21 September 2018
EMA/HMPC/650626/2018
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 24-25 September 2018

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

24 September 2018, 14:00 – 19:00, 2F

25 September 2018, 09:00 – 13:00, 2F

(AESGP hearing at MLWP: 25 September 2018, 14.00 – 16.00, Room 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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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 24-25 September 2018.

End of membership (IE): Rachel Cox (alternate); End of mandate: 03 August 2018

1.2. Adoption of agenda

HMPC agenda for 24-25 September 2018

Time schedule for 24-25 September 2018

1.3. Adoption of the minutes

HMPC minutes for 23-24 July 2018

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. 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

None

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 Cynarae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; Presentation

3. Referral procedures

None

4. Guidelines and guidance documents

4.1. Non-clinical/clinical safety and efficacy and multidisciplinary

4.1.1. Guideline on non-clinical documentation in applications for marketing authorisation/registration of well-established and traditional herbal medicinal products (EMEA/HMPC/32116/2005 Rev.1)

Action: for adoption
Documents: Revised Guideline, OoC

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

Action: for adoption
Documents: Draft revised PS, OoC; SWP subgroup comments; Presentation

4.2. Quality

4.2.1. Q&A on elemental impurities - evaluation in herbal medicinal products

Report: HMPC Chair

Action: for adoption
Document: Draft Q&A

4.3. Regulatory / Procedural

4.3.1. Template for information exchange for the preparation of the assessment report supporting the establishment of European Union monographs and European Union list entries (EMA/HMPC/137093/2006 rev.2)

Report: ORGAM DG Chair
Action: for adoption
Document: Draft revised template

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: HMPC Chair

- Meeting report from Q DG virtual meeting held on 06 Sep 2018
  Action: for adoption
  Document: Meeting report

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report from ORGAM DG virtual meeting held on 04 Sep 2018
  Action: for adoption
  Document: Meeting report

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
- SRLM meetings in 2019
  Action: for discussion

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair
Action: for information
Documents: Agenda 10 September 2018

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

5.3.1. Coordination with PDCO/PRAC

- Discussion paper on necessary data for contraindication for use in children
  Action: for discussion
  Document: Draft Discussion paper

5.3.2. Coordination with QWP

- Herbal specific addition to Q&A ' How to use a CEP'
  Action: for discussion
  Document: Comment on Draft Q&A

5.3.3. Information for the package leaflet regarding ethanol used as an excipient in medicinal products for human use

Action: for discussion
Document: Report (Annex to excipient guideline EMA/CHML/43486/2018)

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with the European Commission

- Clarification of classification on Saccharomyces cerevisiae CBS 5926
  Report: HMPC Chair
  Action: for discussion
  Documents: EMA letter to EC, EC response, Draft MO, draft LE, draft AR, draft LOR

- AESGP proposal on the simplification of variations specific to herbal medicinal product
  Report: HMPC Chair
  Action: for discussion
  Document: AESGP proposal on the simplification of variations specific to herbal medicinal product

5.4.2. Coordination with European Pharmacopoeia

- EDQM expert group meetings
  Action: for information
  Document: Agenda 13B

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 discussion
Document: Presentation

5.5. Cooperation with International Regulators

5.5.1. AYUSH information on Indian medicinal plants

Report: AYUSH experts
Action: for discussion
Document: Presentation

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

5.6.1. AESGP – hearing at MLWP September 2018

Report: MLWP Chair
Action: for discussion
Document: Draft Agenda with List of participants

5.7. Work plan

5.7.1. HMPC work plan 2018

Report: HMPC Chair
Action: for information
Document: Work plan 2018 – current status September 2018

- 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)

Action: for discussion
Document: Presentation

5.7.2. HMPC work plan 2019

Report: HMPC Chair
Action: for discussion
Document: Draft Work plan 2019

5.8. Planning and reporting

5.8.1. HMPC meeting dates 2019

Report: HMPC Chair
Action: for discussion
Document: Presentation

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
Documents: Guideline on the assessment of clinical safety and efficacy; Regulatory Q&A

6. Any other business

6.1. Topics for discussion

6.1.1. Management of references for the review and revision of EU herbal monographs and EU List entries

Action: for discussion
Document: Presentation

6.1.2. EU Telematics strategy 2020-2025

Action: for discussion
Documents: Presentation; Concept Paper

6.1.3. New PhV information on herbal substances relevant for HMPC assessment

Action: for discussion
Document: Presentation

6.1.4. Regulatory Science Engagement Plan to 2025

Action: for discussion
Document: Presentation

6.1.5. Workshop on Pyrrolizidine Alkaloids (PAs)

Action: for discussion
Document: Agenda

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 23-24 July 2018

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 23-24 July 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

6.2.4. Other

- Article on NICE guideline; draft NICE guideline- Cough(acute): antimicrobial prescribing
- 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)
  - Pistacia lentiscus, resinum (mastic) (MO, AR, LoR)

6.2.5. Feedback on national experiences with HMPC monographs and guidelines

- draft template
- summary feedback

6.2.6. Annual Meeting of International Regulatory Cooperation for Herbal Medicines (IRCH), WHO, 07-09 December 2018

Report: HMPC Chair

6.2.7. CZ request regarding classification of β-glucan isolated from Pleurotus ostreatus