



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 January 2019
EMA/HMPC/5189/2019
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 14-16 January 2019

Chair: Marisa Delbò Vice-Chair: Emiel van Galen

14 January 2019, 14:00 – 19:00, 2F

15 January 2019, 09:00 – 19:00, 2F

16 January 2019, 09:00 – 16:00, 2F

Health and safety information

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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 14-16 January 2019. See January 2019 HMPC minutes (to be published post May 2019 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 14-16 January 2019

Time schedule for 14-16 January 2019

1.3. Adoption of the minutes

HMPC minutes for 19-20 November 2018

2. EU herbal monographs and list entries for adoption

2.1. Report on MLWP activities

2.1.1. MLWP minutes 25-27 September 2018

Action: For adoption

Document: MLWP Minutes 25-27 September 2018

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Report: HMPC Chair

Action: for adoption

Rapporteur transfer after March 2019

(Agrimoniae herba)

(Boldi folium)

Calendulae herba

Frangulae cortex

Rhamni purshianae cortex

Rhei radix

Peer-Reviewer transfer after March 2019

Bursae pastoris herba

(Colae semen)

(Lupuli flos)
(Melissae folium)
Rosmarini aetheroleum
Rosmarini folium
(Sabalis serrulatae fructus)
(Thymi herba)
Violae tricoloris herba

New Rapporteur (Revision)

Menthae folium/aetheroleum
Orthosiphonis folium

2.1.3. **Overview of status of HMPC and MLWP assessment work including the Rapporteurship distribution – Status in January 2019**

Report: HMPC Chair, MLWP Chair

Action: For discussion

Documents: Overview

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 Bursae pastoris herba and supporting documents**

Action: for adoption

Documents: Review report; References: 06/06

2.4.2. **Monograph on Leonuri cardiaca herba and supporting documents**

Action: for adoption

Documents: Review report; References: 24/24

2.4.3. **Monograph on Millefolii flos and supporting documents**

Action: for adoption

Documents: Review report; References: 10/06

2.4.4. Monograph on Millefolii herba and supporting documents

Action: for adoption

Documents: Review report; References: 10/06

2.4.5. Monograph on Phaseoli fructus (sine semine) and supporting documents

Action: for adoption

Documents: Review report; References: 09/09

2.4.6. Monograph on Tormentillae rhizoma and supporting documents

Action: for adoption

Documents: Review report; References: 19/18

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

None

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

2.7.1. Monograph on Pistacia lentiscus, resinum (mastix) and supporting documents

Action: for adoption

Documents: MO, AR, LoR, Presentation; References: 101/78

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 estragole

Action: for discussion

Documents: Draft revised PS; OoC; Comments from SE; SWP subgroup comments; Presentation

4.1.2. Public statement on the contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)

Action: for adoption
Documents: Draft public information

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

Action: for discussion
Documents: [PS](#); Expert report; [Statement by EFSA CONTAM panel on Risks for human health related to the presence of pyrrolizidine alkaloids in food](#)

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. Strategic Review and Learning Meetings

- Follow up on Austria Presidency meeting – Vienna, 15-17 Oct 2018
Report: HMPC Chair, HMPC Vice-Chair
Action: for discussion
Documents: Minutes; Presentations on working methodology
- Romania Presidency meeting – April 2019
Action: for discussion
Document: Draft agenda

5.1.2. Preparation of election of Co-opted member

Report: HMPC Chair
Action: for discussion
Documents: Expertise of HMPC members; [HMPC rules of procedure](#)

5.1.3. Preparation of election of QDG Chair

Report: HMPC Chair

Action: for discussion

Documents: Expertise of HMPC members; QDG mandate

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information

Document: Draft Minutes 22 November 2018

5.2.2. Coordination with PDCO/PRAC

- Discussion paper of age limitation of use of cough and cold herbal medicinal products in children

Action: for discussion

Documents: Draft discussion paper, OoC, Draft overview on cough and cold HMPs in EU

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

None

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with the European Commission

None

5.4.2. Coordination with European Pharmacopoeia

- EDQM expert group meetings

Action: for information

5.4.3. Understanding the training needs of NCA assessors involved in the work of the HMPC: Priority needs and plans for training 2019 – 2020

Action: for discussion

Document: Presentation

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

None

5.7. Work plan

5.7.1. HMPC work plan 2019

Report: HMPC Chair

Action: for adoption

Documents: Draft work plan 2019 including Annex 1 (monographs) and Annex 2 (guidelines)

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

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 Menthae piperitae folium and supporting documents

Action: for discussion

Documents: Draft revised MO, AR, LoR; References: 109/205

6.1.3. Monograph on Valerianae radix/Lupuli flos and supporting documents

Action: for discussion

Documents: MO, AR, LoR, OoC, DE comments on AR, Readers guidance; References: 11/35

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

6.2.1. Monograph on Frangulae cortex and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 42/43

6.2.2. Monograph on Hippocastani semen and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/80

6.2.3. Monograph on Menthae piperitae aetheroleum and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, LE; References: 109/205

6.2.4. Monograph on Rhamni purshianae cortex and supporting documents

Action: for discussion

Documents: Draft MO, AR; References: 00/00

6.2.5. Monograph on Rhei radix and supporting documents - postponed

6.2.6. Monograph on Tanaceti parthenii herba and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Presentation; References: 00/103

6.2.7. Monograph on Thymi aetheroleum and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 119/138

6.2.8. Monograph on Trigonellae foenugraeci semen and supporting documents - postponed

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

6.3.1. Public Statement on Centellae asiaticae herba and supporting documents – postponed

6.3.2. Monograph on Hamamelidis cortex and supporting documents

Action: for discussion

Document: Review report, Presentation; References: 00/02

6.3.3. Monograph on Hamamelidis folium and supporting documents

Action: for discussion

Document: Review report, Presentation; References: 00/00

6.3.4. Monograph on Hamamelidis folium et cortex aut ramunculus destillatum and supporting documents

Action: for discussion

Document: Review report, Presentation; References: 00/00

6.3.5. Monograph on Quercus cortex and supporting documents

Action: for discussion

Document: Review report; References: 18/10

6.3.6. Monograph on Solidaginis virgaureae herba and supporting documents

Action: for discussion

Document: Review report; References: 32/19

6.3.7. Monograph on Andrographidis paniculatae folium and supporting documents

Action: for discussion

Document: Review report; References: 25/11

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

None

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

6.5.1. Monograph on Calendulae herba and supporting documents – postponed

6.5.2. Monograph on Cisti cretici folium and supporting documents - postponed

6.5.3. Monograph on Herniariae herba and supporting documents – postponed

6.5.4. Monograph on Menyanthes trifoliata folium and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 55/61

6.5.5. 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

6.5.6. Monograph on *Salviae mitiorrhizae radix et rhizoma* and supporting documents – postponed

6.5.7. Monograph on *Species amarae* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/16

6.5.8. Monograph on *Species digestivae* or *species stomachicae* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/18

6.5.9. Monograph on *Species sedativae* and supporting documents – postponed

6.5.10. Monograph on *Vaccinii macrocarpi fructus* and supporting documents – postponed

6.5.11. Monograph on *Verbenae citriodoraе folium* and supporting documents - postponed

7. Any other business

7.1. Topics for discussion

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

Action: for discussion

Documents: Presentations

7.1.2. PSUSA procedure for *Pelargonii radix*

Action: for discussion

Documents: Presentation

7.1.3. 2019 International Forum on Traditional Chinese Medicine (TCM) and Botanical Medicine to be held in Shenzhen from April 25th to 26th, 2019

Report: HMPC Chair, HMPC Vice-Chair

Action: for discussion

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 19-20 November 2019

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 19-20 November 2019](#)

[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

Overview of status of HMPC/MLWP assessment work

Final Monograph Overview

7.2.2. ARSP

- English template
- English summaries for publication:
 - Wild strawberry leaf
 - Mallow leaf
 - Mallow flower
 - Gentian root
 - Butcher's broom

7.2.3. EU herbal monographs, list entries and public statements – on hold

- Monograph on *Allii sativi bulbosus* and supporting documents
Action: for information
Documents: MO, AR, LoR, OoC
- *Foeniculi amari fructus* and supporting documents – on hold due to Estragole PS
- *Foeniculi amari fructus aetheroleum* and supporting documents – on hold due to Estragole PS
- *Foeniculi dulcis fructus* and supporting documents – on hold due to Estragole PS

7.2.4. Other

- PCWP/HCPWP meetings:
 - PCWP - Meeting Summary PCWP Plenary Meeting 25 Sep 2018
 - PCWP/HCPWP - Meeting Summary PCWP/HCPWP Joint Meeting 25 Sep 2018
 - HCPWP - Meeting Summary for the HCPWP Plenary Meeting 26 Sep 2018
- Adapted HMPC Agenda template
- REFIT Platform Opinion on the submission by businesses on the Traditional Herbal Medicinal Products Directive