28 January 2016
EMA/HMPC/17360/2016 Rev. 2
Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 1-2 February 2016

Chair: Werner Knöss – Vice-Chair: Marisa Delbó

1 February 2016 14:00 – 19:00, 2F

2 February 2016 09:00 – 17:00, 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 1-2 February 2016. See February 2016 HMPC minutes (to be published post April 2016 HMPC meeting).

Renunciation: Gabriela Duchajová, Slovakian member declined her membership with termination date of 1 February 2016. New nomination awaiting.

1.2. Adoption of agenda

HMPC agenda for 1-2 February 2016

1.3. Adoption of the minutes

HMPC minutes for 23-24 November 2015

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP November 2015 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on the 24–26 Nov 2015

2.1.2. Proposal for call of scientific data

- Boldi folium

Report: MLWP Chair
Action: for discussion

2.1.3. Appointment of Rapporteurs and Peer-reviewers

- Revision

Herbal substance: Salviae officinalis folium and Salviae officinalis aetheroleum

- Current Rapporteur Distribution

Document: Presentation

- Appointment of possible rapporteurship for none MLWP members

Documents: MLWP work plan 2016; Presentation revision priorities

2.1.4. Public statement – proposals for minor corrections

- Salviae officinalis aetheroleum

Action: for adoption
Document: PS

See also 2.3.2

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

2.2.1. Monograph on Equiseti herba and supporting documents

Action: for adoption
Documents: MO, AR, LoR, references: 95/127

2.2.2. Monograph on Valerianae aetheroleum and supporting documents

Action: for adoption
Documents: MO, AR, LoR, references: 156/156

2.2.3. List Entry and Monograph on Valerianae radix and supporting documents

Action: for adoption
Documents: MO, LE, AR, LoR, OoC, references: 156/156

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

2.3.1. Monograph on Harpagophyti radix and supporting documents

Action: for adoption
Documents: MO, AR, LoR, references: 57/110

2.3.2. Monograph on Salviae officinalis folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR, references: 61/65

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

2.4.1. Monograph on Pistacia lentiscus (mastix)

Rapporteur: I. Chinou; Peer-reviewer: M. Delbò
Action: for adoption
Documents: MO, AR, LoR, references: 66/71

2.4.2. Monograph on Ricini oleum

Rapporteur: C. Purdel; Peer-reviewer: B. Kroes
Action: for adoption
Documents: MO, AR, LoR, references: 63/79

2.4.3. List entry and Monograph on Sideritis herba

Rapporteur: I. Chinou; Peer-reviewer: B. Kroes
Action: for adoption
Documents: MO, LE, AR, LoR, references: 0/36

2.4.4. Monograph on Silybi mariani fructus

Rapporteur: O. Palomino; Peer-reviewer: W. Knöss
Action: for adoption
Documents: MO, AR, LoR, OoC, references: 95/195

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

2.5.1. Monograph on Origani majoranae herba and supporting documents

Action: for adoption
Documents: MO, AR, LoR

2.5.2. Public statement on Paeoniae radix rubra and supporting documents

Action: for adoption
Documents: PS, AR, LoR

2.5.3. Public statement on Paeoniae radix alba and supporting documents

Action: for adoption
Documents: PS, AR, LoR

3. Referral procedures

None

4. Guidelines and guidance documents

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

None

4.2. Quality

4.2.1. Reflection paper on the use of new analytical methods in the quality control of herbal substances, herbal preparations and (traditional) herbal medicinal products

Report: QDG Chair
Action: for discussion
Document: Draft reflection paper

4.3. Regulatory

4.3.1. Revised CTD guideline on the use of CTD format for Registration Applications

Report: QDG Chair, ORGAM DG Chair
Action: for adoption
Documents: Revised CTD guideline (EMA/HMPC/71049/2007, Rev.2); OoC main text; OoC Appendix 2; SE comments on the Guideline on the use of CTD format for Registration Applications, 7 Dec 2015

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 9 Dec 2015

Action: for information
Document: Draft agenda for the Q DG meeting to be held on 11 Feb 2016

4.4.2. ORGAM DG

Report: ORGAM DG Chair
Action: for adoption
Document: Meeting report from ORGAM DG meeting held on 10 Dec 2015

Action: for information
Document: Draft agenda for the ORGAM DG meeting to be held on 9 Feb 2016

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Overview table of expertise of HMPC members and alternates

Action: for adoption
Documents:
Expertise of HMPC members 2014; Briefing note on competence and expertise of HMPC members and alternates; Annex B EMA recommendation on criteria for competence and expertise of new HMPC members and alternates

5.1.2. Election of HMPC co-opted member (toxicology)

Action: for adoption
Documents: Request for nomination email 22 Oct 2015; Procedure for nomination co-opted members for HMPC; Nomination received

5.1.3. Election of QDG Chair

Action: for adoption
Documents: QDG mandate; QDG waiting list; Croatian nomination of observer in HMPC and QDG; Candidature received

5.1.4. Assessors Training, December 2015 – follow up

Report: QDG Chair
Action: for information
Documents: Presentations

5.1.5. Strategic Review and Learning Meetings – organisational aspects

Report: HMPC Chair, E. V. Galen
Action: for discussion
Documents: Draft agenda, meeting 12-13 April 2016, Netherlands; Information from Slovakia and Malta

5.2. Coordination with EMA Scientific Committees or CMDh-v

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

Rapporteurs: O. Pelkonen, J. Wiesner
Action: for discussion
Documents: New data, provided December 2015; Draft revised PS

5.2.2. Coordination with PDCO

- Report on relevant topics from PDCO meetings

Report: S. Girotto (observer)
Action: for information
Document: Presentation on extrapolation project

5.2.3. Coordination with CMDh group

Report: ORGAM DG Chair
Action: for discussion
Document: Draft Discussion paper on QRD templates for THMP

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

5.3.1. Coordination with PCWP/HCPWP

Observer: S. Bager

- Training session for patients and consumers interested in EMA activities, 25 Nov 2015

Action: for information

- EMA PCWP meeting with all eligible organisations, 26 Nov 2015

Action: for information
Document: Minutes

- Involvement of patient organisations in HMPC activities

Action: for discussion
Document: Presentation

5.3.2. European Union reference date (EURD) list – update for herbal substances

Report: Z. Biro-Sandor
Action: for discussion
Document: Email communication

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13A expert group meeting to be held on 23-25 February 2016
  EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
  Action: for information
  Document: Draft Agenda
- EDQM 13B expert group meeting held on 26-27 January 2016
  EDQM: M. Bald, U. Rose; HMPC Observer: B. Kroes (H. Neef)
  Action: for information
  Document: Draft Agenda
- EDQM TCM expert group meeting held on 19-20 January 2016
  EDQM: M. Bald, U. Rose; HMPC Observer: R. Länger
  Action: for information
  Document: Summary of discussion

5.4.2. HMPC request to EDQM on modification herbal extract monograph

Report: QDG Chair
Action: for adoption
Documents: Request for revision herbal drug extracts; EDQM request form

5.4.3. European Commission - Report: Update on establishment of LE

Action: for discussion

5.4.4. European Commission – health claims for food products containing hydroxy anthracene derivatives

Report: HMPC Chair, L. Anderson
Action: for information
Documents: Email correspondence; HMPC letter to DG SANTE E4, 13 March 2014

5.4.5. EFSA – Guidance on health claims applications and Guidance on immune-GI-defence against pathogens

Report: HMPC Chair; Rapporteurs: G. Calapai; I Kosalec; H. Pinto Ferreira
Action: for information
Documents: General scientific guidance for stakeholders on health claim applications; Outcome of a public consultation of the EFSA NDA Panel; Guidance on the scientific requirements for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms; Outcome of a public consultation of the EFSA NDA Panel

5.5. Cooperation with International Regulators

5.5.1. 8th Annual Meeting of IRCH held in Riyadh, Saudi Arabia, 1-3 December 2015

Report: HMPC Chair, HMPC Vice-Chair
Action: for information
Document: Agenda

5.5.2. HMPC – International representation and cooperation – postponed

Report: HMPC Chair
Action: for discussion
Document: Draft proposal HMPC international cooperation

5.5.3. 2nd Annual Complementary/Herbal Medicines Workshop in the margins of the 10th International Summit of Heads of Medicines Regulatory Agencies (ICMRA), Mexico City, 10 November 2015

Report: HMPC Chair
Action: for information
Documents: Minutes; Summary of action; Presentation

5.5.4. Confidentiality arrangements DG SANTE and EMA with international partners – Request by Swissmedic for observership MLWP

Action: for information

5.5.5. Health Canada request – Assessment of Gelsemium sempervirens

Action: for information
Document: Email, 27 Jan 2016

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

5.6.1. Planned hearings with interested parties in 2016

Action: for discussion

5.7. HMPC work plan

5.7.1. Projects on the HMPC work plan 2016

- Monograph and List entry systematic revision

Action: for discussion

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. Overview of recommendations for the uses of herbal medicinal products in the paediatric population

Rapporteur: S. Girotto

Action: for adoption

Document: Paediatric uses of herbal medicines

6.1.2. Planned restructuration/rewriting of herbal regulatory pages on EMA website

Action: for information

6.1.3. Occurrence and analysis of pyrrolizidine alkaloids – issues on national markets

Report: L. Anderson, HMPC Chair

Action: for information

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 23-24 November 2015

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 23-24 November 2015

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 MLWP assessment work
- Draft agenda of MLWP meeting to be held on 3-4 February 2016

6.2.3. ARSP

- English summaries for publication
  Documents: Willow herb; Centaury; Ivy leaf; Eleutherococcus root

6.2.4. Matching patients friendly therapeutic areas for browse search on herbal medicines for human use with TU indications to ATC therapeutic groups (level 2)

Rapporteur: B. Huber, W. Knöss
Documents: Draft document EMA/568320/2009 Rev. 1; Outcome written procedure

6.2.5. Other

- Comments on draft revised monograph on Thymi herba/Primulae radix. Document: Letter, 11 Jan 2016
- Article 57: Information by Pharmacovigilance Department; Documents: Article 57 Publication Dashboard Report to EMA Committees, Jan 2016; Pharmacovigilance Programme update, Dec 2015