



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 September 2023
EMA/HMPC/358554/2023
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 18-20 September 2023

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

18 September 2023, 13:00 – 18:00, room 2C

19 September 2023, 09:00 – 18:00, room 2C

20 September 2023, 09:00 – 16:00, room 2C

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).

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Table of contents

1.	Introduction	5
1.1.	Welcome and declarations of interest of members, alternates and experts	5
1.2.	Adoption of agenda	5
1.3.	Adoption of the minutes	5
2.	EU herbal monographs and list entries for adoption	5
2.1.	Status of HMPC activities	5
2.1.1.	Overview of HMPC assessment work including the Rapporteurship distribution – Status in September 2023	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers	5
2.1.3.	Request for unscheduled review on Sennae folium and Sennae fructus	5
2.2.	Revised EU herbal monographs and list entries for final adoption	5
2.3.	Revised EU herbal monographs and list entries for public consultation	6
2.3.1.	Monograph on Plantaginis lanceolatae folium and supporting documents - postponed	6
2.3.2.	Monograph on Pelargonii radix and supporting documents	6
2.4.	Reviewed EU herbal monographs and list entries for decision on revision	6
2.4.1.	Monograph on Ononidis radix and supporting documents	6
2.4.2.	Monograph on Pilosellae herba cum radice and supporting documents	6
2.4.3.	Monograph on Polygoni avicularis herba and supporting documents	6
2.4.4.	Monograph on Pruni africanae cortex and supporting documents	6
2.4.5.	Monograph on Rosae flos and supporting documents	6
2.4.6.	Monograph on Sideritis herba and supporting documents	6
2.5.	EU herbal monographs, list entries and public statements for final adoption	7
2.5.1.	Monograph on Cnici benedicti herba and supporting documents	7
2.6.	EU herbal monographs, list entries and public statements for adoption for release for public consultation	7
2.6.1.	Monograph on Cisti cretici herba and supporting documents - postponed	7
2.7.	EU herbal monographs, list entries and public statements - post finalisation	7
3.	Referral procedures	7
4.	Guidelines and guidance documents	7
4.1.	Non-clinical/clinical safety and efficacy and multidisciplinary	7
4.1.1.	Guideline on the assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007)	7
4.2.	Quality	7
4.2.1.	Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin (EMA/HMPC/246816/2005)	7
4.2.2.	Q&A on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010)	7
4.3.	Regulatory / Procedural	8

4.3.1.	Procedure for the preparation of Monographs/List Entries (EMA/HMPC/887331/2022)	8
4.3.2.	Reflection paper on data recommendations for (T)HMPs used in children and adolescents...	8
4.3.3.	Template for Assessment report for the development of EU herbal monographs and EU list entries (EMA/HMPC/418902/2005)	8
4.3.4.	Questions & Answers on the EU framework for (traditional) herbal medicinal products, including those from a 'non-European' tradition (EMA/HMPC/402684/2013).....	8
4.4.	Report on HMPC Drafting Groups activities.....	8
4.4.1.	ORGAM DG	8
4.4.2.	Quality DG - report	8
4.4.3.	Quality DG – 3-year work plan	8

5. Organisational, regulatory and methodological matters 9

5.1.	Mandate and organisation of the HMPC	9
5.1.1.	Strategic Review and Learning Meetings (SRLM).....	9
5.1.2.	HMPC membership.....	9
5.1.3.	Preparation of nomination and appointment of Co-opted members	9
5.1.4.	General update on RWD/RWE projects at EMA.....	9
5.2.	EMA Scientific Committees or CMDh-v	9
5.2.1.	Scientific Coordination Board Meeting.....	9
5.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	9
5.4.	Cooperation within the EU regulatory network.....	10
5.4.1.	Coordination with European Pharmacopoeia	10
5.5.	Cooperation with International Regulators.....	10
5.6.	Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee.....	10
5.6.1.	Association of the European Self-Medication Industry (AESGP) – request for a hearing in November 2023	10
5.7.	Work plan and related activities	10
5.7.1.	HMPC work plan 2023	10
5.8.	Planning and reporting	10
5.8.1.	HMPC meeting organisation 2024	10
5.9.	Legislation and regulatory affairs.....	10
5.10.	Questions from members.....	11
5.10.1.	Query from Slovenia NCA - THMP with vitamins/minerals	11

6. EU herbal monographs and list entries in preparation 11

6.1.	Revision of EU herbal monographs and list entries in preparation for adoption after public consultation	11
6.1.1.	Monograph and List Entry on Foeniculi amari fructus and supporting documents.....	11
6.1.2.	Monograph and List Entry on Foeniculi dulcis fructus and supporting documents.....	11
6.1.3.	Public Statement on Foeniculi amari fructus aetheroleum and supporting documents	11
6.1.4.	Monograph on Hippocastani cortex and supporting documents	11

6.1.5.	Monograph on Rosmarini aetheroleum and supporting documents	11
6.1.6.	Monograph on Rosmarini folium and supporting documents	11
6.2.	Revision of EU herbal monographs and list entries in preparation for public consultation.....	12
6.2.1.	Monograph on Eucalypti aetheroleum and supporting documents - postponed	12
6.2.2.	Monograph on Lavandulae aetheroleum and supporting documents	12
6.2.3.	Monograph on Urticae herba and supporting documents	12
6.2.4.	Monograph on Urticae radix and supporting documents	12
6.3.	Review of EU herbal monographs and list entries in preparation for decision on revision	12
6.3.1.	Monograph on Fragariae folium and supporting documents	12
6.3.2.	Monograph on Malvae sylvestris flos and supporting documents	12
6.3.3.	Monograph on Malvae folium and supporting documents	12
6.3.4.	Monograph on Matricariae aetheroleum and supporting documents.....	12
6.3.5.	Monograph on Symphyti radix and supporting documents.....	12
6.4.	EU herbal monographs and list entries in preparation for adoption after public consultation.....	13
6.5.	EU herbal monographs and list entries in preparation for adoption for release for public consultation	13
6.5.1.	Monograph on Cannabis flos and supporting documents	13
6.5.2.	Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents.....	13
6.5.3.	Monograph on Pruni cerasi stipites and supporting documents.....	13
6.5.4.	Monograph on Species pectoralis and supporting documents.....	13
6.5.5.	Public Statement on Tribuli terrestris herba and supporting documents	13

7. Any other business 13

7.1.	Topics for discussion	13
7.1.1.	Workshop on RWD/RWE for HMPs in children, Bonn, 19 June 2023	13
7.1.2.	Society for Medicinal Plant Research (GA) conference Dublin, 03-05 July 2023	13
7.1.3.	Update common names list.....	14
7.2.	Documents for information.....	14
7.2.1.	HMPC.....	14
7.2.2.	Assessment Report Summary for the Public (ARSP)	14
7.2.3.	Other	14

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 18-20 September 2023. See September 2023 HMPC minutes (to be published post November 2023 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 18-20 September 2023.

Action: For adoption

1.3. Adoption of the minutes

HMPC minutes for 17-19 July 2023.

Action: For adoption

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 2023

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

None

2.1.3. Request for unscheduled review on Sennae folium and Sennae fructus

Rapporteur: HMPC Chair

Action: For discussion

Documents tabled: Email; Request for revision

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 *Plantaginis lanceolatae folium* and supporting documents - postponed

2.3.2. Monograph on *Pelargonii radix* 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 *Ononidis radix* and supporting documents

Action: For adoption

Documents tabled: Review report; References 42/12

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

Action: For adoption

Documents tabled: Review report; References 0/0

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

Action: For adoption

Documents tabled: Review report; References 05/05

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

Action: For adoption

Documents tabled: Review report, Reader's Guidance, References 02/02

2.4.5. Monograph on *Rosae flos* and supporting documents

Action: For adoption

Document tabled: Review report, Reader's Guidance, References 04/03

2.4.6. Monograph on *Sideritis herba* and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's Guidance, References 03/03

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

2.5.1. Monograph on Cnici benedicti herba and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, LoR

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

2.6.1. Monograph on Cisti cretici herba and supporting documents - postponed

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 assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007)

Action: For discussion

Document tabled: [Concept paper](#), Oral report

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

Documents tabled: Draft revised guideline, OoC

4.2.2. Q&A on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010)

Action: For adoption

Document tabled: Draft revised Q&A (Rev.7)

4.3. Regulatory / Procedural

4.3.1. Procedure for the preparation of Monographs/List Entries (EMA/HMPC/887331/2022)

Action: For discussion

Document tabled: Draft Procedure for the preparation of MO and LE

4.3.2. Reflection paper on data recommendations for (T)HMPs used in children and adolescents

Action: For discussion

Documents tabled: Draft reflection paper; Draft Annex: 'Therapeutic areas for adolescents and children for traditional use (TU)'

4.3.3. Template for Assessment report for the development of EU herbal monographs and EU list entries (EMA/HMPC/418902/2005)

Action: For discussion

Document tabled: Draft revised AR template

4.3.4. Questions & Answers on the EU framework for (traditional) herbal medicinal products, including those from a 'non-European' tradition (EMA/HMPC/402684/2013)

Report: HMPC Chair

Action: For adoption

Document tabled: Draft revised Q&A (Rev.1)

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG - report

Report: Nicoleta Carmen Purdel

Action: For information

Document tabled: Minutes

4.4.3. Quality DG – 3-year work plan

Action: For adoption

Document tabled: Draft work plan

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 September 2023

Report: HMPC Chair

Action: For information

Document tabled: Follow-up plan

- Spanish Presidency meeting – 09-10 October 2023

Report: Olga Palomino

Action: For discussion

Document tabled: Draft agenda

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

5.1.3. Preparation of nomination and appointment of Co-opted members

Report: HMPC Chair

Action: For discussion

Document tabled: [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), presentation

5.1.4. 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

Documents tabled: Agenda 15 September 2023, Minutes 26 June 2023

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

5.5. 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) – request for a hearing in November 2023

Report: HMPC Chair

Action: For discussion

Document tabled: Email

5.7. Work plan and related activities

5.7.1. HMPC work plan 2023

Report: HMPC Chair

Action: For discussion

Documents tabled: Work plan 2023, Annex 1, Annex 2 – current status

- (1.3.2) Harmonise the approach for the use of EU herbal monographs in the assessment of combination products

Document tabled: Draft survey

Action: For discussion

- (2.1.1) HMPC position on the role of EU herbal monographs and assessment reports in relationship to borderline issues

Document tabled: Draft-The role of MO and AR in relationship to borderline issues

Action: For discussion

5.8. Planning and reporting

5.8.1. HMPC meeting organisation 2024

Report: HMPC Chair

Action: For information

Document tabled: Email

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

5.10.1. Query from Slovenia NCA - THMP with vitamins/minerals

Action: For discussion

Documents tabled: Email, presentation

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 and List Entry on *Foeniculi amari fructus* and supporting documents

Action: For 3rd discussion

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

6.1.2. Monograph and List Entry on *Foeniculi dulcis fructus* and supporting documents

Action: For 3rd discussion

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

6.1.3. Public Statement on *Foeniculi amari fructus aetheroleum* and supporting documents

Action: For 3rd discussion

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

6.1.4. Monograph on *Hippocastani cortex* and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR, LoR, Reference

6.1.5. Monograph on *Rosmarini aetheroleum* and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR, OoC

6.1.6. Monograph on *Rosmarini folium* and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR

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 Lavandulae aetheroleum and supporting documents

Action: For 12th discussion

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

6.2.3. Monograph on Urticae herba and supporting documents

Action: For 4th discussion

Documents tabled: Draft MO, AR, LoR

6.2.4. Monograph on Urticae radix and supporting documents

Action: For 2nd 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 Fragariae folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.2. Monograph on Malvae sylvestris flos and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.3. Monograph on Malvae folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.4. Monograph on Matricariae aetheroleum and supporting documents

Action: For 1st discussion

Document tabled: Review report

6.3.5. Monograph on Symphyti radix and supporting documents

Action: For 2nd 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 Cannabis flos and supporting documents

Action: For 1st discussion

Document tabled: Presentation

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

Action: For 7th discussion

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

6.5.3. Monograph on Pruni cerasi stipites and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR, LoR

6.5.4. Monograph on Species pectoralis and supporting documents

Action: For 1st discussion

Document tabled: Presentation

6.5.5. Public Statement on Tribuli terrestris herba and supporting documents

Action: For 5th discussion

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

7. Any other business

7.1. Topics for discussion

7.1.1. Workshop on RWD/RWE for HMPs in children, Bonn, 19 June 2023

Report: HMPC Chair

Action: For discussion

Document tabled: Oral report

7.1.2. Society for Medicinal Plant Research (GA) conference Dublin, 03-05 July 2023

Report: HMPC Vice-Chair

Action: For discussion

Document tabled: Oral report, presentation

7.1.3. Update common names list

Action: For discussion

Document tabled: Oral presentation

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 17-19 July 2023

Overview of expertise of members HMPC and subgroups

[Inventory of herbal substances for assessment work](#)

[List of abbreviations used in EMA human medicines scientific committees & CMDh documents and in relation to EMA's regulatory activities](#)

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

- Meeting Summary – PCWP and HCPWP - 27 and 28 June 2023
- Draft Agenda – PCWP and HCPWP Joint meeting - 19 and 20 September 2023
- [European Parliamentary Research Service \(EPRS\) Study: "Health claims made on foods: Findings on the implementation and application of Regulation \(EC\) No 1924/2006"](#)
- New process to submit requests for MWP input
- New voting system – Test voting