



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 November 2020
EMA/HMPC/559321/2020
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 16-18 November 2020

Chair: E. van Galen, Vice-Chair: E. Svedlund

Disclaimers

Some of the information contained in this set 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 on-going 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/127362/2006).

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/MLWP activities	5
2.1.1.	Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in November 2020	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers	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	5
2.4.	Reviewed EU herbal monographs and list entries for decision on revision.....	6
2.4.1.	Monograph on Agropyri repentis rhizoma and supporting documents	6
2.4.2.	Monograph on Carvi aetheroleum and supporting documents	6
2.4.3.	Monograph on Carvi fructus and supporting documents	6
2.4.4.	Monograph on Caryophylli floris aetheroleum and supporting documents.....	6
2.4.5.	Monograph on Chamomillae romanae flos and supporting documents.....	6
2.4.6.	Monograph on Lavandulae aetheroleum and supporting documents	6
2.4.7.	Monograph on Lavandulae flos and supporting documents	6
2.4.8.	Monograph on Solani dulcamarae stipites and supporting documents	6
2.5.	EU herbal monographs, list entries and public statements for final adoption	7
2.5.1.	Monograph on Species amarae and supporting documents.....	7
2.5.2.	Monograph on Species sedativae 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 Saccharomyces cerevisiae CBS 5926 and supporting documents.....	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 the use of herbal medicinal products containing estragole	7
4.2.	Quality.....	7
4.3.	Regulatory / Procedural	7
4.4.	Report on HMPC Drafting Groups activities.....	8
4.4.1.	Quality DG.....	8
4.4.2.	ORGAM 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	8
5.1.2.	Election of Co-opted member (paediatrics)	8
5.1.3.	Elections of Co-opted members (Experimental/non-clinical pharmacology and General and family medicine)	8
5.2.	EMA Scientific Committees or CMDh-v	8
5.2.1.	Scientific Coordination Board Meeting.....	8
5.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	8
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	9
5.5.	Cooperation with International Regulators.....	9
5.6.	Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee	9
5.6.1.	AESGP – hearing to be held on 18 November 2020	9
5.7.	Work plan	9
5.7.1.	HMPC work plan 2020	9
5.7.2.	Draft HMPC work plan 2021	10
5.8.	Planning and reporting	10
5.9.	Legislation and regulatory affairs	10
5.10.	Questions from members.....	10
6.	EU herbal monographs and list entries in preparation	10
6.1.	Revision of EU herbal monographs and list entries in preparation for adoption after public consultation	10
6.1.1.	Monograph on Hyperici herba and supporting documents.....	10
6.2.	Revision of EU herbal monographs and list entries in preparation for public consultation.....	11
6.2.1.	Monograph on Orthosiphonis folium and supporting documents	11
6.2.2.	Monograph on Trigonellae foenugraeci semen and supporting documents	11
6.3.	Review of EU herbal monographs and list entries in preparation for decision on revision	11
6.3.1.	Monograph on Cinnamomi corticis aetheroleum and supporting documents.....	11
6.3.2.	Monograph on Cinnamomi cortex and supporting documents	11
6.3.3.	Monograph on Colae semen and supporting documents.....	11
6.3.4.	Monograph on Fucus vesiculosus and supporting documents - postponed	11
6.3.5.	Monograph on Fumariae herba and supporting documents.....	11
6.3.6.	Monograph on Mate folium and supporting documents	11
6.3.7.	Monograph on Plantaginis lanceolatae folium and supporting documents - postponed.....	12
6.3.8.	Monograph on Rosmarini aetheroleum and supporting documents	12
6.3.9.	Monograph on Rosmarini folium and supporting documents	12
6.3.10.	Monograph on Solidaginis virgaureae herba and supporting documents - postponed	12

6.3.11.	Monograph on Urticae folium and supporting documents	12
6.3.12.	Monograph on Urticae herba and supporting documents	12
6.3.13.	Monograph on Viola tricoloris herba and supporting documents	12
6.3.14.	Monograph on Zingiberis rhizoma and supporting documents	12
6.3.15.	Monograph on Sabalis serrulatae fructus and supporting documents	12
6.4.	EU herbal monographs and list entries in preparation for adoption after public consultation.....	13
6.4.1.	Monograph on Aloysiae citriodorae folium and supporting documents.....	13
6.5.	EU herbal monographs and list entries in preparation for adoption for release for public consultation	13
6.5.1.	Monograph on Andrographidis paniculatae folium and supporting documents	13
6.5.2.	Monograph on Centellae asiaticae herba and supporting documents.....	13
6.5.3.	Monograph on Cisti cretici folium and supporting documents - postponed	13
6.5.4.	Monograph on Hyperici herba and supporting documents.....	13
6.5.5.	Monograph on Salviae miltiorrhizae radix et rhizoma and supporting documents	13
6.5.6.	Monograph on Species digestivae or species stomachicae and supporting documents.....	13
6.5.7.	Monograph on Taraxaci officinalis radix and supporting documents	13
6.5.8.	Monograph on Vaccinii macrocarpi fructus and supporting documents	14
7.	Any other business	14
7.1.	Topics for discussion	14
7.2.	Documents for information.....	14
7.2.1.	HMPC	14
7.2.2.	ARSP.....	14
7.2.3.	EU herbal monographs, list entries and public statements – on hold.....	14
7.2.4.	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 16-18 November 2020. See November 2020 HMPC minutes (to be published post January 2021 HMPC meeting).

New membership:

- Netherlands, Hilda Kuin (alternate) as of 12 November 2020

1.2. Adoption of agenda

HMPC agenda for 16-18 November 2020.

Time schedule for 16-18 November 2020.

1.3. Adoption of the minutes

HMPC minutes for 21-23 September 2020.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC/MLWP activities

2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in November 2020

Report: HMPC Chair

Action: for discussion

Document: 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

None

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

2.4.1. Monograph on *Agropyri repentis rhizoma* and supporting documents

Action: for adoption

Documents: Review report; References: 67/02

2.4.2. Monograph on *Carvi aetheroleum* and supporting documents

Action: for adoption

Documents: Review report; References: 17/15

2.4.3. Monograph on *Carvi fructus* and supporting documents

Action: for adoption

Documents: Review report; References: 17/15

2.4.4. Monograph on *Caryophyllii floris aetheroleum* and supporting documents

Action: for adoption

Documents: Review report; References: 05/05

2.4.5. Monograph on *Chamomillae romanae flos* and supporting documents

Action: for adoption

Documents: Review report; References: 31/38

2.4.6. Monograph on *Lavandulae aetheroleum* and supporting documents

Action: for adoption

Documents: Review report, Readers guidance; References: 43/198

2.4.7. Monograph on *Lavandulae flos* and supporting documents

Action: for adoption

Documents: Review report; References: 00/00

2.4.8. Monograph on *Solani dulcamarae stipites* and supporting documents

Action: for adoption

Documents: Review report; References: 00/00

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

2.5.1. Monograph on Species amarae and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC; References: 10/13

2.5.2. Monograph on Species sedativae and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC, Reader's guidance; References: 35/23

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

2.6.1. Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents

Action: for adoption

Documents for adoption: MO, LoR, AR; References: 2/214

Documents for discussion: Draft PS, presentation, email correspondence EU herbal monographs, list entries and public statements - post finalisation

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 the use of herbal medicinal products containing estragole

Action: for adoption

Documents: PS, OoC

4.2. Quality

None

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

None

4.4.2. ORGAM DG

None

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings

German Presidency meeting – September 2020

Action: for information

Document: Summary of discussions

5.1.2. Election of Co-opted member (paediatrics)

Report: HMPC Chair

Action: for discussion

Documents: Call for nominations, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members

5.1.3. Elections of Co-opted members (Experimental/non-clinical pharmacology and General and family medicine)

Report: HMPC Chair

Action: for adoption

Documents: Call for nominations, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members, Candidatures

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for discussion

Documents: Final agenda 19 October 2020; Draft Minutes 19 October 2020

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: M Bald
Action: for information
Documents: SoD, Senna fruit dry extract, Senna leaf
- EDQM 13B expert group meeting
Report: M Bald
Action: for information
Document: SoD
- EDQM TCM expert group meeting
Report: M Bald
Action: for information
Document: SoD
- EDQM PA working party meeting
Report: R Laenger
Action: for information
Documents: Draft Method (Contaminant pyrrolizidine alkaloids (2.8.26.)), Comments from HMPC

5.4.2. Coordination with the European Commission

- Cannabis for medicinal use
Report: HMPC Chair
Action: for discussion

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. AESGP – hearing to be held on 18 November 2020

Report: HMPC Chair
Action: for discussion
Documents: Agenda, List of participants, Presentations

5.7. Work plan

5.7.1. HMPC work plan 2020

Report: HMPC Chair, HMPC Vice Chair
Action: for discussion
Document: Work plan 2020, Annex 1, Annex 2 – current status November 2020

- Activity area 1-3-1: Implementation of a modified procedure for EU herbal monograph establishment and maintenance
Report: HMPC Vice Chair, HMPC Chair
Action: for discussion
Documents: Presentations, Draft HMPC Plenary Best Practice guide with annexed Reader's Guidance template
- Activity area 1-3-2: Forward planning and prioritisation
Report: HMPC Vice Chair, HMPC Chair
Action: for information
Documents: Proposals from MSs
- Activity area 2-1-3: Use of PhV, non-clinical and real-world data for HMPC relevant safety assessments (see also 5.2.2.)
Report: HMPC Vice Chair
Action: for discussion
Document: Presentation
- Activity area 2-2-1: Development of training on assessment of applications for herbal medicinal products
Report: HMPC Vice Chair
Action: for discussion
Document: Presentation

5.7.2. Draft HMPC work plan 2021

Report: HMPC Chair, HMPC Vice Chair

Action: for discussion

Documents: Draft Work plan 2021, Annex 1, Annex 2

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 discussion

Documents: Draft MO-TU, AR, LoR, OoC, Reader's guidance; References: 03/822

6.2. Revision of EU herbal monographs and list entries in preparation for public consultation

6.2.1. Monograph on *Orthosiphonis folium* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 00/53

6.2.2. Monograph on *Trigonellae foenugraeci semen* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 05/99

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

6.3.1. Monograph on *Cinnamomi corticis aetheroleum* and supporting documents

Action: for discussion

Documents: Review report; References: 00/02

6.3.2. Monograph on *Cinnamomi cortex* and supporting documents

Action: for discussion

Documents: Review report; References: 00/12

6.3.3. Monograph on *Colae semen* and supporting documents

Action: for discussion

Documents: Review report; References: 53/53

6.3.4. Monograph on *Fucus vesiculosus* and supporting documents - postponed

6.3.5. Monograph on *Fumariae herba* and supporting documents

Action: for discussion

Documents: Review report, presentation; References: 00/16

6.3.6. Monograph on *Mate folium* and supporting documents

Action: for discussion

Document: Review report; References: 00/34

6.3.7. Monograph on *Plantaginis lanceolatae folium* and supporting documents - postponed

6.3.8. Monograph on *Rosmarini aetheroleum* and supporting documents

Action: for discussion

Documents: Review report, presentation; References: 10/04

6.3.9. Monograph on *Rosmarini folium* and supporting documents

Action: for discussion

Documents: Review report, presentation; References: 10/07

6.3.10. Monograph on *Solidaginis virgaureae herba* and supporting documents - postponed

6.3.11. Monograph on *Urticae folium* and supporting documents

Action: for discussion

Documents: Review report; References: 28/28

6.3.12. Monograph on *Urticae herba* and supporting documents

Action: for discussion

Documents: Review report; References: 28/28

6.3.13. Monograph on *Violae tricoloris herba* and supporting documents

Action: for discussion

Documents: Review report, Presentation; References: 28/29

6.3.14. Monograph on *Zingiberis rhizoma* and supporting documents

Action: for discussion

Documents: Presentation; References: 00/00

6.3.15. Monograph on *Sabalidis serrulatae fructus* and supporting documents

Action: for discussion

Documents: Reader's guidance; References: 48/00

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

6.4.1. Monograph on *Aloysiae citriodoraefolium* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/31

6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation

6.5.1. Monograph on *Andrographidis paniculataefolium* and supporting documents

Action: for discussion

Document: Reader's guidance; References: 00/00

6.5.2. Monograph on *Centellae asiaticae herba* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/216

6.5.3. Monograph on *Cisti cretici folium* and supporting documents - postponed

6.5.4. Monograph on *Hyperici herba* and supporting documents

Action: for discussion

Documents: MO-WEU

6.5.5. Monograph on *Salviae miltiorrhizae radix et rhizoma* and supporting documents

Action: for discussion

Documents: Draft PS, AR, LoR; References: 00/90

6.5.6. Monograph on *Species digestivae* or *species stomachicae* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/20

6.5.7. Monograph on *Taraxaci officinalis radix* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 00/99

6.5.8. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 459/260

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 21-23 September 2020

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

7.2.2. ARSP

- English template
- English summaries for publication
 - Millefolii herba

7.2.3. EU herbal monographs, list entries and public statements – on hold

None

7.2.4. Other

- HMPC meeting dates 2022-2024