



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 May 2016

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Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Minutes of the meeting on 4-5 April 2016

Chair: Werner Knöss – Vice-Chair: Marisa Delbò

4 April 2016 14:00 – 19:00, 3E

5 April 2016 08:30 – 12:30, 3E

(AESGP hearing at MLWP: 5 April 2016 13:30 – 15:30, Room 3E)

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

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

Of note, this agenda is a working document primarily designed for HMPC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to ongoing 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).

New Co-opted member (toxicology): Heidi Foth; Starting date of mandate: 4 April 2016

1.2. Adoption of agenda

HMPC agenda for 4-5 April 2016; Time schedule

Outcome:

Adopted

Minor changes in time schedule were agreed according to importance of topics.

1.3. Adoption of the minutes

HMPC minutes for 1-2 February 2016

Outcome:

Adopted

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP February 2016 meeting

Report: MLWP Chair

Action: for information

Document: Draft minutes for the MLWP meeting on the 3-4 February 2016

2.1.2. Calls for scientific data

- Monograph systematic review

Report: MLWP Chair

Action: for adoption

Avenae fructus; Avenae herba; Calendulae flos; Myrrha (Commiphora molmol); Oenotherae biennis oleum; Polypodii rhizome; Rusci aculeati rhizome; Sambuci flos; Tanaceti parthenii herba; Thymi aetheroleum; Trigonellae foenugraeci semen; Verbasci flos

Outcome:

Although not prioritised for review in the work plan 2016/2017, the committee agreed to initiate the call for data for start of the systematic review procedure for 12 monographs. A proposal by the secretariat was agreed to split in 3 waves to avoid overload with simultaneous calls for interested parties.

2.1.3. Appointment of Rapporteurs and Peer-reviewers

- Monograph systematic review

Herbal substance

Avenae fructus

Avenae herba

Calendulae flos

Rusci aculeati rhizoma

Trigonellae foenugraeci semen

Valerianae radix/Lupuli flos

Ribis nigri folium

- Appointment of Rapporteur (none MLWP members)

Outcome:

New Rapporteurs for systematic review were endorsed.

The HMPC Chair welcomed new volunteers for Rapporteurship but reminded that it does neither sort the accumulated backlog nor allows a systematic review of all monographs every 5 years. Therefore a modification of the current review/revision procedure should still be pursued as foreseen in the 2016 HMPC work plan.

2.1.4. Change in membership of MLWP

Report: MLWP Chair

Action: for discussion

Document: Resignation of a MLWP member, Beate Huber, 7 March 2016

Outcome:

The HMPC confirmed the need for experience from medical practice ideally with paediatric expertise in the working party. A second choice might be a medical doctor with expertise in non-European traditional medicines such as TCM or Ayurveda.

HMPC secretariat to send out a call for nominations to all HMPC members for candidates to be proposed for possible nomination at the HMPC May meeting.

The HMPC further reflected on possibilities to establish a closer link with PDCO and strengthening the input from medical doctors regarding medical practice acknowledging that the data situation for traditional herbal products is usually scarce requiring pragmatic approaches (see also extrapolation topic in point 5.2.2. of HMPC February meeting).

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

2.2.1. Monograph on *Thymi herba* and *Primulae radix* and supporting documents

Action: for adoption

Documents: MO, AR, LoR, references: 22/22

Outcome:

Final revised monograph and supporting documents with minor changes in monograph adopted by majority vote (23 out of 26). Norway expressed a favourable position.

Divergent opinion: E. van Galen, L. Anderson, M. Delbø

The revision was initiated by new scientific data with regard to the validity and use of the Bronchitis Severity Score (BSS).

The correct name of the monograph was discussed and modified ('and/or' as regards possible source species) taking into account Ph. Eur. definitions.

Divergent opinions referred to doubts in the recognised efficacy to fulfil WEU criteria and the use in children for the TU indication.

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. List Entry and Monograph on *Crataegi folium cum flore*

Rapporteur: J. Wiesner; Peer-reviewer: R. Länger

Action: for adoption

Documents: MO, LE, AR, LoR, OoC, references: 86/89

Outcome:

Final monograph and supporting documents with changes in monograph adopted by majority vote (17 out of 26). Norway expressed a favourable position.

Divergent opinion: E. van Galen, G. Calapai, I. Chinou, L. Anderson, M.H.P. Ferreira, M. Delbø, U. Mockler, W. Dymowski, Z. Biro-Sandor

Due to the high number of divergent opinions based on safety concerns with regard to indication 1 (relieve symptoms of temporary nervous cardiac complaints after serious conditions have been excluded by a medical doctor) founded in diverse therapeutic traditions and practice in the MSs, the Committee raised no objections on the Chairs proposal not to vote but to discontinue the development of a list entry.

Several members expressed their divergent position because in their view any cardiac indication is not considered suitable for self-medication in their MS. Differences in medical

approach, health care customs and patient self-management in the EU were noted and therefore it was agreed not to propose to the Eur. Com. a binding list entry. Although genotoxicity data are available for one preparation, it was specified that safety concerns don't refer to the herbal substance as such but the indication and use in general. The Rapporteur was asked to adapt the AR accordingly.

Further discussion points referred to the tradition, the duration of use (change for indication 1), concerns regarding adolescents and the use of DER instead of drug solvent ratio for tinctures.

2.4.2. [Monograph on *Helichrysi flos*](#)

Rapporteur: W. Dymowski; Peer-reviewer: G. Calapai

Action: for adoption

Documents: MO, AR, LoR, references: 46/49

Outcome:

Final monograph and supporting documents with minor changes in the monograph (section 4.2) adopted by consensus. Norway expressed a favourable position.

No comments had been received during public consultation.

2.4.3. [Monograph on *Polygoni avicularis herba*](#)

Rapporteur: B. Jansone; Peer-reviewer: J. Viguet-Poupelloz

Action: for adoption

Documents: MO, AR, LoR, references: 79/79

Outcome:

Final monograph and supporting documents adopted by majority vote (25 out of 26).

Norway expressed a favourable position.

Divergent opinion: E. van Galen

No comments had been received during public consultation.

The divergent view referred to the wording of the traditional indications 2 and 3.

2.4.4. [Monograph on *Silybi mariani fructus*](#)

Rapporteur: O. Palomino; Peer-reviewer: W. Knöss

Action: for adoption

Documents: MO, AR - TU, MO, AR - WEU/TU, LoR, OoC, SE comments; references: 114/195

Outcome:

Vote on TU/WEU monograph (largely according to published draft monograph): 7 positive (out of 25); Norway expressed a non-favourable position.

Divergent position: B. Razinger, E. S. Leinonen, E. v. Galen, E. Attard, G. Calapai, H. Foth, I. Chinou, I. Kosalec, J. Wiesner, L. Anderson, M.H.P. Ferreira, Marie Heroutová, M. Delbò, M. Nagy, P. Claeson, S. Bager, S. Madsen, U. Mockler, Z. Biro-Sandor

Vote on TU only monograph: 7 positive (out of 25). Norway expressed a non-favourable position.

Divergent position: Adela Núñez Velázquez, A.P. Martins, B. Razinger, D. Kalke, E. Attard, G. Laekeman, G. Calapai, H. Foth, I. Chinou, I. Kosalec, J. Wiesner, L. Anderson, M.H.P. Ferreira, Marie Heroutová, M. Delbò, M. Nagy, R. Länger, S. Madsen, W. Dymowski

Vote on TU only monograph with introduced modified indication (wording includes hepatic disorders): 15 positive (out of 25).

As no simple majority could be reached (17 out of 33 committee members), the Chair decided not to pursue further proposed modifications in the monograph (e.g. removal of a specific preparation). Chair, Rapporteur, Vice Chair, MLWP Chair and EMA secretariat to discuss follow-up including considerations to close the assessment and communicate in a public statement the reasons why a monograph cannot be established.

While old authorisations of one product in most MSs were acknowledged, there was no majority to support a recognised efficacy for the proposed indication based on available clinical evidence for the WEU part of the monograph. The specific use and pharmacological evidence with respect to the liver was recognised by many, but no majority supported a traditional use indication either mentioning hepatic disorders (safety concerns with regard to alcohol abuse and self-medication) or not mentioning hepatic disorders (not reflecting traditional use and plausibility).

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

Outcome:

Adoption postponed to May 2016 meeting.

3. Referral procedures

None

4. Guidelines and guidance documents

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

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

Action: for discussion

Document: Draft reflection paper

Outcome:

Late comments received by the Rapporteur before and during the meeting to be taken into account for modification of the paper. Members invited to provide additional comments by **22 April** 2016.

Rapporteur to submit improved and cleaned version by **30 April** to the secretariat for agreement by all HMPC members.

HMPC members recognised that the PAH regulation is more advanced in the food area. Risks in the medicines area are less widespread and limited to some specific herbal substances. Furthermore it was emphasised that coordination is needed with EDQM as regards testing and the final aim of the reflection paper (primarily asking for data) should be made clear to stakeholders. The UK member and Co-opted member toxicology were asked to support the Rapporteur in finalisation of the RP.

4.2. Quality

4.2.1. Reflection paper on the use of new analytical methods in the quality control of herbal substances, herbal preparations and (traditional) herbal medicinal products – postponed

Report: ODG Chair

Outcome:

Postponed to May 2016 meeting.

4.3. Regulatory

4.3.1. Revised guideline on the use of the CTD format for registration applications

Report: ODG Chair, ORGAM DG Chair

Action: for adoption

Documents: Revised CTD guideline (EMA/HMPC/71049/2007, Rev.2); OoC main text; OoC Appendix 2; Comments SE and DE

Outcome:

Adopted by consensus.

No further modifications were requested. HMPC members noted that final comments had been discussed in an extra TC. Some compromises had to be found such as in keeping the balance between clear messages and simple reference to other existing guidelines as justified. HMPC secretariat to publish the revised documents on the EMA website.

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 11 Feb 2016

Outcome:

Adopted

The DG had finalised the quality part for the revised herbal CTD guideline, mainly as regards comments received on the new Appendix 2 'mock-up module 3' (see above). The group had further discussed the revision of the 'Guideline on quality of herbal medicinal products/ traditional herbal medicinal products' and some topics in coordination with EDQM such as herbal specific issues in relation to Certificates of suitability (CEPs). The EDQM representative emphasised the urgency to get a response regarding the CEP request.

Action: for information

Document: Draft agenda for the Q DG meeting to be held on 4 May 2016

Outcome:

Pyrrrolizidine alkaloid topic (see also 6.1.1) to be added to the May agenda.

4.4.2. [ORGAM DG](#)

Report: ORGAM DG Chair

Action: for adoption

Documents: Meeting reports from ORGAM DG meeting held on 9 Feb and 16 March 2016

Outcome:

Adopted

Action: for information

Documents: Draft agenda for the ORGAM DG meeting to be held on 3 May 2016; Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs (EMA/HMPC/770889/2014)

Outcome:

No further topics proposed by HMPC for ORGAM DG.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. [Mandate of Quality DG](#)

Action: for discussion

Documents: Current QDG mandate; QDG waiting list; Croatian nomination of observer in HMPC and QDG; Candidature received: Dr Friederike Stolte

Outcome:

Only one expression of interest received.

Members to confirm current Q DG members or express interest in new memberships for the HMPC May meeting (active member, observer) for reconsideration by HMPC on Q DG membership in line with upcoming mandate modifications.

Call for expression of interest to be sent out by secretariat by 15 April 2016.

5.1.2. [Assessors Training December 2015 – follow up](#)

Report: QDG Chair

Action: for information

Documents: Summary outcome of group discussions

Outcome:

Once missing summary is available, distribution to all participants of the training and consideration by Q DG for follow-up regarding Q&A, guidelines and coordination with EDQM.

5.1.3. Assessors Training 2016

Report: S. Bager

Action: for discussion

Document: Draft Agenda

Outcome:

HMPC secretariat to contact CMDh Chair, set a date and inform members on specified date end of 2016 (Nov/Dec outside HMPC meeting weeks).

HMPC members were invited to send proposals by **6 May** 2016.

Topic lead to narrow title and agenda topics for a more concrete proposal and agreement at HMPC May meeting.

Several proposals collected were welcomed but it was encouraged to focus the training on a specific type of assessment and assessor due to limitations in participation.

5.1.4. Strategic Review and Learning Meetings – organisational aspects

Report: E. van Galen

Action: for discussion

Document: Draft agenda, meeting 12-13 April 2016, Netherlands

Outcome:

HMPC noted 3 main parts of the agenda (food supplements and PhV; medicinal cannabis, future visions for HMPC) and were invited to contribute in particular to the last topic via short presentations.

No new information was available as regards an HMPC meeting during the upcoming the Slovakian presidency (no strategic meeting planned).

5.2. Coordination with EMA Scientific Committees or CMDh-v

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

Rapporteur: J. Wiesner

Action: for discussion

Documents: New data, provided December 2015; SWP/CHMP preliminary feedback from Oct 2015 and Mar 2016; Overview pulegone development; Draft revised PS; Draft OoC

Outcome:

Rapporteur to modify document according to SWP recommendations for agreement in May 2016.

Rapporteur for the Mentha monographs review to continue with revision according to PS recommendations.

HMPC secretariat to further coordinate with CHMP the follow-up for final publication.

The evolution of threshold calculations was presented and discussed vis-à-vis duration and pattern of use of peppermint oil products taking into account uncertainty factors and safety margins. Rapporteurs should complete the public statement from a herbal perspective and continue with the Mentha monograph revisions based on SWP response. However, before publication overall coordination under lead of CHMP should be awaited in order to align

assessment and measures proposed between HMPs with peppermint oil as active substance and MPs that contain peppermint oil as excipient.

5.2.2. Report from Scientific Coordination Board – 18 March 2016

Report: HMPC Chair

Action: for information

Document: Agenda

Outcome:

HMPC noted highlighted agenda topics including cross committee projects and considerations on options for joint meetings (CMDh, PDCO) for future presidency meetings.

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: Agenda

- EMA PCWP/HCPWP joint meeting, 9 March 2016

Action: for information

Document: Agenda

- Patient involvement within EMA/HMPC

Action: for adoption

Document: Patient involvement within EMA/HMPC

Outcome:

Patient involvement in HMPC activities in principle welcome but adoption postponed. HMPC noted that 5 patient organisations with interest in herbal medicines have been identified. As a training participation of 2-3 per meeting at next meetings agreed.

Specific modalities of involvement to be checked against standard procedures.

HMPC members to send comments by **30 April** 2016.

For adoption at HMPC May meeting.

HMPC reflected as important to foster among patients and consumers the knowledge about HMPC activities and about OTC use in general. The practical implications and limitations (timing) of proposed patient representative activities in standard HMPC (and MLWP) procedures may be checked and eventually more specified.

5.3.2. European Union reference date (EURD) list – update for herbal substances

Report: Z. Biróné Dr Sándor

Action: for discussion

Documents: Email communication; Presentation

Outcome:

HMPC endorsed request to add peppermint oil to EURD list (5 year frequency). Exceptional extension to non-authorised products (e.g. Art. 16a registered) currently not recommended but to be checked again after finalisation of HMPC PS on pulegone/menthofurane and revision of the Mentha monographs.

General issues with inclusion of herbal substances in EURD list (e.g. registered products not in Art. 57 database) were noted. With more experience gained the topic should be re-discussed. It was acknowledged that PSUR alignment and harmonised submission dates and assessment are not in the mandate of HMPC. However, the pros and cons of exceptional inclusion of herbal substances (registered HMP by default excluded) and subsequent scope and frequency decisions may require some feedback from HMPC in some cases.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13A expert group meeting to be held on 23-25 February 2016
EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
Action: for information
Documents: Summary of discussion; Report by I. Chinou; Information on Grindelia
- EDQM 13B expert group meeting to be held on 19-20 April 2016
EDQM: M. Bald, U. Rose; HMPC Observer: H. Neef
Action: for information
Document: Agenda

Outcome:

HMPC noted progress regarding a Ph. Eur. discussion paper on assay requirements potentially available for comments in May, while the survey on essential oils among manufacturers did not bring the expected information.

Changes in botanical names (Senna to be implemented during current revision, Grindelia to be implemented once progressed at Ph. Eur.) with relevance for HMPC monographs were highlighted.

HMPC decided to continue with Saccharomyces monograph, while EDQM may comment during public consultation.

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

Report: QDG Chair

Outcome:

Postponed to May 2016 meeting.

The EDQM representative highlighted the need to get a response soon. Q DG Rapporteur to draft response for Q DG agreement and submission to EDQM.

5.4.3. EFSA – Guidance on traditional foods from third countries and Novel Food - consultations

Report: HMPC Chair; Rapporteurs: G. Calapai; I. Kosalec; H. Pinto Ferreira

Action: for discussion

Document: Email distributed to HMPC, 23 Feb 2016

Outcome:

No need for HMPC comments was identified.

5.4.4. European Commission – Update on establishment of List entries (Melaleuca)

Report: HMPC Chair, M. Delbò

Action: for discussion

Documents: Draft LE; Ph. Eur. Monograph; Letter from Eu. Com. dated 21 March 2016

Outcome:

Compliance with Ph. Eur. monograph description was supported, although the wide definition allowing inclusion of any Melaleuca species was questionable in this specific case. The possible reduction to the substance (preparation) name 'Melaleucae aetheroleum' instead of a complete Ph. Eur. definition regarding species in the title of the LE was discussed. The importance of the actual specification of the substance was emphasised while the inclusion of species was of less relevance.

Rapporteur in liaison with HMPC Chair and secretariat to draft an answer for transmission to the Eur. Com. by **30 April** 2016.

The Rapporteur referred the original Australian ISO standard but also the difficulties to exclude species without a method in the Ph. Eur. monograph allowing such demarcation to other species. Any substance complying with the Ph. Eur. monograph for Melaleuca aetheroleum would be acceptable for medicinal use - independent from which Melaleuca species obtained. The wide definition regarding source plants was considered unfortunate (e.g. vis-à-vis *M. leucadendra* or *M. quinquenervia*) because representing source plants for other essential oils (Cajuput or Niaouli), however, standard procedure and naming according to Ph. Eur. standard was preferred.

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

Action: for discussion

Document: Presentation

Outcome:

HMPC noted first summary. PL still to provide data for update of the report EMA/HMPC/322570/2011 (Rev. 6) on the Agency website and more detailed presentation to the HMPC in May.

HMPC took note of a comparable number of registrations/authorisation in the EU in 2014 and 2015. An increase in MRP and DCP procedures for herbal products was shown. Substances assessed by the HMPC but not marketed in EU MSs as medicines and substances marketed but not assessed by the HMPC were listed.

5.5. Cooperation with International Regulators

5.5.1. 8th Annual Meeting of IRCH held in Riyadh, Saudi Arabia, 1-3 December 2015

Report: HMPC Chair, HMPC Vice-Chair

Action: for information

Documents: Summary Report; Presentations

Outcome:

Postponed to May 2016 meeting.

5.5.2. HMPC – International representation and cooperation

Report: HMPC Chair

Action: for adoption

Document: Draft proposal HMPC international cooperation

Outcome:

Postponed to May 2016 meeting.

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

5.6.1. Hearings with interested parties in 2016

Action: for discussion

Documents: AESGP hearing draft Agenda; Participants list; Presentations

Outcome:

No additional agenda topics were proposed, neither another hearing with other IPs on a specific topic in 2016. It was proposed to hold the established hearing with AESGP at HMPC directly.

HMPC members recognised that many agenda points proposed by AESGP for the hearing with MLWP were not directly linked to monograph establishment but to specific guidance development - mostly still ongoing.

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:

Postponed to May 2016 meeting.

- Cross committee risk/benefit project

Report: S. Madsen

Action: for discussion

Document: Presentation

The aim and composition of the benefit/risk steering group was presented focusing on risk perspectives, old substances and the reasons for their re-evaluation as well as efficacy tables as a tool. Possible improvements for the HMPC assessment methodology (WEU) were discussed addressing future challenges in terms of update, data to be considered and how to be best communicated in particular for drugs with marginal clinical effects. A new update on possible elements of the project for HMPC usage should to be given second half of 2016.

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

Outcome:

Postponed to May 2016 meeting.

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. Occurrence of pyrrolizidine alkaloids – issues on national markets and follow up

Report: HMPC Chair, L. Anderson

Action: for discussion

Documents: Information received from UK, DE, AT; Published articles; Request from NL

Outcome:

HMPC members noted measures taken in UK, DE, AT and SE as well as incoherent data situation. In view of quality issues linked to safety concerns that are not limited to single markets only, the need for coordinated European measures was emphasised. EDQM and European Commission were informed.

HMPC members agreed to

1) Communicate to EDQM accelerated need for development of a validated Ph. Eur. method for PA analysis.

2) Recommend short term temporary measures for national implementation based on harmonised information status. (A task force including regulatory competence and scientific expertise was established to deliver a draft document within 3-4 weeks. Composition: topic leader P. Claeson; members L. Anderson, J. Wiesner, B. Kroes, R. Länger, H. Foth, I. Chinou)

3) To reconsider long term testing requirements and other measures. Initiate accordingly the revision of relevant guidelines as required (quality, specification, GACP; led by Q DG)

4) To inform relevant groups at EMA.

The HMPC agreed as a general direction to improve and harmonise the data situation (in particular which herbal substances affected) in order to define the extent of the problem and concentrate first line on the most imminent ones. It was acknowledged that findings are not limited to substances used in medicines, while recommendations will remain in the scope of MPs. New analytical opportunities that partially led to findings are not homogeneously available across all MSs and capacities limited. The content of PS EMA/HMPC/893108/2011 was re-confirmed as well as the intention to keep PA in medicinal products as low as practically achievable. However, transitory measures for risk management will encompass elements of manufacture and GACP, testing requirements and toxicological considerations.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 1-2 February 2016

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 1-2 February 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 MLWP assessment work
- Draft agenda of MLWP meeting to be held on 6-7 April 2016

6.2.3. ARSP

- English summaries for publication
Documents: Castor oil; Ironwort; Horsetail herb; Valerian root; Valerian essential oil
- English template

6.2.4. Other

- New internal guidance on management of confidentiality and declarations of interests for observers participating in EMA scientific meetings;
Documents: Observers summary for Committees and WPs; Observers at EMA Meetings; Letter to Swissmedic, 23 March 2016

6.2.5. Update on availability of herbal hand books at the Agency library

- Overview of status of availability of herbal hand books at the Agency library - March 2016

List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 4-5 April 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 Heroutova	Member	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
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	
Annamarie O'Sullivan	Alternate	Ireland	No interests declared	
Marisa Delbò	Member (Vice-Chair)	Italy	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Anna Maria Serrilli	Alternate	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	
Steinar Madsen	Member	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Adela Núñez Velázquez	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	
Gioacchino Calapai	Co-opted member	Italy	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Martina Holenková	Expert – in person*	Czech Republic	No interests declared	
Olga Maria Palomino	MLWP member	Spain	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.