



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 November 2022
EMA/HMPC/889321/2022
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 21-23 November 2022

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

21 November 2022, 13:00 – 18:00, room 2C / virtual meeting

22 November 2022, 09:00 – 18:00, room 2C / virtual meeting

23 November 2022, 09:00 – 16:00, room 2C / virtual meeting

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed.

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

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to ongoing procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the [Agency policy on access to documents](#) (EMA/729522/2016).

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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 21-23 November 2022. See November 2022 HMPC minutes (to be published post January 2023 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 21-23 November 2022.

1.3. Adoption of the minutes

HMPC minutes for 19-21 September 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 September 2022

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New Peer Reviewer

Reviews started 2022:

- Agrimoniae herba
- Capsici fructus
- Crataegi folium cum flore
- Ginkgo folium
- Matricariae flos
- Myrtilli fructus siccus
- Myrtilli fructus recens
- Pilosellae herba cum radice
- Pruni africanae cortex
- Ricini oleum
- Rosae flos

- Sideritis herba

New Rapporteur

Re-appointments according to Hungarian membership change for ongoing assessment procedures:

- Sisymbrii officinalis herba (Review – D)
- Symphyti radix (Review – D)
- Urticae herba (Revision – D)
- Urticae radix (Revision – D)
- Vaccinii macrocarpi fructus (1st assessment PF)

2.1.3. Prunus cerasus – proposal for assessment

Action: For discussion

Documents: Proposal for assessment, references

2.1.4. Species pectoralis – proposal for assessment

Action: For discussion

Documents: Proposal for assessment, references

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

2.2.1. Monograph on Hyperici herba and supporting documents

Action: For adoption

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

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

2.3.1. List entry on Foeniculi amari fructus and supporting documents

Action: For adoption

Document tabled: Revised LE, Reader's Guidance

2.3.2. List entry on Foeniculi dulcis fructus and supporting documents

Action: For adoption

Document tabled: Revised LE, Reader's Guidance

2.3.3. Monograph on Rosmarini aetheroleum and supporting documents

Action: For adoption

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

2.3.4. Monograph on Rosmarini folium 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

2.4.1. Monograph on Agrimoniae herba and supporting documents

Action: For adoption

Document tabled: Review report

2.4.2. Monograph on Paullinae semen and supporting documents

Action: For adoption

Document tabled: Review report, Reader's Guidance

2.4.3. Monograph on Tiliae flos and supporting documents

Action: For adoption

Document tabled: Review report, Reader's Guidance

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

2.5.1. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: For adoption

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

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 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)
-

Action: For discussion

Document tabled: Comments on Concept Paper, OoC

4.3. Regulatory / Procedural

- 4.3.1. Procedure for the Appointment by the HMPC of a rapporteur responsible for a scientific evaluation or the establishment of a Community herbal monograph and/or Community LE (EMA/HMPC/108877/2005 Rev. 1)
-

Action: For discussion

See 5.7.1.

4.4. Report on HMPC Drafting Groups activities

- 4.4.1. Quality DG
-

None

- 4.4.2. ORGAM DG
-

None

- 4.4.3. Ad-hoc Quality drafting group
-

Report: Nicoleta Carmen Purdel

Action: For information

Document tabled: Ad-hoc Quality Group Minutes November 2022

- Questions & answers on quality of herbal medicinal products / traditional herbal products (EMA/HMPC/41500/2010 Rev.6)

Action: For discussion

Document tabled: [Quality documentation for medicinal products when used with a medical device](#)

- Guidance on newly used manufacturing techniques regarding herbal preparations

Action: For discussion

Document tabled: Draft concept paper

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

Action: For discussion

Document tabled: Draft concept paper

- Reflection paper on markers used for quantitative and qualitative analysis of herbal medicinal products and traditional herbal medicinal products (EMA/HMPC/253629/2007)

Action: For discussion

Document tabled: Discussion paper

4.4.4. [Update on Quality domain](#)

Action: For discussion

Document tabled: Presentation

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 HMPC SRLM Follow up plan - status November 2022

Report: HMPC Vice Chair

Action: For information

Document tabled: Follow up plan

- Czech Presidency meeting – 10-11 November 2022 (Hosted by Malta)

Report: Marketa Prihodova, Everaldo Attard

Action: For information

Document tabled: Agenda, Presentations

5.1.2. [HMPC membership](#)

Report: HMPC Chair

Action: For information

5.1.3. [Preparation for election of HMPC Chair](#)

Action: For discussion

Documents tabled: [HMPC RoP](#), Presentation

5.1.4. Document collaborative platform – Teams integration

Action: For discussion

Document tabled: Presentation

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

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

- EDQM 13A expert group meeting
Report: Melanie Bald, Bruno Spieldenner
Action: For information
Document tabled: SoD
- EDQM 13B expert group meeting
Report: Melanie Bald, Bruno Spieldenner
Action: For information
Document tabled: SoD
- EDQM TCM expert group meeting
Report: Melanie Bald, Bruno Spieldenner
Action: For information
Document tabled: SoD
- Draft *Cannabis flos* monograph published in Pharmeuropa
Report: Melanie Bald, Bruno Spieldenner
Action: For information

Document tabled: *Cannabis flos* draft monograph Pharmeuropa

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: Communication EMA/HMPC representation, Draft Agenda virtual meeting 23-25 November 2022

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

5.7. **Work plan and related activities**

5.7.1. HMPC work plan 2022

Report: HMPC Chair

Action: For information

Documents tabled: HMPC Work plan, Annex 1, Annex 2 – status November 2022

- Improved use of data sources for HMPC relevant safety assessments

Report: Karin Erika Svedlund

Action: For discussion

Documents tabled: Reader's guidance, Draft Procedure for the preparation of European Union herbal monographs and European Union list entries and appointment of HMPC rapporteurs and peer-reviewers, Draft AR Template

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

Report: Miroslava Horváth Petriková, Peter Voitl

Action: For information

- Evaluation of a harmonised approach for the use of monographs in procedures for combination products

Report: Olga Maria Palomino

Action: For information

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

Report: Ana Paula Martins

Action: For information

See 5.4.2.

- Training on assessment of applications for herbal medicinal products

Report: Karin Erika Svedlund

Action: For information

- Implementation of new architecture for WP/DG

Report: HMPC Chair

Action: For information

See 4.4.3. and 4.4.4.

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

Report: HMPC Vice Chair, Reinhard Länger

Action: For discussion

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

5.7.2. [Preparation of HMPC work plan 2023](#)

Report: HMPC Chair

Action: For discussion

Documents tabled: Draft HMPC 2022 WP report, Template, Template - Proposals for assessment by HMPC, Draft WP 2023, Draft Annex 1 (monographs), Draft Annex 2 (guidance), Presentation

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 Eucalypti aetheroleum and supporting documents - postponed

6.2.2. Monograph on Hippocastani cortex and supporting documents

Action: For 3rd discussion

Documents tabled: Draft MO, AR, LoR

6.2.3. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 7th discussion

Documents tabled: Draft MO, AR, LoR, 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 1st discussion

Documents tabled: Draft MO, AR, LoR

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

6.2.7. Monograph on Zingiberis rhizoma and supporting documents

Action: For 3rd discussion

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

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

6.3.1. Monograph on Capsici fructus and supporting documents - postponed

6.3.2. Monograph on Crataegi folium cum flore and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.3. Monograph on Ginkgo folium and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.4. Monograph on Helichrysi flos and supporting documents

Action: For 2nd 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

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

Document 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

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 14th discussion

Documents tabled: Draft MO, AR, LoR

6.5.2. Monograph on Cnici benedicti herba and supporting documents

Action: For 5th discussion

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

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

Action: For 3rd discussion

Documents tabled: Draft MO

6.5.4. Monograph on Tribuli terrestris herba and supporting documents

Action: For 2nd discussion

Documents tabled: Draft AR

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 19-21 September 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

- DRAFT Agenda - Annual PCWP-HCPWP meeting with all eligible organisation - 15 November 22
- Meeting Summary - PCWP meeting - 22 September 2022
- Meeting Summary - HCPWP meeting - 22 September 2022
- Meeting Summary - PCWP HCPWP meeting - 22 September 2022
- Recording and presentations from the "Multi-stakeholder workshop Patient experience data in medicines development and regulatory decision-making" on 21 September 2022
- Addendum to the Quality Review of Documents templates "adopted by QRD without changes and agreed by CMDh"

- Launch of a public consultation on the “EU Data Quality Framework for medicines regulation” on 18 October 2022