12 July 2016
EMA/HMPC/434600/2016
Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 30-31 May 2016

Chair: Werner Knöss – Vice-Chair: Marisa Delbò

30 May 2016, 14:00 – 19:00, 3E (chaired by M. Delbò)

31 May 2016, 09:00 – 13:00, 3E (chaired by W. Knöss)

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room).

New member (Slovakia): Miroslava Petríková; Starting date of mandate: 21 April 2016.

The three-year mandate of Ewa Backhaus (Alternate Poland) terminated on 20 May 2016. Nomination of a replacement alternate is awaited.

1.2. Adoption of agenda

HMPC agenda for 30-31 May 2016

Time schedule for 30-31 May 2016

Outcome:
The Agenda was adopted.

1.3. Adoption of the minutes

HMPC minutes for 4-5 April 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 April 2016 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on the 6-7 April 2016

Outcome:
HMPC noted explanations for postponement of several packages for adoption, due in part to need for additional clarification at MLWP.

2.1.2. Nominations for new MLWP member

Report: HMPC Chair
Action: for discussion
Documents: Mandate of MLWP; "Call for nominations", 29 April 2016; DE nomination

Outcome:
HMPC agreed to give another opportunity for nominations since only one candidature has been received. Deadline: 5 July 2016.

Following the renunciation of a paediatrician at MLWP, the need for a medical doctor (paediatrics) or medical doctor with expertise in non-European traditional medicines had been agreed at the HMPC April meeting to fill the vacant position. However, only one member had responded to the call.

HMPC secretariat to forward call also to PDCO and HCPWG.

2.1.3. New observer at MLWP – Swissmedic

Action: for information
Documents: Observers summary for Committees and WPs; Observers at EMA meetings; CV N. Rickenbacher

Outcome:
HMPC noted newly appointed Swissmedic observer in MLWP alongside observers in other EMA groups as well as observing modalities based on general confidentiality agreement between EMA and Swissmedic.

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

None

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

2.4.1. Public statement on Balsamum peruvianum

Rapporteur: P. Claeson; Peer-reviewer: W. Knöss
Action: for adoption
Documents: PS, AR, LoR, References: 34/34

Outcome:
Final public statement and supporting documents adopted by majority vote (22 out of 23). Norway was not present. Divergent opinion: Dr Zsuzsanna Birone Sandor

HMPC secretariat to also inform excipients DG since Peru balsam is also used as excipient in medicinal products.

No new data have been received during public consultation that changed the HMPC opinion on the safety profile of the substance.

The divergent opinion referred to the possibility of a monograph taking into account >30 years of use in combination medicinal products in some MSs without adverse events (Eudravigilance database), inclusion in Annex of NtA Vol. 3B Excipients in the label and package leaflet of medicinal products for human use (July 2003, CPMP/463/00), and possible use of Peru balsam extracts/distillates in cosmetics (up to 0.4%). However, a majority did not support the proposal that safety concerns could be addressed by appropriate warnings in SmPC in line with e.g. Comm. E monograph and upfront sensitivity test for allergic reactions.

2.4.2. Public statement on Salviae fruticosae folium

Rapporteur: C. Cavaleiro; Peer-reviewer: I. Chinou
Action: for adoption
Documents: PS, AR, LoR, References: 21/26

Outcome:
Final public statement and supporting documents adopted by consensus. Norway was not present.

No new data have been received during public consultation that allowed establishment of an EU herbal monograph.

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

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

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

2.5.3. List Entry and Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents - postponed

2.5.4. Public statement on Silybi mariani fructus and supporting documents

Action: for discussion
Documents: PS, AR, LoR, OoC

Outcome:
HMPC noted procedural, regulatory and scientific concerns by EMA secretariat regarding the content and publication of a (draft) public statement after previous publication of a draft monograph vis-à-vis HMPC standard procedure and practice.

A majority agreed to not close the assessment with a PS but ideally a final monograph.

The HMPC Vice Chair proposed a break out session lead by medical doctors to find an appropriate solution with emphasis on the TU indication. Rapporteur and Peer-reviewer to initiate a small group to present a proposal for discussion at MLWP in July.

Some members emphasised the lack of evidence for the WEU, safety concerns regarding the TU indication and exhaustive discussions at MLWP and HMPC. However, a majority endorsed the view that without new data after publication of a draft monograph the assessment closure via PS appears neither justified nor in line with HMPC standard procedure. Furthermore authorisations and registration of medicinal products in many MS as well as strong liver-related claims of other product categories on the market were mentioned to strive for an appropriate indication and finalise the assessment with a monograph.

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 adoption
Documents: Draft reflection paper; EU Court of Justice Case T-14/06

Outcome:
Reflection paper with minor editorial changes was adopted by consensus.

A more advanced regulation in the food area was noted. It was agreed that the paper as such does not give guidance but is a problem statement to stimulate the discussion. Only after consultation and review of all data the need and appropriate form of guidance will be decided.

4.2. Quality

4.2.1. Recommendations on contaminations with pyrrolizidine alkaloids (PAs) in herbal medicinal products

Action: for adoption
Documents: Draft public statement; Comments from DE; Break out session PA 06/04/2016 summary; Draft Lines to take; HMPC Chair presentation at Inspectors working group (GMDP IWG) in May 2016; Inspectors feedback; ES comments and email received 27 May 2016

Outcome:
Public statement with changes was adopted by majority.

Because of the urgency considered by several MSs, HMPC agreed to publish PS without public consultation or prior consultation of other groups. After publication EMA secretariat to inform EFSA, EDQM and Inspectors working group.

HMPC welcomed data provided by AESGP and report from the task force looking into safety and quality aspects and drafting the PS. In addition updates on initiated measures in some MS were given and the need for a coordinated approach with reference to a common document emphasised.

Members discussed the relationship between the previous PS on PA and the new PS in particular regarding the toxicological assessment. The period of use, toxicological models and acceptable levels of exposure were discussed. A majority considered the new assessment as an independent approach to deal transitorily with the contamination issue and acceptable limits, while the previous assessment/threshold in principle stands and may be reviewed after about 2-3 years. The primary focus on quality aspects was emphasised, i.e. necessary testing regimes (such as possible skip testing) and measures as well as need for clarification of contamination sources such as identification of most problematic substances to first concentrate on vis-à-vis limited testing resources. Divergent opinions referred to the volume and rationale of the toxicological justification in the new PS.

4.3. Regulatory

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair
Action: for adoption
Documents: Meeting report from Q DG meeting held on 4 May 2016; QDG proposals for guideline revisions to address PAs

Outcome:
QDG meeting report was adopted.

The DG had discussed the follow-up on the quality assessors training 2015 towards development of new Q&A and consideration in guidance documents. Furthermore a request by EDQM on early manufacturing steps in the context of certificates on suitability was discussed considering a need for additional guidance to be developed on GACP/GMP (see 5.4.2).

Upon proposal from QDG, HMPC agreed on a stepwise guidance update regarding controls of pyrrolizidine alkaloid contamination with some changes to be included in guidelines EMA/HMPC/201116/2005 Rev. 2 (quality; revision ongoing), EMA/HMPC/162241/2005 Rev. 2 (specifications; revision planned) and EMEA/HMPC/246816/05 (GACP; revision not yet scheduled).

Action: for information
Document: Draft agenda for the Q DG meeting to be held on 30 June 2016

Outcome:
No further topics proposed by HMPC; finalisation of the CEP topic requested (see 5.4.2).

4.4.2. ORGAM DG

Report: ORGAM DG Chair

Action: for adoption
Document: Meeting report from ORGAM DG meeting held on 3 May 2016

Outcome:
ORGAM meeting report was adopted.
The group had the final discussion on the herbal annex to the QRD template (see 5.4.2).

Action: for information
Document: Draft agenda for the ORGAM DG meeting held on 28 June 2016

Outcome:
Endorsed. The ORGAM Chair announced a review of actions agreed in the ORGAM work plan.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Mandate of Quality DG and expression of interest for members/observers

Action: for discussion
Documents: Overview of QDG member interests; New nominations; New draft mandate

Outcome:
Response from all current Q DG members and new nominations for active members/ observers were received and summarised.

New draft mandate aligned with CHMP standard mandate for DGs and temporary WPs. After final regulatory and legal check, the mandate is foreseen for adoption at the HMPC July meeting.

QDG Chair in liaison with HMPC Chair to present list of active members/ observers for re-nomination according to new mandate in July.

5.1.2. Assessors Training 3-4 November 2016

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

Outcome:
Topic leader noted comments for further development of the draft agenda. Members invited to send proposals or volunteer for presentations. Deadline 30 June 2016.

Topic leader to present an improved agenda for adoption at the HMPC July meeting.

5.1.3. Strategic Review and Learning Meetings

Report: HMPC Chair; E. van Galen
Action: for discussion
Documents: Presentations; Email from HMPC Chair, 26 May 2016; Summary in presentation; Transfer from Utrecht – Follow up

Outcome:
Postponed to July 2016 meeting.

Discussion on proposals from the NL Strategic and learning meeting for future structure/working methodology of HMPC (+subgroups) including breakout sessions on key issues postponed to the July meeting.

5.1.4. Procedural guidance – minor revision of procedure for calls for scientific data

Action: for adoption
Document: Procedure for calls for scientific data for use in HMPC assessment work (EMA/HMPC/1004/2006 Rev 5)

Outcome:
Minor changes in procedure and template were adopted. HMPC secretariat to publish revised procedure.

Adaptations referred to the electronic format and the initiation of calls for review of monographs, which does not follow a systematic 4/5 year schedule but is proposed individually by MLWP. The preference of peer reviewed data and complete search overview from industry was confirmed but the explicit requirement deleted in view of 10 years' experience and final responsibility of the Rapporteur. No additional check by ORGAM was considered necessary.

5.1.5. Revision of Procedure for nomination and appointment of co-opted members in CHMP, CVMP and HMPC

Action: for adoption
Document: Procedure for nomination and appointment of co-opted members in CHMP, CVMP and HMPC

Outcome:
Procedure for nomination and appointment of co-opted members was adopted.

Previous HMPC specific document is superseded by new document applicable for CHMP, CVMP and HMPC.

Some details were clarified and the amended procedure describes requirements regarding decisions on area of expertise, number of co-opted members and quorum adjustment, eligible candidates and nominations, appointment procedure, meeting participation and Rapporteurship.

HMPC secretariat will publish revised procedure after adoption by CHMP and CVMP.

5.1.6. DG meeting dates 2017

Action: for adoption
Document: DG dates for 2017

Outcome:
DG dates for 2017, previously discussed with the DGs, were adopted.

HMPC reminded on early notification of non-availability as meeting dates (within HMPC schedule) and room bookings cannot usually be ad-hoc changed.

Request for changes in meeting frequency or more ftf meeting should be justified based on work plan/ additional tasks and submitted in June to allow budget requests.

5.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: for information

Outcome:
HMPC noted recent developments. Updated documents will be provided by DG excipients secretariat for comments to HMPC mid-June when circulating to all working parties before adoption by CHMP.

Once available, HMPC Rapporteurs to draft comments and indicate consequences for HMPC RP on ethanol in medicines for children and the monograph template.

It was emphasised that the guideline on labelling is not guidance on acceptable limits. Three levels of labelling according to age group and associated risks are planned, whereby after many comments from the herbal industry analogies with alcohol containing foods/beverages are re-considered for appropriate risk communication. HMPC comments are considered important but will only be possible once the consolidated documents are provided to HMPC.

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

Action: for discussion
Documents: PS; OoC; CHMP Safety Working Party response to HMPC/CHMP questions on Pulegone and Menthofuran; Peppermint oil content JMV to HMPC

Outcome:
HMPC welcomed SWP recommendations. Still remaining points for clarification on existing thresholds or excipients were noted, requiring close coordination as regards communication, content and timing.

HMPC revised public statement to be further kept on hold until communication strategy agreed at SciCo Board before publication.

MLWP to finalise proposal for specific consequences in peppermint oil monograph in order to clarify SWP threshold consequences for high-posology products.

The committee welcomed CHMP adopted thresholds based on the 7 answers by SWP on the assessment allowing now finalisation of the PS. Furthermore checking consequences for Mentha monograph revision for those products still above the higher threshold will now be

possible – a task given to MLWP and eventually requiring new contact with EDQM. It was noted that the excipients question (nicotine chewing gums), the trigger to ask CHMP for coordination, was still open and some questions regarding communication and follow up between CHMP and CMDh still need to be clarified.

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

Action: for adoption
Document: Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual recognition and Decentralised procedures for (T)HMPs (EMA/HMPC/770889/2014)

Outcome:
QRD template was adopted with changes by a majority.

Remaining questions without ORGAM consensus were clarified and directly implemented.

HMPC secretariat to transmit to CMDh for discussion and adoption as herbal specific annex to standard QRD templates.

All points were clarified in line with reasonable practice and standard wordings in monographs, acknowledging that some compromises have to be made.

In view of reference to an earlier adopted patient leaflet template for herbal tea preparations, publication should be re-discussed during the HMPC July meeting, since it was decided in 2012 to distribute among NCAs but not to publish on the EMA website.

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 – postponed
- EMA PCWP/HCPWP joint meeting, 9 March 2016 – postponed
- Patient involvement within EMA/HMPC
  Action: for adoption
  Document: Patient involvement within EMA/HMPC

  Outcome:
  Patient involvement within EMA/HMPC was adopted.

- Nomination of HMPC representative at the HCPWP & PCWP
  Action: for adoption
  Document: Letter to the Chair of the HMPC, 11 May 2016

  Outcome:
  Previous HMPC representative S. Bager (DK) was re-confirmed for another 3 years. In addition S. Madsen (NO) was appointed as alternate with main focus on the HCPWP.

5.3.2. Coordination with Innovation Task Force and CHMP

Action: for discussion
Documents: European Commission's note to EMA, 13 May 2016; Annex

Outcome:
Article 57 request with 60 days procedural deadline agreed to be relevant for HMPC.
AT member supported by SE alternate volunteered to act as Co-Rapporteurs alongside the main CHMP Rapporteur (AT).
Timetable to be specified and distributed. HMPC scientific coordinator to draft AR for comments.

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

Report: J. Wiesner, G. Laekeman
Action: for discussion
Document: Meeting report, 30 March 2016

Outcome:
No immediately relevant topics for HMPC were identified.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13A expert group meeting to be held on 8-10 June 2016
  EDQM: M. Bald; HMPC Observer: I. Chinou
  Action: for information
  Document: Draft Agenda
- EDQM 13B expert group meeting held on 19-20 April 2016
  EDQM: M. Bald; HMPC Observer: H. Neef
  Action: for information
  Document: Summary of discussion
- EDQM TCM expert group meeting held on 26-27 April 2016
  EDQM: M. Bald; HMPC Observer: R. Länger
  Action: for information
  Document: Summary of discussion

  Outcome:
  HMPC noted highlighted latest developments in the three expert groups.

  Progress with some monographs that were proposed by HMPC was welcomed that give in the future a reliable quality standard that can be referred to in EU herbal monographs.

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

Report: QDG Chair
Action: for discussion
Document: Milk Thistle dry extract – Indena – List of marketed products & list of submitted ASMFs

Outcome:
Postponed as no consensus found so far. Q DG to re-discuss at their next meeting for a common position for endorsement by Inspectors and HMPC that can be communicated to EDQM.

Members were invited for comments - in particular from those five MSs where the ASMF has already been available.

5.4.3. Request to EDQM for development of a method for pyrrolizidine alkaloids (PAs)

Report: QDG Chair, HMPC Chair
Action: for discussion
Document: Letter from HMPC Chair, 12 May 2016

See also 4.2.1

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

Action: for discussion
Documents: Presentation; EMA/HMPC/322570/2011 Rev. 6

Outcome:
Postponed to July 2016 meeting.

5.5. Cooperation with International Regulators

None

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

5.6.1. Hearing with AESGP at MLWP April meeting

Report: HMPC Chair, MLWP Chair
Action: for adoption
Document: Draft hearing report

Outcome:
Hearing report with minor change was adopted for publication.

5.6.2. Request to AESGP regarding data on pyrrolizidine alkaloids (PAs)

Report: HMPC Chair, P. Claeson
Action: for discussion

Documents: Letter on 'Data on contamination of herbal medicinal products with PA', 21 April 2016; AESGP response letter; BAH code of practice; New confidential information 30 May 2016: expert report; PA database extract; Explanation
See also 4.2.1

Outcome:
HMPC welcomed data provided to HMPC for use within the regulatory medicines network. However, given the nature of these selected industry standards/data that are mostly confidential, not published nor peer reviewed, EMA secretariat clarified that publication e.g. as attachment is not possible, while reference to these papers in EMA documents should be carefully checked and limited.

HMPC agreed that provided data are a good starting point but that there are still open question to confine the extent of the issue, draw conclusions on herbal substances affected and possible measures to effectively reduce risks of contamination (see also 4.2.1).

5.7. HMPC work plan

5.7.1. Projects on the HMPC work plan 2016

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

Outcome:
HMPC Chair reminded topic leaders that already half a year (4 out of 6 meetings) will be gone in July. Initiatives confirmed to be realistic end of 2015 should therefore be approached this side of the summer to allow completion by end 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:
No background details for the list were given. To be discussed during the July meeting when non-European and international cooperation will be given some focus.

It was proposed that other internal and external initiatives including requested consultancy from European herbal experts could be discussed/coordinated with EMA international affairs department and Eur. Com. representative.

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

5.9.1. Request for clarification on acceptable period for traditional use for products marketed in new Member States

Report: L. Anderson
Action: for discussion
Documents: Request, 17 May 2016; Legal clarification, 27 May 2016

Outcome:
With reference to notice to applicants the EMA legal department clarified previous interpretation by the Commission on acceptance of the period of medicinal use in new EU MSs. Likewise the specific cases for Liechtenstein and EEA/EFTA states previously discussed and minuted for TU and WEU were confirmed.

HMPC agreed to extend the HMPC regulatory Q&A with all aspects as common reference point. HMPC secretariat to draft for ORGAM check and adoption HMPC in July.

Medicinal use of a herbal medicinal product, or a corresponding product, which has taken place for 15 years in a MS before its accession to the EU (and which is supported by relevant bibliographical or expert evidence) has to be taken into account for the purpose of traditional-use registration as a fulfilment of the condition requiring at least 15 years of medicinal use within the Union.

It was also confirmed that medicinal use which has taken place on the territory of the EEA EFTA States is to be taken into account for the purpose of the application of Article 16c(1)(c). A new consultation with the Eur. Com. on this topic was not considered necessary.

6. Any other business

6.1. Topics for discussion

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 4-5 April 2016

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 4-5 April 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 31 May-2 June 2016

6.2.3. ARSP

- English summaries for publication
- Documents: Thyme-primula; Hawthorn leaf and flower; Sandy everlasting; Knotgrass
- English template

6.2.4. Other

- Response letter from HMPC Chair, 24 May 2016 to European Commission – Clarification on establishment of List entries (Melaleuca)
- Minghetti P, Franzè S, Zaccara V, Raso F, Morazzoni P.: "Innovation in Phytotherapy: Is a New Regulation the Feasible Perspective in Europe?" Planta Med 2016, 82(7):591-595

List of participants

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 30-31 May 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	
Markéta Příhodová	Alternate	Czech Republic	No restrictions applicable to this meeting	
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 Bíróné 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	
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	
Burt H Kroes	Alternate	Netherlands	No interests declared	
Steinar Madsen	Member	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Nadia Grigoras	Member	Romania	No interests declared	
Miroslava Petrikova	Member	Slovakia	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	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	
Melanie Bald	Observer (via TC)	EDQM	No interests declared	
Silvia Girotto	Co-opted member	Italy	No interests declared	