



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2015
EMA/HMPC/776470/2015
Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 23-24 November 2015

Chair: Werner Knöss – Vice-Chair: Marisa Delbó

23 November 2015 14:00 – 19:00, 3E

24 November 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 23-24 November 2015. See November 2015 HMPC minutes (to be published post February 2016 HMPC meeting).

New Spanish alternate: Cristina Martinez Garcia; Starting date of mandate: 06 October 2015.

New Lithuanian member: Rugile Pilviniene; Starting date of mandate: 14 October 2015.

Observers: Dr. Manoj Nesari, Ministry of AYUSH and Prof. Vinod Kumar Joshi, Banaras Hindu University, India

1.2. Adoption of agenda

HMPC agenda for 23-24 November 2015.

1.3. Adoption of the minutes

HMPC minutes for 28-29 September 2015.

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP September 2015 meeting

Report: MLWP Chair

Action: for information

Document: Draft minutes for the MLWP meeting on the 29 Sept – 1 Oct 2015

2.1.2. Monographs – proposals for minor corrections

- Vitis viniferae folium

Rapporteur: I. Chinou; Peer-reviewer: B. Kroes; Report: MLWP Chair

Action: for adoption

Documents: MO; AR; e-mail 21 Aug 2015

- Echinacea purpurea herba

Rapporteur: S. Kreft, B. Razinger; Peer-reviewer: J. Wiesner

Action: for discussion

Documents: Letter 24 Sept 2015; Echinaceae purpureae herba MO posology

2.1.3. Appointment of Rapporteurs and Peer-reviewers

- First assessment

Herbal substance: Vaccinium macrocarpon Aiton, fructus

Herbal substance: Malva sylvestris L., folium and flos

- Current Rapporteur Distribution

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 Althaeae radix and supporting documents

Action: for public consultation

Documents: MO; AR; LoR; references: 71/73

2.2.2. Monograph on Centaurii herba and supporting documents

Action: for final adoption

Documents: MO; AR; LoR; references: 41/78

2.2.3. Monograph on Hederae helicis folium and supporting documents

Action: for final adoption

Documents: MO; AR; OoC; LoR; references: 164/164

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

2.3.1. Monograph on Epilobii herba and supporting documents

Rapporteur: R. Länger; Peer-reviewer: M. Heroutová; Expert: A. Obmann

Action: for adoption

Documents: MO; AR; LoR; references: 54/56

2.3.2. 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: 142/142

2.3.3. Public statement on Uncariae tomentosae cortex and supporting documents

Rapporteur: Z. Biró-Sándor; Peer-reviewer: R. Länger

Action: for adoption

Documents: PS; AR; LoR; references: 131/143

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

2.4.1. Public statement on Balsamum peruvianum and supporting documents

Action: for adoption
Documents: Draft PS; AR; LoR

2.4.2. Monograph on Pruni africanae cortex and supporting documents

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

2.4.3. Public statement on Salviae fruticosae folium and supporting documents

Action: for adoption
Documents: Draft PS; AR; LoR

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 discussion
Documents: PS; OoC; letter from HMPC to CHMP June 2015; SWP response Oct 2015

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 Sept 2015; SWP response April 2014

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

Rapporteurs: K. Reh, W. Kubelka
Action: for adoption for public consultation
Document: Draft reflection paper

4.3. Regulatory

4.3.1. 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 15 October 2015

Action: for information

Document: Draft agenda for the Q DG meeting to be held on 9 December 2015

4.4.2. ORGAM DG

Report: ORGAM DG Chair

Action: for adoption

Document: Meeting report from ORGAM DG meeting held on 13 October 2015

Action: for information

Document: Draft agenda for the ORGAM DG meeting to be held on 10 December 2015

Action: for discussion

Documents: CTD guideline (EMA/HMPC/71049/2007); draft OoC (clinical and pre-clinical part)

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 elections

- Co-opted member, toxicology
- QDG Chair

Action: for discussion

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

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 – organisational aspects

Action: for information

Documents: Organisation of strategic review and learning meetings under European Presidency; 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. Coordination with CHMP: drafting group on excipients: ethanol as an excipient (after public consultation)

Action: for information

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

See also 4.1.1

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

See also 4.1.2

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

Action: for information

Documents: Email 27 Aug 2015; email communication 12-16 Oct 2015

5.2.5. Coordination with PDCO

- Expert support for herbal combination product

Report: W. Knöss, A. P. Martins, L. Anderson

Action: for information

- Report on relevant topics from PDCO meetings

Report: S. Girotto (observer)

Action: for information

Document: Presentation

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

5.3.1. Coordination with PCWP/HCPWP

Observer: S. Bager

- Work plan for the EMA PCWP 2016

Action: for adoption

Document: Work plan

- Work plan for the EMA HCPWP 2016

Action: for adoption

Document: Work plan

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

Action: for information

Document: Draft agenda

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

Action: for information

Document: Draft agenda

5.3.2. Coordination with QRD group

QRD templates for THMPs in mutual recognition and decentralised procedures

Report: ORGAM Chair

Action: for discussion

Document: Comments received by QRD Group

5.4. Cooperation within the EU regulatory network

5.4.1. HMPC Chair presentation at 89th EMA MB meeting, 2 October 2015

Report: HMPC Chair

Action: for information

Documents: Presentation; [press release](#)

5.4.2. European Pharmacopeia

- EDQM 13A expert group meeting held on 3-4 November 2015
EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
Action: for information
Documents: Agenda; EDQM monographs on Hippocastani semen and Hippocastani seminis extractum siccum normatum
- EDQM 13B expert group meeting held on 22-23 September 2015
EDQM: M. Bald, U. Rose; HMPC Observer: B. Kroes (H. Neef)
Action: for information
Document: Summary of decisions
- EDQM TCM expert group meeting held on 15-16 September 2015
EDQM: M. Bald, U. Rose; HMPC Observer: R. Länger
Action: for information
Document: Summary of decisions
- Appointment of HMPC observers and meeting dates 2016
Action: for discussion
Document: DG dates for 2016

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

- Action:** for adoption
Documents: Timetable; list of questions
- Action:** for information
Documents: Survey - [EMA/HMPC/322570/2011](#); presentation

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

- Action:** for information

5.5. Cooperation with International Regulators

5.5.1. AYUSH information on Indian medicinal plants

- Report: M. Nesari, V.K. Joshi
Action: for discussion
Documents: Response letter from HMPC Chair 2 Sept 2015; Letter 5 Nov 2015; presentation

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 Aug 2015

5.5.3. HMPC – International representation and cooperation

Report: HMPC Chair

Action: for adoption

Document: Draft proposal HMPC international cooperation

5.5.4. 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

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](#) status; presentation; tracking tool; MLWP work plan 2015 status; Q DG work plan 2015 status; ORGAM DG work plan 2015 status
- Monograph and List entry systematic revision
Action: for discussion
Document: Presentation

5.7.2. HMPC draft work plan 2016

Report: HMPC Chair

Action: for adoption

Documents: HMPC draft work plan 2016; MLWP draft work plan 2016; Q DG draft work plan 2016; ORGAM DG draft work plan 2016

5.8. Planning and reporting

5.8.1. Meeting dates

Action: for information

Document: HMPC/MLWP 2016 to 2018

5.9. Legislation and regulatory affairs

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

Rapporteur: R. Länger

Action: for discussion

Documents: Letter 15 May 2015; Response Oct 2015; Annex conclusion

6. Any other business

6.1. Topics for discussion

6.1.1. ADAPT-SMART – presentation

Action: for discussion

6.1.2. Herbal assessment report summary for the public

Action: for discussion

Document: Presentation

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 28-29 September 2015

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 28-29 September 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 24-26 November 2015

6.2.3. ARSP

- English summaries for publication
- ARSP translations in all EU languages; for publication, member states feedback

6.2.4. Other

- Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: [Commission work programme 2016](#) 'No time for business as usual', Strasbourg, 27.10.2015 com(2015) 610 final; [Annex II: REFIT Initiatives](#)
- Article 57: Information by Pharmacovigilance Department; Documents: Article 57 Publication Dashboard Report to NCAs; Article 57 Publication Dashboard Report to EMA Committees; Pharmacovigilance programme update, Oct 2015
- [EFSA CEF Panel: Scientific Opinion on Flavouring Group Evaluation 208 Revision 1 \(FGE.208Rev1\): Consideration of genotoxicity data on representatives for 10 alicyclic aldehydes EFSA Journal 2015;13\(7\):4173](#)
- IARC monographs on the evaluation of carcinogenic risks to humans. [Some drugs and herbal products. Volume 108](#). International Agency for Research on Cancer. WHO, Lyon 2015. (includes Ginkgo, Kava-Kava, pulegone, Aloe)
- Rethinking traditional Chinese medicines for cancer. Editorial. The Lancet Oncology. Vol 16, Nov. 2015
- The Nobel Prize in Physiology or Medicine 2015: William C. Campbell, Satoshi Ōmura, Youyou Tu (for artemisinin isolation from TCM for treatment of malaria). [Press release](#)
- Episalvan (previously known as Oleogel) – final positive CHMP opinion and assessment report on product from herbal origin on 19 November 2015 meeting