents: Revision of MO; Annex

See also 4.4.3

6.1.3. Follow up on Public Statement on Pyrrolizidine alkaloid contaminations

Action: for discussion

Documents: Herbal Board questions on PA public statement; questions on PA

6.1.4. Preparedness for UK's withdrawal from the EU

Action: for discussion
Document: Presentation

See also 5.2.1.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 27-28 Mar 2017

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 27-28 Mar 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 30-31 May-01 Jun 2017

6.2.3. ARSP

- English template
- English summaries for publication:
 - Aloes
 - Diuretic herbal tea combinations
 - Rose flower
 - Raspberry leaf

6.2.4. Other

- Meeting dates for 2019-2021
- User manual on CxMP/WP/SAG members, alternates and experts representing CxMP or EMA officially at external meetings; Documents: User Manual; Approval form; Overview; Presentation
- Adulteration warning Singapore herbal remedies 4th Apr 2017; Document: PHQ 1001 Khasiat Penawar Herna Qaseh Serata Herb
- Herbal substances assessed by HMPC currently without Ph. Eur. Monographs as quality standard

- Survey on uptake of the traditional use registration and implementation of Directive 2004/24/EC in EU Member States, 2016