5 May 2015
EMA/HMPC/301016/2015 Corr.[1]
Scientific Committee Support

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 9-10 March 2015

Chair: Werner Knöss – Vice-Chair: Marisa Delbó

9 March 2015, 14:00 – 19:00, room 3F
10 March 2015, 09:00 – 13:00, room 3F

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.

Disclaimer

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

Of note, these minutes are a working document primarily designed for HMPC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes 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

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 9-10 March 2015.

No new or revised conflict of interests was declared and no restriction in the involvement of members in relation to agenda topics was identified.

HMPC membership, new participants

No changes announced.

1.2. Adoption of agenda of the meeting

Agenda for the meeting on the 9-10 March 2015

Adopted

Time schedule

1.3. Adoption of the minutes of the previous meeting

Minutes for the meeting on 27-28 January 2015

Adopted

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

Report: MLWP Chair
Action: information
Documents: draft minutes for the MLWP meeting on the 28-30 January 2015
overview of status of MLWP assessment work

Change of Rapporteurship for Harpagophyti radix

Action: adoption

The HMPC appointed a new Rapporteur for Harpagophyti radix (review/revision)

2.2. Revised EU herbal monographs and list entries for public consultation/final adoption after systematic review/revision

2.2.1. Monograph on Lini semen and supporting documents

Rapporteur: J. Wiesner, Peer-reviewer: H. Pinto Ferreira
Action: adoption as final
Documents: MO, AR, LoR; references 78/165

Final revised monograph adopted by consensus.

NO expressed a favourable position.

Members discussed the contraindications and warnings according to the respective indications on the TU and WEU part of the monograph leading to a change in section 4.3 (TU part). Furthermore questions regarding the data situation for use in adolescents and possible undesirable effects were raised. However, no further changes to the MLWP proposal were performed. Due to the nature of the changes during the revision (minor), the revised monograph and supporting documents were adopted as final without need for public consultation.

2.3. EU herbal monographs and list entries (post finalisation)

2.3.1. Monograph and List entry on Melaleucae alternifoliae aetheroleum and supporting documents

Rapporteur: M. Delbò, Peer-reviewer: J. Viguet-Poupelloz,
Action: discussion
Documents: MO, LE, AR, LoR; OoC, (as adopted);
MO, LE, AR, LoR; OoC, (editorial changes)

Post adoption editorial changes in the monograph plus an additional sentence in the section special warning and precaution for use were presented and accepted. The reviewed version was considered suitable for publication.

Proposed minor changes were reviewed one by one and a final wording of the monograph agreed. Equivalent corrections to be taken over for the LE if relevant before transmission to the Eur. Com.

The HMPC Chair reminded on sometimes necessary final polishing, however changes that may potentially go beyond 'editorial' should be agreed between Rapporteur, Peer-reviewer and Chair to decide on need for final agreement by the Committee.

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

2.4.1. Monograph on Pilosellae herba cum radice and supporting documents

Rapporteur: O. Palomino, Peer-reviewer: G. Calapai/M. Delbò
Action: adoption
Documents: MO, AR, LoR; references 18/21, OoC
Documents for *information*: e-mails dated 02/03 Feb 2015, Liste A of Ph.Fr. 10th éd. 01/96

Adoption postponed. After final clarification by Rapporteur/ peer reviewer as regards substance name, posology in the monograph, and amendments in the AR, monograph and supporting documents to be presented for adoption at HMPC May 2015 meeting.

HMPC secretariat to follow-up collecting the correct names in all EU languages.

The HMPC discussed the herbal substance name, the posology vis-à-vis information in the AR from traditional uses/products and some possible amendments in the AR.

While some useful information had been received from EDQM and the French agency on the traditionally used substance, current material of commerce and their definition, a final

decision on the reviewed documents (including correct plant name in all languages) was agreed for the next meeting.

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

2.5.1. Public statement on Balsam peruvianum and supporting documents

Action: adoption
Documents: PS, AR, LoR (drafts)

Adoption postponed.

France, Spain and other members to provide relevant product and safety data to the Rapporteur if available.

Rapporteur to amend AR and reconsider conclusions for discussion at the MLWP May 2015 meeting.

According to information from 2 MS, only partially available to the Rapporteur so far, products (mono and combination) without known safety/PhV issues can still be found on the market, despite the acknowledged high allergenic potential of the substance as such. Members discussed the available knowledge and current situation in diverse MS taking into account a possible distinction between use as fragrance or medicinal active substance as well as route of administration, strength/posology and history of use.

Following provision of new data, the Rapporteur was asked to modify the AR accordingly and re-evaluate all available data for discussion at the MLWP May meeting.

2.5.2. Monograph on Epilobii herba and supporting documents

Rapporteur: R. Länger, Peer-reviewer: M. Heroutová, Expert: A. Obmann
Action: adoption
Documents: MO, AR, LoR (drafts)

Draft monograph with a change in section 4.2 and supporting draft documents adopted by consensus for release for 3 months public consultation.

A minor posology change was introduced in the monograph. Following peer-review suitable standard wordings in the AR overall conclusions were discussed. It was acknowledged that no data on genotoxicity are available and consequently a LE was not proposed. Another consequence is that applications for registration of THMP according to Art. 16a of Dir. 2001/83/EC containing *E. angustifolium* and/or *E. parviflorum* should include data obtained from an AMES test according to the currently valid OECD guideline 471 - even if an application is based on the future EU herbal monograph. A majority agreed that it should be clear to applicants from HMPC guidelines on non-clinical documentation, genotoxicity testing and the recent revision of the herbal CTD guideline. However, the mentioning in the overall conclusion of a substance-specific AR was not deemed necessary. Future consideration may be given to such conclusions with the next revision of the AR template standard wordings.

2.5.3. Public statement on Uncariae tomentosae cortex and supporting documents

Rapporteur: Z. Biró-Sandor, Peer-reviewer: R. Länger
Action: adoption

Documents: PS, AR, LoR (drafts)

Draft PS and supporting documents adopted vote for release for 3 months public consultation.

The HMPC noted some variation and historical development as regards use of different plant parts due to resources available (root bark versus stem bark) with products on the market in some MS. Via the public statement it is intended to obtain more data on the traditional use to re-evaluate the available evidence and the possibility for a monograph including suitable indications. Concerns were raised on the level of detail and scope of scientific conclusions in the assessment which should be focused on the traditional use in the regulatory framework of Dir. 2001/83/EC, i.e. tailored to data supporting the suitable use as THMP.

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. Revised 'Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products' (rev 5)

Report: Q DG Chair
Action: adoption
Document: Quality Q & A

Adopted by consensus.
HMPC secretariat to publish revised document on the EMA website replacing current rev 4.

Revision 5 pertains to updates in 'Q&A 1' on microbiological quality and a newly added 'Q&A 10' under 'testing' with respect to benzene impurities. For the latter final adjustments had been performed by the drafting group to better reflect the situation in different preparations (e.g. 'oleoresins') according to solvent removal in line with the Ph. Eur. extract definitions.

The revised Q&A document revision 5 will be published and replace the current revision 4 on the herbal quality website.

4.3. Regulatory

4.3.1. Appendix 2 (quality dossier mock-up) to the Guideline on the use of the CTD format in the preparation of a registration application for THMPs (draft rev 2)

Report: Q DG Chair
Action: adoption for public consultation
Documents: draft CTD format mock-up module 3 – P part
draft CTD format mock-up module 3 – S part

Adopted by consensus for 3 months public consultation starting after final editorial review.

HMPC secretariat to combine and edit revised body text (adopted in January 2015) and appendix 2 mock up S and P part including requested amendments in Appendix 2 title page (disclaimer and box text).

The new appendix 2 consisting of a mock-up S- and P part was welcomed as very useful amendment of the herbal CTD guideline for European harmonisation in the particular important quality part of THMP dossiers. The HMPC discussed the scope and necessary disclaimer as the given example can neither demonstrate exhaustively all requirements for all specific cases nor should be understood as a minimum mandatory content of module 3 for herbal products. It should be seen as an example of a typical dossier, in particular useful for less experienced companies in the field. A minor change was introduced on the title page taking into account the wording of appendix 1 (best practice guide). The final wording of scope, disclaimer and explanation on the boxes used (indicating specific additional data) should be agreed between Rapporteur and Q DG Chair and finalised in liaison with the secretariat and HMPC/ DG Chairs before publication of the draft revision for public consultation. Furthermore it was requested to update the S- part (3.2.S.4.4.) according to the current requirements for pesticide testing.

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 11-12 February 2015

Action: adoption

Adopted.

During the face to face meeting the group finalised draft appendix 2 (mock-up) for the CTD guideline, finalised the amendment of the Q & A on quality of HMP/THMP (EMA/HMPC/41500/2010 Rev.5) (see above), discussed coordination topics with QWP and EDQM as well as comments received on the draft reflection paper (RP) on microbiological aspects. The finalisation of the RP was proposed despite concerns expressed both from industry and regulators with respect to scope and intention vis-à-vis existing Ph. Eur. standards and guidelines. While general considerations to be considered by applicants should be kept in the RP, more specific guidance should be developed thereafter using the Q&A format. A first evaluation was performed on the need to update and revise the main herbal quality guidelines in line with the DG work plan.

Draft agenda for the Q DG meeting to be held on 26 March 2015

Action: information

4.4.2. ORGAM DG

Report: ORGAM DG Chair

Meeting report from the ORGAM DG meeting held on 10 February 2015

Action: adoption

Adopted.

Draft agenda for the ORGAM DG meeting to be held on 24 March 2015

Action: information

Proposal for amendments to QRD template for herbal medicinal products/THMPs- Annex III, SmPC, labelling and PL

Rapporteurs: R. Länger, E. v. Galen, S. Bodemann, M. Delbò
Action: information
Documents: Draft discussion paper on QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs

HMPC agreed to further development of the document to be finalised by ORGAM for discussion at HMPC May 2015 meeting as basis for coordination with QRD group.

The ORGAM DG Chair explained that the document is not intended for publication but a comprehensive basis for discussion on the suitability/limits of the standard QRD template for THMPs/HMPs with the QRD group in order to explore the possibility to generate a specific template if appropriate. It was clarified that the original focus were THMP but during the discussions at ORGAM some issues were noted to be equally applicable to HMP (e.g. strength). Some members expressed doubts about the scope as authorised HMP (e.g. WEU) may not differ in their features substantially from other MP. The HMPC Chair asked all members to send their comments to the Rapporteurs. After discussions at the next ORGAM meeting, it is intended to finalise the document at the HMPC May meeting for submission to the QRD group.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. HMPC Rules of procedure and meeting dates

HMPC rules of procedure
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004738.pdf

Meeting dates for HMPC and MLWP in 2014 - 2018
Action: information

HMPC members noted standard schedule for HMPC in May but may consider participation at hearing with AESGP at the beginning of the MLWP May 2015 meeting.
Changes in meeting dates for 2016 -2018 are not likely but can currently not be excluded completely if meeting distribution at the EMA across committees needs to be aligned and evened out. If this is the case, it will be announced timely to allow early booking for the delegates.

5.1.2. Strategic Review & Learning Meetings

Organisation of a HMPC strategic review & learning meeting during Latvian presidency
Report: HMPC Chair

Action: information

Document: draft agenda

HMPC members were informed on initial invitations sent out, draft agenda and speakers/presentations identified so far.

The HMPC Chair provided some details for the scheduled meeting 'HMPC on the Road to 2020 – Future Challenges' which will be co-chaired by the Latvian and German agency representatives and dedicated to two strategic topics (Future Tasks and Organisation of HMPC and Evolutions and Harmonisation of Quality Requirements) plus information on regulation of herbal medicines in Latvia as well as research in the field.

5.1.3. Working methodology and procedural guidance

New agenda template for EMA scientific committees

EMA: L. D'Apote
Action: information

HMPC members noted background for layout and content changes based on new cross committee template.

Members welcome to submit comments to the secretariat for possible improvements towards suitability for the HMPC.

HMPC members noted work in progress and mentioned points causing some confusion which could be clarified. Further fine-tuning is envisaged. The HMPC Chair expressed understanding for the harmonisation process as regards format/structure as previously expressed with other Chairs at the scientific coordination board as long as the document serves its purpose and reflects the reality of the framework and current practice of each committee. Particularities for the HMPC (e.g. importance of DGs and guidelines, IPs but not applicants, procedures or substances instead of products) should be taken into account e.g. in disclaimer or avoidance of categories/headings that are not applicable.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. General coordination

Scientific Coordination Board Meeting 29 Jan 2015

Report: HMPC Chair
Action: information
Document: agenda

HMPC Members noted report by HMPC Chair and relevance of topics for the HMPC such as work plan development and coordination between committees.

HMPC within its specific operational framework is less involved in cross-committee projects planned for 2015. This may be reconsidered for the following years with more time given to plan ahead. The HMPC Chair expressed the intent to explore options for such coordination on topics (e.g. related to assessment methodology, safety, specific population groups such as children, patient involvement) relevant for the work of the HMPC which has also been foreseen in the HMPC work plan 2015.

HMPC Observers at other Committees and Working Parties
Action: discussion
Document: EMEA policy on appropriate coordination between the scientific committees of the agency
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004626.pdf
Presentation

HMPC to discuss at May 2015 meeting to define priorities and modalities of future coordination based on overview of previously appointed observers and reporting practice.

According to the' EMA policy of appropriate coordination between committees and the history at the HMPC as regards appointed observers and their variable status, degrees of involvement/feedback, the committee necessities should be confirmed or re-considered and future modalities determined defining roles of observers and secretariats.

Update on EMA benefit-risk methodology project and activities
Action: discussion
Presentation

HMPC members to consider involvement based on presented project background and features for discussion and possible appointment of one HMPC member as steering group member at the May 2015 meeting.

The history of the 'ProACT-URL' a qualitative framework for structured decision making and similar frameworks was presented as well as objectives, outcomes (e.g. examples for the 'Effects Table') and their implementation. Following a brief introduction into main features of the IMI-PROTECT project the future role/activities of the benefit-risk methodology steering group (previously CHMP, now cross agency) was outlined. Members discussed the transferability/scope of e.g. assessment templates for the tasks of the HMPC, acknowledging similarity to the HMPC WEU assessment, while for traditional use a different benefit/risk approach applies - yet some methodological aspects may be transferable in an adjusted form. Members were asked to consider involvement and - if necessary - request more information via the secretariat. The HMPC Chair favoured an active HMPC involvement beyond pure observership.

5.2.2. Coordination with PRAC and other Pharmacovigilance topics

Pharmacovigilance Programme – awareness session

Action: information
Presentation

Overview on current status PhV Information systems and Services presented.

List of about 60 herbal substances included in EMA medical literature monitoring to be provided to HMPC once available.

The current EMA activities based on the new pharmacovigilance legislation were presented giving background, scope, current status and expected benefits for the five main elements: medical literature monitoring, the Eudravigilance database, the PSUR repository, the Art. 57 database and the pharmacovigilance fee implementation. It was acknowledged that the framework is tailored for new active substances and many provisions do not or only partially apply to registered THMP. However, some coordination was beneficial in the past (e.g. EURD

list - inclusion of herbal substances for harmonised PSUR assessment via EMA) and may eventually be necessary in the future (e.g. herbal substances in literature monitoring). Some points were raised as regards data publication and access, as well as applicability of fees and other provisions for THMP manufacturers. Further questions on PhV provisions for HMP/THMP and need for EMA involvement/coordination specific for herbal products may be channelled via the secretariat.

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

5.3.1. Coordination with QWP

Guideline on Manufacture of the Finished Dosage Form

Report: Q DG Chair
Action: discussion
Documents: draft Guideline on manufacture of the finished dosage form
ToD from 74th Joint CHMP/CVMP QWP 3 - 5 February 2015 meeting

HMPC noted scheduled adoption of the guideline at CHMP March meeting.

Q DG to check whether comments from a herbal perspective are necessary and if relevant submit directly to QWP secretariat for consideration before anticipated publication beginning April 2015.

5.3.2. Coordination with Joint CVMP/CHMP ad hoc expert group on 3Rs

Report: G. Laekeman and J. Wiesner
Action: discussion
Document: meeting report March 2015

Postponed to May 2015.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

EDQM 13A Expert Group meeting held on 3-4 March 2015

EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
Action: information
Documents: Meeting report

HMPC invited to appoint a regulatory expert in essential oils for participation at discussions during 13A group meetings based on expertise and available resources.

EDQM secretariat to check whether available data (following recent draft revised monograph on Menthae piperitae oleum for Pharmeuropa) on natural variability of essential oil (pulegone, menthofuran) can be provided to HMPC.

The EDQM representative reported that instead of the planned overarching working party on essential oils the work would be integrated into group 13A. Additional experts are considered to be brought having experience in manufacturing, use in products and their regulation. For the latter e.g. the HMPC/QDG Rapporteur for the reflection paper and Q&A

on essential oils may participate. HMPC and secretariat will explore the possibility in line with workload, timing and frequency as well as the available EMA budget.

The HMPC was informed that *Picrorrhiza* was taken from work programme and Ph. Eur. monograph development discontinued due to resource / availability problems and the adopted HMPC PS.

The HMPC Chair emphasised the need for coordination regarding peppermint oil because current or revised specifications and limits in the Ph. Eur. monograph are important for the finalisation of the public statement on pulegone/menthofuran and revision of the existing EU herbal monograph and list entry.

EDQM 13B Expert Group meeting held on 20-21 January 2015

EDQM: M. Bald, U. Rose; HMPC Observer: H. Neef
Action: information
Documents: Summary of decisions

EDQM secretariat to check whether additional information on Pilosella (herb with parts of the root or flowering herb with parts of the root) can be provided to the HMPC secretariat.

The HMPC was informed on ongoing activities and outcomes at group 13 B including the monograph on fresh herbal drugs and several herbal substances with existing EU herbal monographs or under assessment at HMPC. The Greek request regarding the species issue for mastix, currently also under MLWP evaluation, was highlighted by the MLWP Chair.

5.4.2. EFSA

Public consultation on draft Guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms.

Action: discussion, Appointment of Rapporteurs
Documents: e-mail dated 09/02/2015
http://www.efsa.europa.eu/en/consultations/call/150209.htm

Rapporteurs appointed: H. Pinto-Ferreira, G. Calapai, I. Kosaleć

Rapporteurs to check need for HMPC comments in liaison with HMPC Chair and secretariat.

If required, information of HMPC and submission before 23 March 2015.

The HMPC had previously provided comments on the same topic (end of 2010). HMPC comments together with comments from other relevant groups at EMA will be collected and submitted by the EMA Head of EU Institutional Liaison Office to the EFSA contact point.

Public consultation on Conclusions and Recommendations of the EFSA/WHO Expert Working Group on TTC

Action: information
Documents: e-mail dated 12/02/2015
http://www.efsa.europa.eu/en/consultations/call/150212.htm

No need for direct HMPC comments was identified due to limitations of TTC concept for multi-compound mixtures.

Postponed to May 2015.

5.4.3. Revised framework of interaction with patients and consumers and their organisations

Action: information
Presentation
See also 6.2.3.

HMPC observer at PCWP to draft a proposal for possible future options for patient involvement in HMPC work for discussion at May 2015 meeting.

HMPC to be provided an overview on patient organisations that previously expressed interest in herbal medicines.

Legal basis (Art. 78 of Reg (EC) 726/2004), history, objectives, scope and working methodology regarding patient involvement were briefly presented. The revised framework adopted by MB (2014) aims for clarification of objectives and methodology consolidation. Main elements (network maintenance, pool of experts, promote participation, capacity building, transparency) are outlined in an action plan and annex to the Agency work plan. It was noticed that herbal products are not the main focus of PCWP and patient organisations as regards non-product specific and product-specific involvement in EMA activities, communication or training. Although HMPC is one of two committees not having regular representatives from patient organisations, one HMPC member (also PCWP member and HMPC observer there) emphasised that patient involvement in EMA herbal activities might nonetheless also be promoted. He will draft a proposal as starting point for discussion in May. EMA will check information on patient organisations that have previously expressed interest in HMP.

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

None

5.7. HMPC work plan

5.7.1. HMPC work programme 2012 – 2015

Action: information
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2011/12/WC500119957.pdf

5.7.2. HMPC work plan 2015

Action: discussion
http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2015/01/WC500181439.pdf

Update on activities on HMPC 2015 work plan planned for May 2015 meeting.

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

5.9.1. Questions by members

Test on uniformity of mass of delivered doses from multidose containers
Report: R. Länger
Action: discussion
Document: e-mail dated 03/03/2015

Batch release test by definition in Ph. Eur. confirmed by EDQM.

Due to known issues NCAs to consider specific request for change to EDQM.

A different approach regarding the test on uniformity of mass of delivered doses from multidose containers has been noted during procedures. Some MS accept that the test is performed once and described in the pharmaceutical development. Others make reference to the Ph. Eur. as the test is included in the release specification (monograph 'Liquid preparations for oral use') and therefore mandatory. However, examples were mentioned where such test would not contribute to the quality assurance/documentation of the manufactured batch.

The EDQM representative confirmed the test as mandatory part of the batch release specification but acknowledged that the need in all cases had been questioned before. A request for reconsideration may therefore be sent to EDQM.

6. Any other business

6.1. Topics for discussion

6.1.1. Proposal by Kew Gardens to map a plant list

Report: M. Delbò
Action: discussion
Documents: e-mail from M. Delbò on 14 November 2014; Proposal from Kew Gardens

Currently no basis and practical modalities of cooperation identified.

Vice Chair in liaison with HMPC Chair to draft a response letter.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 27-28 January 2015

Common names of herbal substances in all EU official languages

Meeting report from HMPC meeting held on 27-28 January 2015
http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2014/04/WC500164759.pdf

Overview of status of HMPC assessment work – priority list
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017724.pdf

Inventory of herbal substances for assessment work – alphabetical order
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf

Abbreviations in HMPC minutes
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf

6.2.2. MLWP

TOC of MLWP meeting held on 28-30 January meeting 2015

Draft agenda of MLWP meeting to be held on 10-12 March 2015

6.2.3. PCWP/HCPWP

Minutes of the PCWP meeting with all eligible organisations held on 26 November 2014

PCWP/HCPWP – Joint meeting held on 4 March 2015 - Draft agenda

Presentation by HMPC observer 4 March 2015

PCWP – Information session on Biosimilars held on 5 March 2015- Draft agenda

6.2.4. Other

New publication: Phytopharmacy: An Evidence-Based Guide to Herbal Medicinal Products; SE. Edwards, I da Costa Rocha, EM. Williamson, M Heinrich; ISBN: 978-1-118-54356-6; 416 pages; April 2015, Wiley-Blackwell

http://eu.wiley.com/WileyCDA/WileyTitle/productCd-1118543564,subjectCd-MDM0.html

List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 9-10 March 2015 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	
Heidi Neef	Member	Belgium	No interests declared	
Elena Mustakerova (via TC)	Member	Bulgaria	No interests declared	
Kapka Kaneva	Alternate	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Darko Trumbetić	Alternate	Croatia	No interests declared	
Maria Stavrou	Member	Cyprus	No interests declared	
Marie Heroutova	Member	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No interests declared	
Marje Zernant	Alternate	Estonia	No interests declared	
An Le	Member	France	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 Bíróné Sándor	Member	Hungary	No interests declared	
Una Mockler	Alternate *Replacing HMPC 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 restrictions applicable to this meeting	
Artūras Kažemekaitis	Member	Lithuania	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	
Ana Paula Martins	Member	Portugal	No interests declared	
Nadia Grigoras	Member	Romania	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Milan Nagy	Alternate *Replacing HMPC member*	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Per Claeson	Member	Sweden	No interests declared	
Erika Svedlund (via TC)	Alternate	Sweden	No interests declared	
Linda Anderson	Member	United Kingdom	No interests declared	
Sue Harris	Alternate	United Kingdom	No interests declared	
Gioacchino Calapai	Co-opted member	Italy	No interests declared	
Olavi Pelkonen	Co-opted member	Finland	No restrictions applicable to this meeting	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Melanie Bald (via TC)	Counseil de l'Europe		No interests declared	
Meeting run with support from relevant EMA staff				