



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 July 2018
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Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 23-24 July 2018

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

23 July 2018, 14:00 – 19:00, 2F

24 July 2018, 09:00 – 13:00, 2F

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 23-24 July 2018. See July 2018 HMPC minutes (to be published post September 2018 HMPC meeting).

End of membership (UK): Sue Harris (alternate); End of mandate: 27 June 2018

New membership (Romania): Ligia Elena Dutu alternate; Start of mandate: 21 June 2018

1.2. Adoption of agenda

HMPC agenda for 23-24 July 2018

Time schedule for 23-24 July 2018

1.3. Adoption of the minutes

HMPC minutes for 04-05 June 2018

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Appointment of Rapporteurs and Peer-reviewers

Changes of Rapporteurs for MO review

Millefolii flos and Millefolii herba - Rapporteur

Phaseoli fructus (sine semine) – Co-Rapporteur

2.1.2. Report from the MLWP June 2018 meeting

Report: MLWP Chair/MLWP Vice-Chair

Action: for information

Document: Draft minutes for the MLWP meeting on 05-07 June 2018

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

2.2.1. Monograph on Curcumae longae rhizoma and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 00/132

2.2.2. Monograph on Sennae folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC; References: 173/217

2.2.3. Monograph on Sennae fructus and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC; References: 173/217

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 Myrrhra (Commiphora molmol) and supporting documents

Action: for adoption

Document: Review outcome; References: 09/09

2.4.2. Monograph on Trigonellae foenugraeci semen and supporting documents

Action: for adoption

Document: Review outcome; References: 30/30

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 Agni casti fructus and supporting documents

Action: for discussion

Documents: MO, AR, LoR; References: 109/98

2.7.2. Monograph on Pistacia lentiscus, resinum (mastix) and supporting documents

Action: for discussion

Documents: MO, AR, LoR; References: 73/73; Presentation

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; Comments from SE; SWP subgroup comments; Presentation

4.2. Quality

None

4.3. Regulatory / Procedural

4.3.1. Procedure for the review and revision of European Union herbal monographs and European Union list entries (EMA/HMPC/124695/2011 Rev.2)

Action: for adoption

Documents: Draft procedure; Review outcome template; OoC

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair

- Meeting report from Q DG virtual meeting held on 21 Jun 2018
Action: for adoption
Document: Meeting report
- Draft agenda for the Q DG virtual meeting to be held 06 Sep 2018
Action: for information
Document: Draft agenda

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report from ORGAM DG virtual meeting held on 18 Jun 2018
Action: for adoption
Document: Meeting report
- Agenda ORGAM DG meeting to be held on 04 Sep 2018
Action: for information
Document: Draft agenda

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings

Austria Presidency meeting – Vienna, 15-17 Oct 2018

Action: for discussion

Document: Revised Draft Agenda; Invitation; Practical information

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information

Documents: Minutes 03 May 2018; Agenda 16 July 2018; HMPC Chair remarks

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 the European Commission

- Clarification of classification on *Saccharomyces cerevisiae* CBS 5926
Action: for discussion
Documents: Draft MO, LE, AR, LoR

5.4.2. Coordination with European Pharmacopoeia

- EDQM 13A expert group meetings
Action: for information
Document: SoD
- EDQM 13B expert group meetings
Action: for information
Document: SoD
- EDQM TCM expert group meetings
Action: for information
Document: SoD
- EDQM PA working party
Document: SoD

5.4.3. Understanding the training needs of NCA assessors involved in the work of the HMPC: Priority needs and plans for training 2018 – 2020

Action: for information

Document: Presentation

5.4.4. EMA Implementation Plan of the new medical device and in vitro diagnostic regulation

Action: for discussion

Document: Presentation

5.5. Cooperation with International Regulators

5.5.1. EU – India/AYUSH communication

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

5.6.1. Question on HMPC assessment and national monograph use

Report: HMPC Chair

Action: for adoption

5.7. Work plan

5.7.1. HMPC work plan 2018

Report: HMPC Chair

Action: for information

Document: Work plan 2018 – current status July 2018

- 1.3.2. Activity area: Forward planning and prioritisation

Action: for discussion

- 1.3.3. Activity area: Coordination on safety assessments of herbal constituents
 - Public statement on Contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (PAs) (EMA/HMPC/328782/2016)
 - Reflection paper on Polycyclic Aromatic Hydrocarbons

Action: for discussion

Documents: Presentation; EFSA statement June 2017: Risks for human health related to the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

5.9.1. WEU/Bibliographic application regarding Art. 10a Dir. 2001/83/EC for HMPs – Reference to other products

Report: HMPC Chair

Action: for discussion

6. Any other business

6.1. Topics for discussion

None

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 04-05 June 2018

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 04-05 June 2018](#)

[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

6.2.2. MLWP

- Overview of status of HMPC/MLWP assessment work

6.2.3. ARSP

- English template
- English summaries for publication:
 - Pale coneflower root
 - Evening primrose
 - Pelargonium root

6.2.4. Other

- EU herbal monographs, list entries and public statements post adoption
 - Allii sativi bulbus: Scientific literature compilation and open questions; post adoption delays (MO, AR, LoR, OoC)
 - Cynarae: post adoption delays (MO, AR, LoR)
- 6th Annual GP-TCM meeting at Royal Kew Gardens, London on 6 June – Symposium programme
- Paediatric Overview (2017 update)

6.2.5. Feedback on national experiences with HMPC monographs and guidelines

- draft template

- summary feedback

6.2.6. [Workshop on Pyrrolizidine Alkaloids, 12-13 September 2018 \(see also 5.7.1.\)](#)

Report: HMPC Chair

Documents: Agenda; Registration form

6.2.7. [Annual Meeting of International Regulatory Cooperation for Herbal Medicines \(IRCH\), WHO, 07-09 December 2018](#)

Report: HMPC Chair