30 January 2018
EMA/HMPC/124848/2018
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 20-21 November 2017

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

20 November 2017, 14:00 – 19:00, 2F

21 November 2017, 09:00 – 13:00, 2F

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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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).

The Committee welcomed new Commission representative (Unit B4 - Medicinal products – Quality, safety, innovation; Health and Food Safety Directorate General).

1.2. Adoption of agenda

HMPC agenda for 20-21 November 2017

Time schedule for 20-21 November 2017

Outcome:
Agenda adopted.

1.3. Adoption of the minutes

HMPC minutes for 18-19 September 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 September 2017 meeting

- Report: MLWP Chair
  Action: for information
  Document: Draft minutes for the MLWP meeting on 19-21 September 2017

  The HMPC was informed that Jacqueline Viguet Poupelloz ended her membership in MLWP.

Secretariat to publish a call for nomination. Candidates should ideally be herbal experts with experience in writing HMPC monographs. If not available, also a clinical expert (clinical assessor or medical doctor) would strengthen the competence of the working party.

- Work plan 2018
  Action: for discussion
  Documents: MLWP work plan 2018, list of monographs due for review

  Outcome:
  Postponed

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Changes of Rapporteurs for Monograph revision

Cynarae folium – Peer-review
Tanaceti parthenii herba – Rapporteur
Frangulae cortex – Peer-review
Hyperici herba – Peer-review
Oenotherae biennis – Peer-review

Outcome:
Endorsed.

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

2.2.1. Monograph on Hederae helicis folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 0/294

Outcome:
Final revised monograph and supporting documents adopted by majority vote (23 out of 29). The Norwegian delegate expressed a favourable position.

Divergent opinions: Linda Anderson, Silvia Girotto, Rachel Cox, Wojciech Dymowski, Alessandro Assisi, Eeva Sofia Leinonen

Because HMPC decided not to change the indication as proposed by MLWP, no major changes can be found in the revised monograph and hence a public consultation was not deemed necessary.

Rapporteur to provide full text references before publication of the monograph.

Divergent positions referred to the available clinical evidence for use in adults and/or children with respect to all or specific preparations included in the monograph under well-established use.

2.2.2. Monograph on Meliloti herba and supporting documents

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

Outcome:
Final revised monograph and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

2.2.3. Monograph on Pelargonii radix and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC MO, OoC AR; References: 99/93

Outcome:
Adoption postponed.

A list of 5 questions by the Rapporteur as basis for final decision on the monograph content was discussed. The HMPC Chair requested MLWP to discuss, agree and provide the answers in relation to the previous decisions taken as basis for final adoption in January 2018.

The committee discussed (i) the specific data situation for the substance, (ii) the comparison to other monograph revisions following the bronchitis severity score acceptance (limited scope of the revision) and (iii) the evaluation of clinical data in general for well-established use acceptance. Five aspects were highlighted: (1) pre-definition for significant endpoint difference, (2) clinical relevance (3) consideration of secondary endpoints (4) study population (5) requirement for published independent studies.

It was pointed out that 'if there are derogations from a fundamental principle, these should be justified in the AR'. Members were asked to provide their opinions, once a consolidated proposal has been provided by MLWP in order to allow the final adoption.

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

2.3.1. Monograph on Curcumae longae rhizoma and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 0/142

Outcome:
Draft revised monograph with a minor change and supporting documents adopted by consensus for public consultation.

Minor amendments in the Assessment report were requested from the Rapporteur.

The committee agreed to exceptionally accept later provided documents for public consultation. Members asked to scientifically justify in the AR changes during the revision of the monograph.

2.3.2. Monograph on Valerianae radix/Lupuli flos and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 04/48

Outcome:
Draft revised monograph and supporting documents adopted by majority vote for public consultation.

Some minor editorial changes in the monograph were requested.

Five members flagged a negative opinion in line with views previously expressed on the first version of the monograph.

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

2.4.1. Monograph on Glycini semen and supporting documents – postponed to March 2018

2.4.2. Public statement on Piperis methystici rhizoma and supporting documents

Action: for adoption
Documents: PS, AR, LoR, OoC on PS; References: 160/160

Outcome:
Final public statement and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

Secretariat to perform editorial, regulatory and legal check before publication.

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

2.5.1. Monograph on Cisti cretici folium and supporting documents – postponed to Jan 2018

2.6. EU herbal monographs, list entries and public statements - post finalisation

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 adoption
  Document: OoC
- **Action**: for information
  Documents: Presentation; Reflection paper; QDG discussion paper on follow up

  Outcome:
  OoC was adopted for publication.

  HMPC welcomed the stepwise approach proposed by Interested Parties and the willingness to contribute to the collection and sharing of data. At present, the data available on levels of contamination found in herbal medicinal products is limited and is not yet sufficient to serve

as a basis for specific guidance or standard controls. However, taking into account the existing regulations in the food sector, the HMPC will reflect on appropriate consideration of potential contamination during the ongoing revision of herbal quality guidelines. Some exchange with stakeholders and assessors on experiences with substances at risk and possible future actions is expected during the assessors training in December 2017.

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 virtual meeting held on 19 Oct 2017
  Action: for adoption
  Document: Meeting report
- Draft agenda for the Q DG virtual meeting to be held on 07 Dec 2017
  Action: for information
  Document: Draft agenda
- Work Plan 2018
  Action: for discussion
  Documents: Draft work plan; Q DG 2018 meeting dates

Outcome:
Meeting report was adopted. Updates were given by the QDG Chair on the Work plan 2018 and the forthcoming meetings (virtual and face-to-face) in December.

The progress with drafting activities was reported as well as other topics discussed including revision of the herbal specification guideline, the follow-up on the reflection paper on Polycyclic Aromatic Hydrocarbons (see 4.1.1) and the preparation of the HMPC assessors training in December. The DG had discussed further coordination topics with EDQM and QWP, quality-related requests from NCAs as well as the status of the work plan 2017 and the draft work plan 2018.

HMPC agreed to the request by one member state that the initiative regarding variations in HMP (as informed by AESGP) should be added to the Q DG agenda for a proposal to HMPC in January on the follow-up.

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report
  Action: for adoption
  Document: Meeting report from ORGAM DG meeting held on 17 Oct 2017
- Agenda

Action: for information
Document: Draft agenda for the ORGAM DG meeting to be held on 05 Dec 2017

- Work Plan 2018
Action: for discussion
Documents: Draft work plan; ORGAM 2018 meeting dates

Outcome:
Meeting report was adopted. No changes were proposed for the draft agenda and the work plan 2018.

The ORGAM Chair asked for more members of HMPC or MLWP for the drafting group to allow drafting activities 2018 as outlined in the work plan.

Secretariat to send out a call for volunteers to participate regularly or for single topics.

If membership at ORGAM does not allow coverage of all ORGAM topics, members of HMPC/MLWP will be invited for rapporteurship as per single topic because many items on the ORGAM agenda are crucial for working methodology, procedures and outcome of HMPC/MLWP.

4.4.3. Template update – Template on HMPC opinion on list entry or revision of a list entry

Report: ORGAM DG Chair
Action: for adoption
Document: Draft template

Outcome:
The revised template was adopted by consensus for future use regarding list entry adoption/revision and communication to the Commission.

Upon request by a member the relevance of information provided to the Commission including divergent opinions was clarified.

4.4.4. Disclaimer for EU herbal monographs

Report: ORGAM DG Chair
Action: for discussion
Document: Draft Q&A

Outcome:
The new Q&A on SmPC versus monograph was adopted by consensus.

The Q&A will be added to the summarised regulatory Q&A document (EMA/HMPC/345132/2010) and a revised version (Rev.4) published.

The Italian member highlighted a divergent opinion with regard to question 2 of the Q&A already expressed previously when EMA/HMPC/345132/2010 was adopted by majority.

4.4.5. Feedback from EU procedures and pharmacovigilance (see also 5.7.1. – Project 1.3.5.)

Report: ORGAM DG Chair
Action: for discussion

Document: Draft proposal

Outcome:
HMPC agreed to have a regular feedback from finalised European procedures in order to identify new information relevant for the update of monographs but also appliance of guidelines.
A first draft of a template collecting such data was endorsed.
Rapporteurs to collect this information were appointed. In parallel a regular feedback on new PhV information with relevance for EU herbal monographs should be collected.
ORGAM in liaison with the secretariat to finalise the draft template, check and link to the review/ revision procedure as well as modify the HMPC agenda structure as required.

After procedural/legal scrutiny and a first round testing, the template and the feedback received should be presented at HMPC for discussion of the specific implementation.

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, HMPC Vice-chair
  Estonia Presidency meeting – Bucharest, 11-12 Oct 2017 – follow up
  Action: for discussion
  Documents: Presentations; Follow-up discussion paper

- Report
  Austria Presidency meeting – Vienna, 15-17 Oct 2018
  Action: for information
  Document: SRLM meeting dates

Outcome:
HMPC noted a follow-up discussion paper presented by the HMPC Vice-Chair resulting from the Bucharest SRLM and options for implementation of improvement proposals presented by the secretariat. Further discussion was agreed for the January meeting.

5.1.2. Election of Co-opted members

Report: HMPC Chair
Action: for adoption
Documents: Expertise of HMPC members; Call for nominations from 16 Oct; Candidatures

Outcome:
HMPC re-elected as co-opted member for General and Family Medicine: Maria Helena Pinto Ferreira and Experimental/Non-clinical pharmacology: Gert Laekeman for a renewed 3 year mandate starting on 24 November 2017 as well as for Paediatric medicine: Silvia Girotto (new mandate start 27 January 2018).

No candidates were nominated for an expert in clinical pharmacology. The mandate of G. Calapai finished on 23 November 2017.

The HMPC agreed to repeat the call. If no candidates are found for the next HMPC meeting either another area of expertise should be identified or the HMPC should be continued with 4 co-opted members instead of 5.

The need for clinical expertise was confirmed - either general or focused on the most common areas herbal medicinal products are used. Also experience with conducting clinical trials was mentioned as potential valuable complement for the committee.

5.1.3. Preparation for election of MLWP Chair

Report: HMPC Chair
Action: for discussion
Document: Mandate

Outcome:
HMPC noted that the mandate of the MLWP Chair expires 27 January 2018.
Secretariat to send out a call for candidates for election at the January HMPC meeting.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair
Action: for information
Documents: Agenda: 11 Dec 2017; Minutes: 21 Sep 2017

Outcome:
Postponed.

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

5.3.1. Coordination with Safety Working Party – Assessment of estragole

Action: for information
Documents: SWP response, PS, OoC, Presentation
Outcome:
HMPC noted presentation by Rapporteur regarding the SWP response to questions and discussion at CHMP.
HMPC agreed that MLWP should discuss and modify the HMPC draft PS as basis for (a) CHMP decision /CMDh follow-up regarding products with estragole containing excipients and (b) the revision of relevant herbal monographs.
Revised PS to be re-discussed and coordination with SWP/CHMP and CMDh to be agreed at January HMPC meeting.

Consequences of SWP response and HMPC decision and follow-up scenarios were discussed. Toxicological considerations were presented in view of the widespread use of estragole containing food as well as common use of medicines and combination products with substances containing estragole in several member states. Furthermore the implications for monographs/LEs on fennel and anise were debated.

Post-meeting note: *At MLWP it was decided that Rapporteurs revise the PS and re-discuss at the MLWP March meeting.*

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM 13A expert group meeting held on 7-8 Nov 2017
  Report: M. Bald (EDQM)
  Action: for information
  Document: SoD
- EDQM 13B expert group meeting held on 20-21 Sep 2017
  Report: M. Bald (EDQM)
  Action: for information
  Document: SoD
- EDQM TCM expert group meeting held on 19-20 Sep 2017
  Report: M. Bald (EDQM)
  Action: for information
  Document: SoD

Outcome:
HMPC noted SoDs and updates on 13A, 13B and TCM expert groups given by the EDQM representative.

She briefed on relevant monographs newly added to the work programme, drafts in Pharmeuropa and those ready for final adoption. Highlighted were in particular for 13A Aetherolea, Myrtilli fructus recentis extractum siccum raffinatum et normatum and Menthae piperitae aetheroleum; for 13B three monographs on Cannabis as well as Allium sativum powder, Camellia sinensis, and Aesculus cortex; finally for TCM the assay alternatives pilot project and Aconiti radix preparata.

It was confirmed that no change has been introduced regarding pulegone/menthofuran levels in Menthae aetheroleum despite the HMPC PS and EDQM comments on 'normal ranges' in essential oils in this regard (minimum content). It was further clarified that for sweet fennel oil no product had been identified and therefore proposed to delete the monograph.

5.4.2. Coordination with EFSA

- Safety assessment of hydroxyanthracene derivatives (HAD)- update
  Report: J. Wiesner
  Action: for discussion
  Document: Response from EFSA, 18 Oct 2017

Outcome:
HMPC agreed to uphold interaction and exchange of documents regarding the safety assessment of HAD. It was agreed to send specific comments on the draft document and also refer to previous communication to the Commission regarding wider safety considerations. J. Wiesner and L. Anderson to provide comments by 30 of November to the secretariat.

Regarding green tea, some general comments regarding the HMPC assessment and its limitation to the herbal tea are to be provided by 30 November for forwarding to EFSA. C. Purdel and G. Laekeman to provide comments by 30 of November to the secretariat.

5.5. Cooperation with International Regulators

5.5.1. EU – India/AYUSH communication

- Information on 8th EU India Joint WG, Delhi 13-14 July 2017 and Bilateral EMA – India at Summit Heads of Agencies, Kyoto 23-27 October 2017
  Action: for discussion

  Outcome:
  The Committee noted a short summary of the international affairs division activities and recent contacts with Indian authorities. Challenges in getting a consistent communication to facilitate HMPC assessment work were discussed.

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

None

5.7. HMPC work plan

5.7.1. HMPC work plan 2017

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

  Outcome:
  The status of projects on the work plan was discussed one by one. Some activities will be finalised in 2018.

- Project 1.3.1. Forward planning and prioritisation
  Report: HMPC Chair; ORGAM Chair
  Action: for discussion
  Document: Proposal for assessment received from IPs and NCAs; Summary products 2016 vs. available monographs

  Outcome:
  HMPC noted summary of substances on the market without EU standards so far compiled from the latest survey, and summary proposals received from IPs and NCAs. Proposals to be discussed at MLWP, validated and selected for prioritisation and MLWP work plan and agreement by HMPC in January for addition to the HMPC work programme ('priority list').

- Project 1.3.5. European collaboration (see also 4.4.5)
  Report: R. Laenger
  Action: for adoption
  Documents: Presentation; Questionnaire template

  Outcome:
  See 4.4.5.

- Project 2.1.1. Patients involvement in assessment work
  Report: S. Bager
  Action: for discussion

  Outcome:
  Feedback from patient representatives and future proposals to be summarised and presented at January 2018 meeting.

- Project 2.1.2. Coordination on safety assessments of herbal constituents
  Report: H. Foth
  Action: for discussion

  Outcome:
  The topic lead announced a draft document on three key points (pregnancy, signal value, range of exposure) to be shared with other toxicologists and presented at the January 2018 meeting.

- Project 2.1.3. Cooperation with Academia
  Report: MLWP Chair
  Action: for discussion

  Outcome:
  The topic lead reported on data collected from Academia members of HMPC/MLWP and announced a document with specific proposals for the January 2018 meeting.

5.7.2. HMPC work plan 2018

- Report: HMPC Chair
  Action: for discussion
  Documents: Draft Work plan 2018, Presentation, Proposals received

  Outcome:
  No new proposals have been received after the HMPC September meeting. The main points were presented by the Chair and agreed.

  Chair, Vice Chair and secretariat to transfer to the work plan template and specify objectives and activities including realistic deliverables for comments by HMPC members and final adoption at the HMPC January 2018 meeting.

  One additional point on developments in the medical device regulation was raised as potentially relevant given that a range of herbal products is marketed as medical device in many MS. Addition to work plan to be considered if a specific action can be identified for 2018.

5.8. Planning and reporting

5.8.1. HMPC 2017 assessors training

Report: QDG Chair
Action: for discussion

Documents: Draft agenda; Participants list

Outcome:
Updates were given by the QDG Chair on the draft agenda and the participants for the HMPC 2017 assessors training.

Some final gaps in speakers will be closed in cooperation between secretariat and members involved in preparation.

5.9. Legislation and regulatory affairs

None

6. Any other business

6.1. Topics for discussion

6.1.1. Questions from NCAs on Public Statement on Pyrrolizidine alkaloid contaminations

Report: HMPC Chair
Action: for discussion
Documents: Response to questions from BE & NL; Literature

Outcome:
The toxicological input on two questions was still missing. H. Foth to draft a response for final discussion at the HMPC January meeting.

The Chair proposed to provide the finalised response to all HMPC members before the January meeting to allow response to the requesting NCAs. Otherwise adoption via written procedure is foreseen.

6.1.2. European Union herbal monograph on Saccharomyces cerevisiae CBS 5926

Action: for discussion
Documents: Presentation; Reminder email from HMPC chair from 03 Nov

Outcome:
Postponed.

6.1.3. Preparedness for UK's withdrawal from the EU - Postponed

6.1.4. User manual on CxMP/EMA external representation

Action: for discussion
Documents: Presentation; User manual

Outcome:
Postponed.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 18-19 September 2017

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 18-19 September 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 21-23 Nov 2017

6.2.3. Other

- PCWP/HCPWP meetings:
  - Minutes of the PCWP/HCPWP joint meeting held on 27-28 June 2017 (EMA/355452/2017): for information
  - Minutes of the PCWP/HCPWP joint meeting held on 20 September 2017 (EMA/626905/2017): for information
  - Report of the Information session on antimicrobial resistance held on 19 Sep 2017: for information
  - Draft Agenda - Training session for patients, consumers and healthcare professionals interested in EMA activities (21 Nov) - (EMA/662990/2017): for information
  - Agenda of the PCWP meeting with all eligible organisations (22 Nov) (EMA/663268/2017): for information
- UK's withdrawal from the EU and the evidence of 15 years of traditional use in the EU: for information
- WHO-IRCH new draft Terms of References: for information
- AESGP proposal on the simplification of variations specific to herbal medicinal products: for information
- EU herbal monographs, list entries and public statements post adoption: for information
  - Publication delays 2016/2017 updates
  - Remaining publication delays:
    - Allii sativi bulbus
    - Pistacia lentiscus (mastix)

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 20-21 November 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	
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	
Marie Heroutova	Member	Czech Republic	No interests declared	
Markéta Příhodová	Alternate	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	
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	
Rachel Cox	Alternate	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Gioacchino Calapai	Member	Italy	No interests declared	
Silvia Girotto	Member	Italy	No interests declared	
Evita Skukauska	Member	Latvia	No interests declared	
Rugile Pilviniene	Member	Lithuania	No interests declared	
Everaldo Attard	Member	Malta		
Emiel Van Galen	Member	Netherlands	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Maria Helena Pinto Ferreira	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	

Barbara Razinger	Alternate	Slovenia	No interests declared	
Adela Nunew Velazquez	Alternate	Spain	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	
Isabelle Holmquist	EC Representative	European Commission	Full involvement	