21 March 2018
EMA/HMPC/188141/2018 - ver.3
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 26-27 March 2018

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

26 March 2018, 14:00 – 19:00, 2F

27 March 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 26-27 March 2018. See March 2018 HMPC minutes (to be published post May 2018 HMPC meeting).

1.2. Adoption of agenda

HMPC agenda for 26-27 March 2018

Time schedule for 26-27 March 2018

1.3. Adoption of the minutes

HMPC minutes for 29-30 January 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 Monograph revision

2.1.2. Report from the MLWP January 2018 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on 30 January - 01 February 2018

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

2.2.1. Monograph on Agni casti fructus and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 00/98

2.2.2. Monograph on Calendulae flos and supporting documents

Action: for adoption
Documents: MO, AR, LoR, LE; References: 01/93

2.2.3. Monograph on Cimicifugae rhizoma

Action: for adoption
Documents: MO, AR, LoR, OoC; References: 49/145

2.2.4. Monograph on Cynarae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 00/115

2.2.5. Monograph on Sambuci flos and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 03/31

2.2.6. Monograph on Verbasci flos and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 04/44

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

2.3.1. Monograph on Gentianae radix and supporting documents

Action: for adoption
Documents: Draft MO, AR, LoR; References: 08/47

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

2.4.1. Silybi mariani fructus and supporting documents

Action: for discussion
Documents: MO, AR, LoR, OoC

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

2.5.1. Monograph on Fragariae folium and supporting documents

Action: for adoption
Documents: Draft MO, AR, LoR; References: 18/124

2.5.2. Monograph on Malvae folium and supporting documents

Action: for adoption
Documents: Draft MO, AR, LoR; References: 00/119

2.5.3. Monograph on Malvae sylvestris flos and supporting documents

Action: for adoption
Documents: Draft MO, AR, LoR; References: 00/119

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

2.6.1. Monograph on Avenae fructus and supporting documents

Action: for adoption
Documents: Review outcome; References: 00/63

Action: for information
Documents: MO, AR, LoR

2.6.2. Monograph on Avenae herba and supporting documents

Action: for adoption
Documents: Review outcome; References: 00/63

Action: for information
Documents: MO, AR, LoR

3. Referral procedures

None

4. Guidelines and guidance documents

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

None

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 – postponed for May 2018

Report: QDG Chair

4.2.2. Guideline on quality of herbal medicinal products[1]/traditional herbal medicinal products (EMA/HMPC/201116/2005) Rev. 3 – postponed for May 2018

Report: QDG Chair

4.2.3. Guideline on quality of water for pharmaceutical use (EMA/150605/2018)

Action: for discussion
Documents: Guideline; Presentation; Concept paper

[1] Throughout the guideline and unless otherwise specified, the term "herbal medicinal product" (HMP) includes "traditional herbal medicinal product" (THMP).
The terms "herbal substance" and "herbal preparation" should be considered as equivalent to the terms "herbal drug" and "herbal drug preparation" as defined in the European Pharmacopoeia.

4.3. Regulatory / Scientific

4.3.1. Procedure for calls for scientific data for use in HMPC assessment works (EMA/HMPC/1004/2006 Rev. 4)

Report: ORGAM Chair
Action: for adoption
Document: Procedure

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: QDG Chair

- Meeting report from Q DG face to face meeting held on 22 Feb 2018
  Action: for adoption
  Document: Meeting report
- Draft agenda for the Q DG virtual meeting to be held 19 Apr 2018
  Action: for information
  Document: Draft agenda
- Nomination for new observers at QDG
  Action: for adoption
  QDG mandate

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report from ORGAM virtual meeting held on 14 Mar 2018
  Action: for adoption
  Document: Meeting report
- Agenda ORGAM DG meeting to be held on 23 Apr 2018
  Action: for information
  Document: Draft agenda

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Election of Co-opted member

Report: HMPC Chair
Action: for adoption
Documents: Expertise of HMPC members; Call for nominations from 28 Feb 2018

5.1.2. Timing of Chair elections

Action: for discussion

Document: Presentation

5.1.3. Strategic Review and Learning Meetings

Report: HMPC Chair, HMPC Vice-chair
Austria Presidency meeting – Vienna, 15-17 Oct 2018
Action: for discussion
Document: Draft Agenda

5.1.4. Organisation of HMPC-MLWP during 2018-2019

Action: for discussion
Document: Presentation

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 11 Dec 2017; Agenda 12 Mar 2018; Minutes 12 March 2018

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 European Pharmacopoeia

- EDQM 13A expert group meeting to be held on 6-7 March 2018
  Action: for information
  Document: Agenda, SoD

- EDQM 13B expert group meeting held on 23-24 Jan 2018
  Action: for information
  Document: SoD

- EDQM TCM expert group meeting to be held on 24-25 January 2018
  Action: for information
  Document: SoD

- EDQM PA working party

5.4.2. Coordination with EFSA

None

5.5. Cooperation with International Regulators

5.5.1. EU – India/AYUSH communication

Action: for discussion
Document: Information from AYUSH dated 16 March 2018; Letter dated 16 March 2018

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

5.6.1. Requests by Interested Parties

- Requests for hearing by EUROCAM
  Report: HMPC Chair
  Action: for information
  Document: email communication

- Request for IP status by ECHAMP
  Report: HMPC Chair
  Action: for information
  Document: Request dated 18 Jan 2018

5.6.2. Question on HMPC assessment and national monograph use

Report: HMPC Chair
Action: for discussion
Document: Draft letter dated 25 Jan 2018; Hederae helicis folium MO, AR, LoR; Literature

5.7. Work plan

5.7.1. HMPC work plan 2018

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

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

6. Any other business

6.1. Topics for discussion

6.1.1. Questions from NCAs on Public statement on pyrrolizidine alkaloid contaminations

Action: for discussion

Documents: Response to questions received in May 2017; HMPC response dated 15 Mar 2018; Literature

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 29-30 January 2018

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 29-30 January 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
- Draft agenda of MLWP meeting to be held on 27-28 March 2018

6.2.3. ARSP

- English template
- English summaries for publication:
  - Uvae Ursi

6.2.4. Other

- PCWP/HCPWP meetings:
  - Draft Agenda of the PCWP/HCPWP joint meeting – 17-18 April 2018
  - Draft PCWP/HCPWP Work Plan for 2018-2019
- HMPC comments on Ethanol used as an excipient in medicinal products for human use submitted on 23 Feb 2018
- HMPC comments on EFSA Safety assessment of green tea submitted on 23 Feb 2018
- HMPC request to EC on Clarification on classification on Saccharomyces cerevisiae CBS 5926 submitted on 30 Jan 2018
- EFSA opinion on: Human acute exposure assessment to tropane alkaloids
- Proposed Q&A from EC for NTA on traditional 15 years of use
- Critical evaluation of causality assessment of herb–drug interactions in patients
- EU herbal monographs, list entries and public statements post adoption
  - Remaining publication delays:
    - Allii sativi bulbus

- Pistacia lentiscus (mastix)

6.2.5. Feedback on national experiences with HMPC monographs and guidelines

- draft template
- summary feedback, examples feedback received