28 September 2015
EMA/HMPC/635496/2015
Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 28-29 September 2015

Chair: Werner Knöss – Vice-Chair: Marisa Delbó

28 September 2015 14:00 – 19:00, 3E

29 September 2015 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 28-29 September 2015. See September 2015 HMPC minutes (to be published post November 2015 HMPC meeting).

New Irish member: Una Mockler and alternate: Annamarie O'Sullivan; Starting date of mandates: 12 September 2015

1.2. Adoption of agenda

HMPC agenda for 28-29 September 2015.

1.3. Adoption of the minutes

HMPC minutes for 6-7 July 2015.

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP July 2015 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on the 7-9 July 2015

2.1.2. New herbal substances proposed for assessment

- *Malva sylvestris* L.
  Report: MLWP Chair
  Action: for adoption
  Document: Email by W. Dymowski 1 July 2015

- *Vaccinium macrocarpon* Aiton
  Report: MLWP Chair
  Action: for adoption
  Documents: HMPC guidance documents: (EMEA/HMPC/328575/2007 Rev.1) and (EMEA/HMPC/107399/2005 Rev. 1), request by Herbapol, email by EMA 17 December 2014

  See also 5.4.2.

2.1.3. Prioritisation of monograph revisions

Action: for discussion
Documents: Presentation, draft discussion paper on solutions for revision, draft MLWP revision priority list, draft MLWP work plan 2016, EMA/HMPC/124695/2011 Rev. 1, EMA/HMPC/326440/2007 Rev.2

See also 5.7.1

2.1.4. Appointment of Rapporteurs and Peer-reviewers

- First Assessment

  See also 2.1.2.

- Revisions
  Rapporteur:
  Herbal substance: Salicis cortex
  Peer-reviewer:
  Herbal substance: Agni casti fructus
  Herbal substance: Cimicifugae racemosae rhizoma
  Herbal substance: Myrrha

  See also 2.1.3.

2.1.5. Cancellation of assessment work for Cinnamomi camphorae cortex/folium

Action: for adoption
Document: Presentation

2.2. Revised EU herbal monographs and list entries for public consultation / final adoption after systematic review / revision

2.2.1. Monograph on Centaurii herba and supporting documents

Rapporteur: E. van Galen/B. Kroes; Peer-reviewer: I. Chinou
Action: for adoption
Documents: MO, AR, LoR; references: 41/75

2.2.2. Monograph on Pelargonii radix and supporting documents

Action: for adoption (for public consultation)
Documents: MO unchanged, revised AR, revised LoR; references: 73/105

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

2.3.1. Monograph on Myrtilli fructus recens and supporting documents

Rapporteur: E. Widy-Tyszkiewicz; Peer-reviewer: G. Calapai, M. Delbò
Action: for adoption
Documents: MO, AR, LoR; references: 150/182

2.3.2. Monograph on Myrtilli fructus siccus and supporting documents

Rapporteur: E. Widy-Tyszkiewicz; Peer-reviewer: G. Calapai, M. Delbò
Action: for adoption
Documents: MO, AR, LoR; references: 150/182

2.3.3. Monograph on Sabalis serrulatae fructus and supporting documents

Rapporteur: G. Laekeman/A. Vlietinck; Peer-reviewer: L. Anderson
Action: for adoption
Documents: MO, AR, OoC, LoR; references: 76/116
Documents for information: Email correspondence during peer-review, OoC on AR

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

2.4.1. Monograph on Helichrysi flos and supporting documents

Action: for adoption
Documents: Draft MO, AR, LoR

2.4.2. Monograph on Origani majoranae herba and supporting documents - postponed

2.4.3. Monograph on Polygoni avicularis herba and supporting documents

Action: for adoption
Documents: Draft MO, AR, LoR

2.4.4. Public statement on Salviae fruticosae folium 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. Public statement on the use of herbal medicinal products containing pulegone/ menthofuran

Rapporteurs: O. Pelkonen, J. Wiesner
Action: for information
Documents: PS, OoC, letter from HMPC to CHMP 06/2015, SWP response 11/2014

4.1.2. Public statement on the use of herbal medicinal products containing estragole

Rapporteurs: O. Pelkonen, J. Wiesner
Action: for information
Documents: PS, OoC, letter from HMPC to CHMP 09/2015, SWP response 04/2014, outcome written procedure

4.1.3. Concept paper on the revision of the "Guideline on the assessment of clinical S&E in the preparation of Community Herbal Monographs for Well-established and of Community Herbal Monographs/Entries to THMP/Substance/Preparations"

Rapporteurs: P. Claeson, S. Girotto
Action: for adoption
Document: Concept paper

4.2. Quality

None

4.3. Regulatory

4.3.1. Revised public statement on herbal substances containing constituents associated with safety concerns

Rapporteurs: M. Delbò
Action: for adoption
Document: Rev. PS

4.3.2. 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
Action: for adoption
Document: Draft document EMA/568320/2009 Rev. 1

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 10 September 2015

Action: for information
Document: Draft agenda for the Q DG meeting to be held on 15 October 2015

Action: for adoption
Document: Draft work plan 2016

4.4.2. ORGAM DG

Report: ORGAM DG Chair
Action: for information
Document: Draft agenda for the ORGAM DG meeting to be held on 13 October 2015

Action: for discussion
Document: Draft work plan 2016

See also 5.7.1.

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 discussion
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. Preparation of upcoming co-opted member election

Action: for discussion
Documents: Procedure for nomination/election of co-opted members for HMPC, email by O. Pelkonen 20 July 2015

5.1.3. Assessors Training, 7-8 December 2015

Report: QDG Chair
Action: for adoption
Document: Draft agenda

5.1.4. Strategic Review and Learning Meeting held in Bonn, 17-19 June 2015

Report: HMPC Chair
Action: for discussion
Document: Minutes

5.1.5. Strategic Review and Learning Meeting – organisational aspects

Action: for information
Documents:
Principles for organisation of NCA hosted meetings; Responsibilities for confidentiality in NCA hosted meetings

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting - postponed

5.2.2. Coordination with CHMP: drafting group on excipients: ethanol as an excipient (after public consultation) - postponed

5.2.3. Coordination with CHMP: Public statement on the use of herbal medicinal products containing pulegone/ menthofuran

See also 4.1.1

5.2.4. Coordination with CHMP: Public statement on the use of herbal medicinal products containing estragole

See also 4.1.2

5.2.5. Coordination with PRAC and other Pharmacovigilance topics

PhV/EMA literature monitoring for herbal substances

Action: for information
Document: Presentation

5.2.6. Coordination with CMDh: Article 46 assessment work sharing, Paediatric Working Party

Action: for discussion
Document: Email by U. Mathes 27 August 2015

See also 2.2.2.

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

5.3.1. Coordination with PCWP/HCPWP

Observer: S. Bager
Action: for discussion

Documents:
Minutes of the PCWP plenary meeting held on 3 June 2015
Minutes of the PCWP/HCPWP joint meeting held on 4 June 2015
Minutes of the HCPWP meeting held on 4 June 2015
Agenda from PCWP/HCPWP joint Workshop on risk minimisation measures to be held on 16 September 2015
Draft Agenda from PCWP/HCPWP joint meeting to be held on 17 September 2015

5.3.2. Coordination with SWP

Report from SWP meetings
Observer: O. Pelkonen
Action: for information
Document: Oral report

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13A expert group meeting held on 2-3 June 2015
  EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
  Action: for information
  Document: Summary of decisions
- EDQM 13B expert group meeting held to be held on 22-23 September 2015
  EDQM: M. Bald, U. Rose; HMPC Observer: B. Kroes (H. Neef)
  Action: for information
  Document: Agenda, Report
- EDQM TCM expert group meeting held on 5-6 May 2015
  EDQM: M. Bald, U. Rose; HMPC Observer: R. Länger
  Action: for information
  Document: Summary of decisions
- EDQM TCM expert group meeting to be held on 15-16 September 2015
  EDQM: M. Bald, U. Rose; HMPC Observer: R. Länger
  Action: for information
  Document: Agenda

5.4.2. EMA survey on uptake of TUR scheme in EU Member States

Action: for information
Documents: Survey - EMA/HMPC/322570/2011, presentation

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

5.5. Cooperation with International Regulators

5.5.1. Update on status of confidentiality arrangements with DG SANTE and EMA with international partners

Action: for information
Document: Update of confidentiality arrangement

5.5.2. 8th Annual Meeting of IRCH held in Riyadh, Saudi Arabia, 1-3 December 2015

Report: HMPC Chair
Action: for information
Documents: Draft agenda, email by WHO 18 August 2015

5.5.3. HMPC – International representation and cooperation

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

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

None

5.7. HMPC work plan

5.7.1. Projects on the HMPC work plan 2015

- HMPC work plan 2015
  Action: for information
  Documents: HMPC work plan 2015, presentation, tracking tool
- Regulatory guidance for non-European interested parties and harmonisation of assessment practice for herbal substances of non-European origin
  Rapporteur: E. van Galen
  Action: for discussion
  Document: Draft discussion paper on procedure for submission of new proposals / scientific data for the assessment of substances from non-European traditions

  See also 4.4.2

- European collaboration: Coordination with EU bodies concerning different frameworks under which herbal ingredients can be regulated
  Report: HMPC Chair
  Action: for discussion
  Document: Email dated 20 July on EFSA 'Draft General scientific guidance for stakeholders on health claim applications' for comments

5.7.2. HMPC work plan 2016

Report: HMPC Chair
Action: for discussion
Document: Draft work plan 2016

5.8. Legislation and regulatory affairs

5.8.1. Comments on draft revised monograph on Thymi herba/Primulae radix

Rapporteur: R. Länger
Action: for discussion
Documents: Letter 15 May 2015 and email August 2015, response by EMA 30 July 2015

5.8.2. Reflection of divergent opinions on ARSP

Action: for discussion
Document: Letter by E. S. Leinonen 3 September 2015, draft EMA position

5.8.3. Consequences of LEs for legal status of products in member states

Action: for discussion
Document: Letter by E. S. Leinonen 3 September 2015, draft EMA position

6. Any other business

6.1. Topics for discussion

6.1.1. AYUSH information on Indian medicinal plants assessed at the EMA

Report: HMPC Chair
Action: for discussion
Document: Response letter from HMPC Chair 2 September 2015

See also 5.5

6.1.2. CMDh discussion: Question on potential serious risk to public health during ongoing DCP procedure on THMP

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 6-7 July 2015

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 6-7 July 2015

Overview of status of HMPC assessment work – priority list

Inventory of herbal substances for assessment work – alphabetical order

Abbreviations in HMPC minutes

6.2.2. MLWP

- Overview of status of MLWP assessment work
- Draft agenda of MLWP meeting to be held on 29 September-1 October 2015

6.2.3. Other

- ARSP (EN); for publication
- ARSP translations in all EU languages; for publication, member states feedback (6 ARSP)
- News story at EMA website, August 2015; Public-friendly information on herbal medicines now available
- Meeting dates: HMPC/MLWP 2016-2018, HMPC drafting groups 2016
- CHMP document on Peer Review Best Practice
- FDA Draft Guidance for Industry: Botanical Drug Development guidance for Industry, 2015
- MMD available for Orgam & Quality Drafting Groups – October 2015
- EFSA Conference on Food Safety 14-16 October 2015