



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 September 2022
EMA/HMPC/767056/2022
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 19-21 September 2022

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

19 September 2022, 13:00 – 18:00, room 2C / virtual meeting

20 September 2022, 09:00 – 18:00, room 2C / virtual meeting

21 September 2022, 09:00 – 16:00, room 2C / virtual meeting

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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.

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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 19-21 September 2022. See September 2022 HMPC minutes (to be published post November 2022 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 19-21 September 2022.

1.3. Adoption of the minutes

HMPC minutes for 18-20 July 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

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 Fumariae herba and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Readers guidance

2.3.2. Monograph on Rosmarini aetheroleum and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

2.3.3. Monograph on Rosmarini folium and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

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 Epilobii herba and supporting documents

Action: For adoption

Document tabled: Review report

2.4.3. Monograph on Eschscholziae herba and supporting documents

Action: For adoption

Document tabled: Review report

2.4.4. Monograph on Paullinae semen and supporting documents

Action: For adoption

Documents tabled: Review report, Readers guidance

2.4.5. Monograph on Tiliae flos and supporting documents

Action: For adoption

Documents tabled: Review report, Readers guidance

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

4.1.2. Guideline on the clinical assessment of fixed combinations of herbal substances / herbal preparations (EMA/HMPC/166326/2005)

Action: For information

Document tabled: Email communication

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 information

Document tabled: Email communication

4.3. Regulatory / Procedural

4.3.1. Procedure for the review and revision of EU herbal monographs and EU list entries

Action: For adoption

Documents tabled: Revised procedure (Rev. 3), Revised template

4.3.2. 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 information

Documents tabled: Presentation

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 September 2022

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

Action: For discussion

Document tabled: Overview of existing quality QAs

- Guidance on newly used manufacturing techniques regarding herbal preparations

Action: For information

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

Action: For information

- 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 information

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 September 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: Draft Agenda

5.1.2. HMPC membership

Membership update

Report: HMPC Chair

Action: For information

5.1.3. General update on RWD/RWE projects at EMA

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 discussion

Documents tabled: List of potential plants containing estragole

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

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 discussion

Documents tabled: Draft Questions & Answers, Draft call for data

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

None

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 August 2022

5.7.2. Improved use of data sources for HMPC relevant safety assessments

Report: Karin Erika Svedlund; Experts: Zsuzsanna Biróne Sándor, Nicoleta Carmen Purdel, Reinhard Länger, Alessandro Assisi

Action: For discussion

Documents tabled: AR Template, Readers guidance, Procedure for the preparation of Community MO for TU herbal medicinal products, Procedure for the preparation of Community MO for WEU herbal medicinal products, Standard operating procedure on the establishment of EU herbal MO and EU LE and related documents, Procedure for the preparation of an entry to the Community list of herbal substances, preparations and combinations thereof for TU herbal medicinal products'

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

Report: Miroslava Horváth Petriková, Peter Voitl; Experts: Jacqueline Wiesner, Peter Šišovský, Maria Helena Pinto Ferreira

Action: For discussion

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

Report: Olga Maria Palomino; Experts: Reinhard Länger, Wojciech Dymowski, Sarah Kellaghan, Jacqueline Wiesner, Heidi Foth, Maria da Graça Ribeiro Campos, Gert Laekeman

Action: For information

See 4.1.2.

5.7.5. Collaboration with EC on the feasibility to establish a EU herbal monograph for Cannabis flos

Report: Ana Paula Martins; Experts: Barbara Razinger, Everaldo Attard, Burt Kroes, Ioanna Chinou, Pierre Duez

Action: For information

See 5.4.2.

5.7.6. Training on assessment of applications for herbal medicinal products

Report: Karin Erika Svedlund; Experts: Jacqueline Wiesner, Reinhard Länger, Nicoleta Carmen Purdel, Burt Kroes

Action: For discussion

Documents tabled: Presentation, Herbal medicinal product applications

5.7.7. Implementation of new architecture for WP/DG

Report: HMPC Chair; Experts: Nicoleta Carmen Purdel, Ioanna Chinou, Jacqueline Wiesner, Olga Maria Palomino, Susanne Flemisch, Stefanie Bodemann, Knut Almgren

Action: For discussion

Document tabled: Presentation

5.7.8. Preparation of HMPC work plan 2023

Report: HMPC Chair

Action: For discussion

Documents tabled: Draft HMPC 2022 WP report, Template

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 12th 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 Foeniculi amari fructus and supporting documents

Action: For 1st discussion

Documents tabled: Draft LE, Reader's Guidance

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

Action: For 1st discussion

Documents tabled: Draft LE, Reader's Guidance

6.2.3. Monograph on *Hippocastani cortex* and supporting documents

Action: For 2nd discussion

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

6.2.4. Monograph on *Lavandulae aetheroleum* and supporting documents

Action: For 6th discussion

Documents tabled: Draft MO, AR, LoR, Presentation

6.2.5. Monograph on *Pelargonii radix* and supporting documents

Action: For 4th discussion

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

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

Action: For 1st discussion

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

6.2.7. Monograph on *Urticae herba* and supporting documents - postponed

6.2.8. Monograph on *Zingiberis rhizoma* and supporting documents

Action: For 2nd discussion

Documents tabled: Draft 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

Action: For 1st discussion

Document tabled: Review report

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 1st discussion

Document tabled: Presentation

6.3.4. Monograph on Helichrysi flos and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.5. Monograph on Matricariae flos and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.6. Monograph on Melaleucae aetheroleum and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.7. Monograph on Ononidis radix and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.8. Monograph on Origani majoranae herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.9. Monograph on Pilosellae herba cum radice and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.10. Monograph on Polygoni avicularis herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.11. Monograph on Pruni africanae cortex and supporting documents - postponed

6.3.12. Monograph on Rosae flos and supporting documents - postponed

6.3.13. Monograph on Rubi idaei folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.14. Monograph Sideritis herba and supporting documents - postponed

6.3.15. Monograph on Sisymbrii officinalis herba and supporting documents

Action: For 2nd discussion

Document tabled: Review report

6.3.16. Monograph on Symphyti radix and supporting documents - postponed

6.4. EU herbal monographs and list entries in preparation for adoption after public consultation

6.4.1. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: For 4th discussion

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

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

Action: For 4th discussion

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

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

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 18-20 July 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

- EMA records management system – update on Sharepoint migration