



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 May 2015
EMA/HMPC/290448/2015
Scientific Committee Support

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 4-5 May 2015

Chair: Werner Knöss – Vice-Chair: Marisa Delbó

4 May 2015, 14:00 – 19:00, room 2F

5 May 2015, 08:30 – 12:30, room 2F

(AESGP hearing at MLWP: 5 May 2015, 13.30 – 15.30, room 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 4-5 May 2015. See May 2015 HMPC minutes (to be published post July 2015 HMPC meeting).

Changes to membership, new participants: Marcel Bruch, member for Luxembourg, Xavier De Cuyper, alternate for Belgium

1.2. Adoption of agenda of the meeting

HMPC agenda for 4-5 May 2015

Time schedule

1.3. Adoption of the minutes

HMPC minutes for 9-10 March 2015

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP March meeting

Report: MLWP Chair

Action: for information

Documents: Draft minutes for the MLWP meeting on the 10-12 March 2015

Overview of status of MLWP assessment work

Common names of herbal substances in all EU official languages

2.1.2. Prioritisation/cancellation of substances for assessment – Appointment of Rapporteurs/Peer reviewers

Report: MLWP Chair

Action: for adoption

First assessment to be added to HMPC inventory and priority list:

-Valerianae aetheroleum

-Piperis methystici rhizoma proposed for HMPC assessment (proposal DE)

Revision: New rapporteur for Frangulae cortex, Rhamni purshianae cortex, Rhei radix:

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

None

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

2.3.1. Monograph on Capsici fructus and supporting documents

Rapporteur: R. Länger; Peer-reviewed: M. Heroutová

Action: for adoption

Documents: MO, AR, LoR, OoC; references 178/206

2.3.2. Monograph on Pilosellae herba cum radice and supporting documents

Rapporteur: O. Palomino, Peer-reviewer: G. Calapai/M. Delbò

Action: adoption

Documents: MO, AR, LoR; references 18/21, OoC

Documents for information: e-mails dated 02-03/02/2015, 26/03/2015, list A of Ph.Fr. 10th éd. 01/96

2.3.3. Monograph on Symphyti radix and supporting documents

Rapporteur: Z. Biró-Sándor; Peer-reviewer: J. Wiesner

Action: for adoption

Documents: MO, AR, LoR, OoC; references 48/70

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

2.4.1. Monograph on Ricini oleum and supporting documents

Action: for adoption for public consultation

Documents: MO, AR, LoR (drafts)

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

Action: for discussion/adoption

Documents: revised public statement, overview of comments, comments from Sweden

4.1.2. [Public statement on the use of herbal medicinal products containing estragole](#)

Action: for discussion/adoption

Documents: overview of comments, draft reflection paper

4.2. Quality

- 4.2.1. Planned Revision 3 of the 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products'
([EMA/HMPC/CHMP/CVMP/214869/2006](#))
-

Report: Q DG Chair
Action: for adoption
Document: concept paper

- 4.2.2. Planned Revision 3 of the 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMP/THMPs'
([EMA/CPMP/QWP/2820/00 Rev. 2](#), [EMA/CVMP/815/00 Rev. 2](#),
[EMA/HMPC/162241/2005 Rev. 2](#))
-

Report: Q DG Chair
Action: for adoption
Document: concept paper

- 4.2.3. Reflection paper on microbiological aspects of HMP/THMP
-

Report: Q DG Chair
Action: for adoption
Documents: final reflection paper, final reflection paper (track changes), overview of comments

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 meeting held on 26 March 2015

Action: for adoption

Draft agenda for the Q DG meeting to be held on 21 May 2015

Action: for information

- 4.4.2. ORGAM DG
-

Report: ORGAM DG Chair

Meeting report from the ORGAM DG meeting held on 24 March 2015

Action: for adoption

Draft agenda for the ORGAM DG meeting to be held on 19 May 2015

Action: for information

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review & Learning Meetings

Strategic Review & Learning HMPC-Meeting under the Latvian Presidency (co-hosted by BfArM) 18-19 June 2015

Report: HMPC Chair

Action: for information
Document: draft agenda

5.1.2. Assessors Training 2015

Report: HMPC Chair

Action: for discussion
Document: draft agenda

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. General coordination

Scientific Coordination Board Meeting 30 March 2015

Report: HMPC Chair

Action: information
Document: agenda

HMPC Observers at other Committees and Working Parties

Action: discussion
Presentation

EMA benefit-risk methodology project and activities

Action: discussion, appointment of member for steering group

5.2.2. Coordination with CHMP

Drafting group on excipients: ethanol as an excipient (after public consultation)

Action: for information

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

5.3.1. Interaction with PCWP - Revised framework of interaction with patients and consumers and their organisations

Proposal for future option for patients involvement in HMPC work

Rapporteur: S. Bager

Action: for discussion
Document: presentation

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

Action: for discussion
Document: meeting report March 2015

5.3.3. Coordination with QRD group

QRD template for THMPs in mutual recognition and decentralised procedures

Report: ORGAM Chair

Action: for discussion

Document: draft discussion paper on QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

EDQM 13B expert group meeting held on 21-22 April 2015

EDQM: M. Bald, U. Rose; HMPC Observer: H. Neef

Action: for information

Document: agenda, summary of decisions

EDQM TCM expert group meeting to be held on 5 - 6 May 2015

EDQM: M. Bald, U. Rose; HMPC Observer: R. Laenger

Action: for information

Document: agenda

EDQM 13A expert group meeting held on 2-3 June 2015

EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou

Action: for information

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.

Rapporteurs: G. Calapai, H. Pinto-Ferreira, I. Kosalec

Action: for information

Document: comments by HMPC, Gastroenterology DG, EMA`s anti-infectives & vaccines service, submitted 23/03/2015

5.4.3. EU Network Training Centre

Action: for information

Document: presentation

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

Action: for information

Document: presentation, draft status report

5.5. Cooperation with International Regulators

5.5.1. Response by AYUSH, India on data request for five Indian plants

Report: HMPC Chair

Action: for discussion

Documents: e-mail dated 24/04/2015, Ayurvedic medicinal plants PCIM AYUSH input, HMPC letter to Indian authorities March 2013

5.5.2. HMPC – International representation and cooperation

Report: HMPC Chair

Action: for discussion

Documents: draft proposal HMPC international cooperation

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

5.6.1. Hearing with AESGP at MLWP

Action: for discussion

Documents: draft agenda, participants list, presentation

5.6.2. Requirements for essential oils - Request for revision of HMPC Quality Q&A

Action: for discussion

Documents: e-mails dated 24/11/2014, 16/04/2015 by C. Valder, Frey + Lau GmbH, comments

5.7. HMPC work plan

5.7.1. [HMPC work programme 2012 – 2015](#)

Action: for information

5.7.2. [HMPC work plan 2015](#)

Action: for discussion

Monograph and List entry systematic revision – long term strategy

Report: I. Chinou (W. Knöss, M. Delbo)

Forward planning and prioritisation – identification of herbal substances requiring European standards as basis for national assessments

Document: *reflection paper*

Report: B. Kroes (W. Dymowski, I. Chinou, H. Neef, R. Länger)

Regulatory guidance for non-European interested parties and harmonisation of assessment practice for herbal substances of non-European origin

Report: W. Knöss (E. v. Galen)

European and International collaboration

Report: W. Knöss (E. v. Galen, S. Bager, M. Delbo, A.P. Martins, H. Neef)

5.8. Planning and reporting

5.8.1. EU Medicines Agencies Network Strategy 2020

Report: HMPC Chair

Action: for discussion

Documents: EU Medicines Agencies Network Strategy 2020, ([EMA/MB/151414/2015](#)), [EMA press release 31/03/2015](#), HMPC Chair comments dated 24/02/2015

5.9. Legislation and regulatory affairs

None

6. Any other business

6.1. Topics for discussion

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 9-10 March 2015

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 9-10 March 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

TOC of MLWP meeting held on 10-12 March meeting 2015

Draft agenda of MLWP meeting to be held on 5-7 May 2015

6.2.3. Other

Rapid Alert - Type I - W.-W. Les Herbes Pures J.B. Ltée

Coordination with Kew Gardens: e-mail W. Dymowski dated 10/04/2015