28 March 2017
EMA/HMPC/220735/2017 Corr.[1]
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 30-31 January 2017

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

30 January 2017, 14:00 – 19:00, 2F

31 January 2017, 09:00 – 17:00, 2F

Disclaimers

Some of the information contained in this set of minutes is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this set of minutes 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).

[1] Correction in participant list

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room).

End of membership (Sweden): Erika Svedlund alternate; End date of mandate: 1 January 2017

New European Commission representative.

Upcoming changes regarding member/alternate where announced for Latvia and Sweden (to be specified after completion of the nomination process).

For training purposes, a first representative of a patient organisation observed the meeting. As agreed in 2016, 1-2 representatives will observe at HMPC meetings until July 2017.

1.2. Adoption of agenda

HMPC agenda for 30-31 January 2017

Time schedule for 30-31 January 2017

Outcome:
The agenda was adopted. The time-schedule was endorsed.

1.3. Adoption of the minutes

HMPC minutes for 21-22 November 2016

Outcome:
The minutes were adopted with a minor change (2.2.3.).

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP November 2016 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on the 22-24 Nov 2016

2.1.2. Prioritisation of substances for assessment

- Three tea combinations (loss of appetite, gastrointestinal complaints, nervous tension/to aid sleep)
  Action: for discussion
  Documents: Procedure on management of proposals from interested parties for Community list entries or Community herbal monographs, Guideline on the documentation to be submitted for inclusion into the 'community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'; Draft monograph Species diureticae; Templates: Species amarae – Proposal for assessment by HMPC; Species digestivae – Proposal for assessment by HMPC; Species sedativae – Proposal for assessment by HMPC; Presentation; Suggestions; List of Standardzulassungen – BfArM

  Outcome:
  Key data and justification were provided by the Rapporteurs (see 2.1.3) for 'Species amarae' and 'Species digestivae'.

  HMPC agreed to start the assessment for:

  • Herbal tea combinations traditionally used for loss of appetite (historically often called 'Species amarae')

  • Herbal tea combinations traditionally used in digestive disorders

  (historically often called 'Species digestivae or stomachicae')

  • Herbal tea combinations traditionally used for nervous tensions and to aid sleep (historically often called 'Species sedativae'; one call, to be separated later if required)

  Substances will be added to HMPC inventory and priority list and calls for data initiated.

  Rapporteurs to provide missing information if necessary for call and update of tracking documents.

2.1.3. Appointment of Rapporteurs and Peer-reviewers

- Changes of Rapporteurs and Peer-reviewers

  Outcome:
  New Rapporteurs and Peer-reviewers were agreed.

2.1.4. Polypodii rhizoma

Action: for discussion
Documents: Revision of MO; Annex

See also 4.4.3.

Postponed to March 2017 meeting.

2.1.5. Change in membership of MLWP

Report: MLWP Chair
Action: for discussion
Documents: Resignation letter from a MLWP member, A. J. Vlietinck, 24 Nov 2016; List of expertise

Postponed to March 2017 meeting.

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

2.2.1. Monograph on Oleae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 30/183

Outcome:
Final revised monograph with minor changes in sections 4.2, 4.3 and 4.4 and supporting documents adopted by majority vote (22 out of 27). The Norwegian delegate expressed a favourable position.

Divergent opinion: P. Claeson, Zs. Birone-Sandor, E. V. Galen, E. Leinonen, G. Laekeman

Before publication, missing full-text references to be provided to the secretariat.

The posology, traditional use evidence and indication were discussed as regards consistency between literature, AR and monograph. Reference was made to the compromise solution during the first assessment, when it was decided having for safety reasons only one part of the tradition (weak 'diuretic' effect) reflected in the indication for THMP.

Divergent opinions referred mostly to the indication, target group and warnings with concerns about the suitability for self-medication and demarcation between possibility of use, clarity of circumstances and need for medical monitoring.

2.2.2. Monograph on Salicis cortex and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 95/132

Outcome:
Final revised monograph and supporting documents with minor changes in monograph sections 4.2, and 4.4 adopted by majority vote (21 out of 28). The Norwegian delegate expressed a favourable position.

Divergent opinion: A. M. Serrilli, E. V. Galen, G. Calapai, L. Anderson, R. Cox, S. Girotto, W. Dymowski

Contraindications and warnings were discussed as regards available clinical evidence, comparability to other salicylate containing products and subsequent deductible risks such as Reyes syndrome. Also some general points on the revision and divergent views compared to the first assessment were raised.

Divergent views referred mostly to the non-acceptance of a recognised efficacy for well-established use, and partially to the traditional use as regards plausibility of the indications, contraindications and warnings taking into account the content of the herbal substance.

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

2.3.1. List Entry and Monograph on Menthae piperitae aetheroleum and supporting documents

Action: for adoption
Documents: LE, MO, AR, LoR, References: 107/205; Presentation

Outcome:
Adoption postponed and monograph and supporting documents returned to MLWP.

Concerns were raised regarding the posology in the WEU part of the monograph, in particular for children, taking into account limits given in the HMPC public statement on pulegone/menthofuran and corresponding CMDh and CHMP communication, the Ph. Eur. specification, 'normal pulegone/menthofuran content' of commercial oils and refinement possibilities.

Rapporteur and MLWP were asked to check possibilities regarding posology and duration considering essential oil specifications from the data available before finalising the draft revised monograph. Members were invited to send comments from experiences in national procedures.

2.3.2. Monograph on Menthae piperitae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 107/205

Outcome:
Draft revised monograph adopted by consensus for release for 3 months public consultation.

No safety/consistency concerns as expressed for the essential oil (see 2.3.1) were raised and the document was adopted.

Post-meeting note:

Due to possible final changes in draft revised AR and LoR regarding the essential oil monograph (shared supporting documents, see above) the draft monograph will exceptionally be published without draft AR/LoR.

2.3.3. Monograph on Ribis nigri folium and supporting documents

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

Outcome:
Draft revised monograph and supporting documents with changes in the monograph adopted by consensus for release for 3 months public consultation.

One warning was deleted and minor editorial amendments included.

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

2.4.1. Monograph on Lecithinum ex soya and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC; References: 46/46; Presentation

Outcome:
Final monograph with minor changes in sections 4.2 and 4.3 and supporting documents adopted by majority vote (23 out of 24). The Norwegian delegate was not available to vote.

Divergent opinion: R. Cox

The posology for adolescents was discussed and corrected as well as a contraindication deleted. The allergenic potency is still captured in the AR and a 2005 HMPC public statement. The divergent opinion referred to the suitability of the indication for self-medication with THMP. Otherwise suitable indications were not re-discussed (see 2.5.3 HMPC July 2016 minutes).

2.4.2. Public statement on Paeoniae radix, alba and supporting documents

Action: for adoption
Documents: PS, AR, LoR, OoC; References: 136/143

Outcome:
Final public statement and supporting documents adopted by consensus.

The Norwegian delegate expressed a favourable position.

2.4.3. Public statement on Paeoniae radix, rubra and supporting documents

Action: for adoption
Documents: PS, AR, LoR, OoC; References: 143/150

Outcome:
Final public statement and supporting documents adopted by consensus.

The Norwegian delegate expressed a favourable position.

2.4.4. Monograph on Soiae oleum raffinatum and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 7/7

Outcome:
Final monograph and supporting documents adopted by majority vote (27 out of 28). The Norwegian delegate expressed a favourable position.

Divergent opinion: E. V. Galen

No changes were introduced in the monograph. The divergent opinion was linked to concerns regarding the use as bath additive in conditions associated with mild recurrent eczema.

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

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

Action: for adoption
Documents: none

2.5.2. Public statement on Glycini semen and supporting documents

Action: for adoption
Documents: PS, AR, LoR

Outcome:
Draft public statement and supporting documents adopted by consensus for release for 3 months public consultation.

The list of specific extracts was corrected and aligned with the AR.

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

Action: for discussion
Documents: LE, MO, AR, LoR; Comments received 13 Dec 2016; EDQM comments, 7 Dec 2016 + attachment; Email communication from SI, IE

Outcome:
HMPC agreed to have clarifications from the Eur. Com. on essential questions linked to the nature and classification of the substance before continuation of assessment work.
To draft a letter by 6 March 2017 for agreement by HMPC before submission to the Eur. Com.

The applicability of the broad herbal substance definition regarding fungi and the borderline to biologicals was discussed. Associated issues were highlighted such as appropriate quality control for live bio-therapeutic products, demarcation between herbal substance and preparation and safety considerations. It was acknowledged that classification concerns were partially raised but not clarified at time of HMPC prioritisation. Doubts were also expressed on the classification of a medicine at all in awareness that yeast products are

differently regulated across Member States. While some members reckoned that a harmonised monograph could be useful under consideration of specific quality requirements, the HMPC agreed to the proposal to request a general clarification of the borderline and applicability of the THMP framework before continuation with the monograph development.

3. Referral procedures

None

4. Guidelines and guidance documents

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

None

4.2. Quality

None

4.3. Regulatory

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair

- Meeting report from Q DG meeting held on 7 Dec 2016
  Action: for adoption
  Document: Meeting report
- Draft agenda for the Q DG face to face meeting to be held on 23-24 Feb 2017
  Action: for information
  Document: Draft agenda

Outcome:
Meeting report adopted. WHO draft guidelines on good herbal processing practices (GHPP) for herbal medicines to be added to the February agenda.

The QDG Chair reported that the review of the herbal specification guideline in line with the quality guideline revision (currently kept on hold) had been started. The approach to review the concept of markers had been agreed. Furthermore coordination topics with EDQM (pyrrolizidine alkaloids, assay requirements), documents under development at MLWP (peppermint oil monograph) and at the Quality WP as well as questions from NCAs with potential for Q&A development had been discussed.

A WHO good processing practice document provided to EMA but also EDQM had raised some concerns and QDG will take the lead to compile comments for HMPC agreement (extended deadline 3 March).

- Meeting dates 2017 – updated
  Action: for information
  Document: Meeting dates

- Change in membership of QDG
  Action: for discussion
  Document: Resignation letter from a QDG member, M. Co, 20 Jan 2017

  Outcome:
  Secretariat to send out a call for interest (expertise: quality assessor) for possible appointment in March 2017.

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report
  Action: for adoption
  Document: Meeting report from ORGAM DG meeting held on 14 Dec 2016

- Agenda
  Action: for information
  Document: Draft agenda for the ORGAM DG meeting to be held on 21 Feb 2017

- Meeting dates 2017 – updated
  Action: for information
  Document: Meeting dates

  Outcome:
  Meeting report adopted. No ORGAM DG meeting can take place until a new ORGAM DG Chair elected (mandate expired 26 January) (see also 4.4.5). Meeting dates will be adapted as required after the HMPC March meeting.

4.4.3. Proposal for the revision process of the EU monographs/List entries

Report: ORGAM DG Chair, A. P. Martins
Action: for discussion
Documents: Draft procedure; Template example

Postponed to March 2017 meeting.

4.4.4. Disclaimer for EU herbal monographs

Report: M. Delbò
Action: for discussion
Documents: Presentation; Disclaimer for EU herbal monographs

Postponed to March 2017 meeting.

4.4.5. Mandate and membership of ORGAM DG

Report: ORGAM DG Chair
Action: for discussion
Documents: Presentation; Confirmation of interest expressed for membership; Email correspondence, 23 Jan 2017; Current mandate; Possible future mandate

Outcome:
Upon call only 3 current members confirmed interest. No interest was expressed for the position of the ORGAM Chair (see 4.4.6).

All members expressed importance of ORGAM DG activities; however, no new volunteers among ORGAM members, HMPC members/alternates were identified to become Chair. In a tour de table the HMPC members were asked to consider maintaining a DG with own mandate and Chair or alternatively the possibility of small, topic-specific groups in case that no candidature for Chairmanship will be presented and no ORGAM DG can be re-appointed.

HMPC secretariat to send out a new call for expression of interest for ORGAM DG membership and Chairmanship with the deadline of 3 March 2017 to be taken into consideration for the HMPC decision in March 2017 meeting.

ORGAM work plan adopted in November 2016 to be published in line with other work plans but corrected in case no ORGAM DG can be constituted in March 2017.

4.4.6. Election of ORGAM DG Chair

Action: for adoption
Documents: Email on call for interest, 13 Dec 2016; Candidatures: none

Postponed to March 2017 meeting.
The ORGAM DG Chair's fourth mandate expired on 26 January 2017. No candidatures were received by the beginning of the meeting.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Election of HMPC Vice-Chair

Action: for adoption
Documents: Email on call for interest, 13 Dec 2016; HMPC rules of procedure; Candidatures

Outcome:
Election for the position of Vice-Chair took place on 30 January 2017, in accordance with the 'Procedure for the election of the HMPC Chair and Vice-Chair' (EMA/604262/2016) based on the HMPC rules of procedure (EMA/HMPC/139800/2004 Rev 3).

Emiel Van Galen was elected as new HMPC Vice-Chair for a three year mandate starting 30 January 2017

5.1.2. Strategic Review and Learning Meetings

Report: HMPC Chair, E. V. Galen, E. Attard

- Transfer from Utrecht, 12-13 Apr 2016 – follow up
  Action: for discussion
  Documents: Email from HMPC Chair, 26 May 2016; Summary in presentation; Summary of Strategic Review meeting in NL 2016; Transfer from Utrecht – follow up; Breakout session groups – follow up; Presentation – Future of HMPC (breakout sessions)

  Postponed to March 2017 meeting.

- Presidency meeting – Malta, 26-28 Apr 2017 – update
  Action: for information
  Documents: Agenda; Presentation; Email correspondence, 16 Jan 2017; Organisation of Strategic Review & Learning Meetings (SRLM) of EMA Scientific Committees under the EU Presidency; Organisational aspects of SRLM; Presentation by EMA

  Outcome:
  The MT delegate informed that invitations have been sent out. HMPC noted documents on organisational aspects of SRLM as established in 2016 including participation possibilities for non-NCA affiliated co-opted members.

  HMPC agreed with the MT delegate to change the agenda towards less but more strategic relevant topics for the HMPC work. All members were invited to contribute actively.

- Possibility for Presidency meeting – Estonia, Jul-Dec 2017
  Action: for information

  Outcome:
  HMPC was informed that no HMPC SRLM is currently scheduled under the upcoming Estonian presidency.

5.1.3. Procedural guidance – revised SOP on MO & LE establishment

Action: for information
Documents: SOP; Presentation

Outcome:
HMPC noted completion of the review/streamlining of all internal HMPC secretariat guidance documents, publication of the fundamental SOP on the EMA website and listing of HMPC procedural guidance with need for update.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Action: for information
Documents: Minutes from meeting held on 10 Jun 2016; Agenda from the meeting held on 22 Sep 2016 and 31 Jan 2017

Postponed to March 2017 meeting.

5.2.2. Coordination with PDCO- Public workshop on extrapolation of efficacy and safety

Action: for information
Document: Presentation

Outcome:
HMPC noted workshop content, main aspects of the project and next step as regards reflection paper and implementation of the framework.
No direct relevance for HMPC was detected due to the completely different data situation for extrapolation possibilities within the herbal framework (see also HMPC Feb 2016 minutes 5.2.2).

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

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

- Joint CVMP/CHMP ad hoc expert group meeting on 3Rs
  Report: G. Laekeman
  Action: for discussion
  Documents: Meeting report, 18-19 Oct 2016; Presentation
- New structure J3RsWG - Joint CVMP/CHMP ad hoc expert group
  Action: for discussion
  Documents: J3RsWG Mandate 2017-2019; J3RsWG Work plan 2017; Email correspondence, 9 Jan 2017; Thank you letter to G. Laekeman

  Postponed to March 2017 meeting.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM 13A expert group meeting held on 8-10 Nov 2016
  EDQM: M. Bald; HMPC Observer: I. Chinou
  Action: for information
  Document: Summary of decisions
- EDQM 13A expert group meeting to be held on 28 Feb - 1 Mar 2017
  EDQM: M. Bald; HMPC Observer: I. Chinou
  Action: for information
  Documents: none
- EDQM 13B expert group meeting held on 24-25 Jan 2017
  EDQM: M. Bald; HMPC Observer: B. H. Kroes
  Action: for information
  Documents: Agenda, Report
- EDQM TCM expert group meeting held on 31 Jan – 1 Feb 2017
  EDQM: M. Bald; HMPC Observer: R. Länger
  Action: for information
  Document: Agenda

Outcome:
HMPC noted update on expert group activities given by the EDQM representative.

The EDQM representative highlighted in particular (1) 'assay alternatives' with a specific pilot case study for decision first at Ph. Eur. groups whether to continue, (2) the need for coordination on WHO draft documents (definitions), (3) Sisymbrium monograph development and the need to limit the amount of cardioglycosides (Rapporteur/MLWP to check). The 13B observer report emphasised additionally as relevant the naming of substances (Mate, Passiflora, Arctium, Grindelia) without discussion on follow-up. Following deletion of *Solanum dulcamara* from the EDQM work program the observer recommended to save resources and not to develop HMPC monographs when there are no products on the EU market. No observer reports were available for 13A and TCM. In addition the observership back-up principle and challenges with overlapping dates was raised.

5.4.2. Pharmacovigilance – Eudravigilance database and Art.16a registered products

Action: for discussion
Document: Email correspondence, 17 Oct 2016

Postponed to March 2017 meeting.

5.5. Cooperation with International Regulators

5.5.1. 9th Annual Meeting of IRCH held in New Delhi, India, 8-10 November 2016

Action: for discussion
Document: Agenda

Postponed to March 2017 meeting.

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

5.6.1. EUCOPE

Report: HMPC Chair
Action: for discussion
Documents: Letter to HMPC, 25 Jul 2016; Response from HMPC, 12 Oct 2016

Outcome:
HMPC noted main points raised and further discussed the relevance of the AR. Follow-up: (1) transparency on changes: to be discussed during the revision of the review/revision procedure; (2) Hearings possibilities: discussed during work plan 2017 development (see 5.7.2); (3) use of reflection papers at NCAs: purpose of reflection papers to be considered carefully by HMPC when drafting.

5.7. HMPC work plan

5.7.1. Projects on the HMPC work plan 2016

Action: for discussion
Documents: Work plan 2016 – current status; HMPC work plan tracking tool 2016

Postponed to March 2017 meeting.

5.7.2. HMPC work plan 2017

- HMPC work plan 2017
  Report: HMPC Chair
  Action: for adoption
  Document: Draft work plan

  Outcome:
  HMPC work plan was adopted and will be published at the EMA website.

  The Chair went through all topics to finalise the work plan as regards content, leads and participating members. Some minor amendments were introduced. She highlighted the responsibility of the topic leads to get the activities for 2017 implemented. A regular update will be given on each meeting.

- Cooperation with Academia – general recommendations on scientific work for important topics
  Report: HMPC Chair
  Action: for discussion
  Documents: Email communication 21 Dec 2016 and 12 Jan 2017

  Outcome:
  The EMA general framework and herbal specific objectives for 2017 were discussed and agreed to keep the point in the work plan 2017.

- Organisation of hearings with Interested Parties in 2017
  Report: MLWP Chair
  Action: for discussion
  Document: Proposal by MLWP Chair, 14 Nov 2016

  Outcome:
  Ideas for hearings were exchanged and accordingly reflected in the 2017 work plan.

  The next hearing was requested by AESGP for the MLWP March meeting. In addition a hearing to be initiated HMPC/MLWP (invitation of interested parties second half of 2017) on a broader subject was proposed for which topic and objectives will be further specified.

5.8. Planning and reporting

5.8.1. Meeting dates

Action: for information
Document: HMPC/MLWP 2019 to 2021

Outcome:
HMPC noted scheduled meeting dates. Major objections to be sent asap to the secretariat.

5.9. Legislation and regulatory affairs

5.9.1. Evidence on the period of traditional use

Report: E. V. Galen
Action: for discussion
Documents: Request to EC, 20 Dec 2016; Presentation by E. V. Galen; Presentation

Outcome:
HMPC noted legal view by EMA and Eur. Com. There is no general rule applicable to all overseas countries or territories (OCTs) with the EU relating to the application of Art. 16c(1)(c) of Directive 2001/83/EC. Specific cases with no possibilities (Macau, Hong Kong) have been checked and clarified in Nov 2016. Furthermore, pursuant to Art. 198 TFEU (ex Article 182 TEC), Annex II to the TFEU provides a list of OCTs which may have 'special relations' with certain EU MS. Even if an OCT with the EU is specifically listed under Annex II to the TFEU, "special relations" must still be formally defined and the relevant agreement between the EU and the specific OCT with the EU would need to be identified on a case by case basis in order to allow such medicinal use to be taken into account for the purpose of the application of Art. 16c(1)(c).

HMPC asked the Eur. Com. to further clarify these possibilities in order to achieve a harmonised approach across EU MS. For re-discussion and decision on follow-up in March 2017.

6. Any other business

6.1. Topics for discussion

6.1.1. ARSP

- English template
- English summaries for publication:
  - Boldo leaf
  - Ginseng root
  - Iceland moss
  - Tree tea oil
  - Restharrow root

No comments were made before publication of 5 new herbal summaries checked by HMPC secretariat, Rapporteurs and patient representatives.

6.1.2. Update on Management Board data gathering exercise

Action: for discussion

Outcome:
Postponed to March 2017 meeting.

6.1.3. Follow up on Public Statement on Pyrrolizidine alkaloid contaminations/Update of activities in Member States

Report: HMPC Chair
Action: for discussion
Documents: EDQM response on Pyrrolizidine alkaloids, 8 Dec 2016; List of questions; Data provided, 16 Dec 2016; CMDh press release

Outcome:
HMPC Chair summarised the discussion at CMDh.
New data provided by IP and distributed among HMPC members were welcomed. HMPC acknowledged that it is not known how representative the selected batch data are. Further evaluation is needed to detect most urgent testing requirements.
As follow-up the topic was given importance in the HMPC 2017 work plan (see 5.7.2) and will also be discussed at the HMPC presidency meeting in April.

Some members gave an update on their national situations. Possibilities for skip testing were not always considered appropriate since findings so far are often surprising and do not allow unambiguous exclusion of substances without contamination risks. It was acknowledged that national measures may differ also according to market and testing possibilities, which may cause challenges for MRP/DCP procedures for which the CMDh discussion and press release was useful.

To follow the activities as specified in the 2017 work plan, a break out session at the margin of the HMPC March meeting will be organised.

6.1.4. Survey to committee's members 2016 – follow up

Action: for discussion
Document: Presentation

Postponed to March 2017 meeting.

6.1.5. Information on initiative within the European Commission REFIT consultation

Report: Zs. Birone-Sandor
Action: for discussion

Postponed to March 2017 meeting.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 21-22 Nov 2016

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 21-22 Nov 2016

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 1-2 Feb 2017

6.2.3. Other

- MLWP work plan 2017; Document: Draft work plan 2017, Outcome of written procedure
- QDG work plan 2017; Document: Draft work plan 2017
- ORGAM work plan 2017; Document: Draft work plan 2017
- PCWP meeting:
  - PCWP Work plan 2017 (EMA/540720/2016): for adoption (silent adoption)
- HCPWP meeting:
  - HCPWP Work plan 2017 (EMA/493549/2016): for adoption (silent adoption)
  - Minutes of the PCWP/HCPWP joint meeting - 20 Sep 2016 (EMA/625038/2016): for information
- PCWP/HCPWP meetings:
  - Report of the PCPWP/HCPWP workshop on social media – 19 Sep 2016 (EMA/625077/2016): for information
- Paediatric overview (update 2016)

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 30-31 January 2017 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Marisa Delbò	Chair	Italy	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Heidi Neef	Member	Belgium	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Elena Mustakerova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Marie Heroutova	Member	Czech Republic	No interests declared	
Markéta Příhodová	Alternate	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Eeva Sofia Leinonen	Member	Finland	No interests declared	
An Le	Member	France	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Zoi Karampourmpouni	Alternate	Greece	No interests declared	
Zsuzsanna Bíróné Dr Sándor	Member	Hungary	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Una Mockler	Member (via TC)	Ireland	No restrictions applicable to this meeting	
Rachel Cox	Alternate	Ireland	No interests declared	
Gioacchino Calapai	Co-opted member	Italy	No interests declared	
Silvia Girotto	Co-opted member	Italy	No interests declared	
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Dace Kalke	Member	Latvia	No interests declared	
Baiba Jansone	Alternate	Latvia	No interests declared	
Evita Skukauska	Expert – in person*	Latvia	No interests declared	
Everaldo Attard	Member (via TC)	Malta	No interests declared	
Sara Camilleri	Expert	Malta	No interests declared	
Emiel Van Galen	Member	Netherlands	No interests declared	
Steinar Madsen	Member	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Nadia Grigoras	Member	Romania	No interests declared	
Miroslava Petrikova	Member	Slovakia	No interests declared	
Samo Kreft	Member	Slovenia	No restrictions applicable to this meeting	
Cristina Martinez Garcia	Alternate	Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Per Claeson	Member	Sweden	No interests declared	
Malin Söderberg	Expert – in person*	Sweden	No interests declared	
Linda Anderson	Member	United Kingdom	No interests declared	
Melanie Bald	Observer (via TC)	EDQM	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the agenda topics or activities they participated in.