



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 July 2020
EMA/HMPC/302450/2020
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 6-8 July 2020

Chair: E. van Galen, Vice-Chair: E. Svedlund

6 July 2020, 10:00 – 17:00, virtual meeting

7 July 2020, 09:00 – 17:00, virtual meeting

8 July 2020, 09:00 – 16:00, virtual meeting

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Of note, this agenda is a working document primarily designed for HMPC members and the work the Committee undertakes.

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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 6-8 July 2020. See July 2020 HMPC minutes (to be published post September 2020 HMPC meeting).

End of membership:

- Paediatric medicine, Silvia Girotto (co-opted member) as of 3 June 2020

1.2. Adoption of agenda

HMPC agenda for 6-8 July 2020

Time schedule for 6-8 July 2020

1.3. Adoption of the minutes

HMPC minutes for 4-6 May 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 July 2020

Report: HMPC Chair

Action: for discussion

Document: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Reviews

Cinnamomi corticis aetheroleum - New Rapporteur

Cinnamomi cortex - New Rapporteur

2.2. Fucus vesiculosus - New Rapporteur Revised EU herbal monographs and list entries for final adoption

2.2.1. Monograph on Tanacetii parthenii herba and supporting documents

Action: for adoption

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

2.2.2. Monograph on Thymi aetheroleum and supporting documents

Action: for adoption

Documents: MO, AR, LoR, Readers guidance; References: 122/137

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

None

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

2.5.1. Monograph on Herniariae herba and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC, Readers guidance; References: 35/24

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

2.6.1. Monograph on Menyanthes trifoliata folium and supporting documents

Action: for adoption

Documents: MO 1st proposal, MO 2nd proposal, AR, LoR, Readers guidance; References: 77/77

2.6.2. Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 2/214

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 information

Documents: [Draft revised PS](#), Comments received

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 discussion

Document: See 4.1.3.

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

Action: for adoption

Document: Draft Revised combined public statement

4.2. Quality

4.2.1. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)

Action: for discussion

Documents: Draft revised Guideline, OoC

4.2.2. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3)

Action: for information

Document: [Revised Guideline](#)

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

Germany Presidency meeting – September 2020

Action: for information

5.1.2. Co-opted member (paediatrics)

Report: HMPC Chair

Action: for discussion

Documents: [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members

5.1.3. Divergent positions at CXMP

Action: for discussion

Document: Presentation

5.1.4. Organisation of September 2020 HMPC meeting

Action: for information

Document: [Information from EMA website](#)

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information

Documents: Draft Minutes 07 May 2020, Draft agenda 19 October 2020

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 European Pharmacopoeia

- EDQM 13A expert group meeting
Report: M Bald
Action: for information
Document: SoD

5.4.2. Coordination with the European Commission

- Planned COMMISSION REGULATION (EU) amending Annex III to Regulation (EC) No 1925/2006 as regards botanical species containing hydroxyanthracene derivatives
Report: HMPC Chair
Action: for information
Documents: HADs Article 8 Safety Concerns, HMPC letter to EC , Outcome written procedure
- Cannabis for medicinal use
Report: HMPC Chair
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 in November 2020

Report: HMPC Chair
Action: for information

5.6.2. AESGP proposal for the 2nd revision of EU Monograph on Sennae folium to align with Ph. Eur.

Report: HMPC Chair
Action: for discussion

5.6.3. EUCOPE – possible hearing in 2020

Report: HMPC Chair
Action: for information

5.7. Work plan

5.7.1. HMPC work plan 2020

Report: HMPC Chair, HMPC Vice Chair
Action: for discussion
Document: Work plan 2020, Annex 1, Annex 2 – current status July 2020

- Activity area 2-1-3: Use of PhV, non-clinical and real-world data for HMPC relevant safety assessments
Report: HMPC Chair
Action: for discussion
Document: Proposal
- Activity area 2-2-1: Development of training on assessment of applications for herbal medicinal products

Report: HMPC Vice Chair

Action: for discussion

Document: Presentation

5.8. Planning and reporting

5.8.1. Future-proofing - Human Medicines – Committees

Action: for discussion

Document: Presentation

5.9. Legislation and regulatory affairs

None

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 Millefolii herba and supporting documents

Action: for discussion

Documents: Draft MO, LE, AR, LoR; References: 59/73

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

None

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

6.3.1. Monograph on Agropyri repentis rhizoma and supporting documents

Action: for discussion

Documents: Review report; References: 67/02

6.3.2. Monograph on Carvi aetheroleum and supporting documents

Action: for discussion

Documents: Review report; References: 17/17

6.3.3. Monograph on Carvi fructus and supporting documents

Action: for discussion

Documents: Review report; References: 17/17

6.3.4. Monograph on Fucus vesiculosus and supporting documents – postponed

6.3.5. Monograph on Juniperi aetheroleum and supporting documents

Action: for discussion

Documents: Review report, readers guidance; References: 9/0

6.3.6. Monograph on Juniperi pseudo-fructus and supporting documents

Action: for discussion

Documents: Review report, readers guidance; References: 10/01

6.3.7. Monograph on Lavandulae aetheroleum and supporting documents

Action: for discussion

Document: Presentation

6.3.8. Monograph on Lavandulae flos and supporting documents

Action: for discussion

Document: Presentation

6.3.9. Monograph on Rosmarini aetheroleum and supporting documents – postponed

6.3.10. Monograph on Rosmarini folium and supporting documents – postponed

6.3.11. Monograph on Solidaginis virgaureae herba and supporting documents – postponed

6.3.12. Monograph on Colae semen and supporting documents

Action: for discussion

Documents: Review report; References: 60/62

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 *Andrographidis paniculatae folium* and supporting documents – postponed

6.5.2. Monograph on *Centellae asiaticae herba* and supporting documents – postponed

6.5.3. Monograph on *Salviae miltiorrhizae radix et rhizoma* and supporting documents – postponed

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

Action: for discussion

Documents: Draft MO, AR, LoR; References: 51/234

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 4-6 May 2020

Overview of expertise of members HMPC and subgroups

[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
 - Rhei radix
 - Rhamni purshianae

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

- Yichang Yang: Use of herbal drugs to treat COVID-19 should be with caution
- Monograph on *Menthae piperitae aetheroleum* and supporting documents - post adoption editorial changes
- Monograph on *Menthae piperitae folium* and supporting documents - post adoption editorial changes