27 May 2016
EMA/HMPC/373146/2016
Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda for the meeting on 30-31 May 2016

Chair: Werner Knöss – Vice-Chair: Marisa Delbò

30 May 2016, 14:00 – 19:00, 3E

31 May 2016, 09:00 – 13:00, 3E

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 30-31 May 2016. See May 2016 HMPC minutes (to be published post July 2016 HMPC meeting).

New member (Slovakia): Miroslava Petríková; Starting date of mandate: 21 April 2016

1.2. Adoption of agenda

HMPC agenda for 30-31 May 2016

Time schedule for 30-31 May 2016

1.3. Adoption of the minutes

HMPC minutes for 4-5 April 2016

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP April 2016 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on the 6-7 April 2016

2.1.2. Nominations for new MLWP member

Report: HMPC Chair
Action: for discussion
Documents: Mandate of MLWP; "Call for nominations", 29 April 2016; DE nomination

2.1.3. New observer at MLWP – Swissmedic

Action: for information
Documents: Observers summary for Committees and WPs; Observers at EMA meetings; CV N. Rickenbacher

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

None

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

2.4.1. Public statement on Balsamum peruvianum

Rapporteur: P. Claeson; Peer-reviewer: W. Knöss
Action: for adoption
Documents: PS, AR, LoR, references: 34/34

2.4.2. Public statement on Salviae fruticosae folium

Rapporteur: C. Cavaleiro; Peer-reviewer: I. Chinou
Action: for adoption
Documents: PS, AR, LoR, references: 21/26

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

2.5.1. Monograph on Allii sativi bulbus and supporting documents – postponed

2.5.2. Monograph on Cisti cretici folium and supporting documents – postponed

2.5.3. List Entry and Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents – postponed

2.5.4. Public statement on Silybi mariani fructus and supporting documents

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

3. Referral procedures

None

4. Guidelines and guidance documents

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

4.1.1. Reflection paper on herbal medicinal products containing polycyclic aromatic hydrocarbons (PAH)

Action: for adoption
Documents: Draft reflection paper; EU Court of Justice Case T-14/06

4.2. Quality

4.2.1. Recommendations on contaminations with pyrrolizidine alkaloids (PAs) in herbal medicinal products

Report: P. Claeson, L. Anderson, I. Chinou, H. Foth, B. Kroes, R. Länger, J. Wiesner
Action: for adoption
Documents: Draft public statement; Comments from DE; Break out session PA 06/04/2016 summary; Draft Lines to take; HMPC Chair presentation at Inspectors working group (GMDP IWG) in May 2016; Inspectors feedback; ES comments and email received 27 May 2016

4.3. Regulatory

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair
Action: for adoption
Documents: Meeting report from Q DG meeting held on 4 May 2016; QDG proposals for guideline revisions to address PAs

Action: for information
Document: Draft agenda for the Q DG meeting to be held on 30 June 2016

4.4.2. ORGAM DG

Report: ORGAM DG Chair

Action: for adoption
Document: Meeting report from ORGAM DG meeting held on 3 May 2016

Action: for information
Document: Draft agenda for the ORGAM DG meeting to be held on 28 June 2016

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Mandate of Quality DG and expression of interest for members/observers

Action: for discussion
Documents: Overview of QDG member interests; New nominations; New draft mandate

5.1.2. Assessors Training 3-4 November 2016

Report: S. Bager
Action: for discussion
Document: Draft Agenda

5.1.3. Strategic Review and Learning Meetings

Report: HMPC Chair; E. van Galen
Action: for discussion
Documents: Presentations; Email from HMPC Chair, 26 May 2016; Summary in presentation; Transfer from Utrecht – Follow up

5.1.4. Procedural guidance – minor revision of procedure for calls for scientific data

Action: for adoption
Document: Procedure for calls for scientific data for use in HMPC assessment work (EMA/HMPC/1004/2006 Rev 5)

5.1.5. Revision of Procedure for nomination and appointment of co-opted members in CHMP, CVMP and HMPC

Action: for adoption
Document: Procedure for nomination and appointment of co-opted members in CHMP, CVMP and HMPC

5.1.6. DG meeting dates 2017

Action: for adoption
Document: DG dates for 2017

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Coordination with CHMP: drafting group on excipients: ethanol as an excipient

Rapporteurs: J. Wiesner, S. Girotto
Action: for information

5.2.2. Coordination with CHMP/SWP - Public statement on the use of herbal medicinal products containing pulegone/menthofuran

Rapporteur: J. Wiesner
Action: for discussion
Documents: PS; OoC; CHMP Safety Working Party response to HMPC/CHMP questions on Pulegone and Menthofuran

5.2.3. Coordination with CMDh – Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual recognition and Decentralised procedures for (T)HMPs

Report: ORGAM Chair
Action: for adoption
Document: Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual recognition and Decentralised procedures for (T)HMPs (EMA/HMPC/770889/2014)

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

5.3.1. Coordination with PCWP/HCPWP

Observer: S. Bager

- EMA PCWP/HCPWP session on communication and information on medicines, 8 March 2016 – postponed
- EMA PCWP/HCPWP joint meeting, 9 March 2016 – postponed
- Patient involvement within EMA/HMPC
  Action: for adoption
  Document: Patient involvement within EMA/HMPC
- Nomination of HMPC representative at the HCPWP & PCWP
  Action: for adoption
  Document: Letter to the Chair of the HMPC, 11 May 2016

5.3.2. Coordination with Innovation Task Force and CHMP

Action: for discussion
Documents: European Commission's note to EMA, 13 May 2016; Annex

5.3.3. Joint CVMP/CHMP ad hoc expert group meeting on 3Rs (JEG 3Rs = Replacement, Reduction, Refinement)

Report: J. Wiesner, G. Laekeman
Action: for discussion
Document: Meeting report, 30 March 2016

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13A expert group meeting to be held on 8-10 June 2016
  EDQM: M. Bald; HMPC Observer: I. Chinou
  Action: for information
  Document: Draft Agenda
- EDQM 13B expert group meeting held on 19-20 April 2016
  EDQM: M. Bald; HMPC Observer: H. Neef
  Action: for information
  Document: Summary of discussion
- EDQM TCM expert group meeting held on 26-27 April 2016
  EDQM: M. Bald; HMPC Observer: R. Länger
  Action: for information
  Document: Summary of discussion

5.4.2. HMPC comments to EDQM on CEPs for herbal active ingredients

Report: QDG Chair
Action: for discussion
Document: Milk Thistle dry extract – Indena – List of marketed products & list of submitted ASMFs

5.4.3. Request to EDQM for development of a method for pyrrolizidine alkaloids (PAs)

Report: QDG Chair, HMPC Chair
Action: for discussion
Document: Letter from HMPC Chair, 12 May 2016

See also 4.2.1

5.4.4. Survey on uptake of the traditional use registration and implementation of Directive 2004/24/EC in EU Member States, 2015

Action: for discussion
Documents: Presentation; EMA/HMPC/322570/2011 Rev. 6

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

5.6.1. Hearing with AESGP at MLWP April meeting

Report: HMPC Chair, MLWP Chair
Action: for adoption
Document: Draft hearing report

5.6.2. Request to AESGP regarding data on pyrrolizidine alkaloids (PAs)

Report: HMPC Chair, P. Claeson
Action: for discussion
Documents: Letter on 'Data on contamination of herbal medicinal products with PA', 21 April 2016; AESGP response letter; BAH code of practice

See also 4.2.1

5.7. HMPC work plan

5.7.1. Projects on the HMPC work plan 2016

Action: for discussion
Document: Work plan 2016 – current status, HMPC work plan tracking tool 2016

- Harmonisation of assessment practice for herbal substances of non-European origin
  Report: E. van Galen
  Action: for discussion
  Document: Draft list of Ayurvedic herbs

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

5.9.1. Request for clarification on acceptable period for traditional use for products marketed in new Member States

Report: L. Anderson
Action: for discussion
Document: Request, 17 May 2016

6. Any other business

6.1. Topics for discussion

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 4-5 April 2016

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 4-5 April 2016

Overview of status of HMPC assessment work – priority list

Inventory of herbal substances for assessment work – alphabetical order

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 31 May-2 June 2016

6.2.3. ARSP

- English summaries for publication
  Documents: Thyme-primula; Hawthorn leaf and flower; Sandy everlasting; Knotgrass
- English template

6.2.4. Other

- Response letter from HMPC Chair, 24 May 2016 to European Commission – Clarification on establishment of List entries (Melaleuca)
- Minghetti P, Franzè S, Zaccara V, Raso F, Morazzoni P.: "Innovation in Phytotherapy: Is a New Regulation the Feasible Perspective in Europe?" Planta Med 2016, 82(7):591-595