



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/668124/2020
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Final Agenda for the meeting on 11-13 January 2021

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

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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 11-13 January 2021. See January 2021 HMPC minutes (to be published post March 2021 HMPC meeting).

New membership:

- Ireland, Sarah Kellaghan (member) as of 01 December 2020
- Denmark, Rahat Nazmi (alternate) as of 07 December 2020

1.2. Adoption of agenda

HMPC agenda for 11-13 January 2021.

Time schedule for 11-13 January 2021.

1.3. Adoption of the minutes

HMPC minutes for 16-18 November 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 January 2021

Report: HMPC Chair

Action: for discussion

Document: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Report: HMPC Chair

Action: for adoption

New Rapporteur-New Peer Reviewer (see also 5.7.2):

New assessments to start in 2021 (see also 5.7.1, activity area 1-3-2)

- Cnici benedicti herba
Documents: Proposal (PL), Supporting literature, Summary of proposals
- Cimicifugae rhizoma/ Hyperici herba
Documents: Proposal (AT), Summary of proposals

- Tribulus terrestris herba
Documents: Proposal (CZ), Summary of proposals

Periodic reviews to start in 2021

Monographs/LEs adopted in 2012

- Cucurbitae semen
- Fraxini folium
- Grindeliae herba
- Hippocastani cortex
- Levistici radix
- Liquiritiae radix
- Rhodiolae roseae rhizoma et radix
- Tiliae flos
- Urticae radix

Monographs/LEs adopted in 2013

- Camelliae sinensis non fermentatum folium
- Cichorii intybi radix
- Eucalypti folium
- Juglandis folium
- Marrubii herba
- Origani dictamni herba
- Paullinae semen
- Thymi herba

Monographs/LEs adopted in 2014

- Arnicae flos
- Curcumae xanthorrhizae rhizoma
- Eucalypti aetheroleum
- Ginseng radix
- Lichen islandicus

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 Orthosiphonis folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR, Reader's guidance; References: 09/46

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, Review of doses of herbal teas infusion or decoction;
References: 67/02

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

2.5.1. Monograph on *Aloysiae citriodora* folium and supporting documents

Action: for adoption

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

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

2.6.1. Public statement on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

Action: for adoption

Document for adoption: PS

Documents for discussion: LoR, AR; References: 2/214

2.6.2. Public statement on *Salviae miltiorrhizae* radix et rhizoma and supporting documents

Action: for adoption

Documents: PS, AR, LoR; References: 00/89; SE comments

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

Action: for adoption

Documents: MO, AR, LoR, Reader's guidance; References: 75/99

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 the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination of herbal MPs with PAs (EMA/[HMPC/893108/2011 Rev. 1](#))
-

Action: for discussion
Documents: [Draft PS](#), OoC

4.2. Quality

- 4.2.1. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/[HMPC/201116/2005 Rev. 3](#))
-

Action: for information
Documents: Draft revised Guideline, OoC, email correspondence, AT comments

- 4.2.2. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/[HMPC/162241/2005 Rev. 3](#))
-

Action: for information
Document: [Draft Guideline](#)

4.3. Regulatory / Procedural

- 4.3.1. HMPC Plenary Best Practice Guide
-

Action: for adoption
Document: HMPC Plenary Best Practice guide with annexed Reader's Guidance template

- 4.3.2. Regulatory Q&A on herbal medicinal products – update
-

Action: for discussion
Documents: New additional Q&A on use combination monographs; [Regulatory Q&A on herbal medicinal products](#)

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

- Portugal Presidency meeting – March 2021
Action: for information
Document: Topics for the Agenda
- Slovenia Presidency meeting – November 2021
Action: for information
Document: Cancellation of SRLM

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for discussion

Documents: Final Agenda 30 November 2020, Draft Agenda 14 December 2020,
Presentation from HMPC Chair

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

5.3.1. Public statement on the use of herbal medicinal products containing estragole

Action: for discussion

Documents: Questions to SWP, Final PS, OoC

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
- EDQM 13B expert group meeting
Report: M Bald
Action: for information
- EDQM TCM expert group meeting
Report: M Bald
Action: for information
- Joint EDQM-EMA forum
Action: for information
Document: Draft minutes

5.4.2. Coordination with the European Commission

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

5.5. Cooperation with International Regulators

5.5.1. IRCH – WHO 12th annual virtual meeting

Report: HMPC Chair
Action: for information
Documents: Report, Agenda, Participants list

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

5.6.1. AESGP

Report: HMPC Chair
Action: for adoption
Document: Summary of hearing held on 18 November 2020

5.6.2. EUCOPE

- Hearing to be held in March 2021
Report: HMPC Chair
Action: for discussion
Document: Request for hearing
- Digital Conference on the European Health Economy
Report: HMPC Chair
Action: for information
Documents: Questions on BW Event Session on Health claims; List of participants

5.7. Work plan

5.7.1. HMPC work plan 2020

Report: HMPC Chair, HMPC Vice Chair
Action: for discussion
Documents: Work plan 2020, Annex 1, Annex 2

- Activity area 1-3-1: Implementation of a modified procedure for EU herbal monograph establishment and maintenance
Report: HMPC Vice Chair
Action: for discussion
Document: PhV survey results
- Activity area 1-3-2: Forward planning and prioritisation
Report: HMPC Vice Chair

Action: for discussion

Documents: Summary of proposals, Draft New Template - Proposals for assessment by HMPC

- Activity area 2-1-3: Use of PhV, non-clinical and real-world data for HMPC relevant safety assessments

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

Documents: Presentations; Course description template

5.7.2. [Draft HMPC work plan 2021](#)

Report: HMPC Chair, HMPC Vice Chair

Action: for adoption

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

5.8. [Planning and reporting](#)

5.8.1. [Big Data Training Signpost](#)

Action: for discussion

Document: Presentation

5.8.2. [Introduction of new Executive Director Emer Cooke](#)

Action: for discussion

Document: Oral Presentation

5.9. [Legislation and regulatory affairs](#)

None

5.10. [Questions from members](#)

5.10.1. [Nitrosamines and HMPs](#)

Action: for discussion

Documents: CMDh practical guidance for Marketing Authorisation Holders; Question from AT

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 *Foeniculi amari fructus* and supporting documents

Action: for discussion

Document: See 6.2.3; References: 00/00

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

Action: for discussion

Document: See 6.2.3.; References: 00/00

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

Action: for discussion

Document: Presentation; References: 00/00

6.2.4. Monograph on *Hyperici herba* and supporting documents

Action: for discussion

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

6.2.5. Monograph on *Juniperi pseudo-fructus* and supporting documents - postponed

6.2.6. Monograph on *Lavandulae aetheroleum* and supporting documents - postponed

6.2.7. Monograph on *Pelargonii radix* and supporting documents - postponed

6.2.8. Monograph on *Sabalis serrulatae fructus* and supporting documents

Action: for discussion

Document: Reader's guidance

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

Action: for discussion

Documents: Draft MO, AR, LoR; References: 08/100

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

Document: Review report; References: 00/02

6.3.2. Monograph on Cinnamomi cortex and supporting documents

Action: for discussion

Document: Review report; References: 00/12

6.3.3. Monograph on Colae semen and supporting documents - postponed

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, Reader's guidance, Presentation; References: 00/16

6.3.6. Monograph on Mate folium and supporting documents

Action: for discussion

Documents: Review report, email correspondence; References: 00/34

6.3.7. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: for discussion

Document: Review report; References: 00/09

6.3.8. Monograph on Rosmarini aetheroleum and supporting documents

Action: for discussion

Documents: Review report, Presentation; References: 05/05

6.3.9. Monograph on Rosmarini folium and supporting documents

Action: for discussion

Documents: Review report, Presentation; References: 08/08

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

Action: for discussion

Document: Review report; References: 33/19

6.3.11. Monograph on *Urticae folium* and supporting documents

Action: for discussion

Document: Review report; References: 08/11

6.3.12. Monograph on *Urticae herba* and supporting documents

Action: for discussion

Document: Review report; References: 07/06

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

Action: for discussion

Documents: Review report, email correspondence; References: 28/25

6.3.14. Monograph on *Zingiberis rhizoma* and supporting documents

Action: for discussion

Document: Presentation

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 *Andrographidis paniculatae folium* and supporting documents - postponed

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

Action: for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 00/216

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

Action: for discussion

Documents: Draft MO, AR, LoR; References: 00/50

6.5.4. Monograph on Species digestivae or species stomachicae and supporting documents

Action: for discussion

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

6.5.5. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 475/249

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 16-18 November 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
 - Species amarae
 - Species sedativae

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

None

7.2.4. Other
