



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2019
EMA/HMPC/517402/2019
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 23-25 September 2019

Chair: Marisa Delbò Vice-Chair: Emiel van Galen

23 September 2019, 14:00 – 19:00, 2D

24 September 2019, 09:00 – 19:00, 2D

25 September 2019, 09:00 – 16:00, 2D

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

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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 September 2019	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers	5
2.1.3.	Andrographidis paniculatae herba in combination - possibility for monograph establishment	6
2.1.4.	Public statement on Centellae asiaticae herba and supporting documents – possibility for monograph establishment.....	7
2.1.5.	Monograph on Sabalis serrulatae fructus and supporting documents - request for unscheduled monograph revision.....	7
2.2.	Revised EU herbal monographs and list entries for final adoption	7
2.2.1.	Monograph on Frangulae cortex and supporting documents	7
2.2.2.	Monograph on Valerianae radix/Lupuli flos and supporting documents.....	7
2.3.	Revised EU herbal monographs and list entries for public consultation	7
2.3.1.	Monograph on Rhamni purshianae cortex and supporting documents	7
2.3.2.	Monograph on Rhei radix and supporting documents.....	7
2.3.3.	Monograph on Tanacetii parthenii herba and supporting documents.....	7
2.3.4.	Monograph on Thymi aetheroleum and supporting documents.....	7
2.4.	Reviewed EU herbal monographs and list entries for decision on revision.....	8
2.4.1.	Monograph on Hamamelidis cortex and supporting documents	8
2.4.2.	Monograph on Hamamelidis folium and supporting documents	8
2.4.3.	Monograph on Hamamelidis folium et cortex aut ramunculus destillatum and supporting documents.....	8
2.5.	EU herbal monographs, list entries and public statements for final adoption	8
2.6.	EU herbal monographs, list entries and public statements for adoption for release for public consultation.....	8
2.7.	EU herbal monographs, list entries and public statements - post finalisation.....	8
2.7.1.	Monograph on Pistacia lentiscus, resinum (mastic) and supporting documents	8
3.	Referral procedures	8
4.	Guidelines and guidance documents	8
4.1.	Non-clinical/clinical safety and efficacy and multidisciplinary.....	8
4.1.1.	Public statement on the use of herbal medicinal products containing estragole	8
4.1.2.	Public statement on the contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016) - postponed	9

4.1.3.	Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011) - postponed.....	9
4.2.	Quality.....	9
4.3.	Regulatory / Procedural	9
4.3.1.	Procedure on management of proposals submitted by interested parties for EU List Entries or EU Herbal Monographs (EMA/HMPC/328575/2007 Rev.2)	9
4.4.	Report on HMPC Drafting Groups activities.....	9
4.4.1.	Quality DG.....	9
4.4.2.	ORGAM DG	9

5. Organisational, regulatory and methodological matters 9

5.1.	Mandate and organisation of the HMPC	9
5.1.1.	Strategic Review and Learning Meetings	9
5.1.2.	Preparation for election of HMPC Chair	9
5.2.	Coordination with EMA Scientific Committees or CMDh-v	9
5.2.1.	Scientific Coordination Board Meeting.....	9
5.2.2.	Coordination with PDCO/PRAC - postponed	10
5.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	10
5.3.1.	QRD Template – update of Addendum for THMP	10
5.3.2.	Coordination with PCWP/ HCPWP	10
5.4.	Cooperation within the EU regulatory network	10
5.4.1.	Coordination with European Pharmacopoeia	10
5.4.2.	Herbal EU NTC curriculum: Draft principles and priorities for training	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
5.7.	Work plan	10
5.7.1.	HMPC work plan 2019	10
5.8.	Planning and reporting	11
5.8.1.	Move to EMA building, meeting dates Dec 2019, Jan 2020	11
5.9.	Legislation and regulatory affairs	11
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
6.2.	Revision of EU herbal monographs and list entries in preparation for public consultation.....	11
6.2.1.	Monograph on Trigonellae foenugraeci semen and supporting documents - postponed	11
6.2.2.	Monograph on Millefolii herba 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 Arctii radix and supporting documents.....	11
6.3.2.	Monograph on Filipendulae ulmariae flos and supporting documents - postponed	11
6.3.3.	Monograph on Filipendulae ulmariae herba and supporting documents - postponed	11
6.3.4.	Monograph on Juniperi aetheroleum and supporting documents - postponed.....	11
6.3.5.	Monograph on Juniperi pseudo-fructus and supporting documents - postponed	11
6.3.6.	Monograph on Orthosiphonis folium and supporting documents.....	11
6.3.7.	Monograph on Taraxaci folium and supporting documents	12
6.3.8.	Monograph on Taraxaci radix cum herba and supporting documents	12
6.3.9.	Monograph on Quercus cortex and supporting documents.....	12
6.3.10.	Monograph on Rosmarini aetheroleum and supporting documents - postponed.....	12
6.3.11.	Monograph on Rosmarini folium and supporting documents - postponed	12
6.3.12.	Monograph on Solidaginis virgaureae herba and supporting documents.....	12
6.3.13.	Monograph on Zingiberis rhizoma and supporting documents – request for unscheduled revision	12
6.4.	EU herbal monographs and list entries in preparation for adoption after public consultation.....	12
6.5.	EU herbal monographs and list entries in preparation for adoption for release for public consultation	12
6.5.1.	Monograph on Calendulae herba and supporting documents	12
6.5.2.	Monograph on Cisti cretici folium and supporting documents - postponed	12
6.5.3.	Monograph on Menyanthes trifoliata folium and supporting documents.....	12
6.5.4.	Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents.....	13
6.5.5.	Monograph on Salviae mitiorrhizae radix et rhizoma and supporting documents	13
6.5.6.	Monograph on Species amarae and supporting documents.....	13
6.5.7.	Monograph on Species sedativae and supporting documents.....	13
6.5.8.	Monograph on Vaccinii macrocarpi fructus and supporting documents	13
6.5.9.	Monograph on Verbenae citriodoraе folium and supporting documents	13
7.	Any other business	13
7.1.	Topics for discussion	13
7.1.1.	Develop a strategy for use of PhV data/tools in HMPC assessment	13
7.1.2.	PSUSA procedure for Pelargonii radix	13
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 23-25 September 2019. See September 2019 HMPC minutes (to be published post November 2019 HMPC meeting).

New nomination membership:

- IE, Sheena Kennedy (member) as of 01 September 2019
- LU, Clémence Varret (alternate) as of 06 August 2019
- DK, Karoline Holm Felding (alternate) as of 22 September 2019

End of membership:

- IE, Una Mockler (alternate) as of 30 July 2019
- LU, Jacqueline Genoux-Hames (alternate) as of 02 August 2019
- DK, Nina Durr (alternate) as of 21 September 2019

1.2. Adoption of agenda

HMPC agenda for 23-25 September 2019

Time schedule for 23-25 September 2019

1.3. Adoption of the minutes

HMPC minutes for 08-10 July 2019

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 September 2019

Report: HMPC Chair

Action: for discussion

Document: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Report: HMPC Chair

Action: for adoption

Documents: Presentation, Call for Rapporteurs/Peer Reviewers 2019-07-22, List A with volunteers

Rapporteur /PR transfer following new policy (step A Chairs to members/alternates):

New assessments

Cisti cretici folium - new Rapporteur

Menyanthis trifoliatae folium - new Peer-Reviewer

Saccharomyces cerevisiae CBS 5926 - new Peer-Reviewer

Allii sativi bulbus - new Peer-Reviewer

Pistacia lentiscus, resina (mastic) - new Rapporteur; new Peer-Reviewer

Species digestivae or species stomachicae - new Peer-Reviewer

Centellae asiaticae herba - new Peer-Reviewer

Reviews

Hamamelidis cortex - new Peer-Reviewer

Hamamelidis folium - new Peer-Reviewer

Hamamelidis destillatum - new Peer-Reviewer

Orthosiphonis folium - new Peer-Reviewer

Revisions

Frangulae cortex - new Peer-Reviewer

Hippocastani semen - new Peer-Reviewer

Menthae piperitae aetheroleum - new Peer-Reviewer

Menthae piperitae folium - new Peer-Reviewer

Rhamni purshianae cortex - new Peer-Reviewer

Rhei radix - new Peer-Reviewer

Foeniculi amari fructus - new Rapporteur

Foeniculi amari fructus aetheroleum - new Rapporteur

Foeniculi dulcis fructus - new Rapporteur

Guidelines

Public statement on contamination of HMP/THMP with pyrrolizidine alkaloids (PAs)
(EMA/HMPC/328782/2016)

2.1.3. [Andrographidis paniculatae herba in combination - possibility for monograph establishment](#)

Action: for adoption

Documents: Proposal to HMPC for assessment; References: 00/09

2.1.4. Public statement on Centellae asiaticae herba and supporting documents – possibility for monograph establishment

Action: for adoption

Document: Review report; References: 00/22

2.1.5. Monograph on Sabalis serrulatae fructus and supporting documents - request for unscheduled monograph revision

Action: for adoption

Documents: Briefing document, Presentation, References

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

2.2.1. Monograph on Frangulae cortex and supporting documents

Action: for adoption

Document: Draft MO, AR, LoR, OoC; References: 42/43

2.2.2. Monograph on Valerianae radix/Lupuli flos and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC, Readers guidance; References: 11/35

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

2.3.1. Monograph on Rhamni purshianae cortex and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 51/38

2.3.2. Monograph on Rhei radix and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 55/57

2.3.3. Monograph on Tanacetii parthenii herba and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 00/104

2.3.4. Monograph on Thymi aetheroleum and supporting documents

Action: for adoption

Documents: Draft MO, AR, LoR; References: 122/138

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

2.4.1. Monograph on Hamamelidis cortex and supporting documents

Action: for adoption

Document: Review report, Corrected MO; References: 00/02

2.4.2. Monograph on Hamamelidis folium and supporting documents

Action: for adoption

Document: Review report; References: 00/00

2.4.3. Monograph on Hamamelidis folium et cortex aut ramunculus destillatum and supporting documents

Action: for adoption

Document: Review report; References: 00/00

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

2.7.1. Monograph on Pistacia lentiscus, resinum (mastic) and supporting documents

Action: for adoption

Documents: MO, AR; presentation; References: 102/79

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 discussion

Documents: Draft revised PS; OoC; Presentations/recommendations from Rapporteurs;
Questions for finalisation

4.1.2. Public statement on the contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016) - postponed

4.1.3. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011) - postponed

4.2. Quality

None

4.3. Regulatory / Procedural

4.3.1. Procedure on management of proposals submitted by interested parties for EU List Entries or EU Herbal Monographs (EMA/HMPC/328575/2007 Rev.2)

Report: ORGAM DG Chair

Action: for adoption

Documents: Draft revised procedure, OoC, email correspondence

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

Finnish Presidency meeting – Czech Republic, Prague – 5-6 November 2019

Action: for discussion

Document: Draft Agenda, Registration form, Practical information, Invitation letter

5.1.2. Preparation for election of HMPC Chair

Action: for discussion

Documents: [HMPC RoP](#), Presentation

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information
Document: Draft Agenda

5.2.2. Coordination with PDCO/PRAC - postponed

- Discussion paper of age limitation of use of cough and cold herbal medicinal products in children

5.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

5.3.1. QRD Template – update of Addendum for THMP

Action: for discussion
Document: Proposals for template improvement, [Addendum to the Quality Review of Documents templates for SmPC](#) for THMPs

5.3.2. Coordination with PCWP/ HCPWP

Action: for adoption
Document: PCWP HCPWP Work plan 2019-2022

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13B expert group meetings

Action: for information
Document: SoD

5.4.2. Herbal EU NTC curriculum: Draft principles and priorities for training

Action: for discussion
Documents: Draft Herbal EU NTC curriculum, Draft curriculum principles, Draft curriculum priorities, Presentation

5.5. Cooperation with International Regulators

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

None

5.7. Work plan

5.7.1. HMPC work plan 2019

Report: HMPC Chair
Action: for information
Document: Work plan 2019, Annex 1, Annex 2 – current status September 2019

5.8. Planning and reporting

5.8.1. Move to EMA building, meeting dates Dec 2019, Jan 2020

Action: for discussion
Document: Presentation

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 Trigonellae foenugraeci semen and supporting documents - postponed

6.2.2. Monograph on Millefolii herba and supporting documents

Action: for discussion
Documents: Draft MO, LE, AR, LoR; New References: 08/08

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

6.3.1. Monograph on Arctii radix and supporting documents

Action: for discussion
Document: Review report; References: 58/33

6.3.2. Monograph on Filipendulae ulmariae flos and supporting documents - postponed

6.3.3. Monograph on Filipendulae ulmariae herba and supporting documents - postponed

6.3.4. Monograph on Juniperi aetheroleum and supporting documents - postponed

6.3.5. Monograph on Juniperi pseudo-fructus and supporting documents - postponed

6.3.6. Monograph on Orthosiphonis folium and supporting documents

Action: for discussion

Documents: Review report, supporting documents; References: 05/04

6.3.7. Monograph on Taraxaci folium and supporting documents

Action: for discussion

Document: Review report; References: 00/16

6.3.8. Monograph on Taraxaci radix cum herba and supporting documents

Action: for discussion

Document: Review report; References: 00/14

6.3.9. Monograph on Quercus cortex and supporting documents

Action: for discussion

Document: Review report; References: 18/10

6.3.10. Monograph on Rosmarini aetheroleum and supporting documents - postponed

6.3.11. Monograph on Rosmarini folium and supporting documents - postponed

6.3.12. Monograph on Solidaginis virgaureae herba and supporting documents

Action: for discussion

Document: Review report; References: 21/19

6.3.13. Monograph on Zingiberis rhizoma and supporting documents – request for unscheduled revision

Action: for 1st discussion

Document: Review report; References: 137/25

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 Calendulae herba and supporting documents

Action: for discussion

Documents: Draft PS, Draft AR, email communication, Draft preliminary MO, Comments from SE, [Uptake of the traditional use registration](#); References: 00/00

6.5.2. Monograph on Cisti cretici folium and supporting documents - postponed

6.5.3. Monograph on Menyanthes trifoliata folium and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 59/73

6.5.4. Monograph on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

Action: for discussion

Documents: Draft MO, Draft LE, Draft AR, Draft LoR; References: 02/188

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

Action: for discussion

Documents: Draft MO, AR, LoR, Additional information NL; References: 00/32

6.5.6. Monograph on *Species amarae* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/16

6.5.7. Monograph on *Species sedativae* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 35/44

6.5.8. Monograph on *Vaccinii macrocarpi fructus* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/18

6.5.9. Monograph on *Verbenae citriodoraе folium* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/22

7. Any other business

7.1. Topics for discussion

7.1.1. Develop a strategy for use of PhV data/tools in HMPC assessment

Action: for discussion

Documents: Presentation

7.1.2. PSUSA procedure for *Pelargonii radix*

Action: for discussion

Documents: MO, Presentation

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 23-25 September 2019

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 08-10 July 2019](#)

[Overview of status of HMPC assessment work – priority list](#)

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

[Abbreviations in HMPC agendas/minutes](#)

Common names of herbal substances in all languages

Overview of status of HMPC/MLWP assessment work

Final Monograph Overview

7.2.2. ARSP

- English template
- English summaries for publication

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

- Monograph on *Allii sativi bulbos* and supporting documents – unsolved post-adoption issues
- Monograph on *Foeniculi amari fructus* and supporting documents – awaiting Estragole PS finalisation
- Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents – awaiting Estragole PS finalisation
- Monograph on *Foeniculi dulcis fructus* and supporting documents – awaiting Estragole PS finalisation
- Monograph on *Menthae piperitae folium* and supporting documents – awaiting finalisation shared AR with *Menthae aetheroleum* for final adoption
Documents: MO, AR, LoR
- Monograph on *Species digestivae* or *species stomachicae* and supporting documents - awaiting Estragole PS finalisation

7.2.4. Other

- Draft programme: Borderline Products Workshop, 22–23 October 2019, Uppsala, Sweden
- PCWP/HCPWP meetings:
 - PCWP - Meeting Summary PCWP Plenary Meeting 24 Sep 2019
 - PCWP/HCPWP - Meeting Summary PCWP/HCPWP Joint Meeting 25 Sep 2019
 - HCPWP - Meeting Summary for the HCPWP Plenary Meeting 24 Sep 2019