



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 July 2019
EMA/HMPC/381730/2019
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 8-10 July 2019

Chair: Marisa Delbø Vice-Chair: Emiel van Galen

08 July 2019, 14:00 – 19:00, 2D

09 July 2019, 09:00 – 19:00, 2D

10 July 2019, 09:00 – 16:00, 2D

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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 08-10 July 2019. See July 2019 HMPC minutes (to be published post September 2019 HMPC meeting).

New nomination membership (BE): Patricia Bodart (member) as of 21 May 2019

End of membership (BE): Heidi Neef (member) as of 20 May 2019

End of membership (SI): Samo Kreft (member) as of 27 June 2019

Swap of roles membership (SI): Barbara Razinger (from alternate to member) as of 27 June 2019

1.2. Adoption of agenda

HMPC agenda for 08-10 July 2019

Time schedule for 08-10 July 2019

1.3. Adoption of the minutes

HMPC minutes for 13-15 May 2019

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC/MLWP activities

2.1.1. Overview of status of HMPC and MLWP assessment work including the Rapporteurship distribution – Status in July 2019

Report: HMPC Chair

Action: For discussion

Document: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Report: HMPC Chair

Action: for adoption

Rapporteur transfer

Orthosiphonis folium

Species amarae

Peer-Reviewer transfer

Polypodii rhizoma

Hippocastani cortex

2.1.3. Andrographidis paniculatae folium in combination and supporting documents – possibility for monograph establishment - postponed

2.1.4. Monograph on Sabalis serrulatae fructus and supporting documents - request for for unscheduled monograph revision - postponed

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

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

Action: for adoption

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

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

2.3.1. Monograph on Rhamni purshianae cortex and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 27/38

2.3.2. Monograph on Tanaceti parthenii herba and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 00/104

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

2.4.1. Monograph on Hamamelidis cortex and supporting documents

Action: for adoption

Document: Review report; References: 00/02

2.4.2. Monograph on Hamamelidis folium and supporting documents

Action: for adoption

Document: Review report; References: 00/18

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

Action: for adoption

Document: Review report; References: 00/18

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

2.6.1. Monograph on Herniariae herba and supporting documents

Action: for adoption

Documents: MO, AR, LoR, Readers guidance; References: 34/31

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

None

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; Presentations

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 Romanian Presidency meeting – 4-5 April 2019
Action: for discussion
Documents: BPG PRAC plenary, HMPC Readers Guidance template
- Finnish Presidency meeting – Czech Republic, Prague – 5-6 November 2019
Action: for discussion
Document: Draft programme proposal

5.1.2. Election of QDG Chair

Action: for adoption
Documents: 2nd Call for nomination; [ODG mandate](#)

5.1.3. Rapporteurs at HMPC

Action: for discussion
Documents: Presentation, [HMPC rules of procedure](#), [MLWP 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

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 - postponed

- Cannabis for medicinal use

5.4.2. Coordination with European Pharmacopoeia

- EDQM 13A expert group meetings
Action: for information
- EDQM 13B expert group meetings
Action: for information
- EDQM TCM expert group meetings
Action: for information

- EDQM PA expert group meetings
Action: for information
- Certification procedure - Steering Committee meeting held on 28 May 2019
Report: HMPC Chair
Action: for discussion
Document: Agenda

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 – possible hearing in November 2019

Report: HMPC Chair

Action: for information

5.7. Work plan

5.7.1. HMPC work plan 2019

Report: HMPC Chair

Action: for information

Document: Work plan 2019, Annex 1, Annex 2 – current status July 2019

5.8. Planning and reporting

5.8.1. Update on BCP and HMPC meeting dates

Action: for information

Document: Oral report

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

5.10.1. QRD Template

Action: for discussion

Document: Proposals for template improvement, [Addendum to the Quality Review of Documents templates for SmPC](#) for THMPs

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 Frangulae cortex and supporting documents

Action: for discussion

Document: Draft MO, AR, LoR, OoC; References: 42/43

6.1.2. Monograph on Hyperici herba (traditional use) and supporting documents

Action: for discussion

Documents: Draft MO (TU), MO (WEU), AR, LoR, Readers guidance; References: 02/557

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

6.2.1. Monograph on Rhei radix and supporting documents

Action: for discussion

Documents: MO, AR, LoR; References: 55/57

6.2.2. Monograph on Thymi aetheroleum and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 121/138

6.2.3. Monograph on Trigonellae foenugraeci semen and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Review report; References: 00/98

6.2.4. Monograph on Millefolii herba and supporting documents

Action: for discussion

Documents: Draft MO, LE, AR; New References: 08/08

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

Action: for discussion

Document: Review report; References: 00/22

6.3.2. Monograph on Taraxaci folium and supporting documents - postponed

6.3.3. Monograph on Taraxaci radix cum herba and supporting documents - postponed

6.3.4. Monograph on Rosmarini aetheroleum and supporting documents - postponed

6.3.5. Monograph on Rosmarini folium and supporting documents - postponed

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

Action: for discussion

Documents: Discussion paper, Draft preliminary MO, [Uptake of the traditional use registration](#); References: 00/00

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

6.5.3. Monograph on Menyanthes trifoliata folium and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 68/73

6.5.4. Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents

Action: for discussion

Documents: Draft MO, Draft LE, Draft AR, Draft LoR; References: 02/188

6.5.5. Monograph on Species amarae and supporting documents

Action: for discussion

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

6.5.6. Monograph on Vaccinii macrocarpi fructus and supporting documents - postponed

6.5.7. Monograph on Verbenae citriodora folium and supporting documents

Action: for discussion

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 - postponed

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

Report: HMPC Vice-Chair
Action: for discussion
Document: Feedback report

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 13-15 May 2019

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 13-15 January 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:
 - None

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

- Monograph on *Allii sativi bulbus* and supporting documents
Documents: MO, AR, LoR, OoC

- Monograph on *Foeniculi amari fructus* and supporting documents
- Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents
- Monograph on *Foeniculi dulcis fructus* and supporting documents
- Monograph on *Menthae piperitae folium* and supporting documents
Documents: MO, AR, LoR
- Monograph on *Pistacia lentiscus, resinum (mastic)* and supporting documents
Documents: MO, AR, LoR; Comments received on package: RO, PL, AT; SE; New reference: Paraschos *et al.* 2012
- Monograph on *Species digestivae* or *species stomachicae* and supporting documents

7.2.4. Other

- The European Herb Growers Association (EUROPAM) position on drying (dehydration) factors for medicinal and aromatic plants (MAPs)