30 April 2020
EMA/HMPC/239419/2020
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda for the meeting on 4-6 May 2020

Chair: E. van Galen Vice-Chair: vacant

4 May 2020, 10:00 – 17:00, virtual meeting

5 May 2020, 09:00 – 17:00, virtual meeting

6 May 2020, 09:00 – 15:00, virtual meeting

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 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).

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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 4-6 May 2020. See May 2020 HMPC minutes (to be published post July 2020 HMPC meeting).

Swap of roles:

- CZ, Marketa Prihodova (member) as of 10 March 2020
- CZ, Marie Heroutova (alternate) as of 10 March 2020
- NL, Burt Kroes (member) as of 29 April 2020

End of membership:

- IT, Alessandro Assisi (member) as of 8 March 2020

1.2. Adoption of agenda

HMPC agenda for 4-6 May 2020

Time schedule for 4-6 May 2020

1.3. Adoption of the minutes

HMPC minutes for 2-4 March 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 May 2020

Report: HMPC Chair
Action: for discussion
Document: Overview

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New assessments
Salviae mitiorrhizae radix et rhizoma – New Peer reviewer

Reviews
Centaurii herba – New Rapporteur
Curcumae longae rhizoma – New Rapporteur
Curcumae xanthorrhizae rhizoma – New Rapporteur

Revisions

Bursae pastoris herba – New Peer reviewer

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

2.2.1. Monograph on Rhamni purshianae cortex and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 51/41

2.2.2. Monograph on Rhei radix and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC; References: 55/62

2.2.3. Monograph on Tanaceti parthenii herba and supporting documents

Action: for discussion
Documents: MO, AR, LoR; References: 0/108; Question to patient representatives, comments from patient representatives

2.2.4. Monograph on Thymi aetheroleum and supporting documents - postponed

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 Filipendulae ulmariae herba and supporting documents

Action: for adoption
Documents: Review report; References: 15/15

2.4.2. Monograph on Filipendulae ulmariae flos and supporting documents

Action: for adoption
Documents: Review report; References: 0/3

2.4.3. Monograph on Pelargonii radix and supporting documents

Action: for adoption
Documents: Review report; References: 0/6

2.4.4. Monograph on Sabalis serrulatae fructus and supporting documents

Action: for adoption
Documents: Review report, Readers guidance; References: 15/1

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 Menyanthes trifoliata folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR, Readers guidance; References: 46/74

2.6.2. Monograph on Aloysiae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 0/31

2.6.3. Monograph on Species amarae and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 10/21

2.6.4. Monograph on Species sedativae and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 36/22

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 contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)

Action: for discussion
Document: see 4.1.2.

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

Action: for discussion

Document: Revised combined public statement

4.2. Quality

4.2.1. 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 discussion

Documents: Revised Guideline, OoC

4.2.2. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)

Action: for discussion

Documents: Revised Guideline, OoC

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. Revised CxMP Rules of Procedure for emergency situations

Action: for adoption

Documents: Revised Rules of Procedure, Comparative table

5.1.2. Election of HMPC Vice-Chair

Action: for adoption

Documents: Call for candidates, HMPC RoP, Candidatures

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information

Documents: Agenda dated 17 April 2020, Draft agenda for 07 May 2020

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

5.3.1. QRD Template – update of Addendum for THMP

Action: for discussion
Documents: Proposal for Update of the Addendum, Addendum to the Quality Review of Documents templates for SmPC for THMPs

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
  Document: SoD March 2020
- EDQM PA expert group meetings
  Action: for adoption
  Documents: Draft method for determination of Pyrrolizidine Alkaloids published in Pharmeuropa; draft comments

5.4.2. Herbal EU NTC curriculum

Action: for information
Document: Course description template

5.4.3. Coordination with the European Commission

- Planned COMMISSION REGULATION (EU) amending Annex III to Regulation (EC) No 1925/2006 as regards botanical species containing hydroxyanthracene derivatives
  Report: HMPC Chair
  Action: for discussion
  Document: Draft HMPC comments
- Cannabis for medicinal use
  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

None

5.7. Work plan

5.7.1. HMPC work plan 2020

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

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

5.9.1. Impact of Brexit on traditional and well-established use evidence

Action: for discussion
Documents: Email correspondence dated 10 February 2020, market overview template

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 Millefolii herba and supporting documents - postponed

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 - postponed

6.2.2. Monograph on Trigonellae foenugraeci semen and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR, References 0/98

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

6.3.1. Monograph on Juniperi aetheroleum and supporting documents

Action: for discussion
Documents: Review report; References: 7/6

6.3.2. Monograph on Juniperi pseudo-fructus and supporting documents

Action: for discussion

Documents: Review report; References: 10/10

6.3.3. Monograph on Solidaginis virgaureae herba and supporting documents - postponed

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

6.4.1. Monograph on Herniariae herba and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, OoC, Readers guidance; References: 35/24

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

6.5.1. Monograph on Centellae asiaticae herba and supporting documents - postponed

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

6.5.3. Monograph on Salviae miltiorrhizae radix et rhizoma and supporting documents - postponed

6.5.4. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 51/234

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 2-4 March 2020

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 2-4 March 2020

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

Final Monograph Overview

7.2.2. ARSP

- English template
- English summaries for publication
  - none

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

- Monograph on Allii sativi bulbus and supporting documents
  Documents: MO, AR, LoR
- Monograph on Foeniculi amari fructus and supporting documents
- 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 Species digestivae or species stomachicae and supporting documents - awaiting Estragole PS finalisation

7.2.4. Other

- CMDh practical guidance for Marketing Authorisation Holders of nationally authorised products (incl. MRP/DCP) in relation to the Art. 5(3) Referral on Nitrosamines (March 2020, CMDh/412/2019, Rev.4; Q&A 1.5 regarding THMPs)