6 March 2015
EMA/HMPC/108187/2015
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Draft agenda for the meeting on 9-10 March 2015

Chair: Werner Knöss – Vice-Chair: Marisa Delbó

9 March 2015, 14:00 – 19:00, room 3F
10 March 2015, 09:00 – 13:00, room 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. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the meeting report once the procedures are finalised.

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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2015. Reproduction is authorised provided the source is acknowledged.

Table of contents

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 9-10 March 2015. See March 2015 HMPC minutes (to be published post May 2015 HMPC meeting).

HMPC membership, new participants

1.2. Adoption of agenda of the meeting

Agenda for the meeting on the 9-10 March 2015

Time schedule

1.3. Adoption of the minutes of the previous meeting

Minutes for the meeting on 27-28 January 2015

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

Report: MLWP Chair
Action: information
Documents: draft minutes for the MLWP meeting on the 28-30 January 2015
overview of status of MLWP assessment work

Change of Rapporteurship for Harpagophyti radix

Action: adoption

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

2.2.1. Monograph on Lini semen and supporting documents

Action: adoption as final
Documents: MO, AR, LoR; references 78/165

2.3. EU herbal monographs and list entries (post finalisation)

2.3.1. Monograph and List entry on Melaleucae alternifoliae aetheroleum and supporting documents

Rapporteur: M. Delbò, Peer-reviewer: J. Viguet-Poupelloz,
Action: discussion
Documents: MO, LE, AR, LoR; OoC, (as adopted);
MO, LE, AR, LoR; OoC, (editorial changes)

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

2.4.1. Monograph on Pilosellae herba cum radix and supporting documents

Action: adoption
Documents: MO, AR, LoR; references 18/21, OoC
Documents for *information*: emails dated 02/03 Feb 2015, Liste A of Ph.Fr. 10th éd. 01/96

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

2.5.1. Public statement on Balsam peruvianum and supporting documents

Action: adoption
Documents: PS, AR, LoR (drafts)

2.5.2. Monograph on Epilobii herba and supporting documents

Action: adoption
Documents: MO, AR, LoR (drafts)

2.5.3. Public statement on Uncariae tomentosae cortex and supporting documents

Action: adoption
Documents: PS, AR, LoR (drafts)

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. Revised 'Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products' (rev 5)

Report: Q DG Chair
Action: adoption
Document: Quality Q & A

4.3. Regulatory

4.3.1. Appendix 2 (quality dossier mock-up) to the Guideline on the use of the CTD format in the preparation of a registration application for THMPs (draft rev 2)

Report: Q DG Chair
Action: adoption for public consultation
Documents: draft CTD format mock-up module 3 – P part
draft CTD format mock-up module 3 – S part

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair;

Meeting report from Q DG meeting held on 11-12 February 2015

Action: adoption

Draft agenda for the Q DG meeting to be held on 26 March 2015

Action: information

4.4.2. ORGAM DG

Report: ORGAM DG Chair;

Meeting report from the ORGAM DG meeting held on 10 February 2015

Action: adoption

Draft agenda for the ORGAM DG meeting to be held on 24 March 2015

Action: information

Proposal for amendments to QRD template for herbal medicinal products/THMPs- Annex III, SmPC, labelling and PL

Rapporteurs: R. Länger, E. v. Galen, S. Bodemann, M. Delbò;
Action: information
Documents: Draft discussion paper on QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. HMPC Rules of procedure and meeting dates

HMPC rules of procedure
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004738.pdf

Meeting dates for HMPC and MLWP in 2014 - 2018
Action: information

5.1.2. Strategic Review & Learning Meetings

Organisation of a HMPC strategic review & learning meeting during Latvian presidency
Report: HMPC Chair

Action: information
Document: draft agenda

5.1.3. Working methodology and procedural guidance

New agenda template for EMA scientific committees

Action: information

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. General coordination

Scientific Coordination Board Meeting 29 Jan 2015

Report: HMPC Chair
Action: information
Document: agenda

HMPC Observers at other Committees and Working Parties

Action: discussion
Document: EMEA policy on appropriate coordination between the scientific committees of the agency
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004626.pdf
Presentation

Update on EMA benefit-risk methodology project and activities

Action: discussion
Presentation

5.2.2. Coordination with CHMP

5.2.3. Coordination with PRAC and other Pharmacovigilance topics

Pharmacovigilance Programme – awareness session

Action: information
Presentation

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

5.3.1. Coordination with QWP

Guideline on Manufacture of the Finished Dosage Form

Report: Q DG Chair;
Action: discussion
Documents: draft Guideline on manufacture of the finished dosage form
ToD from 74th Joint CHMP/CVMP QWP 3 - 5 February 2015 meeting

5.3.2. Coordination with Joint CVMP/CHMP ad hoc expert group on 3Rs

Action: discussion
Document: meeting report March 2015

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

EDQM 13A Expert Group meeting held on 3-4 March 2015

EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
Action: information
Documents: Meeting report

EDQM 13B Expert Group meeting held on 20-21 January 2015

EDQM: M. Bald, U. Rose; HMPC Observer: H. Neef
Action: information
Documents: Summary of decisions

5.4.2. EFSA

Public consultation on draft Guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms.

Action: discussion, Appointment of Rapporteurs
Documents: email dated 09/02/2015
http://www.efsa.europa.eu/en/consultations/call/150209.htm

Public consultation on Conclusions and Recommendations of the EFSA/WHO Expert Working Group on TTC

Action: information
Documents: email dated 12/02/2015
http://www.efsa.europa.eu/en/consultations/call/150212.htm

5.4.3. Revised framework of interaction with patients and consumers and their organisations

Action: information
Presentation

5.5. Cooperation with International Regulators

None

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 programme 2012 – 2015

Action: information
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2011/12/WC500119957.pdf

5.7.2. HMPC work plan 2015

Action: discussion
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2015/01/WC500181439.pdf

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

5.9.1. Questions by members

Test on uniformity of mass of delivered doses from multidose containers

Action: discussion
Document: email dated 03/03/2015

6. Any other business

6.1. Topics for discussion

6.1.1. Proposal by Kew Gardens to map a plant list

Report: M. Delbò
Action: discussion
Documents: Email from M. Delbò on 14 November 2014; Proposal from Kew Gardens

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 27-28 January 2015

Common names of herbal substances in all EU official languages

Meeting report from HMPC meeting held on 27-28 January 2015
http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2014/04/WC500164759.pdf

Overview of status of HMPC assessment work – priority list
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017724.pdf

Inventory of herbal substances for assessment work – alphabetical order
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf

Abbreviations in HMPC minutes
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf

6.2.2. MLWP

TOC of MLWP meeting held on 28-30 January meeting 2015

Draft agenda of MLWP meeting to be held on 10-12 March 2015

6.2.3. PCWP/HCPWP

Minutes of the PCWP meeting with all eligible organisations held on 26 November 2014

PCWP/HCPWP – Joint meeting held on 4 March 2015 - Draft agenda

Presentation by HMPC observer 4 March 2015

PCWP – Information session on Biosimilars held on 5 March 2015- Draft agenda

6.2.4. Other

New publication: Phytopharmacy: An Evidence-Based Guide to Herbal Medicinal Products; SE. Edwards, I da Costa Rocha, EM. Williamson, M Heinrich; ISBN: 978-1-118-54356-6; 416 pages; April 2015, Wiley-Blackwell

http://eu.wiley.com/WileyCDA/WileyTitle/productCd-1118543564,subjectCd-MDM0.html