



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2017
EMA/HMPC/59024/2017
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 30-31 January 2017

Chair: Marisa Delbò

30 January 2017, 14:00 – 19:00, 2F

31 January 2017, 09:00 – 17:00, 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).



Table of contents

| | | |
|-------------|-----------------------------------------------------------------------------------------------------------------------|----------|
| 1. | Introduction | 5 |
| 1.1. | Welcome and declarations of interest of members, alternates and experts | 5 |
| 1.2. | Adoption of agenda..... | 5 |
| 1.3. | Adoption of the minutes | 5 |
| 2. | European Union herbal monographs and list entries | 5 |
| 2.1. | Report on MLWP activities | 5 |
| 2.1.1. | Report from the MLWP November 2016 meeting..... | 5 |
| 2.1.2. | Prioritisation of substances for assessment | 5 |
| 2.1.3. | Appointment of Rapporteurs and Peer-reviewers | 6 |
| 2.1.4. | Polypodii rhizoma | 6 |
| 2.1.5. | Change in membership of MLWP..... | 6 |
| 2.2. | Revised EU herbal monographs and list entries for final adoption | 6 |
| 2.2.1. | Monograph on Oleae folium and supporting documents | 6 |
| 2.2.2. | Monograph on Salicis cortex and supporting documents | 6 |
| 2.3. | Revised EU herbal monographs and list entries for public consultation | 6 |
| 2.3.1. | List Entry and Monograph on Menthae piperitae aetheroleum and supporting documents.... | 6 |
| 2.3.2. | Monograph on Menthae piperitae folium and supporting documents..... | 6 |
| 2.3.3. | Monograph on Ribis nigri folium and supporting documents | 6 |
| 2.4. | EU herbal monographs, list entries and public statements for final adoption | 7 |
| 2.4.1. | Monograph on Lecithinum ex soya and supporting documents | 7 |
| 2.4.2. | Public statement on Paeoniae radix, alba and supporting documents..... | 7 |
| 2.4.3. | Public statement on Paeoniae radix, rubra and supporting documents | 7 |
| 2.4.4. | Monograph on Soiae oleum raffinatum and supporting documents | 7 |
| 2.5. | EU herbal monographs, list entries and public statements for adoption for release for public consultation..... | 7 |
| 2.5.1. | Monograph on Cisti cretici folium and supporting documents – postponed..... | 7 |
| 2.5.2. | Public statement on Glycini semen and supporting documents..... | 7 |
| 2.5.3. | List Entry and Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents..... | 7 |
| 3. | Referral procedures | 7 |
| 4. | Guidelines and guidance documents | 8 |
| 4.1. | Non-clinical/clinical safety and efficacy and multidisciplinary..... | 8 |
| 4.2. | Quality..... | 8 |
| 4.3. | Regulatory | 8 |
| 4.4. | Report on HMPC Drafting Groups activities..... | 8 |
| 4.4.1. | Quality DG..... | 8 |
| 4.4.2. | ORGAM DG | 8 |

| | | |
|--------|---------------------------------------------------------------------------|---|
| 4.4.3. | Proposal for the revision process of the EU monographs/List entries | 9 |
| 4.4.4. | Disclaimer for EU herbal monographs..... | 9 |
| 4.4.5. | Mandate and membership of ORGAM DG | 9 |
| 4.4.6. | Election of ORGAM DG Chair | 9 |

5. Organisational, regulatory and methodological matters 9

| | | |
|-------------|----------------------------------------------------------------------------------------------------------------------|-----------|
| 5.1. | Mandate and organisation of the HMPC | 9 |
| 5.1.1. | Election of HMPC Vice-Chair | 9 |
| 5.1.2. | Strategic Review and Learning Meetings | 9 |
| 5.1.3. | Procedural guidance – revised SOP on MO & LE establishment | 10 |
| 5.2. | Coordination with EMA Scientific Committees or CMDh-v | 10 |
| 5.2.1. | Scientific Coordination Board Meeting..... | 10 |
| 5.2.2. | Coordination with PDCO- Public workshop on extrapolation of efficacy and safety | 10 |
| 5.3. | Coordination with EMA Working Parties/Working Groups/Drafting Groups | 10 |
| 5.3.1. | Joint CVMP/CHMP ad hoc expert group meeting on 3Rs (JEG 3Rs = Replacement, Reduction, Refinement)..... | 10 |
| 5.4. | Cooperation within the EU regulatory network | 10 |
| 5.4.1. | European Pharmacopeia | 10 |
| 5.4.2. | Pharmacovigilance – Eudravigilance database and Art.16a registered products..... | 11 |
| 5.5. | Cooperation with International Regulators..... | 11 |
| 5.5.1. | 9 th Annual Meeting of IRCH held in New Delhi, India, 8-10 November 2016..... | 11 |
| 5.6. | Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee | 11 |
| 5.6.1. | EUCOPE..... | 11 |
| 5.7. | HMPC work plan | 11 |
| 5.7.1. | Projects on the HMPC work plan 2016 | 11 |
| 5.7.2. | HMPC work plan 2017 | 11 |
| 5.8. | Planning and reporting | 12 |
| 5.8.1. | Meeting dates | 12 |
| 5.9. | Legislation and regulatory affairs | 12 |
| 5.9.1. | Evidence on the period of traditional use | 12 |

6. Any other business 12

| | | |
|-------------|--------------------------------------------------------------------------------------------------------------------|-----------|
| 6.1. | Topics for discussion | 12 |
| 6.1.1. | ARSP..... | 12 |
| 6.1.2. | Update on Management Board data gathering exercise..... | 12 |
| 6.1.3. | Follow up on Public Statement on Pyrrolizidine alkaloid contaminations/Update of activities in Member States | 12 |
| 6.1.4. | Survey to committee's members 2016 – follow up | 12 |
| 6.1.5. | Information on initiative within the European Commission REFIT consultation | 13 |
| 6.2. | Documents for information | 13 |

| | | |
|--------|-------------|----|
| 6.2.1. | HMPC | 13 |
| 6.2.2. | MLWP | 13 |
| 6.2.3. | Other | 13 |

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 30-31 January 2017. See January 2016 HMPC minutes (to be published post March 2017 HMPC meeting).

End of membership (Sweden): Erika Svedlund alternate; End date of mandate: 1 January 2017

New European Commission representative

1.2. Adoption of agenda

HMPC agenda for 30-31 January 2017

Time schedule for 30-31 January 2017

1.3. Adoption of the minutes

HMPC minutes for 21-22 November 2016

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP November 2016 meeting

Report: MLWP Chair

Action: for information

Document: Draft minutes for the MLWP meeting on the 22-24 Nov 2016

2.1.2. Prioritisation of substances for assessment

- Three tea combinations (loss of appetite, gastrointestinal complaints, nervous tension/to aid sleep)
Action: for discussion
Documents: [Procedure on management of proposals from interested parties for Community list entries or Community herbal monographs](#), [Guideline on the documentation to be submitted for inclusion into the 'community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'](#); [Draft monograph Species diureticae](#); Templates: Species amarae – Proposal for assessment by HMPC; Species digestivae – Proposal for assessment by HMPC; Species sedativae – Proposal for assessment by HMPC; Presentation; Suggestions by C. Purdel; List of Standardzulassungen – BfArM

2.1.3. Appointment of Rapporteurs and Peer-reviewers

- Changes of Rapporteurs and Peer-reviewers

2.1.4. Polypodii rhizoma

Action: for discussion

Documents: Revision of MO; Annex

See also 4.4.3.

2.1.5. Change in membership of MLWP

Report: MLWP Chair

Action: for discussion

Documents: Resignation letter from a MLWP member, A. J. Vlietinck, 24 Nov 2016; List of expertise

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

2.2.1. Monograph on Oleae folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 30/183

2.2.2. Monograph on Salicis cortex and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 95/132

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

2.3.1. List Entry and Monograph on Menthae piperitae aetheroleum and supporting documents

Action: for adoption

Documents: LE, MO, AR, LoR, References: 107/205; Presentation

2.3.2. Monograph on Menthae piperitae folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 107/205

2.3.3. Monograph on Ribis nigri folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 44/44

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

2.4.1. Monograph on Lecithinum ex soya and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC; References: 46/46; Presentation

2.4.2. Public statement on Paeoniae radix, alba and supporting documents

Action: for adoption

Documents: PS, AR, LoR, OoC; References: 130/143

2.4.3. Public statement on Paeoniae radix, rubra and supporting documents

Action: for adoption

Documents: PS, AR, LoR, OoC; References: 138/150

2.4.4. Monograph on Soiae oleum raffinatum and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 7/7

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

Action: for adoption

2.5.2. Public statement on Glycini semen and supporting documents

Action: for adoption

Documents: PS, AR, LoR

2.5.3. List Entry and Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents

Action: for discussion

Documents: LE, MO, AR, LoR; Comments received 13 Dec 2016; EDQM comments, 7 Dec 2016 + attachment; Email communication from SI, IE

3. Referral procedures

None

4. Guidelines and guidance documents

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

None

4.2. Quality

None

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 7 Dec 2016
Action: for adoption
Document: Meeting report
- Draft agenda for the Q DG face to face meeting to be held on 23-24 Feb 2017
Action: for information
Document: Draft agenda
- Meeting dates 2017 – updated
Action: for information
Document: Meeting dates
- Change in membership of QDG
Action: for discussion
Document: Resignation letter from a QDG member, M. Co, 20 Jan 2017

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report
Action: for adoption
Document: Meeting report from ORGAM DG meeting held on 14 Dec 2016
- Agenda
Action: for information
Document: Draft agenda for the ORGAM DG meeting to be held on 21 Feb 2017
- Meeting dates 2017 – updated
Action: for information
Document: Meeting dates

4.4.3. Proposal for the revision process of the EU monographs/List entries

Report: ORGAM DG Chair, A. P. Martins

Action: for discussion

Documents: Draft procedure; Template example

4.4.4. Disclaimer for EU herbal monographs

Report: M. Delbò

Action: for discussion

Documents: Presentation; Disclaimer for EU herbal monographs

4.4.5. Mandate and membership of ORGAM DG

Report: ORGAM DG Chair

Action: for discussion

Documents: Presentation; Confirmation of interest expressed for membership; Email correspondence, 23 Jan 2017; [Current mandate](#); [Possible future mandate](#)

4.4.6. Election of ORGAM DG Chair

Action: for adoption

Documents: Email on call for interest, 13 Dec 2016

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Election of HMPC Vice-Chair

Action: for adoption

Documents: Email on call for interest, 13 Dec 2016; [HMPC rules of procedure](#); Candidatures

5.1.2. Strategic Review and Learning Meetings

Report: HMPC Chair, E. van Galen, E. Attard

- Transfer from Utrecht, 12-13 Apr 2016 – follow up

Action: for discussion

Documents: Email from HMPC Chair, 26 May 2016; Summary in presentation; Summary of Strategic Review meeting in NL 2016; Transfer from Utrecht – follow up; Breakout session groups – follow up; Presentation – Future of HMPC (breakout sessions)

- Presidency meeting – Malta, 26-28 Apr 2017 – update

Action: for information

Documents: Agenda; Presentation; Email correspondence, 16 Jan 2017; Organisation of Strategic Review & Learning Meetings (SRLM) of EMA Scientific Committees under the EU Presidency; Organisational aspects of SRLM; Presentation by EMA

- Possibility for Presidency meeting – Estonia, Jul-Dec 2017

Action: for information

5.1.3. Procedural guidance – revised SOP on MO & LE establishment

Action: for information

Documents: [SOP](#); Presentation

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Action: for information

Documents: Minutes from meeting held on 10 Jun 2016; Agenda from the meeting held on 22 Sep 2016 and 31 Jan 2017

5.2.2. Coordination with PDCO- Public workshop on extrapolation of efficacy and safety

Action: for information

Document: Presentation

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

5.3.1. Joint CVMP/CHMP ad hoc expert group meeting on 3Rs (JEG 3Rs = Replacement, Reduction, Refinement)

- Joint CVMP/CHMP ad hoc expert group meeting on 3Rs
Report: G. Laekeman
Action: for discussion
Documents: Meeting report, 18-19 Oct 2016; Presentation
- New structure J3RsWG - Joint CVMP/CHMP ad hoc expert group
Action: for discussion
Documents: J3RsWG Mandate 2017-2019; J3RsWG Work plan 2017; Email correspondence, 9 Jan 2017; Thank you letter to G. Laekeman

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13A expert group meeting held on 8-10 Nov 2016
EDQM: M. Bald; HMPC Observer: I. Chinou
Action: for information
Document: Summary of decisions
- EDQM 13A expert group meeting held on 28 Feb - 1 Mar 2017
EDQM: M. Bald; HMPC Observer: I. Chinou
Action: for information
- EDQM 13B expert group meeting held on 24-25 Jan 2017
EDQM: M. Bald; HMPC Observer: B. H. Kroes
Action: for information
Documents: Agenda, Report

- EDQM TCM expert group meeting held on 31 Jan – 1 Feb 2017
EDQM: M. Bald; HMPC Observer: R. Länger
Action: for information
Document: Agenda

5.4.2. Pharmacovigilance – Eudragilance database and Art.16a registered products

Action: for discussion
Document: Email correspondence, 17 Oct 2016

5.5. Cooperation with International Regulators

5.5.1. 9th Annual Meeting of IRCH held in New Delhi, India, 8-10 November 2016

Action: for discussion
Document: Agenda

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

5.6.1. EUCOPE

Report: HMPC Chair
Action: for discussion
Documents: Letter to HMPC, 25 Jul 2016; Response from HMPC, 12 Oct 2016

5.7. HMPC work plan

5.7.1. Projects on the HMPC work plan 2016

Action: for discussion
Documents: Work plan 2016 – current status; HMPC work plan tracking tool 2016

5.7.2. HMPC work plan 2017

- HMPC work plan 2017
Report: HMPC Chair
Action: for adoption
Document: Draft work plan
- Cooperation with Academia – general recommendations on scientific work for important topics
Report: HMPC Chair
Action: for discussion
Documents: Email communication 21 Dec 2016 and 12 Jan 2017
- Organisation of hearings with Interested Parties in 2017
Report: MLWP Chair
Action: for discussion
Document: Proposal by MLWP Chair, 14 Nov 2016

5.8. Planning and reporting

5.8.1. Meeting dates

Action: for information
Document: HMPC/MLWP 2019 to 2021

5.9. Legislation and regulatory affairs

5.9.1. Evidence on the period of traditional use

Report: E. v. Galen
Action: for discussion
Documents: Request to EC, 20 Dec 2016; Presentation

6. Any other business

6.1. Topics for discussion

6.1.1. ARSP

- English template
- English summaries for publication:
 - Boldo leaf
 - Ginseng root
 - Iceland moss
 - Tree tea oil
 - Restharrow root

6.1.2. Update on Management Board data gathering exercise

Action: for discussion

6.1.3. Follow up on Public Statement on Pyrrolizidine alkaloid contaminations/Update of activities in Member States

Report: HMPC Chair
Action: for discussion
Documents: EDQM response on Pyrrolizidine alkaloids, 8 Dec 2016; List of questions; Data provided 16 Dec 2016; [CMDh press release](#)

6.1.4. Survey to committee's members 2016 – follow up

Action: for discussion
Document: Presentation

6.1.5. Information on initiative within the European Commission REFIT consultation

Report: Zs. Birone-Sandor

Action: for discussion

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 21-22 Nov 2016

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 21-22 Nov 2016](#)

[Overview of status of HMPC assessment work – priority list](#)

[Inventory of herbal substances for assessment work](#)

[Abbreviations in HMPC agendas/minutes](#)

Common names of herbal substances in all languages

6.2.2. MLWP

- Overview of status of HMPC/MLWP assessment work
- Draft agenda of MLWP meeting to be held on 1-2 Feb 2017

6.2.3. Other

- MLWP work plan 2017; Document: Draft work plan 2017, Outcome of written procedure
- QDG work plan 2017; Document: Draft work plan 2017
- ORGAM work plan 2017; Document: Draft work plan 2017
- PCWP meeting:
 - PCWP Work plan 2017 (EMA/540720/2016): for adoption (silent adoption)
- HCPWP meeting:
 - HCPWP Work plan 2017 (EMA/493549/2016): for adoption (silent adoption)
 - Minutes of the PCWP/HCPWP joint meeting - 20 Sep 2016 (EMA/625038/2016): for information
- PCWP/HCPWP meetings:
 - Report of the PCWP/HCPWP workshop on social media – 19 Sep 2016 (EMA/625077/2016): for information
- Paediatric overview (update 2016)