



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 March 2020
EMA/HMPC/81088/2020
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 2-4 March 2020

Chair: vacant Vice-Chair: vacant

2 March 2020, 14:00 – 19:00, 1C

(HMPC Chair elections: 2 March 2020, 14.00 – 15.00, 1C)

3 March 2020, 09:00 – 18:00, 1C

4 March 2020, 09:00 – 16:00, 1C

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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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. | EU herbal monographs and list entries for adoption | 5 |
| 2.1. | Status of HMPC/MLWP activities | 5 |
| 2.1.1. | Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in January 2020..... | 5 |
| 2.1.2. | Appointment of Rapporteurs and Peer-reviewers | 5 |
| 2.2. | Revised EU herbal monographs and list entries for final adoption | 5 |
| 2.3. | Revised EU herbal monographs and list entries for public consultation | 5 |
| 2.4. | Reviewed EU herbal monographs and list entries for decision on revision..... | 6 |
| 2.4.1. | Monograph on Absinthii herba and supporting documents..... | 6 |
| 2.4.2. | Monograph on Filipendulae ulmariae flos and supporting documents - postponed | 6 |
| 2.4.3. | Monograph on Filipendulae ulmariae herba and supporting documents - postponed | 6 |
| 2.4.4. | Monograph on Pelargonii radix and supporting documents - postponed | 6 |
| 2.4.5. | Monograph on Sabalis serrulatae fructus and supporting documents - postponed | 6 |
| 2.5. | EU herbal monographs, list entries and public statements for final adoption | 6 |
| 2.6. | EU herbal monographs, list entries and public statements for adoption for release for public consultation..... | 6 |
| 2.6.1. | Monograph on Species amarae and supporting documents – see also 6.5.2. | 6 |
| 2.7. | EU herbal monographs, list entries and public statements - post finalisation | 6 |
| 2.7.1. | Monograph on Allii sativi bulbos and supporting documents - postponed..... | 6 |
| 3. | Referral procedures | 6 |
| 4. | Guidelines and guidance documents | 7 |
| 4.1. | Non-clinical/clinical safety and efficacy and multidisciplinary..... | 7 |
| 4.1.1. | Public statement on the contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)..... | 7 |
| 4.1.2. | Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011) | 7 |
| 4.2. | Quality | 7 |
| 4.3. | Regulatory / Procedural | 7 |
| 4.4. | Report on HMPC Drafting Groups activities..... | 7 |
| 4.4.1. | Quality DG..... | 7 |
| 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. | Election of HMPC Chair | 7 |

| | | |
|--------------|--|-----------|
| 5.2. | Coordination with EMA Scientific Committees or CMDh-v | 7 |
| 5.2.1. | Scientific Coordination Board Meeting..... | 7 |
| 5.3. | Coordination with EMA Working Parties/Working Groups/Drafting Groups | 8 |
| 5.3.1. | QRD Template – update of Addendum for THMP | 8 |
| 5.4. | Cooperation within the EU regulatory network..... | 8 |
| 5.4.1. | Coordination with European Pharmacopoeia | 8 |
| 5.4.2. | Herbal EU NTC curriculum..... | 8 |
| 5.4.3. | Coordination with the European Commission | 8 |
| 5.5. | Cooperation with International Regulators..... | 8 |
| 5.6. | Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee | 9 |
| 5.6.1. | AESGP – hearing | 9 |
| 5.7. | Work plan | 9 |
| 5.7.1. | Draft HMPC work plan 2020 | 9 |
| 5.8. | Planning and reporting | 9 |
| 5.8.1. | UK withdrawal from the EU – update..... | 9 |
| 5.9. | Legislation and regulatory affairs | 9 |
| 5.9.1. | Impact of Brexit on traditional and well-established use evidence | 9 |
| 5.10. | Questions from members..... | 9 |
| 6. | EU herbal monographs and list entries in preparation | 9 |
| 6.1. | Revision of EU herbal monographs and list entries in preparation for adoption after public consultation | 9 |
| 6.1.1. | Monograph on Hyperici herba and supporting documents - postponed | 9 |
| 6.1.2. | Monograph on Millefolii herba and supporting documents - postponed | 9 |
| 6.1.3. | Monograph on Rhamni purshianae cortex and supporting documents | 9 |
| 6.1.4. | Monograph on Rhei radix and supporting documents..... | 10 |
| 6.1.5. | Monograph on Tanaceti parthenii herba and supporting documents..... | 10 |
| 6.1.6. | Monograph on Thymi aetheroleum and supporting documents..... | 10 |
| 6.2. | Revision of EU herbal monographs and list entries in preparation for public consultation..... | 10 |
| 6.2.1. | Monograph on Orthosiphonis folium and supporting documents..... | 10 |
| 6.3. | Review of EU herbal monographs and list entries in preparation for decision on revision | 10 |
| 6.3.1. | Monograph on Juniperi aetheroleum and supporting documents | 10 |
| 6.3.2. | Monograph on Juniperi pseudo-fructus and supporting documents..... | 10 |
| 6.3.3. | Monograph on Rosmarini aetheroleum and supporting documents – postponed | 10 |
| 6.3.4. | Monograph on Rosmarini folium and supporting documents - postponed | 10 |
| 6.4. | EU herbal monographs and list entries in preparation for adoption after public consultation..... | 10 |
| 6.4.1. | Monograph on Herniariae herba and supporting documents - postponed..... | 10 |

| | | |
|-------------|--|-----------|
| 6.5. | EU herbal monographs and list entries in preparation for adoption for release for public consultation | 11 |
| 6.5.1. | Monograph on Centellae asiaticae herba and supporting documents..... | 11 |
| 6.5.2. | Monograph on Menyanthes trifoliata folium and supporting documents..... | 11 |
| 6.5.3. | Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents..... | 11 |
| 6.5.4. | Monograph on Salviae miltiorrhizae radix et rhizoma and supporting documents | 11 |
| 6.5.5. | Monograph on Species sedativae and supporting documents..... | 11 |
| 6.5.6. | Monograph on Vaccinii macrocarpi fructus and supporting documents | 11 |
| 6.5.7. | Monograph on Verbenae citriodorae folium and supporting documents | 11 |
| 7. | Any other business | 11 |
| 7.1. | Topics for discussion | 11 |
| 7.1.1. | Develop a strategy for use of PhV data/tools in HMPC assessment - postponed | 11 |
| 7.1.2. | Patients representatives involvement in HMPC assessment work..... | 11 |
| 7.1.3. | Guidance developments currently on hold..... | 12 |
| 7.2. | Documents for information..... | 12 |
| 7.2.1. | HMPC..... | 12 |
| 7.2.2. | ARSP..... | 12 |
| 7.2.3. | EU herbal monographs, list entries and public statements – on hold..... | 12 |
| 7.2.4. | Other | 12 |

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 2–4 March 2020. See March 2020 HMPC minutes (to be published post May 2020 HMPC meeting).

New nomination membership:

- CY, Antri Kouroufexi (member) as of 24 January 2020
- CY, Maria Yiannitsarou (alternate) as of 24 January 2020

End of membership:

- CY, Maria Stavrou (member) as of 23 January 2020
- CY, Elli Loizidou (alternate) as of 23 January 2020

1.2. Adoption of agenda

HMPC agenda for 2-4 March 2020

Time schedule for 2-4 March 2020

1.3. Adoption of the minutes

HMPC minutes for 13-15 January 2020

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC/MLWP activities

2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in January 2020

Report: HMPC Chair

Action: for discussion

Document: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

None

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

None

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

None

2.4. Reviewed EU herbal monographs and list entries for decision on revision

2.4.1. Monograph on Absinthii herba and supporting documents

- **Action:** for adoption
Documents: Review report; References: 0/6
- **Action:** for information
Document: PS on the use of herbal medicinal products containing thujone

2.4.2. Monograph on Filipendulae ulmariae flos and supporting documents - postponed

2.4.3. Monograph on Filipendulae ulmariae herba and supporting documents - postponed

2.4.4. Monograph on Pelargonii radix and supporting documents - postponed

2.4.5. Monograph on Sabalis serrulatae fructus and supporting documents - postponed

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

None

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

2.6.1. Monograph on Species amarae and supporting documents – see also 6.5.2.

Action: for adoption
Documents: MO, AR, LoR; References: 10/13

2.7. EU herbal monographs, list entries and public statements - post finalisation

2.7.1. Monograph on Allii sativi bulbus and supporting documents - postponed

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 contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)
-

Action: for discussion
Document: Draft revised PS

- 4.1.2. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011)
-

Action: for discussion
Document: [PS](#)

4.2. Quality

None

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

- 4.4.1. Quality DG
-

None

- 4.4.2. ORGAM DG
-

None

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

- 5.1.1. Election of HMPC Chair
-

Action: for adoption
Documents: New call for candidates, [HMPC RoP](#), Candidatures

5.2. Coordination with EMA Scientific Committees or CMDh-v

- 5.2.1. Scientific Coordination Board Meeting
-

Action: for information
Document: Agenda dated 5 February 2020

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

5.3.1. QRD Template – update of Addendum for THMP

Report: R Laenger

Action: for discussion

Document: Proposal for Update of the Addendum, [Addendum to the Quality Review of Documents templates for SmPC](#) for THMPs

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13A expert group meeting 3-4 March 2020
Action: for information
Document: Draft Agenda
- EDQM 13B expert group meeting 21-22 January 2020
Action: for information
Document: Summary of decisions
- EDQM TCM expert group meeting 4-5 February 2020
Action: for information
Document: Summary of decisions
- EDQM PA expert group meetings

Action: for discussion

Document: [Draft method for determination of Pyrrolizidine Alkaloids published in Pharmeuropa](#)

5.4.2. Herbal EU NTC curriculum

Action: for discussion

Document: Course description template

5.4.3. Coordination with the European Commission

Cannabis for medicinal use

Action: for discussion

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

5.6.1. AESGP – hearing

Action: for adoption
Document: Hearing report

5.7. Work plan

5.7.1. Draft HMPC work plan 2020

Report: HMPC Chair
Action: for adoption
Document: Work plan 2020, Annex 1, Annex 2 – current status February 2020

5.8. Planning and reporting

5.8.1. UK withdrawal from the EU – update

Action: for discussion
Document: Presentation

5.9. Legislation and regulatory affairs

5.9.1. Impact of Brexit on traditional and well-established use evidence

Action: for discussion
Document: Email correspondence

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation

6.1.1. Monograph on Hyperici herba and supporting documents - postponed

6.1.2. Monograph on Millefolii herba and supporting documents - postponed

6.1.3. Monograph on Rhamni purshianae cortex and supporting documents

Action: for discussion
Document: Draft MO, AR, LoR; References: 51/41

6.1.4. Monograph on Rhei radix and supporting documents

Action: for discussion

Document: Draft MO, AR, LoR, OoC; References: 55/59

6.1.5. Monograph on Tanaceti parthenii herba and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 0/108; Question to patient representatives

6.1.6. Monograph on Thymi aetheroleum and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 122/138

6.2. Revision of EU herbal monographs and list entries in preparation for public consultation

6.2.1. Monograph on Orthosiphonis folium and supporting documents

Action: for discussion

Documents: Readers guidance, presentation

6.3. Review of EU herbal monographs and list entries in preparation for decision on revision

6.3.1. Monograph on Juniperi aetheroleum and supporting documents

Action: for discussion

Documents: Review report; References: 7/6

6.3.2. Monograph on Juniperi pseudo-fructus and supporting documents

Action: for discussion

Documents: Review report; References: 7/10

6.3.3. Monograph on Rosmarini aetheroleum and supporting documents – postponed

6.3.4. Monograph on Rosmarini folium and supporting documents - postponed

6.4. EU herbal monographs and list entries in preparation for adoption after public consultation

6.4.1. Monograph on Herniariae herba and supporting documents - postponed

6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation

6.5.1. Monograph on *Centellae asiaticae herba* and supporting documents

Action: for discussion
Documents: Draft MO, AR; References: 0/0

6.5.2. Monograph on *Menyanthes trifoliata folium* and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR; References: 45/72, Comments received from members

6.5.3. Monograph on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

Action: for discussion
Documents: Draft MO, Draft LE, Draft AR, Draft LoR, EMA letter to EC, EC response;
References: 02/188

6.5.4. Monograph on *Salviae miltiorrhizae radix et rhizoma* and supporting documents

Action: for discussion
Documents: Draft PS, AR, LoR, additional information provided by PR; References: 0/62

6.5.5. Monograph on *Species sedativae* and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR; References: 35/16

6.5.6. Monograph on *Vaccinii macrocarpi fructus* and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR; References: 51/226

6.5.7. Monograph on *Verbenae citriodoraefolium* and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR; References: 02/32

7. Any other business

7.1. Topics for discussion

7.1.1. Develop a strategy for use of PhV data/tools in HMPC assessment - postponed

7.1.2. Patients representatives involvement in HMPC assessment work

Report: S Bager, A Le, G Laekeman

Documents: email communication

7.1.3. [Guidance developments currently on hold](#)

Report: E.v. Galen;

Action: For discussion

Documents: QDG meeting report 06 Sep 2018, ORGAM meeting report 4 Sep 2018, Annex 2 to HMPC work plan 2020

7.2. Documents for information

7.2.1. [HMPC](#)

Table of Decisions from HMPC meeting held on 13-15 January 2020

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 13-15 January 2020](#)

[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

Final Monograph Overview

7.2.2. [ARSP](#)

- English template
- English summaries for publication
 - Hippocastani semen
 - Menthae piperitae aetheroleum
 - Menthae piperitae folium

7.2.3. [EU herbal monographs, list entries and public statements – on hold](#)

- Monograph on Foeniculi amari fructus and supporting documents – awaiting Estragole PS finalisation
- Monograph on Foeniculi amari fructus aetheroleum and supporting documents – awaiting Estragole PS finalisation
- Monograph on Foeniculi dulcis fructus and supporting documents – awaiting Estragole PS finalisation
- Monograph on Species digestivae or species stomachicae and supporting documents - awaiting Estragole PS finalisation

7.2.4. [Other](#)

- PCWP/HCPWP meetings:
 - Meeting Summary from the Annual PCWP/HCPWP meeting with all eligible organisations, 20 November 2019

- Agenda for the PCWP/HCPWP Joint Meeting, 3-4 March 2020
- PA-Workshop - 29-30 September 2020 in Kaiserslautern, Germany
- Feyaerts et al.: Striking essential oil: tapping into a largely unexplored source for drug discovery. Scientific reports. Nature research
- 12th Int. Symposium Chromatography of Natural Products & 11th Int. Conference on TCM Pharmaceutical Analysis & Annual Meeting of Specialty Committee of TCM Pharmaceutical Analysis, Lublin, Poland May 26th-29th, 2020