



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 March 2016
EMA/HMPC/69315/2016
Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 4-5 April 2016

Chair: Werner Knöss – Vice-Chair: Marisa Delbó

4 April 2016 14:00 – 19:00, 3E

5 April 2016 08:30 – 12:30, 3E

(AESGP hearing at MLWP: 5 April 2016 13.30 – 15.30, room 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).



Table of contents

| | | |
|-------------|--|----------|
| 1. | Introduction | 4 |
| 1.1. | Welcome and declarations of interest of members, alternates and experts | 4 |
| 1.2. | Adoption of agenda..... | 4 |
| 1.3. | Adoption of the minutes | 4 |
| 2. | European Union herbal monographs and list entries | 4 |
| 2.1. | Report on MLWP activities | 4 |
| 2.1.1. | Report from the MLWP February 2016 meeting..... | 4 |
| 2.1.2. | Calls for scientific data | 4 |
| 2.1.3. | Appointment of Rapporteurs and Peer-reviewers | 4 |
| 2.1.4. | Change in membership of MLWP..... | 5 |
| 2.2. | Revised EU herbal monographs and list entries for final adoption | 5 |
| 2.2.1. | Monograph on Thymi herba and Primulae radix and supporting documents | 5 |
| 2.3. | Revised EU herbal monographs and list entries for public consultation | 5 |
| 2.4. | EU herbal monographs, list entries and public statements for final adoption | 5 |
| 2.4.1. | List Entry and Monograph on Crataegi folium cum flore | 5 |
| 2.4.2. | Monograph on Helichrysi flos..... | 5 |
| 2.4.3. | Monograph on Polygoni avicularis herba | 5 |
| 2.4.4. | Monograph on Silybi mariani fructus | 5 |
| 2.5. | EU herbal monographs, list entries and public statements for adoption for release for public consultation..... | 6 |
| 2.5.1. | Monograph on Cisti cretici folium and supporting documents – postponed..... | 6 |
| 3. | Referral procedures | 6 |
| 4. | Guidelines and guidance documents | 6 |
| 4.1. | Non-clinical / clinical safety and efficacy and multidisciplinary | 6 |
| 4.1.1. | Reflection paper on herbal medicinal products containing polycyclic aromatic hydrocarbons (PAH) | 6 |
| 4.2. | Quality..... | 6 |
| 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 – postponed ... | 6 |
| 4.3. | Regulatory | 6 |
| 4.3.1. | Revised guideline on the use of the CTD format for registration applications | 6 |
| 4.4. | Report on HMPC Drafting Groups activities..... | 6 |
| 4.4.1. | Quality DG..... | 6 |
| 4.4.2. | ORGAM DG | 7 |
| 5. | Organisational, regulatory and methodological matters | 7 |
| 5.1. | Mandate and organisation of the HMPC | 7 |
| 5.1.1. | Mandate of Quality DG | 7 |

| | | |
|-------------|--|-----------|
| 5.1.2. | Assessors Training December 2015 – follow up | 7 |
| 5.1.3. | Assessors Training 2016 | 7 |
| 5.1.4. | Strategic Review and Learning Meetings – organisational aspects | 7 |
| 5.2. | Coordination with EMA Scientific Committees or CMDh-v | 7 |
| 5.2.1. | Coordination with CHMP/SWP - Public statement on the use of herbal medicinal products containing pulegone/menthofuran..... | 7 |
| 5.2.2. | Report from Scientific Coordination Board – 18 March 2016 | 8 |
| 5.3. | Coordination with EMA Working Parties/Working Groups/Drafting Groups | 8 |
| 5.3.1. | Coordination with PCWP/HCPWP | 8 |
| 5.3.2. | European Union reference date (EURD) list – update for herbal substances..... | 8 |
| 5.4. | Cooperation within the EU regulatory network | 8 |
| 5.4.1. | European Pharmacopeia | 8 |
| 5.4.2. | HMPC comments to EDQM on CEPs for herbal active ingredients - postponed | 8 |
| 5.4.3. | EFSA – Guidance on traditional foods from third countries and Novel Food - consultations .. | 9 |
| 5.4.4. | European Commission – Update on establishment of List entries (Melaleuca) | 9 |
| 5.4.5. | Survey on uptake of the traditional use registration and implementation of Directive 2004/24/EC in EU Member States, 2015 - Preliminary outcome..... | 9 |
| 5.5. | Cooperation with International Regulators..... | 9 |
| 5.5.1. | 8th Annual Meeting of IRCH held in Riyadh, Saudi Arabia, 1-3 December 2015..... | 9 |
| 5.5.2. | HMPC – International representation and cooperation | 9 |
| 5.6. | Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee | 9 |
| 5.6.1. | Hearings with interested parties in 2016..... | 9 |
| 5.7. | HMPC work plan | 9 |
| 5.7.1. | Projects on the HMPC work plan 2016 | 9 |
| 5.8. | Planning and reporting | 10 |
| 5.9. | Legislation and regulatory affairs | 10 |
| 6. | Any other business | 10 |
| 6.1. | Topics for discussion | 10 |
| 6.1.1. | Occurrence of pyrrolizidine alkaloids – issues on national markets and follow up..... | 10 |
| 6.2. | Documents for information..... | 10 |
| 6.2.1. | HMPC | 10 |
| 6.2.2. | MLWP..... | 10 |
| 6.2.3. | ARSP..... | 11 |
| 6.2.4. | Other | 11 |
| 6.2.5. | Update on availability of herbal hand books at the Agency library | 11 |

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 April 2016. See April 2016 HMPC minutes (to be published post May 2016 HMPC meeting).

New co-opted member (toxicology): Heidi Foth; Starting date of mandate: 4 April 2016

1.2. Adoption of agenda

HMPC agenda for 4-5 April 2016; time schedule

1.3. Adoption of the minutes

HMPC minutes for 1-2 February 2016

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP February 2016 meeting

Report: MLWP Chair

Action: for information

Document: Draft minutes for the MLWP meeting on the 3-4 February 2016

2.1.2. Calls for scientific data

- Monograph systematic review

Report: MLWP Chair

Action: for adoption

Avenae fructus; Avenae herba; Calendulae flos; Myrrha (Commiphora molmol); Oenotherae biennis oleum; Polypodii rhizome; Rusci aculeati rhizome; Sambuci flos; Tanacetii parthenii herba; Thymi aetheroleum; Trigonellae foenugraeci semen; Verbasci flos

2.1.3. Appointment of Rapporteurs and Peer-reviewers

- Monograph systematic review

Herbal substance

Avenae fructus

Avenae herba

Calendulae flos

Rusci aculeati rhizoma

Trigonellae foenugraeci semen

Valerianae radix/Lupuli flos

- Appointment of Rapporteur (none MLWP members)

2.1.4. Change in membership of MLWP

Report: MLWP Chair

Action: for discussion

Document: Resignation of a MLWP member, Beate Huber, 7 March 2016

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

2.2.1. Monograph on Thymi herba and Primulae radix and supporting documents

Action: for adoption

Documents: MO, AR, LoR, references: 22/22

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

None

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

2.4.1. List Entry and Monograph on Crataegi folium cum flore

Rapporteur: J. Wiesner; Peer-reviewer: R. Länger

Action: for adoption

Documents: MO, LE, AR, LoR, OoC, references: 84/89

2.4.2. Monograph on Helichrysi flos

Rapporteur: W. Dymowski; Peer-reviewer: G. Calapai

Action: for adoption

Documents: MO, AR, LoR, references: 46/49

2.4.3. Monograph on Polygoni avicularis herba

Rapporteur: B. Jansone; Peer-reviewer: J. Viguier-Poupelloz

Action: for adoption

Documents: MO, AR, LoR, references: 1/79

2.4.4. Monograph on Silybi mariani fructus

Rapporteur: O. Palomino; Peer-reviewer: W. Knöss

Action: for adoption

Documents: MO, AR - TU, MO, AR - WEU/TU, LoR, OoC, SE comments; references: 114/195

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

2.5.1. Monograph on Cisti cretici folium and supporting documents – postponed

None

3. Referral procedures

None

4. Guidelines and guidance documents

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

4.1.1. Reflection paper on herbal medicinal products containing polycyclic aromatic hydrocarbons (PAH)

Action: for discussion
Document: Draft reflection paper

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 – postponed

Report: QDG Chair

4.3. Regulatory

4.3.1. Revised guideline on the use of the 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; Comments SE and DE

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 11 Feb 2016
Action: for information
Document: Draft agenda for the Q DG meeting to be held on 4 May 2016

4.4.2. ORGAM DG

Report: ORGAM DG Chair

Action: for adoption

Documents: Meeting reports from ORGAM DG meeting held on 9 Feb and 16 March 2016;

Action: for information

Documents: Draft agenda for the ORGAM DG meeting to be held on 3 May 2016; Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs (EMA/HMPC/770889/2014)

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Mandate of Quality DG

Action: for discussion

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

5.1.2. Assessors Training December 2015 – follow up

Report: QDG Chair

Action: for information

Document: Summary outcome of group discussions

5.1.3. Assessors Training 2016

Report: S. Bager

Action: for discussion

Document: Draft Agenda

5.1.4. Strategic Review and Learning Meetings – organisational aspects

Report: E. van Galen

Action: for discussion

Documents: Draft agenda, meeting 12-13 April 2016, Netherlands

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

Rapporteur: J. Wiesner

Action: for discussion

Documents: New data, provided December 2015; SWP/CHMP preliminary feedback from Oct 2015 and Mar 2016; Overview pulegone development; Draft revised PS; Draft OoC

5.2.2. Report from Scientific Coordination Board – 18 March 2016

Report: HMPC Chair

Action: for information

Document: Agenda

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

5.3.1. Coordination with PCWP/HCPWP

Observer: S. Bager

- EMA PCWP/HCPWP session on communication and information on medicines, 8 March 2016

Action: for information

Document: Agenda

- EMA PCWP/HCPWP joint meeting, 9 March 2016

Action: for information

Document: Agenda

- Patient involvement within EMA/HMPC

Action: for adoption

Document: Patient involvement within EMA/HMPC

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: Summary of discussion, report by I. Chinou, information on Grindelia
- EDQM 13B expert group meeting to be held on 19-20 April 2016
EDQM: M. Bald, U. Rose; HMPC Observer: H. Neef
Action: for information
Document: Agenda

5.4.2. HMPC comments to EDQM on CEPs for herbal active ingredients - postponed

Report: ODG Chair

5.4.3. EFSA – Guidance on traditional foods from third countries and Novel Food - consultations

Report: HMPC Chair; Rapporteurs: G. Calapai; I. Kosalec; H. Pinto Ferreira

Action: for discussion

Document: Email distributed to HMPC, 23 Feb 2016

5.4.4. European Commission – Update on establishment of List entries (Melaleuca)

Report: HMPC Chair, M. Delbo

Action: for discussion

Document: Draft LE; Ph. Eur. Monograph, letter from Eu. Com. dated 21 March 2016

5.4.5. Survey on uptake of the traditional use registration and implementation of Directive 2004/24/EC in EU Member States, 2015 - Preliminary outcome

Action: for discussion

Document: Presentation

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

Documents: Summary Report; Presentations

5.5.2. HMPC – International representation and cooperation

Report: HMPC Chair

Action: for adoption

Document: 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. Hearings with interested parties in 2016

Action: for discussion

Documents: AESGP hearing draft Agenda; Participants list

5.7. HMPC work plan

5.7.1. Projects on the HMPC work plan 2016

Action: for discussion

Document: Work plan 2016 – current status, HMPC work plan tracking tool 2016

- Cross committee risk/benefit project
Report: S. Madsen
Action: for discussion
Document: Presentation
- Harmonisation of assessment practice for herbal substances of non-European origin
Report: E. van Galen
Action: for discussion
Document: draft list of Ayurvedic herbs

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. Occurrence of pyrrolizidine alkaloids – issues on national markets and follow up

Report: HMPC Chair, L. Anderson

Action: for discussion

Documents: Information received from UK, DE, AT; Published articles, request from NL

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 1-2 February 2016

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 1-2 February 2016](#)

[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 6-7 April 2016

6.2.3. ARSP

- English summaries for publication
Documents: Castor oil, Ironwort, Horsetail herb, Valerian root, Valerian essential oil
- English template

6.2.4. Other

- New internal guidance on management of confidentiality and declarations of interests for observers participating in EMA scientific meetings;
Documents: Observers summary for Committees and WPs; Observers at EMA Meetings

6.2.5. Update on availability of herbal hand books at the Agency library

- Overview of status of availability of herbal hand books at the Agency library - March 2016