



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 May 2023
EMA/HMPC/174041/2023
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 10-12 May 2023

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

10 May 2023, 09:00 – 20:00, room 2C

11 May 2023, 09:00 – 18:00, room 2C

12 May 2023, 09:00 – 12:00, room 2C

Health and safety information

In accordance with the Agency's health and safety policy, delegates were 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 May 2023	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers	5
2.1.3.	Maydis stigma – new proposal for assessment.....	5
2.2.	Revised EU herb monographs and list entries for final adoption.....	5
2.2.1.	Monograph on Fumariae herba and supporting documents.....	5
2.3.	Revised EU herbal monographs and list entries for public consultation	6
2.3.1.	Monograph on Ginseng radix and supporting documents.....	6
2.3.2.	Monograph on Plantaginis lanceolatae folium and supporting documents	6
2.4.	Reviewed EU herbal monographs and list entries for decision on revision.....	6
2.4.1.	Monograph on Ginkgo folium and supporting documents	6
2.4.2.	Monograph on Matricariae flos and supporting documents	6
2.4.3.	Monograph on Melaleucae aetheroleum and supporting documents.....	6
2.4.4.	Monograph on Myrtilli fructus siccus and supporting documents.....	6
2.4.5.	Monograph on Myrtilli fructus recens and supporting documents.....	6
2.4.6.	Monograph on Ricini oleum and supporting documents.....	6
2.4.7.	Monograph on Rubi idaei folium and supporting documents	7
2.4.8.	Monograph on Sisymbrii officinalis herba and supporting documents	7
2.5.	EU herbal monographs, list entries and public statements for final adoption	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	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.	Public statement on use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005 Rev 1)	7
	Guideline on the assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007)	7
4.1.2.	7	
4.2.	Quality.....	8

4.2.1.	Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin (EMA/HMPC/246816/2005)	8
4.3.	Regulatory / Procedural	8
4.3.1.	Procedure for the preparation of Monographs/List Entries	8
4.4.	Report on HMPC Drafting Groups activities.....	8
4.4.1.	ORGAM DG	8
4.4.2.	Quality DG.....	8
5.	Organisational, regulatory and methodological matters	8
5.1.	Mandate and organisation of the HMPC	8
5.1.1.	Strategic Review and Learning Meetings (SRLM).....	8
5.1.2.	HMPC membership.....	9
5.1.3.	New Experts Management Tool / EMA	9
5.1.4.	HMPC traineeship project: revision of the Q/A document on the EU framework for (T)HMPs	9
5.1.5.	100 th HMPC meeting celebration	9
5.2.	EMA Scientific Committees or CMDh-v	9
5.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	9
5.4.	Cooperation within the EU regulatory network.....	9
5.4.1.	Coordination with European Pharmacopoeia	9
5.4.2.	Coordination with the European Commission	10
5.5.	Cooperation with International Regulators.....	10
5.5.1.	India — EC/EMA joint technical working group on Ayurveda	10
5.6.	Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee.....	10
5.7.	Work plan and related activities	10
5.7.1.	HMPC work plan 2023	10
5.8.	Planning and reporting	10
5.9.	Legislation and regulatory affairs.....	10
5.10.	Questions from members.....	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 on Foeniculi amari fructus and supporting documents	11
6.1.2.	Monograph on Foeniculi dulcis fructus and supporting documents	11
6.1.3.	Monograph on Foeniculi amari fructus aetheroleum and supporting documents	11
6.2.	Revision of EU herbal monographs and list entries in preparation for public consultation.....	11
6.2.1.	Monograph on Eucalypti aetheroleum and supporting documents - postponed	11
6.2.2.	Monograph on Lavandulae aetheroleum and supporting documents	11
6.2.3.	Monograph on Pelargonii radix and supporting documents	11
6.2.4.	Monograph on Rhodiolae roseae rhizoma et radix and supporting documents	11

6.2.5.	Monograph on Urticae herba and supporting documents	11
6.2.6.	Monograph on Urticae radix and supporting documents - postponed	12
6.2.7.	Monograph on Zingiberis rhizoma 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 Capsici fructus and supporting documents	12
6.3.2.	Monograph on Ononidis radix and supporting documents.....	12
6.3.3.	Monograph on Origani majoranae herba and supporting documents.....	12
6.3.4.	Monograph on Pilosellae herba cum radice and supporting documents.....	12
6.3.5.	Monograph on Polygoni avicularis herba and supporting documents	12
6.3.6.	Monograph on Pruni africanae cortex and supporting documents	12
6.3.7.	Monograph on Rosae flos and supporting documents.....	12
6.3.8.	Monograph on Sideritis herba and supporting documents.....	13
6.3.9.	Monograph on Symphyti radix and supporting documents - postponed.....	13
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 Hyperici herba/Cimicifugae rhizoma and supporting documents.....	13
6.5.2.	Monograph on Tribuli terrestris herba and supporting documents - postponed.....	13
7.	Any other business	13
7.1.	Topics for discussion	13
7.1.1.	Feedback - Pharmacovigilance herbal MP conference at Kew Gardens, 13-14 April 2023 ...	13
7.1.2.	Society for Medicinal Plant Research (GA) conference Dublin, 03-05 July 2023	13
7.2.	Documents for information.....	13
7.2.1.	HMPC.....	13
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 10-12 May 2023. See May 2023 HMPC minutes (to be published post July 2023 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 10-12 May 2023.

1.3. Adoption of the minutes

HMPC minutes for 13-15 March 2023.

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 May 2023

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New assessments starting in 2023

- Pruni cerasi stipites
- Cannabis flos
- Maydis stigma

2.1.3. Maydis stigma – new proposal for assessment

Action: For adoption

Documents: Validated proposal for assessment, references

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

2.2.1. Monograph on Fumariae herba and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

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

2.3.1. Monograph on Ginseng radix and supporting documents

Action: For adoption

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

2.3.2. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: For discussion

Documents tabled: MO, email

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

2.4.1. Monograph on Ginkgo folium and supporting documents

Action: For adoption

Document tabled: Review report

2.4.2. Monograph on Matricariae flos and supporting documents

Action: For adoption

Document tabled: Review report

2.4.3. Monograph on Melaleucae aetheroleum and supporting documents

Action: For adoption

Document tabled: Review report

2.4.4. Monograph on Myrtilli fructus siccus and supporting documents

Action: For adoption

Document tabled: Review report

2.4.5. Monograph on Myrtilli fructus recens and supporting documents

Action: For adoption

Document tabled: Review report

2.4.6. Monograph on Ricini oleum and supporting documents

Action: For adoption

Document tabled: Review report

2.4.7. Monograph on Rubi idaei folium and supporting documents

Action: For adoption

Documents tabled: Review report

2.4.8. Monograph on Sisymbrii officinalis herba 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

2.6.1. Monograph on Cisti cretici herba and supporting documents

Action: For discussion

Documents tabled: MO, AR

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. Public statement on use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005 Rev 1)

Action: For adoption

Document tabled: Public statement –correction 1

4.1.2. Guideline on the assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007)

Action: For discussion

Document tabled: [Concept paper](#), OoC, presentation

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

4.3. Regulatory / Procedural

4.3.1. Procedure for the preparation of Monographs/List Entries

Action: For discussion

Document tabled: Procedure for the preparation of MO and LE, Reader's Guidance

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

Report: Nicoleta Carmen Purdel

Action: For information

Documents tabled: Minutes, QDG proposal on CEP

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 May 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: Final Agenda, presentations
- Spanish Presidency meeting – 09-10 October 2023
Report: Olga Palomino
Action: For discussion

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

5.1.3. New Experts Management Tool / EMA

Action: For information

Document tabled: Presentation

5.1.4. HMPC traineeship project: revision of the Q/A document on the EU framework for (T)HMPCs

Action: For information

Document tabled: Presentation

5.1.5. 100th HMPC meeting celebration

Report: HMPC Chair

Action: For information

5.2. EMA Scientific Committees or CMDh-v

None

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
Action: For information
Document tabled: SoD
- EDQM 13B expert group meeting
Report: Melanie Bald
Action: For information
Document tabled: SoD
- EDQM TCM expert group meeting
Report: Melanie Bald
Action: For information

Document tabled: SoD

5.4.2. Coordination with the European Commission

5.5. Cooperation with International Regulators

5.5.1. India – EC/EMA joint technical working group on Ayurveda

Report: HMPC Chair

Action: For information

Document tabled: Agenda meeting held on 29 March 2023

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 discussion

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

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

Action: For discussion

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

Action: For information

- (2.2.2) Training on assessment of applications for herbal medicinal products

Action: For discussion

- (2.3.1) Implement new working methodology for HMPC – new main procedure and revised template documents

Action: For discussion

Documents tabled: Draft revised AR template with comments, Reader's guidance

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 *Foeniculi amari fructus* and supporting documents

Action: For 3rd discussion

Documents tabled: Reader's Guidance, OoC, references, presentation

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

Action: For 3rd discussion

Documents tabled: Reader's Guidance, OoC, references, presentation

6.1.3. Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents

Action: For 1st discussion

Documents tabled: Reader's Guidance, OoC, references, presentation

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 10th discussion

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

6.2.3. Monograph on *Pelargonii radix* and supporting documents

Action: For 7th discussion

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

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

Action: For 3rd discussion

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

6.2.5. Monograph on *Urticae herba* and supporting documents

Action: For 3rd discussion

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

6.2.6. Monograph on *Urticae radix* and supporting documents - postponed

6.2.7. Monograph on *Zingiberis rhizoma* and supporting documents

Action: For 6th discussion

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

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 2nd discussion

Document tabled: Review report

6.3.2. Monograph on *Ononidis radix* and supporting documents

Action: For 3rd discussion

Document tabled: Review report, Reader's guidance

6.3.3. Monograph on *Origanum majoranae herba* and supporting documents

Action: For 3rd discussion

Document tabled: Review report

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

Action: For 2nd discussion

Document tabled: Presentation

6.3.5. Monograph on *Polygonum avicularis herba* and supporting documents

Action: For 3rd discussion

Document tabled: Review report

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

Action: For 1st discussion

Document tabled: Presentation

6.3.7. Monograph on *Rosae flos* and supporting documents

Action: For 1st discussion

Document tabled: Presentation

6.3.8. Monograph on Sideritis herba and supporting documents

Action: For 1st discussion

Document tabled: Presentation

6.3.9. Monograph on Symphyti radix and supporting documents - postponed

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 Hyperici herba/Cimicifugae rhizoma and supporting documents

Action: For 5th discussion

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

6.5.2. Monograph on Tribuli terrestris herba and supporting documents - postponed

7. Any other business

7.1. Topics for discussion

7.1.1. Feedback - Pharmacovigilance herbal MP conference at Kew Gardens, 13-14 April 2023

Action: For discussion

Documents tabled: Programme, report, presentation

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

Action: For discussion

Document tabled: Draft programme

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 13-15 March 2023

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 – report update

7.2.3. Other

- COMMISSION REGULATION (EU) 2023/648 of 20 March 2023 authorising a health claim made on foods and referring to the reduction of disease risk: a combination containing a standardised artichoke leaf dry extract, monacolin K in red yeast rice, standardised garlic extract and others 'reduces blood LDL-cholesterol concentrations' (based on EFSA assessment Q-2012-00968; <https://www.efsa.europa.eu/en/efsajournal/pub/3327>).