



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 May 2022
EMA/HMPC/225479/2022
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 16-18 May 2022

Chair: Emiel Van Galen, Vice-Chair: Karin Erika Svedlund

16 May 2022, 13:00 – 18:00, room 1D / virtual meeting

17 May 2022, 09:00 – 18:00, room 1D / virtual meeting

18 May 2022, 09:00 – 16:00, room 1D / virtual meeting

Health and safety information

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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 16-18 May 2022. See May 2022 HMPC minutes (to be published post July 2022 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 16-18 May 2022.

1.3. Adoption of the minutes

HMPC minutes for 28-30 March 2022.

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 2022

- Overview of HMPC/MLWP assessment work
Report: HMPC Chair
Action: For discussion
Document tabled: Overview
- Update on Vaccinii macrocarpi fructus for July meeting
Report: HMPC Vice-Chair
Action: For discussion
- Update on Hippocastani cortex
Report: Wojciech Dymowski
Action: For discussion

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

2.3.1. Monograph on *Foeniculi amari fructus* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance

2.3.2. Public statement on *Foeniculi amari fructus aetheroleum* and supporting documents

Action: For adoption

Documents tabled: PS, Presentation, Reader's Guidance

2.3.3. Monograph on *Foeniculi dulcis fructus* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance

2.3.4. Monograph on *Fumariae herba* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Readers Guidance

2.3.5. Monograph on *Juniperi pseudo-fructus* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Readers Guidance, Annex,

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

2.4.1. Monograph on *Curcumae xanthorrhizae rhizoma* and supporting documents

Action: For adoption

Documents tabled:

2.4.2. Monograph on *Ginseng radix* and supporting documents - postponed

2.4.3. Monograph on *Paullinae semen* and supporting documents

Action: For adoption

Document tabled: Review report, Readers Guidance

2.4.4. Monograph on Urticae radix and supporting documents

Action: For adoption

Document tabled: Review report

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

None

3. Referral procedures

None

4. Guidelines and guidance documents

4.1. Non-clinical/clinical safety and efficacy and multidisciplinary

4.1.1. Guideline on Assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007) for public consultation

Action: For adoption

Document tabled: Concept paper on the revision of the guideline

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 (SRLM)

- French Presidency virtual meeting – 14 April 2022
Report: An Le
Action: For information
Document tabled: Final agenda, Summary, Presentations, Follow up plan
- Swedish Presidency meeting – 18/19 April 2023
Report: Karin Erika Svedlund
Action: For information

5.1.2. HMPC membership

Membership update
Report: HMPC Chair
Action: For information

5.1.3. Election of Co-opted member (Non-clinical toxicology)

Report: HMPC Chair
Action: For discussion
Documents: Call for candidatures dated 01 April 2022, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#)

5.1.4. Timing of transmission of comments from interested parties received during public consultation

Action: For discussion

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

None

5.2.2. Coordination with QRD and CMDh – Update on Herbal specifics for QRD template ([CMDh/349/2016, Rev.0 - EMA/HMPC/770889/2014](#))

Action: For discussion
Documents tabled: Addendum to the QRD templates, Responses

5.2.3. Coordination with CMDh - List of estragole-containing plants

Action: For discussion

Documents tabled: List of potential plants containing estragole with a HMPC monograph

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: Melanie Bald
Action: For information
Document tabled: SoD
- EDQM TCM expert group meeting - postponed

5.4.2. Coordination with the European Commission

- Revision of EU pharmaceutical legislation (human)
- Collaboration with EC on the feasibility to establish an EU herbal monograph for Cannabis flos
Report: HMPC Chair
Action: For discussion
Documents tabled: Draft Questions & Answers

5.4.3. Borderline between medical devices and medicinal products

Action: For discussion

Documents tabled: [Guidance on borderline between medical devices and medicinal products under Regulation \(EU\) 2017/745 on medical devices](#), [Guidance - MDCG endorsed documents and other guidance \(europa.eu\)](#)

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. Association of the European Self-Medication Industry (AESGP) – hearing on 18 May 2022

- AESGP hearing

Report: HMPC Chair

Action: For discussion

Documents tabled: AESGP Proposal on combinations of traditionally used herbal extracts based on monographs, Draft Agenda (email communication), Article for discussion,

- Post hearing discussion

Report: HMPC Chair;

Action: For discussion

5.7. Work plan and related activities

5.7.1. HMPC work plan 2022

Report: HMPC Chair

Action: For information

Document tabled: HMPC Work plan, Annex 1, Annex 2

5.7.2. Quality domain governance and draft multiannual work plan

Report: HMPC Chair, Nicoleta Carmen Purdel; Expert: Kristine Hvolby

Action: For discussion

Document tabled: Ad-hoc Quality Group Minutes 21 April 2022

5.7.3. Improved use of data source for HMPC relevant safety assessment

Report: HMPC Vice-Chair, Nicoleta Carmen Purdel

Action: For discussion

Documents tabled: Review report template

5.7.4. Evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

Report: Miroslava Petriková, Peter Voitl

Action: For discussion

Documents tabled: Presentation

5.7.5. Development of training on assessment of applications for herbal medicinal products

Report: HMPC Vice-Chair

Action: For discussion

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

6.1.1. Monograph on Hyperici herba and supporting documents

Action: For 10th discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance

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

6.2.1. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 4th discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance

6.2.2. Monograph on Pelargonii radix and supporting documents

Action: For 2nd discussion

Documents tabled: Reader's Guidance

6.2.3. Monograph on Plantaginis lanceolatae folium and supporting documents - postponed

6.2.4. Monograph on Rosmarini aetheroleum and supporting documents

Action: For 5th discussion

Documents tabled: Draft MO, AR, Reader's Guidance

6.2.5. Monograph on Rosmarini folium and supporting documents

Action: For 5th discussion

Documents tabled: Draft MO, AR

6.2.6. Monograph on Urticae herba and supporting documents

Action: For 1st discussion

Document tabled: MO, AR, LoR

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

6.3.1. Monograph on *Camelliae sinensis non fermentatum folium* and supporting documents

Action: For 4th discussion

Document tabled: Review report, Readers Guidance

6.3.2. Monograph on *Sisymbrii officinalis herba* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.3. Monograph on *Tiliae flos* and supporting documents

Action: For 2nd discussion

Documents tabled: Review report, Readers Guidance

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 *Cisti cretici herba* and supporting documents – postponed

6.5.2. Monograph on *Cnici benedicti herba* and supporting documents – postponed

6.5.3. Monograph on *Hyperici herba/Cimicifugae rhizoma* and supporting documents

Action: For 2nd discussion

Documents tabled: Presentation

6.5.4. Monograph on *Tribuli terrestris herba* and supporting documents

Action: For 1st discussion

Document tabled: Presentation

7. Any other business

7.1. Topics for discussion

7.1.1. Filsuvez (birch bark extract)

Action: For discussion

Documents tabled: [CHMP opinion on Filsuvez](#)

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 28-30 March 2022

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)

None

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

None

7.2.4. Other

- Rai M, Kosalec I, editors. Promising Antimicrobials from Natural Products. Springer 2022
- EDQM – Suspension of a CEP - Flucloxacillin sodium - Sandoz Industrial Products S.A.