



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2023
EMA/HMPC/938569/2022
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 23-25 January 2023

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

23 January 2023, 13:00 – 18:00, room 2C / virtual meeting

24 January 2023, 09:00 – 18:00, room 2C / virtual meeting

25 January 2023, 09:00 – 16:00, room 2C / 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 23-25 January 2023. See January 2023 HMPC minutes (to be published post March 2023 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 23-25 January 2023.

1.3. Adoption of the minutes

HMPC minutes for 21-23 November 2022.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC activities

2.1.1. Overview of HMPC assessment work including the Rapporteurship distribution – Status in January 2023

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New assessments to start in 2023

- Pruni cerasi stipites
- Species pectoralis

Periodic reviews to start in 2023

- Mastic (Mastix, Pistaciae lentisci resina)
- Allii sativi bulbus
- Lecithinum ex soya
- Soiae oleum raffinatum
- Species diureticae
- Fragariae folium
- Malvae sylvestris flos
- Malvae folium
- Silybi mariani fructus

2.1.3. Pruni cerasi stipites – proposal for assessment

Action: For adoption

Documents: Validated proposal for assessment, references

2.1.4. Species pectoralis – proposal for assessment

Action: For adoption

Documents: Validated proposal for assessment, references

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 Hippocastani cortex and supporting documents

Action: For adoption

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

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

None

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

2.6.1. Monograph on Cnici benedicti herba and supporting documents

Action: For adoption

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

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 the clinical assessment of fixed combinations of herbal substances / herbal preparations (EMA/HMPC/166326/2005)
-

Action: For discussion

Document tabled: Draft concept paper

4.2. Quality

- 4.2.1. Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin (EMA/HMPC/246816/2005) - postponed

- 4.2.2. Guideline on declaration of herbal substances and herbal preparations (EMA/HMPC/CHMP/CVMP/287539/2005 Rev.1)
-

Action: For adoption

Document tabled: Concept Paper on Revision

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

- 4.4.1. Herbal Quality DG – preparation of Chair election and member re-appointment
-

Report: HMPC Chair, Nicoleta Carmen Purdel

Action: For discussion

Document tabled: [Mandate QDG](#); Proposal, Presentation

- 4.4.2. ORGAM DG
-

None

- 4.4.3. Ad-hoc Quality drafting group
-

Report: Nicoleta Carmen Purdel

Action: For information

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings (SRLM)

- HMPC SRLM Follow up plan - status January 2023

Report: HMPC Vice Chair

Action: For information

Document tabled: Follow up plan

- Swedish Presidency meeting – 18-19 April 2023

Report: Karin Erika Svedlund

Action: For discussion

Document tabled: Draft Agenda

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

5.1.3. Election of HMPC Chair

Action: For adoption

Documents tabled: Call for expression of interest, Presentation, [HMPC RoP](#), Candidatures

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Document tabled: Agenda 30 September 2022, Minutes 27 June 2022, Presentation

See also 5.8.1

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

Action: For adoption

Document tabled: List of estragole-containing plants

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 – postponed

None

5.4.2. Coordination with the European Commission

Collaboration with EC on the feasibility to establish an EU herbal monograph for Cannabis flos

Report: HMPC Chair

Action: For adoption

5.5. Cooperation with International Regulators

5.5.1. IRCH – WHO 14th annual meeting

Report: HMPC Chair

Action: For information

Documents tabled: Agenda virtual meeting 23-25 November 2022, Presentations

5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

None

5.7. Work plan and related activities

5.7.1. HMPC work plan 2023

Report: HMPC Chair

Action: For adoption

Documents tabled: Work plan 2023, Annex 1, Annex 2, Comments

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

Action: For discussion

- Improved use of data sources for HMPC relevant safety assessments

Action: For discussion

Document tabled: Draft Procedure establishment monographs, Draft revised AR template, EC SmPC guideline, Reader's guidance

- Training on assessment of applications for herbal medicinal products

Action: For discussion

Document tabled: Presentation, Course description

5.8. Planning and reporting

5.8.1. HMPC meeting organisation 2023

Report: HMPC Chair

Action: For adoption

Documents tabled: Options for F2F/virtual meetings 2023

See also 5.2.1

5.8.2. Deadline for document submission for 2nd pre-mail

Action: For discussion

Document tabled: 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 Juniperi pseudo-fructus (galbulus) and supporting documents

Action: For 1st discussion

Documents tabled: 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 Eucalypti aetheroleum and supporting documents - postponed

6.2.2. Monograph on Ginseng radix and supporting documents

Action: For 1st discussion

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

6.2.3. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 8th discussion

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

6.2.4. Monograph on *Pelargonii radix* and supporting documents

Action: For 5th discussion

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

6.2.5. Monograph on *Plantaginis lanceolatae folium* and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR, LoR

6.2.6. Monograph on *Rhodiolae roseae rhizoma et radix* and supporting documents

Action: For 1st discussion

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

6.2.7. Monograph on *Zingiberis rhizoma* and supporting documents

Action: For 4th discussion

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

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

6.3.1. Monograph on *Crataegi folium cum flore* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.2. Monograph on *Ginkgo folium* and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.3. Monograph on *Helichrysi flos* and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.4. Monograph on *Matricariae flos* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.5. Monograph on *Myrtilli fructus siccus* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.6. Monograph on *Myrtilli fructus recens* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.7. Monograph on *Ononidis radix* and supporting documents

Action: For 2nd discussion

Document tabled: Review report, Reader's guidance

6.3.8. Monograph on *Pilosellae herba cum radice* and supporting documents

Action: For 1st discussion

Document tabled: Presentation

6.3.9. Monograph on *Polygoni avicularis herba* and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.10. Monograph on *Pruni africanae cortex* and supporting documents

Action: For 1st discussion

Document tabled: Presentation

6.3.11. Monograph on *Ricini oleum* and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.12. Monograph on *Rosae flos* and supporting documents

Action: For 1st discussion

Document tabled: Presentation

6.3.13. Monograph on *Rubi idaei folium* and supporting documents

Action: For 2nd discussion

Documents tabled: Review report, Reader's guidance

6.3.14. Monograph *Sideritis herba* and supporting documents

Action: For 1st discussion

Document tabled: Presentation

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

Action: For 3rd discussion

Document tabled: Review report, Reader's 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

Action: For 15th discussion

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

6.5.2. Monograph on *Hyperici herba/Cimicifugae rhizoma* and supporting documents - postponed

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

Action: For 3rd discussion

Document tabled: Presentation

7. Any other business

7.1. Topics for discussion

7.1.1. Summary on national experiences with HMPC monographs during MRP/DCP procedures

Action: For discussion

Documents tabled: Proposed action for HMPC, Updated summary on national experiences with HMPC monographs during MRP/DCP procedures

7.1.2. Pharmacovigilance Conference at Kew Gardens

Action: For discussion

Document tabled: Invitation

7.1.3. Availability of ESCOP monographs for HMPC assessment work

Action: For discussion

Document tabled: Email communication

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 21-23 November 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)

On hold

7.2.3. Other

None