



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 April 2021
EMA/HMPC/188939/2021
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 3-5 May 2021

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

3 May 2021, 10:00 – 17:00, virtual meeting

4 May 2021, 09:00 – 17:00, virtual meeting

5 May 2021, 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 3-5 May 2021. See May 2021 HMPC minutes (to be published post July 2021 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 3-5 May 2021.

Time schedule for 3-5 May 2021.

1.3. Adoption of the minutes

HMPC minutes for 1-3 March 2021.

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 May 2021

Report: HMPC Chair

Action: for discussion

Document: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Report: HMPC Chair

Action: for adoption

New Rapporteur and Peer-Reviewer:

New substance for decision on prioritisation

- Tribulus terrestris herba

Documents: Presentation, Proposal (CZ), Summary of proposals

Periodic reviews to start in 2021

- Juglandis folium

Change of rapporteurship

- Cisti cretici folium
- Fumariae herba

- Grindeliae herba
- Origani dictamni herba
- Paullinae semen
- Tiliae flos
- Centellae asiaticae herba
- Cinnamomi corticis aetheroleum
- Cinnamomi cortex
- Colae semen
- Menyanthes trifoliata folium
- Plantaginis lanceolatae folium

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 Colae semen and supporting documents

Action: for adoption

Document: Review report; References: 53/17

2.4.2. Monograph on Fumariae herba and supporting documents

Action: for adoption

Documents: Review report; References: 16/16

2.4.3. Monograph on Mate folium and supporting documents

Action: for adoption

Document: Review report; References: 17/34

2.4.4. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: for adoption

Document: Review report; References: 09/09

2.4.5. Monograph on Violae tricoloris herba and supporting documents

Action: for adoption

Document: Review report; References: 30/22

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

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

Action: for adoption

Documents: MO, AR, LoR; References: 77/73

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

2.6.1. Public statement on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

Action: for adoption

Documents: PS, AR, LoR; References: 04/214

2.6.2. Monograph on *Taraxaci officinalis* radix and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 78/84

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

Action: for adoption

Documents: MO, AR, LoR, Readers Guidance; References: 00/313

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 toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs

Action: for discussion

Documents: Draft PS, OoC, Comments from SWP

4.2. Quality

4.2.1. Guideline on quality of herbal medicinal products/traditional herbal medicinal products

Action: for discussion

Documents: [Draft Guideline](#), OoC, Presentation

4.2.2. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products

Action: for discussion

Documents: [Draft Guideline](#), OoC, Presentation

4.2.3. Nitrosamines and Herbal MPs

Action: for discussion

Documents: CMDh practical guidance for Marketing Authorisation Holders, [Questions and answers for marketing authorisation holders/applicants](#)

4.2.4. Change of assay methods in Ph. Eur. monographs

Action: for discussion

4.3. Regulatory / Procedural

4.3.1. Regulatory Q&A on herbal medicinal products

Action: for adoption

Documents: Proposals for Q&A on use combination monographs; [Regulatory Q&A on herbal medicinal products](#)

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

Portugal Presidency virtual meeting – 17-18 March 2021

Report: A P Martins

Action: for information

Document: Minutes, Presentations

5.1.2. HMPC membership

New membership:

- Austria, Peter Voithl (co-opted member) as of 3 May 2021
- Lithuania, Jūratė Antanavičienė (member) as of 4 March 2021
- Lithuania, Asta Kubilienė (alternate) as of 4 March 2021

End of membership:

- Lithuania, Rugilė Pilvinienė (member) as of 4 March 2021

5.1.3. Election of Co-opted member (Clinical pharmacology)

Report: HMPC Chair

Action: for adoption

Documents: Call for nominations dated 11 March 2021, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Candidature

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information

Documents: Agenda 28 April 2021

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 13B expert group meeting

Report: M Bald

Action: for information

Document: SoD

- EDQM TCM expert group meeting

Report: M Bald

Action: for information

Document: SoD

5.4.2. Coordination with the European Commission

- Cannabis for medicinal use

Report: HMPC Chair

Action: for information

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. Stakeholder meeting (EUCOPE), 5 May 2021 - postponed

5.7. Work plan

5.7.1. HMPC work plan 2021

Report: HMPC Chair, HMPC Vice Chair

Action: for information

Documents: Work plan 2021, Annex 1, Annex 2

- PhV data and experiences in national assessments (National experiences)

Report: HMPC Vice Chair, R Länger

Action: for discussion

Documents: Proposed action for HMPC, Updated summary on national experiences with HMPC monographs and during MRP/DCP procedures; References: 29/29

- PhV data and experiences in national assessments (PhV data)

Report: HMPC Vice Chair

Action: for adoption

Documents: Presentation

- Use of real-world data and requirements for the safe use of herbal substances in children
Report: HMPC Vice Chair, M H P Ferreira, M Petrikova
Action: for information
Document: Presentation
- Development of training on assessment of applications for herbal medicinal products
Report: HMPC Vice Chair, J Wiesner
Action: for discussion
Document: Presentations, Feedback report, Course description

5.8. Planning and reporting

None

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

None

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

6.2.1. Monograph on Agropyri repentis rhizoma and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 74/67

6.2.2. Monograph on Foeniculi amari fructus and supporting documents - postponed

6.2.3. Monograph on Foeniculi amari fructus aetheroleum and supporting documents - postponed

6.2.4. Monograph on Foeniculi dulcis fructus and supporting documents - postponed

6.2.5. Monograph on Juniperi pseudo-fructus and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 15/15

6.2.6. Monograph on Lavandulae aetheroleum and supporting documents - postponed

6.2.7. Monograph on Pelargonii radix and supporting documents - postponed

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

6.3.1. Monograph on Fucus vesiculosus and supporting documents - postponed

6.3.2. Monograph on Rosmarini aetheroleum and supporting documents

Action: for discussion

Documents: Review report, Presentation; References: 05/05

6.3.3. Monograph on Rosmarini folium and supporting documents

Action: for discussion

Documents: Review report, Presentation; References: 08/08

6.3.4. Monograph on Sabalis serrulatae fructus and supporting documents

Action: for discussion

Document: Review report; References 40/37

6.3.5. Monograph on Solidaginis virgaureae herba and supporting documents

Action: for discussion

Document: Review report, Readers Guidance; References 17/17

6.3.6. Monograph on Urticae folium and supporting documents

Action: for discussion

Document: Review report; References: 11/11

6.3.7. Monograph on Urticae herba and supporting documents

Action: for discussion

Document: Review report; References: 06/06

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

Action: for discussion

Documents: Presentation; References: 00/00

6.5.2. Monograph on Centellae asiaticae herba and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 00/196

6.5.3. Monograph on Cisti cretici folium and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance, Botanical overview, Flora Iberica reference, Presentation; References: 00/86

6.5.4. Monograph on Species digestivae and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, email communication; References: 00/21

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 1-3 March 2021

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

HMPC plenary Best Practice Guide with annexed Reader's Guidance template

7.2.2. Assessment Report Summary for the Public (ARSP)

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

None

7.2.4. Other