20 September 2016
EMA/HMPC/626954/2016
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes of the meeting on 11-12 July 2016

Chair: Werner Knöss – Vice-Chair: Marisa Delbò

11 July 2016, 14:00 – 19:00, 3E

12 July 2016, 09:00 – 13:00, 3E

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).

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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).

As new member for Slovenia was announced Samo Kreft (previous alternate) and as alternate Barbara Razinger (previous member); Starting date of mandate: 29 June 2016.

End of mandate: Kapka Kaneva (alternate for Bulgaria) retired; her membership in HMPC ended on 21 June 2016.New nomination is awaited.

The HMPC Chair informed that the European Commission representative T. Engraff will only be available until end of July. A new representative has not been identified yet. The HMPC thanked for the good cooperation during the last 3 years.

The HMPC members noted information by EMA regarding the consequences of the UK referendum. Given the uncertainties of further development in the UK, the Committee was re-assured that all EMA operations continue as usual. There is currently no impact on staff members or any UK representatives at HMPC committees and other working groups. In case of new developments the network including HMPC members and subgroups will be informed accordingly.

1.2. Adoption of agenda

HMPC agenda for 11-12 July 2016

Time schedule for 11-12 July 2016

Outcome:
The agenda was adopted. Additional points/documents added since Thursday 7 July added under agenda point 6 for information were noted.

The time schedule was endorsed.

1.3. Adoption of the minutes

HMPC minutes for 30-31 May 2016

Outcome:
The minutes were adopted and will be published on the EMA/HMPC website.

The records regarding point 4.2.1 were discussed, however no changes were introduced.

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP June 2016 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on the 1-2 June 2016

Outcome:
HMPC noted explanations for postponement of some packages for adoption due to some delays during peer review and the short period since the last meeting.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

- Changes of Rapporteur and Peer-reviewers for Monograph revision
  Grindeliae herba
  Hippocastani cortex

Outcome:
The proposed Rapporteur/Peer reviewer changes were endorsed.

2.1.3. MLWP membership

- Nomination of new MLWP member (medical doctor with expertise in paediatrics)
  Report: HMPC Chair
  Action: for discussion
  Documents: Mandate of MLWP; "Call for nominations", 29 April 2016; Correspondence with PDCO & HCPWG

Outcome:
No proposals were received from PDCO. Proposals from HCPWG were not discussed by HMPC.

M. Delbò proposed the nomination of a quality expert for the vacant position outlined in the previous call for nomination (medical doctor with expertise in paediatrics from 29 April, second deadline 5 July). HMPC agreed to accept this nomination for this position as it was submitted within the deadline. No agreement was reached for any of the 2 candidates and a decision on the appointment postponed to September 2016. The HMPC Chair decided not to re-open or change this call.

- Resignation of M. Delbó as MLWP member
  Report: HMPC Chair, MLWP Chair, M. Delbó
  Action: for discussion
  Documents: Resignation letter, 1 July 2016; IT nomination

  Outcome:
  M. Delbò confirmed commitment to finalise ongoing MLWP work as Rapporteur in her continued HMPC membership and to remain MLWP member until HMPC appoints a replacement for her position. Based on this announcement of resignation although no exact date was provided as per normal practice, HMPC confirmed the need to fill the announced vacancy at MLWP and agreed to open a call for nomination. M. Delbó's membership will automatically cease at the end of the MLWP meeting following the HMPC meeting where a new appointment will be agreed for the opened position. Until then M. Delbó remains MLWP member and MLWP Vice-Chair.

  As required expertise for this position was specified: 1) expert in clinical/non-clinical assessment and 2) experience in herbal regulatory product assessment (=assessor) 3) active participation/contribution to MLWP work is expected. No limitation to a certain curriculum (e.g. medical doctor or practicing doctor, pharmacist) was made.

  HMPC to send out the call for nomination for possible appointment at the HMPC September meeting.

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

2.2.1. Monograph on Althaeae radix and supporting documents

Rapporteur: M. Heroutová; Peer-reviewer: G. Laekeman
Action: for adoption
Documents: MO, AR, LoR, OoC, References: 71/71

Outcome:
Final revised monograph and supporting documents adopted by consensus. The Norwegian member expressed a favourable position.

One additional reference provided from HU on use in children to be taken into account for finalisation and publication.

Editorial changes were introduced in monograph sections 3 and 4.2.

2.2.2. Monograph on Harpagophyti radix and supporting documents

Rapporteur: C. Purdel; Peer-reviewer: I. Chinou
Action: for adoption
Documents: MO, AR, LoR, OoC, OoC 2, References: 57/109

Outcome:
Final revised monograph and supporting documents with changes in monograph (sections 4.1, 4.2, 4.3) and assessment report adopted by consensus. The Norwegian member expressed a favourable position.

Rapporteur to check available references and provide them to the secretariat before publication of the documents. It was agreed to exceptionally take additional IP comments

into account and present in the OoC, although late and not received via the standard channels.

A minor change in indication 2 was introduced in line with other comparable TU indications. The appropriate wording for the duration of use was discussed and agreed. Necessary adaptations will be performed in AR and OoC. The contraindications were revised according to data situation taking out old recommendations not strictly based on clinical evidence.

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. Monograph on Origani majoranae herba – postponed

2.4.2. Monograph on Pruni africanae cortex

Rapporteur: I. Chinou; Peer-reviewer: G. Calapai
Action: for adoption
Documents: MO, AR, LoR, OoC, References: xx/58

Outcome:
Final monograph and supporting documents adopted by consensus. The Norwegian member expressed a favourable position.

Rapporteur to provide full text references before publication of the package.

During editorial review headings in the non-clinical part of the AR should be corrected to reflect the actually studied parameters in line with previously agreed corrections for other ARs (such as Serenoa).

A warning regarding children was deleted in MO section 4.4.

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

Action: for adoption
Documents: MO, AR, LoR

Outcome:
Draft monograph and supporting documents adopted by majority vote for 3 months public consultation.

Minor editorial corrections (e.g. standard extract and dosage terminology) to be performed during editorial review before publication.

Members discussed the suitability of indication 1 (adjuvant for the prevention of atherosclerosis) taking into account available data, the safe use via self-medication and the

need/likelihood to consult a doctor in national health systems. Furthermore the definition of the target patient group ('borderline patients'), the use and availability of statins and the concomitant/adjuvant use vis-à-vis other treatments was subject of the debate. Despite some remaining concerns a majority agreed to indication 1 and the release for public consultation.

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

2.5.3. Monograph on Lecithinum ex soya and supporting documents

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

Outcome:
Draft monograph and supporting documents with a change in the monograph (section 4.7) adopted by majority vote for 3 months public consultation.

The main point for discussion was the acceptance of an indication in hypercholesterolaemia. While agreed that clinical data are insufficient to accept WEU, different views were expressed on the possibility for a TU indication (see also 2.5.1). Despite acceptance for Allium, a majority followed the view of the Rapporteur that for Lecithinum ex soya such indication is not suitable for THMP self-medication. The possibility for enlargement of the indication will be re-discussed after public consultation.

2.5.4. Monograph on Soiae oleum raffinatum and supporting documents

Action: for adoption
Documents: MO, AR, LoR

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

No further questions or changes were brought forward.

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

3. Referral procedures

None

4. Guidelines and guidance documents

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

4.1.1. Revision of 'Guideline on assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs/entries to the Community list for traditional herbal medicinal products/substances/preparations (EMA/HMPC/104613/2005)

Action: for adoption
Document: Draft revised guideline for release for public consultation

Outcome:
Draft revised guideline adopted by consensus for secretariat editorial review and public consultation. Introduction to be amended with a summary of revision 1.

The Rapporteur summarised that changes are not fundamental, but an adaption to established practice (e.g. use in children) as well as agreed interpretations over the years with the Commission (e.g. as regards medical consultation before THMP use for some indications). Some overly extensive sections from 10 years ago were shortened. The legal basis and requirements of chapter 2A Directive 2001/83/EC regarding necessary data (e.g. posology) on age groups was discussed but no changes introduced. As regards scope it was clarified that national assessment practice should largely not deviate from HMPC and the GL may be continued to be used for individual product assessments. However, a widening of the scope was not supported since the HMPC mandate is focused on assessment for MO/LE development; while formal extension to national assessments would require additional coordination with CMDh/CHMP.

4.1.2. Revision of 'Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration' (EMEA/HMPC/32116/2005)

Action: for adoption
Document: Concept paper

Outcome:
Concept paper adopted by consensus for secretariat editorial review and publication.

4.2. Quality

None

4.3. Regulatory

4.3.1. Patient Leaflet template concerning advice on preparations of herbal teas by end-users

Rapporteur: M. Delbó
Action: for discussion
Document: Template

Outcome:
Rapporteur to check document for final necessary updates. Re-discussion and possible adoption for publication scheduled for September 2016.

The document had been adopted in 2013 for distribution and use among NCAs, when it was agreed not to publish due to objections of some MSs. This was considered now as a transparency gap since in the herbal addendum to the QRD template (see 5.2.3) reference is made to this document. The need for such document was discussed.

4.3.2. Revised regulatory questions and answers - EMA/HMPC/345132/2010

Report: ORGAM Chair
Action: for adoption
Documents: Revised Q&A; Clarification from EC, 8 June 2010

Outcome:
Additional Q&A R9-11 agreed based on previous legal clarification with reference to NtA. EMA secretariat and legal/RA support to check R12 and eventually split in two questions for more clarity and possible adoption at HMPC in September 2016.

The new Q&A were discussed in view of existing guidance (NtA) and previously clarified questions to the HMPC including Commission clarifications. One question was identified as still requiring more clarity: general WEU requirements vs. use in EEA vs. specific cases for MA valid and/or used in Liechtenstein to establish 'extensive use' as part of the WEU criteria. The need to address specific cases as well as sufficient clarity will be decided based on a revised version at the next meeting.

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair
Action: for adoption
Document: Meeting report from Q DG meeting held on 28 June 2016

The DG finished the draft revision of the herbal quality guideline which is planned to be presented to the Committee and released for public consultation in conjunction with the revised specification guideline (expected end of 2016). The group further discussed the follow- up on extended quality Q&A, guidance on use of new analytical methods, coordination topics with EDQM, QWP and requests from NCAs.

Action: for information
Document: Draft agenda for the Q DG meeting to be held on 7 September 2016

Outcome:
QDG meeting report was adopted. No HMPC comments or proposals were made on the draft agenda.

The new issues regarding pyrrolizidine alkaloid testing have been considered in the revised quality guideline and will also be taken into account for the specification guideline revision. While agreed that it should also be reflected in the GACP guideline, the need for a complete revision will be discussed at later stage.

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report
  Action: for adoption
  Document: Meeting report from ORGAM DG meeting held on 30 June 2016

- Agenda
  Action: for information
  Document: Draft agenda for the ORGAM DG meeting held on 6 September 2016

  Outcome:
  ORGAM meeting report was adopted. No requests were made regarding agenda points for the September meeting.

  The DG discussed the revision of the 'Procedure for the systematic review of EU herbal MOs and LEs and supporting documents', proposals on update of existing template for EU herbal monographs, addition to regulatory Q&A, final amendments to QRD template specifics for THMPs following a CMDh request, and progression with items on the 2016 work plan.

- Resignation of M. Delbó as ORGAM member effective from 10 July 2016
  Action: for discussion
  Documents: Resignation letter; IT nomination

  Outcome:
  The ORGAM and HMPC Chairs thanked M. Delbó for the long active contribution to the group.

  No decision was made yet on the need and requirements for replacement. To be re-discussed in September 2016. HMPC Chair welcomed ORGAM Chair proposal having a similar overall approach as for Q DG after new mandate adoption and Chair election end of 2016/beginning 2017.

- Draft revised template for EU herbal monographs
  Action: for discussion
  Documents: Draft revised MO template; Proposal from E. Svedlund, 13 June 2016

  Outcome:
  HMPC noted QRGAM rationale on initiative to update monograph template based on QRD template discussion. More elaborated, cautious proposal to be drafted by ORGAM highlighting pros and cons for decision by HMPC in September 2016.

  The committee discussed the relation between EU herbal monograph (no SmPC) and its established standard wordings there vis-à-vis the QRD template and different options regarding changes were presented. The use as core-SmPC and advantages of harmonisation during European procedures as well as the List entry status were taken into account.

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 adoption
Documents: Overview of QDG member interests; New mandate; New nominations; Presentation

Outcome:
HMPC noted background and key changes and adopted the new mandate.

HMPC appointed according to new mandate and proposal by Q DG Chair and HMPC Chair following a call for interest to all MSs:

Active members (mandates start 12/07/2016):

Linda Anderson (Chair, HMPC), Melanie Bald (EDQM), Michèle Brum, Michelle Co, Marisa Delbò (HMPC), Kristine Hvolby, Sari Koski (HMPC), Burt H Kroes (HMPC), Reinhard Länger (HMPC), Heidi Neef (HMPC), Klaus Reh (observer at QWP).

Observers (quality expert pool):

Kristina Andrić, Marie Heroutová (HMPC), Lykke Karlsson, Friederike Stolte, Anna Kruszewska, Jostein Hatlelid, Adela Núñez Velázquez (HMPC).

The number of observers was considered justified to allow a wide range of quality experts having access to background information on quality documents with usually limited discussion time at HMPC. Observers receive mailings (access to MMD documents) and may follow meetings (silent mode during TC; face to face meetings on their own expense). While not eligible to take over formal Rapporteurship, as an extended pool of quality experts involvement is possible upon specific request.

5.1.2. Assessors Training 3-4 November 2016

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

Outcome:
Changes introduced in draft agenda. S. Bager to further develop agenda in liaison with participants, HMPC Chair and HMPC secretariat for final discussion and adoption in September 2016.

The aim of envisaged presentations and training requirements was discussed in particular in terms of European procedures, referrals, risk benefit assessment and pharmacovigilance.

5.1.3. Strategic Review and Learning Meetings

Report: HMPC Chair; E. van Galen
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; Outcome of breakout sessions

Outcome:
Following a proposal from the NL Strategic and Learning meeting, breakout sessions took place in 4 groups for discussion for future structure/working methodology of HMPC.

Primary outcome to be distributed to all HMPC and MLWP members for follow-up discussion in September 2016. Objective is to compile a concise proposal on future working methodology and meeting/organisational structure according to changed environment, needs of the network and experiences over the last 10 years.

First proposals on four key areas were briefly presented: (A) sequence of meetings/balance HMPC vs. MLWP, (B) involvement of HMPC members (C) single Rapporteurs vs. revision teams according to expertise, (D) best practice in document development, commenting and deadlines.

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

Action: for adoption
Documents: Revised SOP on MO & LE establishment; Presentation

Outcome:
Postponed to September 2016 meeting.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting held on 10 June 2016

Report: HMPC Vice-Chair
Action: for discussion
Document: Agenda

Outcome:
Agenda topics were summarised to HMPC members.

Highlighted were the coordination regarding pulegone/menthofuran, cross committee projects (although most without direct HMPC contribution/relevance) and update on collaboration with academic groups with a workshop at EMA in June and planned follow-up at the end of 2016.

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; HMPC letter to EDQM on pulegone/menthofuran, 24 June 2016; Annex

Outcome:

Public statement with minor changes was adopted by consensus.

HMPC secretariat to transmit to CHMP and CMDh for information. Unless major comments or objections received, publication anticipated for beginning of August.

In communication with the EDQM representative it was concluded that no change of the Ph. Eur. monograph on peppermint oil would be advisable. Reduction of pulegone/menthofuran to achieve compliance with the newly established exposure limit by CHMP/SWP/HMPC should be solved for individual products as it is possible to stay within existing Ph. Eur. limits. In view of previous data provided by EDQM no new request by HMPC on range and limits was deemed necessary.

Apart from a two years period to comply with the thresholds on an individual product level no further specific regulatory action or other consequences were deemed appropriate in the HMPC PS. The scope of herbal MPs (not all MPs or excipients) was maintained, yet made clear that it is the general background scientific reference for the opinion of CHMP/SWP as recorded in the CHMP May minutes and the follow-up for CMDh and NCAs.

The Chair thanked the Rapporteurs and the secretariat for the thorough and patient elaboration of the document and at times challenging coordination.

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)

Outcome:

HMPC endorsed ORGAM proposal on CMDh request. The template with added footnote regarding the health care practitioner terminology will be presented in the next CMDh meeting on 18 July 2016 for adoption and publication.

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

Action: for information
Document: Report

- EMA PCWP/HCPWP joint meeting, 9 March 2016

Action: for information
Document: Minutes

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13A expert group meeting held on 8-10 June 2016

EDQM: M. Bald; HMPC Observer: I. Chinou
Action: for information
Document: Summary of discussion

Outcome:
HMPC noted information by EDQM representative on recent developments regarding PA analysis, 'assay alternative' project, essential oils and monograph development.

HMPC learned about the Ph. Eur. commission's view that a feasibility study is first required before the elaboration of a method for PA analysis can be put on the Ph. Eur. work plan.

A new approach via representative examples to demonstrate alternative approaches with respect to assay requirements was announced but is still under discussion and too early to share with HMPC.

The update of the general and specific essential oil monographs continues although a survey attempt among manufacturers to get more information did not provide new information.

The revision of Ph. Eur. monographs on peppermint leaf and peppermint leaf extract was noted and in this context the range and limits in the peppermint oil monograph vis-à-vis the finalised HMPC PS on exposure thresholds pulegone/menthofuran discussed (see 5.2.2).

5.4.2. 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

Outcome:
HMPC noted summarised data.

Alongside a decrease of THMP registration applications in EU MSs a slight increase in use of European procedures (MRP/DCP) was reported.

Data on registered/authorised products were presented including (i) licenced substances without HMPC monograph, (ii) available monographs without corresponding products, (iii) on combination products. The use of the data for HMPC prioritisation for assessment (criteria to close final gaps of assessment needs according to work plan) was suggested. Furthermore an overview on the use of monographs in national assessments, of European procedures and THMP specific referral types was given.

5.5. Cooperation with International Regulators

5.5.1. HMPC – International representation and cooperation

Report: HMPC Chair
Action: for discussion
Document: Draft proposal HMPC international cooperation

Outcome:
Postponed to September 2016 meeting.

5.5.2. Announcement of the 9th Annual Meeting of IRCH to be held in New Delhi, India, 8-10 November 2016

Report: HMPC Chair, HMPC Vice-Chair
Action: for information
Document: Draft Agenda

Outcome:
Postponed to September 2016 meeting.

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

None

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

Outcome:
HMPC noted the June status of routine tasks and specific projects.

- Harmonisation of assessment practice for herbal substances of non-European origin
Report: E. van Galen
Action: for discussion
Documents: Comparative List for Ayurveda Herbs; Discussion paper

Outcome:
HMPC endorsed the proposal. Rapporteur in liaison with HMPC Chair and secretariat to draft a letter to AYUSH contact points for discussion and agreement in September 2016.
A proactive approach based on contacts established in November 2015 was proposed. The aim is to identify in cooperation with Indian authorities suitable substances/preparations

used in Ayurveda that potentially qualify for a EU herbal monograph, taking into account standard procedures and guidance. Two key obstacles were identified: (A) lack of demonstration of 15-years presence on the EU market, and (B) the way the quality of the plant material is defined in the Ayurvedic Pharmacopoeia of India. As solutions was proposed to compare the description of herbal material in Ph. Eur. monographs with Indian definitions (e.g. Ayurvedic Ph monographs). For this purpose, a comparative inventory on Ayurvedic herbs has been drafted, which should be discussed and expanded with Indian experts. As next step HMPC could explore as starting point for HMPC assessment the necessary data to fulfil the 15 years of use requirement for "herbal drugs" with similarity in pharmacopoeia description in India and Europe.

5.7.2. Preparation of HMPC work plan 2017

Action: for information
Document: Presentation

Outcome:
HMPC noted presentation by secretariat. Draft work plan to be developed by HMPC Chair, topic leads and secretariat for discussion in September 2016.

Members invited to send new proposals or suggestions based on experiences from 2015 and 2016.

A draft will be distributed by 15 August 2016 to all HMPC for comments.

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. ARSP

- English summaries for publication
  Documents: xxx
- English template
- Procedural challenges ARSP translations

Outcome: Postponed to September 2016 meeting.

6.1.2. New EMA website “regulatory herbal”

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 30-31 May 2016

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 30-31 May 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 12-14 July 2016

6.2.3. Other

- Updated Welcome Packs uploaded in MMD (MMD/HMPC/General)
- Article 57, Documents: Dashboard report to EMA Committees; EVDAS User Guide
- Q&A on ethanol in the context of the revision of the guideline on ‘Excipients in the label and package leaflet of medicinal products for human use’
- EFSA compendium of Botanicals
- NCS Survey to Committee members, alternates and NCA staff on the service support

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 11-12 July 2016 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Werner Knöss	Chair	Germany	No interests declared	
Reinhard Länger	Member	Austria	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	
Maria Stavrou	Member	Cyprus	No interests declared	
Marie Heroutová	Member	Czech Republic	No interests declared	
Markéta Příhodová	Alternate	Czech Republic	No restrictions applicable to this meeting	
Steffen Bager	Member	Denmark	Indirect interests declared	
Eeva Sofia Leinonen	Member	Finland	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Zoi(Zoe) Karampourmpouni	Alternate	Greece	No interests declared	
Zsuzsanna Biróné Dr Sándor	Member	Hungary	No interests declared	
Una Mockler	Member	Ireland	No restrictions applicable to this meeting	
Marisa Delbò	Member (Vice-Chair)	Italy	No interests declared	
Dace Kalke	Member	Latvia	No interests declared	
Baiba Jansone	Alternate	Latvia	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Emiel Van Galen	Member	Netherlands	No interests declared	
Burt H Kroes	Alternate	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	
Carmen Purdel	Alternate	Romania	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Samo Kreft	Member	Slovenia	Indirect interests declared	

Adela Nunez Velazquez	Member	Spain	No interests declared	
Cristina Martinez Garcia	Alternate	Spain	No interests declared	
Per Claeson	Member	Sweden	No interests declared	
Erika Svedlund	Alternate	Sweden	No interests declared	
Linda Anderson	Member	United Kingdom	No interests declared	
Sue Harris	Alternate	United Kingdom	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Silvia Girotto	Co-opted member	Italy	No interests declared	
Gioacchino Calapai	Co-opted member	Italy	No interests declared	
Melanie Bald	Observer (via TC)	EDQM	No interests declared	