



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 November 2016
EMA/HMPC/790627/2016
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 19-20 September 2016

Chair: Werner Knöss – Vice-Chair: Marisa Delbò

19 September 2016, 14:00 – 19:00, 2F

20 September 2016, 09:00 – 13:00, 2F

Disclaimers

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

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

Note on access to documents

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



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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).

Mandate of member and alternate of Estonia is vacant, informed by NCA. Expiry date for both mandates: 22 September 2016.

End of mandate:

- Annamarie O'Sullivan (Ireland) alternate resigned. Her membership in HMPC ended on 16 August 2016

Tina-Soon Engraff stepped down as European Commission representative with the date of 29 July 2016. No information is available yet on a new representative.

1.2. Adoption of agenda

HMPC agenda for 19-20 September 2016

Time schedule for 19-20 September 2016

Outcome:

The agenda was adopted. The time schedule was endorsed.

1.3. Adoption of the minutes

HMPC minutes for 11-12 July 2016

Outcome:

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

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP July 2016 meeting

Report: MLWP Chair

Action: for information

Document: Draft minutes for the MLWP meeting on the 12-14 July 2016

2.1.2. Appointment of Rapporteurs and Peer-reviewers

- Changes of Rapporteur or Peer-reviewers for Monograph revision

Absinthii herba

Anisi aetheroleum

Anisi fructus

Arctii radix

Outcome:

The proposed Rapporteur/Peer-reviewer changes were endorsed.

2.1.3. MLWP membership

- Call for nominations for **position 1** (medical doctor with expertise in paediatrics)

Report: HMPC Chair

Action: for discussion

Documents: Mandate of MLWP; Email, 29 April 2016; Correspondence with PDCO and HCPWG; DE & IT nominations

- Call for nominations for **position 2** (clinical/non-clinical assessor)

Report: HMPC Chair

Action: for discussion

Documents: Email, 28 July 2016; DE & IT nominations

Outcome:

HMPC agreed on two nominated candidates as proposed by HMPC Chair after discussion with MLWP Chair and HMPC/MLWP Vice-Chair although the expertise originally intended was not fully matched. A practising physician and/or paediatrician had not been nominated. Only one candidate fully matched the expertise required for position 2.

According to previous agreement M. Delbó's membership (and vice-Chairmanship MLWP) automatically ceased at the end of the MLWP meeting following the HMPC meeting.

Post-meeting note:

According to MLWP discussion it was preferred to appoint a new MLWP Vice-Chair already at the following HMPC meeting.

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

2.2.1. Monograph on *Pelargonii radix* and supporting documents – postponed

2.2.2. Monograph on *Salviae officinalis folium* and supporting documents

Rapporteur: G. Fossum; Peer-reviewer: C. Cavaleiro

Action: for adoption

Documents: MO, AR, LoR, OoC, References: 61/68

Outcome:

Final revised monograph and supporting documents adopted by majority vote (25 out of 28). The Norwegian Member was not present.

Divergent opinion: Zs. Birone Sandor, M. Delbó, E. van Galen

The difference between external use by adolescents vis-à-vis adults for potential risks due to thujone were discussed in view of products on the market with > 30 years of use in adolescents. While it was not specified what adequate scientific data would be necessary, reference was made to several discussions at MLWP, general safety concerns for this age group and the 'PS on herbal medicinal products containing thujone'. The wording for adolescents was maintained and no indication considered justified: The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.

Posology wordings regarding night sweats / menopausal women were questioned but not changed with reference to better possibilities finding national solutions for product information and labelling according to respective language.

Divergent opinions referred to the use in adolescents, the preference of 'irritation' over 'inflammation' in the indication and the non-acceptance of an extraction solvent without a specification for a traditional herbal medicinal product.

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

None

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

2.4.1. Monograph on *Origani majoranae herba*

Rapporteur: C. Cavaleiro; Peer-reviewer: M. Heroutová

Action: for adoption

Documents: MO, AR, LoR, References: 34/38

Outcome:

Final monograph with minor changes and supporting documents adopted by majority vote (27 out of 28). The Norwegian Member was not present.

Divergent opinion: L. Anderson

The divergent opinion referred to concerns regarding the traditional use in young children.

2.4.2. Monograph on *Silybi mariani fructus*

Action: for adoption

Documents: MO, AR, LoR, OoC, References: 114/196

Outcome:

Because of major changes to the draft monograph after public consultation (limitation to TU indication) and the importance of the substance on the European market the HMPC decided to allow exceptionally a second public consultation.

Second draft monograph and supporting documents adopted by majority vote for 3 months public consultation.

Following several discussions at HMPC and MLWP a solution supported by a majority of MLWP with a modified TU indication but no WEU indication was presented by the Rapporteur. Members repeated concerns regarding self-medication and hepatic complaints and also questioned the serious conditions to be excluded before starting self-medication with *Silybum*. However, in line with previous communication with the Commission others emphasized that medical upfront diagnosis is required to exclude serious conditions but not for the proper use of the product as such. A majority supported the monograph as provided by the Rapporteur and also the exceptional second public consultation before finalisation.

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

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

Action: for adoption

Documents: LE, MO, AR, LoR

Outcome:

Adoption for public consultation postponed due to concerns about the substance fitting into the definition of herbal substance/ herbal preparation and the borderline to biological MPs.

HMPC discussed to contact CHMP/BWP to find general agreement on correct framework *Saccharomyces* products should be regulated to allow a decision on continuation of monograph development.

Members to send proposals for specific questions to the Rapporteur by **4 October 2016**, which could be forwarded to CHMP/BWP.

Rapporteur and S. Kreft to draft letter with questions for agreement by HMPC Chair and members by **18 October 2016** before submission to CHMP/BWP.

Members discussed 1) definition and potential overlap to biological products, 2) the period of use for individual indications and 3) the wording for use in diarrhoea. Regarding 1) it was referred to previous discussions at time of prioritisation for assessment and also to communication with Ph. Eur.

2.5.2. Monograph on Species diureticae and supporting documents

Action: for adoption

Documents: MO, AR, LoR

Outcome:

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

HMPC noted currently necessary compromises in publication (browse, key word search) of combination monographs (here 4 out of 13 possible substances) within the current structure tailored for mono substances.

Some clarifications were required from the Rapporteur regarding the evidence of use of specific combinations as captured in a novel table in the draft monograph. The HMPC further discussed the possibility of other combination monographs according to experiences with this pilot project.

3. Referral procedures

None

4. Guidelines and guidance documents

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

None

4.2. Quality

None

4.3. Regulatory

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

Rapporteur: M. Delbó

Action: for adoption

Document: Template

Outcome:

The template which was previously adopted for use by NCAs only was now slightly updated and adopted for publication on the EMA website.

It was clarified that advice might be useful for consideration also by applicants - not only NCAs - although not strictly a guideline or mandatory template. A reference can be found in the herbal addendum to the QRD template. The title was modified.

4.3.2. Revised regulatory questions and answers - [EMA/HMPC/345132/2010](#)

Report: ORGAM Chair

Action: for adoption

Documents: Revised Q&A; Clarification from EC, 8 June 2010

Outcome:

Additions to the Regulatory Q&A on herbal medicinal products (Q&A 9-12) was adopted after modification to improve clarity.

HMPC secretariat to amend Q&A document EMA/HMPC/345132/2010 and publish revision 3 on the EMA website.

With reference to NtA and previous communication by the Commission the emphasis was put on the necessity to fulfil general requirements for well-established use in the EU. The separated specific case was welcomed as useful to be added to the Q&A and no modifications were requested.

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 7 September 2016

Action: for information

Document: Draft agenda for the Q DG meeting to be held on 5 October 2016

Outcome:

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

The group had amended the revision of the quality guideline which after final check will be shared with HMPC in November. Release for public consultation was agreed to be kept in conjunction with the revised herbal specification guideline which has now been started. In this context the herbal quality Q&A are currently reviewed for new additions but also reductions when possible to include some questions in the revised guidelines. Furthermore work plan and coordination with EDQM were addressed.

Some future key points requiring communication with Ph. Eur. were discussed to be taken into consideration for the draft work plan 2017 (see also 6.1.4).

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report

Action: for adoption

Document: Meeting report from ORGAM DG meeting held on 6 September 2016

- Agenda

Action: for information

Document: Draft agenda for the ORGAM DG meeting to be held on 6 October 2016

Outcome:

ORGAM meeting report was adopted. No requests were made regarding agenda points for the October meeting with main focus on the revision procedure (see below).

The DG had discussed the revision of the 'Procedure for the systematic review of EU herbal MOs and LEs and supporting documents', proposals on update of existing template for EU herbal monographs, draft work plan 2017, new mandate, membership and future structure for ORGAM DG.

- Draft revised template for EU herbal monographs

Action: for discussion

Document: Presentation

Outcome:

Proposal was considered to need further discussion at MLWP before a possible decision by HMPC.

The different legal/ regulatory status and function of a EU herbal monograph vis-à-vis the QRD template and their applicability for individual product applications were discussed and some concerns were raised. MLWP agreement is required before HMPC decision to go into the proposed direction and transfer the task for template modification back to ORGAM DG.

- Proposal for the revision process of the EU monographs/List entries

Action: for discussion

Document: Presentation

Outcome:

A majority agreed to main steps presented: 1) Defined limited review of relevant data that would trigger need for revision 2) Presentation at HMPC for decision on start revision procedure 3) If yes start full revision of monograph according to standard procedure, if no short addendum to existing AR/LoR on new data not requiring revision of monographs and supporting documents.

ORGAM DG to develop procedure based on experiences gained and the merged reflection paper (reasons and timelines for revision) and procedure for systematic review in order to achieve a streamlined, realistic procedure.

The workload to detect the need for update in relation to the workload to revise completely a monograph and supporting documents was discussed regarding safety, relevance of data, experiences gained and availability of an up-to date monograph for national procedures.

While a majority agreed to the 3 step approach and always full revision if justified by new data, some members highlighted the importance of the assessment report and new references for applicants.

Once a new draft procedure is available, the SE and SI members volunteered to test the new approach with substances due for systematic review.

- Resignation of M. Delbó as ORGAM member effective from 10 July 2016

Action: for discussion

Documents: Resignation letter; IT nomination

- Mandate and membership of ORGAM DG

Action: for discussion

Documents: Presentation; [Current mandate](#); [Possible future mandate](#)

Outcome:

HMPC noted presentation on secretariat and ORGAM view on future need, scope of activities, meeting frequency and membership.

Before adoption of new mandate and new call for expression of interest, HMPC to discuss and decide best future structure at the November meeting. The relevance for the draft work plan 2017 was noted.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Preparation for election of HMPC Chair and Vice-Chair

Action: for discussion

Document: Procedure for the election of HMPC Chair and Vice-Chair

Outcome:

HMPC noted extract from RoP and practical arrangements/timelines. HMPC agreed to dissociate Chair (Nov 2016) and Vice Chair (Jan 2017) election in line with other committees to allow future business continuity and smooth /transparent nomination/election process.

HMPC secretariat to send out call for nominations.

5.1.2. Assessors Training 3-4 November 2016

Report: S. Bager

Action: for adoption

Document: Draft Agenda

Outcome:

Draft Agenda was adopted. HMPC members were reminded on the call for nominations of participants.

Invitations will be sent out by 23 September.

5.1.3. Strategic Review and Learning Meetings

Report: HMPC Chair; E. van Galen

Action: for discussion

Documents: Email from HMPC Chair, 26 May 2016; Summary in presentation; Summary of Strategic Review meeting in NL 2016; Summary: Follow up on "Transfer from Utrecht"; Breakout session groups – follow up

Outcome:

No new comments had been received on the 4 summaries of group discussions in July. The topic was postponed since the Chair considered it as a good starting point for the new Chair to shape the future structure / working methodology according to the changed environment for HMPC activities.

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

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Coordination with CHMP: drafting group on excipients: ethanol as an excipient

Rapporteurs: J. Wiesner, S. Girotto

Action: for information

Documents: Presentation, Q&A on ethanol

Outcome:

HMPC welcomed possibility to discuss the draft and made comments on potential discrepancy in children between the HMPC reflection paper and the proposed wording for the defined medium level suggesting some modification.

DG will take into account comments at upcoming TC for finalisation. After review by QRD the finalised version will be shared with HMPC again before CHMP adoption.

The main point was the appropriate wording according to concentration for the middle band in the absence of specific data. It should be avoided that the suggested warning at lower concentrations could be seen contradictory to a statement on safety in the HMPC-RP at even higher concentrations but also the often agreed safe use for 30 years in monographs in specific cases. Other points raised were the '0 threshold', the wording on the need for ethanol to make the medicine work properly and the suitable unit for ethanol.

5.2.2. Coordination with CMDh – Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual recognition and Decentralised procedures for (T)HMPs

Report: ORGAM Chair

Action: for information

Documents: Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures specific for (T)HMPs (EMA/HMPC/770889/2014; [CMDh/349/2016](#)); [QRD template](#); [Press release](#)

Outcome:

HMPC noted publication of the addendum at the CMDh website. It was proposed to have additionally a link at the EMA website (product information templates together with other QRD templates) and the herbal pages.

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

5.3.1. Coordination with Innovation Task Force and CHMP

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13B expert group meeting held on 13-14 September 2016
EDQM: M. Bald; HMPC Observer: H. Neef
Action: for information
Documents: Draft Agenda, Summary of discussion

- EDQM TCM expert group meeting to be held on 20-21 September 2016
EDQM: M. Bald; HMPC Observer: R. Länger

Action: for information

Document: Draft Agenda

Outcome:

No new information since the July meeting was available due to meeting sequence.

HMPC noted the postponement of a decision on the pyrrolizidine alkaloid analytical development with a feasibility study based on a specific case for possible decision at Ph. Eur. commission in November (see also 6.1.4).

5.5. Cooperation with International Regulators

5.5.1. HMPC – International representation and cooperation

Report: HMPC Chair

Action: for adoption

Document: Draft proposal HMPC international cooperation

Outcome:

Adopted with some additions by the HMPC Chair. The paper should serve as background document in cooperation with the international affairs department for the planning of EMA international engagement in fora related to herbal / traditional medicines in line with the network strategy 2020.

5.5.2. EU-India joint working group July 2016

Action: for discussion

Document: Report

Outcome:

HMPC noted brief feedback from meeting where a presentation from the AYUSH ministry had been given. The opportunity for AYUSH experts to visit EMA in November 2015 as follow-up of the previous meeting had been welcomed by India and cooperation with regard to specific herbal substances encouraged.

Also at this years' meeting both sides agreed to continue cooperation through the HMPC with a focus on selected specific plants, possible *ad hoc* participation of AYUSH Regulators at HMPC meetings and further initiatives to strengthen the communication regarding herbal medicines used in Ayurvedic medicines.

5.5.3. Announcement of the 3rd Complementary and Herbal Medicines workshop at the 11th Summit of Heads of Medicines Regulatory Agencies, Interlaken, Switzerland, 10 October 2016

Report: HMPC Chair

Action: for information

Document: Agenda

Outcome:

HMPC noted Chair's participation at the side workshop usually attended by heads of agencies but not herbal experts. Based on a written report by the Chair the benefit of this

forum driven by TGA should further be monitored vis-à-vis other platforms such as IRCH or ICDRA under the WHO umbrella.

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

Report: HMPC Chair

Action: for information

Document: Draft Agenda

Outcome:

HMPC noted participation of the HMPC Chair and EMA secretariat to further explore role of EMA at IRCH but also follow up on relationship with the AYUSH ministry regarding traditional medicines after their visit at EMA in 2015. Opportunities but also limitations regarding working methodology were discussed.

It was suggested that the EMA experience in working methodology involving many parties would be beneficial for IRCH.

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

5.6.1. EUCOPE

Report: HMPC Chair

Action: for discussion

Documents: Letter to HMPC, 25 July 2016; Draft response from HMPC, September 2016

Outcome:

Discussion postponed. HMPC Chair will review draft response for distribution to all HMPC before sending to the Interested party.

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:

Work plan 2016 topic was postponed. Final report on work plan 2016 activities to be discussed at the HMPC November meeting.

- Harmonisation of assessment practice for herbal substances of non-European origin

Report: E. van Galen

Action: for adoption

Documents: Draft letter to Indian authorities (AYUSH); Inventory list of Ayurveda Herbs, July 2016

Outcome:

HMPC Chair and secretariat to review draft response for liaison with EMA international affairs department and EDQM before sending to AYUSH ministry.

5.7.2. Preparation of HMPC work plan 2017

Report: HMPC Chair

Action: for discussion

Document: Draft working plan

Outcome:

HMPC Chair encouraged members to send proposals for the work plan 2017 to the secretariat by **18 October 2016** in order to allow preparation and final discussion at the HMPC November meeting.

Chairs of MLWP, Q DG and ORGAM DG likewise to have draft work plans for 2017 (annexed to HMPC work plan) ready for adoption in November 2016.

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

6. Any other business

6.1. Topics for discussion

6.1.1. ARSP

- English summaries for publication
Documents: Aniseed; Anise oil; Bearberry leaf; Hop strobili; Passion flower; Primula flower
Primula root; Thyme
- English template
- Procedural challenges ARSP translations (presentation)

Outcome:

Achievements and remaining procedural challenges were presented with respect to translations into all EU languages. The skip of the additional check only performed by some MSs was proposed.

Because of diverse experiences with translations but also the English original topic to be re-discussed at the November 2016 meeting. Discussion should also include the option to elaborate only the English original.

Some members considered translations still not satisfactory -despite templates in all languages- and needing corrections, otherwise it would be better not having translations published at all. From secretariats side it was emphasised that the check is a translation check against the English original summary but not against any HMPC documents. It was also asked for feedback on the improvement of the English template.

6.1.2. Update on Management Board data gathering exercise

Action: for discussion

Outcome:

Postponed to November 2016 meeting.

6.1.3. Information on EMA internal organisational adjustments

Action: for discussion

Document: Presentation

Outcome:

HMPC noted some general adjustments towards a leaner, more effective structure and some affecting the scientific committee support service regarding allocation in the organisation and lead roles with effect from September 2016. Overall the interface between individual secretariat and committee does not change and a broader basis to guarantee business continuity and supporting service was welcomed.

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

Report: HMPC Chair

Action: for discussion

Document: EDQM response on Pyrrolizidine alkaloids, 3 August 2016

Outcome:

Postponed to November 2016 meeting.

6.1.5. Evidence on the period of traditional use

Report: E. v. Galen

Action: for discussion

Document: Question for clarification, 30 August 2016

Outcome:

HMPC noted view of EMA legal department and RA on question submitted by the NL member. Because of the wider importance it was agreed to seek also the view from the European Commission for clarification and justification.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 11-12 July 2016

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 11-12 July 2016](#)

[Overview of status of HMPC assessment work – priority list](#)

[Inventory of herbal substances for assessment work – alphabetical order](#)

[Abbreviations in HMPC agendas/minutes](#)

Common names of herbal substances in all languages

6.2.2. MLWP

- Overview of status of HMPC/MLWP assessment work
- Draft agenda of MLWP meeting to be held on 20-22 September 2016

6.2.3. Other

- Publication on ethanol exposure in children from food, July 2016
- [Update of documents on EU Good Pharmacovigilance Practices \(EU-GVP\)](#)
- PCWP/HCPWP meetings:
 - Report of a joint EMA workshop with patient and healthcare professional representatives about communication on medicines - 8 March 2016 (EMA/194543/2016)
 - Minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting - 9 March 2016 (EMA/183905/2016)
 - Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – Workshop on social media – 19 September 2016 (EMA/825257/2015)
 - Draft Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – 20 September 2016 (EMA/428004/2016)
- PCWP meeting:
 - Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) meeting – 14 June 2016 (EMA/274681/2016)
 - Minutes - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) meeting – 14 June 2016 (EMA/419205/2016)
 - Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) 10th Anniversary meeting – 14 June 2016 (EMA/392315/2016)
- HCPWP meeting:
 - Agenda - EMA Human Scientific Committees' Working Parties with Healthcare Professionals' Organisations (HCPWP) meeting – 15 June (EMA/285607/2016)
 - Minutes - EMA Human Scientific Committees' Working Parties with Healthcare Professionals' Organisations (HCPWP) meeting – 15 June (EMA/418148/2016)

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 19-20 September 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	
Astrid Obmann	Alternate	Austria	No interests declared	
Heidi Neef	Member	Belgium	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Elena Mustakerova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Marie Heroutova	Member	Czech Republic	No interests declared	
Markéta Příhodová	Alternate	Czech Republic	No restrictions applicable to this meeting	
Nina Dürr	Alternate	Denmark	No interests declared	
Eeva Sofia Leinonen	Member	Finland	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Zoi Karampourmpouni	Alternate	Greece	No interests declared	
Zsuzsanna Biróné Dr Sándor	Member	Hungary	No interests declared	
Una Mockler	Member	Ireland	No restrictions applicable to this meeting	
Marisa Delbò	Member (Vice-Chair)	Italy	No interests declared	
Silvia Giroto	Co-opted member	Italy	No interests declared	
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Dace Kalke	Member	Latvia	No interests declared	
Baiba Jansone	Alternate	Latvia	No interests declared	
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	
Nadia Grigoras	Member	Romania	No interests declared	

Miroslava Petrikova	Member	Slovakia	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Samo Kreft	Member	Slovenia	No restrictions applicable to this meeting	
Adela Nunez Velazquez	Member	Spain	No interests declared	
Cristina Martinez Garcia	Alternate	Spain	No interests declared	
Per Claeson	Member	Sweden	No interests declared	
Erika Svedlund	Alternate	Sweden	No interests declared	
Linda Anderson	Member	United Kingdom	No interests declared	
Melanie Bald	Observer (via TC)	EDQM	No interests declared	