30 May 2017
EMA/HMPC/347754/2017 Corr.[1]
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 27-28 March 2017

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

27 March 2017, 14:00 – 19:00, 2F

28 March 2017, 09:00 – 13:00, 2F

(AESGP hearing at MLWP: 28 March 2017, 14.00 – 16.00, Room 2F)

Disclaimers

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

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

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

[1] Correction in participant list

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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 memberships:

Carmen Purdel (Romania) member; start of mandate: 22 Feb 2017

Raluca Iavorszky (Romania) alternate; start of mandate: 22 Feb 2017

Iliana Ionkova (Bulgaria) alternate; start of mandate: 16 Feb 2017

Evita Skukauska (Latvia) member; start of mandate: 20 Feb 2017

Wim Huygh (Belgium) alternate; start of mandate: 14 Feb 2017

Alessandro Assisi (Italy) member; start of mandate: 9 Mar 2017

End of memberships:

Dace Kalke (Latvia) member; end of mandate: 19 Feb 2017

Nadia Grigoras (Romania) member; end of mandate: 21 Feb 2017

For training purposes, two representatives of patient organisations observed the meeting. As agreed in 2016, 1-2 representatives will observe at each of the HMPC meetings until July 2017.

1.2. Adoption of agenda

HMPC agenda for 27-28 March 2017

Time schedule for 27-28 March 2017

Outcome:
Agenda adopted.

1.3. Adoption of the minutes

HMPC minutes for 30-31 Jan 2017

Outcome:
Minutes adopted.

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP February 2017 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on the 1-2 Feb 2017

2.1.2. Change in membership of MLWP

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

Outcome:
As new expertise required was specified a) expert in herbal medicine b) experiences in safety and/or efficacy assessment. As supportive was considered: c) previous regulatory activities (assessor at an authority) or d) experience with drafting monographs.

Secretariat to send out a call to HMPC members for possible appointment at the HMPC May meeting according to nominations.

The HMPC acknowledged that the previous member had a stand-out expertise in phytochemistry which might be difficult to replace. In view of the MLWP tasks and current composition expertise with focus on the safety/efficacy assessment and the willingness to contribute as Rapporteur and Peer-Reviewer was highlighted.

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

None

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

2.3.1. Monograph on Meliloti herba and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 88/94; Presentations; Bibliography assessment

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

Members discussed the exceptional removal of preparations from the original monograph due to incomplete documentation on the use as single active substances. Hence the justification was found missing for inclusion into the revised monograph. Available and just recently received new data on traditionally used preparations were highlighted and the historical and current relevance of the coumarin content discussed.

Several changes were introduced in section 4.2 of the draft revised monograph and adaptation to template standard wordings requested before publication.

2.3.2. Monograph on Sennae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 173/224

Outcome:
Adoption postponed, monograph and supporting documents returned to MLWP.
Rapporteur to provide a revised version - in particular with adaptations in section 2 of the monograph.
See also 2.3.3.

2.3.3. Monograph on Sennae fructus and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 173/224

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

Rapporteur to provide a revised version - in particular with adaptations in section 2 of the monograph.

The content of monograph section 2 was discussed as regards standard declaration of the active substance according to current practice, the covered preparations in the old monograph and AR, the standardisation on hydroxyanthracene derivatives and regulatory consequences of such revision towards specific preparations. A majority supported the 'modernisation' in consistency with the revised AR. Such principle should also be followed for other similar monographs to be revised. Because of consequences for posology section 4.2 and other parts of the monograph a majority preferred re-discussion at MLWP before release for public consultation at HMPC.

2.3.4. Monograph on Uvae ursi folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 15/113

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

HMPC members discussed proposed usage limitations as taken from an old product information and also applied during recent European procedures. However, it was noted that no new safety data are available that allow a scientific justification of such limitation and accordant presentation in the AR. Members reflected on the general principle of scientific assessment by HMPC on the use of a substance based on publically available data. This may

differ from the regulatory practice for specific products (likely with another data situation). The feedback for monograph update will also be subject of further discussion (item on work plan 2017).

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

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

Action: for adoption
Documents: none

Outcome:
Adoption postponed to May 2017 meeting due to late submission.

2.4.2. Monograph on Species diureticae and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC; References: 4/4

Outcome:
Final monograph and supporting documents adopted by majority vote (28 out of 29). The Norwegian delegate expressed a favourable position.
Divergent opinion: E. v Galen.

The HMPC welcomed the first finalised monograph on a herbal tea combination with a more flexible approach for common combinations with substances similarly used.

The divergent opinion referred to the wording of the traditional indication used for herbal 'diuretics' in comparison to real (synthetic) diuretics with proven efficacy.

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

None

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 Polycyclic aromatic hydrocarbons in HMP/THMP

Action: for discussion
Documents: Reflection paper; Presentation

Outcome:
HMPC welcomed the stepwise approach proposed by Interested parties.

The question on necessary risk assessment for some substances and subsequent testing requirements under consideration of food provisions was transferred to QDG to reflect appropriately within the revision of the quality and specification guideline.

After discussion with Interested parties (hearing at MLWP) re-discussion is planned at the HMPC in May for appropriate follow up according to work plan and announcement in the PR.

The lack of specific data for medicines was acknowledged, however, the advanced regulation in the food sector including established limits and testing requirements was noted. Members discussed possible sources of contamination for a limited number of herbal substances for medicinal use as well as eventually required marker substances. While consideration in quality guidance based on risk evaluation will be discussed at Q DG, the safety aspect and follow-up needs further discussion at HMPC/MLWP.

4.2. Quality

None

4.3. Regulatory

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair

- Meeting report from Q DG (FtF) meeting held on 23-24 Feb 2016
  Action: for adoption
  Document: Meeting report

  See also 6.2.4.

- Draft agenda for the Q DG meeting to be held on 20 Apr 2017
  Action: for information
  Document: Draft agenda

Outcome:
Meeting report adopted. Topic on Polycyclic aromatic hydrocarbons in HMP/THMP (see 4.1.1.) to be added to Q DG April agenda.

The drafting group had worked on the detailed review of the herbal specification guideline, which will be continued. Q DG had also compiled comments on a draft WHO guideline on Good Herbal Processing Practice which had been shared with HMPC and EMA manufacturing and quality compliance before submission to WHO. Finally, other coordination activities with EDQM and QWP and the way forward to finalise a draft reflection paper on new analytical methods had been discussed.

- Change in membership of Q DG – appointment of new Q DG member
  Action: for adoption
  Documents: Email on call for interest 7 Mar 2017; Nomination: F. Stolte

Outcome:
Friederike Stolte (DE) appointed by consensus as new member of Q DG starting 28 March 2017.

4.4.2. Mandate and membership of ORGAM DG

Report: HMPC Chair
Action: for discussion
Documents: Presentations; Email on call for interest, 16 Feb 2017; Confirmations of interest expressed for memberships; Current mandate; Possible future mandate for adoption; Work plan

Outcome:
HMPC decided to keep a formal ORGAM Drafting Group with own Chair and mandate.

The new mandate was adopted and will be published on the EMA website.

A new ORGAM DG Chair was elected (see 4.4.3).

Three candidates were appointed as ORGAM DG members: Ana Paula Martins (PT), Klaus Reh (DE) and Stephanie Bodemann (DE) starting 28 March 2017.

Further volunteers could be appointed later and the "core" group could be supplemented by MLWP or HMPC members dealing with specific topics.

The work plan was shortened and revision 1 will replace the currently published work plan as adopted in November 2016.

The meeting schedule (6 times a year between HMPC plenaries) will be maintained. Next meeting: 5 April 2017.

4.4.3. Election of ORGAM DG Chair

Action: for adoption
Documents: Email on call for interest, 16 Feb 2017; Candidatures: Gert Laekeman

Outcome:
Gert Laekeman (BE) was elected as new Chair of the HMPC Organisational Matters Drafting Group with a mandate starting 28 March 2017.

Post meeting note:

The former Chair passed to the new Chair all the necessary information on the previous DG activities to facilitate the continuation of the work and the finalization of the current draft documents.

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

Report: E. V. Galen, A. P. Martins
Action: for discussion
Documents: Draft procedure; Template examples; Presentations

See also 6.1.2

Outcome:
Postponed to May 2017 meeting.

4.4.5. Disclaimer for EU herbal monographs

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

Outcome:
HMPC decided not to follow the proposal by MLWP to publish a disclaimer on the scope of monographs on the EMA website. It was proposed to develop a regulatory Q&A on the matter.

HMPC heard the background of the proposal sourcing from discussions at MLWP about the relevance of the monograph as harmonised core data vis-à-vis the product specific SmPC discussed in national and European procedures. While it had been previously agreed not to change the monograph template having subsequently the disclaimer at each individual monograph, now, neither wording nor place of the general disclaimer on the web found agreement. The secretariat's proposal to consider amending instead the regulatory Q&A on the matter was not objected.

Post meeting note:

A specific Q&A will be developed by the newly re-constituted ORGAM DG.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings

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

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

  Outcome:
  Postponed to May 2017 meeting.

- Presidency meeting – Malta, 26-28 Apr 2017 – update
  Action: for information
  Documents: Draft Agenda; Presentation

  Outcome:
  Maltese Member on behalf of the Maltese Agency invited all HMPC members. Agenda items were discussed as regards availability of speakers and an updated version will be provided by Malta to all HMPC members.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information
Documents: Minutes from meeting held on 10 Jun 2016; Agenda for the meetings: 22 Sep 2016, 31 Jan 2017, 24 Apr 2017

Outcome:
HMPC noted available minutes and agendas. No discussion took place.

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

5.3.1. Coordination with Safety Working Party – Assessment of estragole

Action: for discussion
Documents: PS; OoC; Letter from HMPC Chair to CHMP Chair, 15 Sep 2015; SWP response, 16 Nov 2016; Presentation

Outcome:
Postponed to May 2017 meeting.

Post meeting note:
The topic was discussed at MLWP and adaptation of the public statement with the proposed limits agreed before new coordination by HMPC with CHMP/SWP, CMDh and thereafter with EFSA can start.

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

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

  Outcome:
  HMPC noted documents on re-organised 3R group. No discussion took place.

5.4. Cooperation within the EU regulatory network

5.4.1. European Commission

- European Union herbal monograph on Saccharomyces cerevisiae CBS 5926
  Action: for adoption
  Document: Draft letter
  Action: for discussion
  Documents: Draft MO, draft AR, draft LoR; draft LE; email correspondence

  Outcome:
  Adoption of the draft letter was postponed. Members to send comments by 7 April 2017.

HMPC agreed to draft a short letter with a clear message and question to the Commission while the rationale presented (5 pages plus 2 pages references) should be structured and attached beside the draft assessment report.

For re-discussion and possible adoption at the HMPC May meeting.

The focus of the document as well as some justifications (e.g. on safety) were discussed in terms of relevance for the classification question. While the scientific background is useful to present to the Commission, the question should be focused on the expected legal clarification and relevant consequences for national regulation of products and HMPC activities.

- Update on List Entries
  Action: for information
  Document: List of herbal substances, preparations and combinations thereof for use in THMP

  Outcome:
  Postponed.

5.4.2. European Pharmacopeia

- EDQM 13A expert group meeting held on 28 Feb - 1 Mar 2017
  Report: M. Bald (EDQM); HMPC/Q DG Observer: M. Brum
  Action: for information
  Documents: Agenda; Summary of decisions; Report by M. Brum
- EDQM 13B expert group meeting to be held on 10-11 May 2017
  Report: M. Bald (EDQM); HMPC/Q DG Observer: B. H. Kroes
  Action: for information
  Document: none
- EDQM TCM expert group meeting held on 31 Jan – 1 Feb 2017
  Report: M. Bald (EDQM); HMPC/Q DG Observer: R. Länger
  Action: for information
  Document: Summary of decisions
- EDQM TCM expert group meeting to be held on 26-27 Apr 2017
  Report: M. Bald (EDQM); HMPC/Q DG Observer: R. Länger
  Action: for information
  Document: none

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

  The EDQM secretariat reported the planned establishment of a working party on the pyrrolizidine alkaloid analysis for which specific experts (including regulators) will be invited. Furthermore some progress with essential oil requirements (general discussion and specific monographs) was mentioned.

  For the TCM group progress with some monographs was mentioned. The 'alternative assay' item will take centre stage at the next meeting.

- HMPC herbal substance proposal for Ph. Eur. monograph establishment
  Report: Q DG Chair
  Action: for adoption
  Document: List of herbal substances

  See also 5.7.1

  Outcome:
  HMPC adopted the list as compiled by secretariat and discussed at Q DG for submission to EDQM. It was agreed to flag four out of eight substances (Symphytum, Vaccinium, Helichrysum, Eschscholzia) as priority.

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

Action: for discussion
Documents: Email correspondence by BPI, 17 Oct 2016; Presentation; THMP and simplified registrations for homeopathic medicinal products: PhV requirements and EV access

Outcome:
HMPC members noted recent clarification and communication on the EMA website regarding legislative and technical requirements in particular for THMP.

HMPC members emphasised that the reporting (and access to EudraVigilance) is not only essential to follow and allow comparison of products on adverse events but also for committee tasks when assessing safety of THMP for monograph updates. Therefore a stronger wording was advocated, which will be looked at by EMA.

PhV obligations of Art. 101 to 108b apply by analogy, on the basis of Art.16a (as per Art. 16g(1)) of Dir.2001/83/EC. Registrations holders are not required to submit PSURs, unless a condition in the MA or requested by a NCA (i.e. except when one of the cases provided for in Art. 107b(3)(a) or (b) of Dir. 2001/83/EC is applicable, = EURD list entry).

Companies' access to EudraVigilance to comply with PhV obligations is set out in Art. 24(2), 5th paragraph of Regulation (EC) No 726/2004. The level of access to EudraVigilance data for all stakeholders is set out in the EudraVigilance Access Policy (rev. 3). Access to companies is MP specific and determined on the basis of the data submissions (Art. 57).

Only where MP data are available in the XEVMPD (eXtended EudraVigilance Product Report Message), it can be determined which companies can access suspected adverse reactions in EudraVigilance based on MPs reported as suspect/ interacting.

For access to reports of suspected adverse reactions in EudraVigilance, registration holders should submit and update the information for these medicines using the electronic format referred to as Art. 57 or XEVPRM format. The XEVMPD already allows for data submission for THMP (Chapter 3.II: user guidance & question 1.2 of the document 'Electronic submission of Art. 57(2) data Questions & Answers' (EMA/159776/2013). No fees will be charged for submission of data in the Art. 57 database as Regulation (EU) No 658/2014 does not apply to THMP.

5.4.4. Coordination with EFSA

- Safety assessment of hydroxyanthracene derivatives
  Action: for discussion
  Document: Response from EFSA, 10 Mar 2017

Outcome:
HMPC noted communication by EFSA, welcomed the coordination intentions and agreed to provide all revised documents on hydroxyanthracene derivatives (HADs) containing substances once adopted by HMPC for public consultation.

HMPC agreed sending an observer (toxicology expert) to one of the next meetings to explain safety evaluation within the HMPC assessment.

Further coordination to be discussed at the HMPC May meeting.

HMPC noted history of the HADs containing 'botanical' assessment and respective communication as well as the distinction between 'efficacy' and safety assessment in the food area i.e. substantiation of health claim assessment (NDA panel) versus Eur. Com. triggered Art. 8 procedures on safety (ANS Panel). For laxatives the interaction with EFSA was considered important.

5.4.5. Survey on uptake of the traditional use registration and implementation of Directive 2004/24/EC in EU Member States, 2016 - Preliminary outcome

Action: for information
Document: Presentation

Outcome:
Postponed to May 2017 meeting.

5.5. Cooperation with International Regulators

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

Action: for discussion
Documents: Agenda

Outcome:
Postponed to May 2017 meeting.

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

5.6.1. AESGP – hearing at MLWP

Report: MLWP Chair
Action: for discussion
Document: Draft Agenda with List of participants

Outcome:
HMPC noted and discussed agenda points raised by AESGP. HMPC Chair and Vice Chair will attend the hearing in May, the meeting report will be distributed to HMPC and published.

5.6.2. EUROCAM

Report: HMPC Chair
Action: for information

Documents: Letter to HMPC Chair, 13 Feb 2017; The regulation of herbal medicinal products in the EU – by EUROCAM, 13 Feb 2017

Outcome:
Postponed to May 2017 meeting.

5.7. HMPC work plan

5.7.1. Projects on the HMPC work plan 2016

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

  Outcome:
  Postponed to May 2017 meeting.

- Exchange with EDQM on quality standards as basis for EU herbal monographs– proposal of substances for Ph. Eur. monograph establishment
  Action: for discussion

  See also 5.4.2

  Outcome:
  HMPC noted final status of HMPC 2016 work plan (topics finalised, ongoing, not started). No discussion took place.

  A list with substances proposed for Ph. Eur monograph establishment was agreed. HMPC secretariat to submit to EDQM.

5.7.2. HMPC work plan 2017

- Work plan 2017
  Report: HMPC Chair
  Action: for discussion
  Document: Work plan 2017 – current status

  Outcome:
  Postponed to May 2017 meeting.

- Develop a strategy for cooperation with Academia to include HMPC standards in the teaching activities and to stimulate research
  Report: HMPC Chair
  Action: for information
  Document: Presentation on 'Framework of collaboration between the EMA and Academia'

  Outcome:
  HMPC noted current status of HMPC work plan 2017 (items finalised, ongoing and not yet started).

  HMPC welcomed information on recently adopted framework in view of own plans to strengthen cooperation with academia.

5.8. Planning and reporting

5.8.1. Meeting dates for 2019-2021

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

Outcome:
Meeting dates 2019-2021 were adopted.

HMPC requested to look into possibilities to shift the 3rd and 4th meeting in 2018 (meeting dates 2016-2018 adopted in 2015) to an earlier week.

HMPC secretariat to check and to inform Committee on such possibility by end of April.

5.9. Legislation and regulatory affairs

5.9.1. Comments received on draft PS Piperis methystici rhizoma

Action: for discussion
Documents: Comments, 10 Feb 2017; Response from HMPC Chair, 24 Mar 2017

Outcome:
HMPC agreed to the letter drafted by the EMA legal department.

HMPC secretariat to circulate amended letter before signature and submission.

Further discussion on comments received during public consultation will happen at MLWP according to standard procedure.

6. Any other business

6.1. Topics for discussion

6.1.1. Monographs adopted - not yet published

- Pistacia lentiscus (mastix); Adopted: 2 Feb 2016
- Pruni africanae; Adopted: 12 Jul 2016
- Salviae officinalis folium; Adopted: 20 Sep 2016
- Aloe; Adopted: 22 Nov 2016

Outcome:
Postponed to May 2017 meeting.

6.1.2. Polypodii rhizoma

Action: for discussion
Documents: Revision of MO; Annex

See also 4.4.4

Outcome:
Postponed to May 2017 meeting.

6.1.3. Update on Management Board data gathering exercise – postponed

Action: for discussion
Document: none

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

Action: for discussion
Document: Presentation

Outcome:
HMPC noted overarching outcome of the survey and overall satisfaction with the service. A question regarding search function/ document history to be specified and clarified individually.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 30-31 Jan 2017

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 30-31 Jan 2017

Overview of status of HMPC assessment work – priority list

Inventory of herbal substances for assessment work

Abbreviations in HMPC agendas/minutes

Common names of herbal substances in all languages

6.2.2. MLWP

- Overview of status of HMPC/MLWP assessment work
- Draft agenda of MLWP meeting to be held on 28-30 Mar 2017

6.2.3. ARSP

- English template
- English summaries for publication:
  - Soya-bean lecithin
  - Soya-bean oil
  - Olive leaf
  - Willow bark

No comments were raised on the summaries ready for publication. HMPC secretariat will publish once opinion, monograph and supporting documents are published after editorial review.

6.2.4. Other

- Adulteration warning Singapore herbal remedies Mar 2017, Document: HAS Alert - Anyang herbal blue and red – Final
- WHO guideline on good herbal processing practices (GHPP) – COMPILED comments, Document: Comments on draft technical guidelines
- Correction on templates: MO, AR, Call for scientific data
- PCWP meeting:
  - Minutes - EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations, 30 Nov 2016
- PCWP/HCPWP meetings:
  - Agenda - EMA Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – Workshop on personalised medicines: role of patients, consumers and healthcare professionals, 14 Mar 2017
  - Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting, 15 Mar 2017

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 27-28 March 2017 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Marisa Delbò	Chair	Italy	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Heidi Neef	Member	Belgium	No interests declared	
Wim Huygh	Alternate	Belgium	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Elena Mustakerova	Member	Bulgaria	No interests declared	
Iliana Ionkova	Alternate	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	
Martina Holenkova	Expert	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Eeva Sofia Leinonen	Member	Finland	No interests declared	
An Le	Member	France	No interests declared	
Jacqueline Wiesner	Member	Germany	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
Ioanna Chinou	Member	Greece	No interests declared	
Zoi Karampourmpouni	Alternate	Greece	No interests declared	
Zsuzsanna Bíróné Dr Sándor	Member	Hungary	No interests declared	
Rachel Cox	Alternate	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Silvia Girotto	Co-opted member	Italy	No interests declared	
Evita Skukauska	Member	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	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Raluca Iavorszky	Alternate	Romania	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Barbara Razinger	Alternate	Slovenia	No interests declared	
Cristina Martinez Garcia	Alternate	Spain	No interests declared	
Per Claeson	Member	Sweden	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Malin Söderberg	Expert	Sweden	No interests declared	
Linda Anderson	Member	United Kingdom	No interests declared	
Sue Harris	Alternate	United Kingdom	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Meeting run with support from relevant EMA staff				

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