



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 September 2023
EMA/459382/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 04 September 2023

Vice-Chair: Bruno Sepodes, deputising for the Chair Harald Enzmann

04 September 2023, 09:00–16:00, virtual meeting

Disclaimers

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

Of note, agendas and minutes are working documents primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda/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).

¹ The CHMP PROM is a meeting to discuss CHMP organisational matters and other topics in preparation for the CHMP Plenary meeting. It is a virtual meeting, which usually takes place on Monday before the CHMP Plenary meeting. CHMP members, working party chairs and national experts together with EMA staff are participating in this forum. Depending on the nature of the issue and availability of documents and experts some PROM topics can be discussed at the CHMP Plenary.



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1. Agenda and Minutes

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 the restricted involvement of some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions. See Annex of the current document for the list of participants and restrictions in relation to declarations of interests applicable to the items of this meeting. As the PROM is a preparatory meeting for the CHMP plenary session, restrictions and declarations of interests applicable to the items in the draft agenda of the upcoming CHMP plenary session were also considered.

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. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

The CHMP adopted the PROM agenda for the 04 September 2023 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of the 04 September 2023 meeting will be adopted at the September 2023 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry

2.1.1. Questions and Answers from BWP learnings

Question and answers from selected BWP learnings

Action: For adoption

The BWP reviewed the learnings collected from different meetings and considered how to transfer this knowledge into a published Q&A as reflected in the BWP workplan. The ten learnings selected were recurring issues in submissions and points where the BWP position was clear. The CHMP adopted the Question and answers from selected BWP learnings. The BWP Q&A will be published in the EMA website.

2.1.2. **Agenda and Minutes**

- Draft agenda of the BWP meeting to be held virtually on 4-6 September 2023
- Final minutes of the BWP meeting held virtually on 10-12 July 2023

Action: For information

The CHMP noted the agenda and minutes.

2.2. **Quality Working Party (QWP)**

Chair: Blanka Hirschlerova, Vice-Chairs: Marie-Hélène Sabinotto, Laivi Saaremäe

2.2.1. **Letter from the EC**

QWP Chair: Blanka Hirschlerova

Action: For information

2.2.2. **Agenda**

- Agenda of the 104th QWP meeting held virtually on 26–28 June 2023

Action: for information

The CHMP noted the agenda.

2.3. **Biosimilar Medicinal Product Working Party (BMWP)**

No topics

2.4. **Quality Innovation Group (QIG)**

No topics

2.5. **Formulation Expert Group (FEG)**

No topics

3. **Non-Clinical Domain**

3.1. **Non-Clinical Working Party (NcWP)**

Chair: Susanne Brendler-Schwaab, Vice-Chair: Karen van Malderen

3.1.1. Agenda and Minutes

- Draft minutes for the NcWP meeting held virtually on 11-12 July 2023
- Draft agenda for the NcWP meeting to be held virtually on 29 August and 5 September 2023

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Nominations of new NcWP member

Following the departure of Louise Bang-Lauritsen at the end of April 2023 the NcWP is nominating a new member.

Nominations received

Action: For endorsement

The CHMP endorsed the nomination of Marianne Schmidt as new NcWP member.

3.1.3. Nomination of Non-clinical and New Approach Methodologies ESEC experts

Nomination by NcWP of the experts to enter the Non-clinical and New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Armin Braun, Alexandra Voulgari, Valentina Salvati, Nunzia Sanarico, Marliena Paola Etna, Emanuala Corsini, Bohumila Bichlmaier Suchanová as Non-clinical and New Approach Methodologies ESEC experts.

3.1.4. Appendix 1 to Nitrosamines Q&A: Acceptable intakes established for N-nitrosamines

August 2023 update

Action: for information

The CHMP noted the Appendix 1 to Nitrosamines Q&A: Acceptable intakes established for N-nitrosamines.

3.1.5. NcWP DG - Reflection paper on Covid 19 lessons learned

The Reflection Paper is part of the NcWP workplan 2023-2025. A kick off meeting of the DG was held on 22 August 2023. The list of members is shared with CHMP for information.

Action: for information

The CHMP was informed that the NcWP has established a drafting group to write a reflection paper on Covid 19 lessons learned.

3.2. Joint 3Rs Replacement, Reduction and Refinement Working Party (3Rs)

Chair: Sonja Beken, Vice-Chair: Sarah Adler-Flindt

3.2.1. Minutes

- Draft minutes for the 3RsWP meeting held virtually on 19 June 2023

Action: For information

The CHMP noted the minutes.

3.2.2. Proposal for 3RsWP chair to attend two external meetings

- **Safety Pharmacology Society (SRS) Annual Meeting:** Proposal to have Sonja Beken, the chair of the 3RsWP, representing CHMP/EMA, to attend the SRS Annual Meeting to be held in Brussels on 18-21 September.
- **EFSA Global Summit on Regulatory Science (GSRS) meeting:** Proposal to have Sonja Beken, chair of the 3RsWP, representing CHMP/EMA, to attend the EFSA GSRS meeting on 27-28 September 2023.

Action: For endorsement

The CHMP endorsed the proposal to have Sonja Beken, the chair of the 3RsWP, representing CHMP/EMA, in the SRS Annual meeting and to attend the EFSA GSRS meeting on 27-28 September 2023.

3.2.3. Call for nominations - Batch Release Testing OEG

The Batch Release Testing Operational Experts Group (BRT OEG) is mandated to review protocols related to the quality control and batch release testing of human and (mainly) veterinary medicinal products authorised via the centralised procedure between 1996 and 2013, with a view to promote and implement 3Rs-compliant testing methods within these processes as far as possible. This is a continuation of the activity initiated by the Joint CVMP/CHMP ad-hoc Expert Group on the application of the 3Rs (JEG 3Rs) and Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG) during the existence of these groups between 2011 and 2019, and is in line with the EMA Regulatory Science Strategy to 2025 which aims to promote in silico methodology (e.g. modelling), novel in vitro assays and systematic reviews to reduce animal use, particularly in toxicology/epidemiology and batch control. Thus, the BRT OEG will support the operational work of the CHMP and CVMP regarding the identification and promotion of opportunities for the implementation of 3Rs approaches within quality control and batch release testing processes for centrally authorised human and veterinary medicines.

CHMP Committee members are invited to nominate experts with special knowledge and experience and/or strong interest in the area of: batch release testing of human and veterinary medicines, especially regarding biologicals/immunologicals/vaccines and botulinum neurotoxin products; alternative 3Rs-compliant testing models used or potentially suitable for the batch release and quality control testing of human and veterinary medicinal products; qualification and/or validation (incl. product-specific validation) and regulatory acceptance of 3Rs-compliant testing methods (e.g. performance standards, reference

compounds); 3Rs principles implemented in in vivo studies, i.e. reduction and refinement, including statistical expertise.

Experts should be part of the European Regulatory Network (e.g. assessors working for a NCA, members of the different WPs or experts from academia in institutions/universities with relevant expertise for the BRT OEG). Nominations should be sent to the Agency by 30 September 2023.

Action: for information

The CHMP noted the call for nominations for the Batch Release Testing Operational Experts Group (BRT OEG).

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Agenda and Minutes

- Final agenda and minutes for MWP meeting held virtually on 13 July 2023 are postponed to PROM's agenda in October 2023

Action: For information

Topic postponed to the October PROM meeting.

4.1.2. Nomination of Methodology ESEC experts

Nomination by MWP of EMA staff and new experts to enter the Methodology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination by MWP of Jonathan Bergman (MPA) and EMA staff to enter the Methodology European Specialised Expert Community (ESEC).

4.1.3. Guideline on Data Quality Frameworks

Methodology Working Party and Big Data Steering Group joint guideline on Data Quality Frameworks.

Action: for adoption

The topic was postponed to the October PROM, following comments received from CHMP members.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

Chair: Andre Elferink

5.1.1. Guideline on clinical investigation of medicinal products in the treatment of depression

Guideline on clinical investigation of medicinal products in the treatment of depression to be released (Revision 3) for 6-month public consultation.

Expert: Marion Haberkamp

Action: for adoption

The CHMP adopted the guideline on clinical investigation of medicinal products in the treatment of depression to be released (Revision 3) for 6-month public consultation.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Nomination of new members to the CVS ESEC

Nomination of new CVS ESEC members.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Ana Catarina Fonseca (PT) and Ana Martín Leal (ES) as CVS ESEC members.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Nomination of new member to the Oncology ESEC

Nomination of new Oncology ESEC member.

Action: For endorsement

The CHMP endorsed the nomination of the new Oncology ESEC member.

5.3.2. Cancer Medicines Forum

Update on the Cancer Medicines Forum which was held on 29 June 2023.

Action: For discussion

The CHMP noted the update on the Cancer Medicines Forum which was held on 29 June 2023.

5.3.3. San Antonio Breast Cancer Symposium 5-9 December 2023

New Drug Approval Session at SABCS meeting on 5-9 December 2023. Proposal to have Aaron Sosa Mejia as EMA/CHMP speaker.

Action: For endorsement

The CHMP endorsed the proposal to have Aaron Sosa Mejia as EMA/CHMP speaker.

5.3.4. Agenda and Minutes

- Agenda from the ONCWP meeting held virtually on 12 July 2023
- Minutes from the ONCWP meeting held virtually on 16 June 2023

Action: For information

The CHMP noted the agenda and minutes.

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

No topics

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphly

5.7.1. Minutes

- Minutes of the Blood cluster TC held by Webex on 23 June 2023

Action: For information

The CHMP noted the minutes.

5.8. Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEG)

No topics

6. Patients, Healthcare Professionals and Consumers

6.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

PCWP: Co-chair: Juan Garcia Burgos (EMA)

HCPWP: Co-chair: Juan Garcia Burgos (EMA)

6.1.1. Agenda and Meeting summary

- Agenda of the upcoming PCWP/HCPWP joint meeting to be held by Webex 19-20 September 2023
- Meeting summary of the PCWP/HCPWP joint meeting with all eligible organisations held by Webex on 27-28 June 2023

Action: For information

The CHMP noted the agenda and meeting summary.

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

No topics

7.2. Guideline Consistency Group (GCG)

No topics

7.3. Summary of product characteristics Advisory Group

No topics

8. Joint groups and collaboration with other Scientific committees

8.1. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

No topics

8.2. Collaboration with other Scientific committees

8.2.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 28-31 August 2023

Action: For information

The CHMP noted the summary of recommendations and advice.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP endorsed the proposed learnings.

9.2.2. CHMP co-opted membership

The 3-year co-opted member mandate for Jan Mueller-Berghaus comes to an end on 13.11.2023. His area of expertise is Quality, safety and efficacy of biological medicinal products, including advanced therapies and with specific emphasis on vaccines. The nomination procedure foresees that the CHMP should decide on whether a new co-opted member should be appointed and if so, on the required specific complementary scientific expertise (there could be more than one area). Afterwards a call for nominations will be launched.

Action: For information

The CHMP noted the nomination procedure for a new CHMP co-opted membership and the proposed timelines.

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi, Vice-Chair: Pierre Demolis

10.1.1. Appointment of CHMP peer review for SA

Action: For information

The CHMP noted the list.

10.1.2. Agenda and Table of Decisions

- Agenda from 28-31 August 2023 meeting held by Webex
- Draft Table of Decisions from 28-31 August 2023 meeting held by Webex

Action: For information

The CHMP noted the agenda and the table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 13 September 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 18 September 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 20 September 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.4. ITF meeting

Meeting date: 10 October 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.5. ITF meeting

Meeting date: 19 October 2023

Action: For adoption

The CHMP endorsed the meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Bruno Sepodes

Action: For information

The CHMP Vice-Chair flagged some procedures on the agenda of the upcoming plenary.

11.2. Livmarli – maralixibat - EMEA/H/C/005857/II/0003/G

Mirum Pharmaceuticals International B.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Adam Przybylkowski

Scope: Request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in July 2023.

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in July 2023.

12. Any Other Business

12.1. Rapporteurships

Update

Action: For information

The CHMP noted the update.

12.2. Update on the raw data pilot

The fifth regulatory procedure for the clinical trials raw data pilot has been selected.

It is an IMAA for the Treatment of primary biliary cholangitis (PBC).

Action: For information

The CHMP noted the update on the raw data pilot.

12.3. ACT EU Methodology workshop

Presentation of the vision and objectives of ACT-EU priority action 8 and call for interest for involvement in the upcoming multi-stakeholder methodology workshop as programme committee member and/or scientific experts in sessions.

Action: For information

The CHMP noted the presentation on the ACT EU Methodology workshop.

12.4. Call for experts - Workshop on Acute Respiratory Distress Syndrome

Call for interest for involvement as scientific experts in break-out sessions and panel discussions in the Multistakeholder Workshop planned on 21 November 2023.

The workshop aims at exploring clinical and scientific aspects related to the development of drugs for patients with Acute Respiratory Disease Syndrome (ARDS). The outcome will ultimately inform the finalisation of the guideline on ARDS.

The objective of the workshop is to discuss ARDS syndrome, biomarkers, study population and Standard of Care, primary and secondary endpoints, clinical trial methodology and design. Nominations should be sent to the Agency by 30 September 2023.

Action: For endorsement

The CHMP endorsed the call for interest for involvement as scientific experts in break-out sessions and panel discussions in the Multistakeholder Workshop planned on 21 November 2023.

13. List of Participants

| Name | Role | Member State or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
|-----------------------------|-----------|-----------------------------|--|---|
| Harald Enzmann | Chair | Germany | No interests declared | |
| Daniela Philadelphia | Member | Austria | No interests declared | |
| Christian Gartner | Alternate | Austria | No interests declared | |
| Christophe Focke | Member | Belgium | No restrictions applicable to this meeting | |
| Karin Janssen van Doorn | Alternate | Belgium | No interests declared | |
| Lyubina Racheva Todorova | Member | Bulgaria | No interests declared | |
| Gergana Lazarova | Alternate | Bulgaria | No interests declared | |
| Margareta Bego | Member | Croatia | No interests declared | |
| Selma Arapovic Dzakula | Alternate | Croatia | No interests declared | |
| Helena Panayiotopoulou | Member | Cyprus | No interests declared | |
| Emilia Mavrokordatou | Alternate | Cyprus | No participation in final deliberations and voting on: | COVID-19 vaccines |
| Tomas Radimersky | Member | Czechia | No interests declared | |
| Petr Vrbata | Alternate | Czechia | No interests declared | |
| Thalia Marie Estrup Blicher | Member | Denmark | No interests declared | |
| Aaron Sosa Mejia | Alternate | Denmark | No participation in final deliberations and voting on: | 3.3.3. insulin icodec - EMEA/H/C/005978 |
| Alar Irs | Member | Estonia | No restrictions applicable to this meeting | |
| Edward Laane | Alternate | Estonia | No restrictions applicable to this meeting | 3.3.3. insulin icodec - EMEA/H/C/005978 |
| Outi Mäki-Ikola | Member | Finland | No restrictions applicable to this meeting | |
| Johanna Lähteenvuo | Alternate | Finland | No interests declared | |
| Alexandre Moreau | Member | France | No interests declared | |
| Jean-Michel Race | Alternate | France | No interests declared | |
| Martina Weise | Member | Germany | No restrictions applicable to this meeting | |
| Janet Koenig | Alternate | Germany | No interests declared | |

| Name | Role | Member State or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
|-------------------------|-----------|-----------------------------|---|---|
| Konstantina Alexopoulou | Member | Greece | No interests declared | |
| Anastasia Mountaki | Alternate | Greece | No interests declared | |

| | | | | |
|-----------------------------|---------------------|------------------------------------|--|--|
| Robert Porszasz | Member | Hungary | No interests declared | |
| Beata Maria Jakline Ullrich | Alternate | Hungary | No interests declared | |
| Hrefna Gudmundsdottir | Member | Iceland | No interests declared | |
| Hjalti Kristinsson | Alternate | Iceland | No interests declared | |
| Jayne Crowe | Member | Ireland | No interests declared | |
| Finbarr Leacy | Alternate | Ireland | No interests declared | |
| Paolo Gasparini | Member | Italy | No interests declared | |
| Maria Grazia Evandri | Alternate | Italy | No interests declared | |
| Elita Poplavska | Member | Latvia | No interests declared | |
| Vacant | Alternate | Latvia | | |
| Vlasta Zavadova | Member | Liechtenstein | No interests declared | |
| Vilma Petrikaite | Member | Lithuania | No interests declared | |
| Larisa Gorobets | Alternate | Lithuania | No restrictions applicable to this meeting | |
| Martine Trauffler | Member | Luxembourg | No interests declared | |
| Alexandra Branchu | Alternate | Luxembourg | No participation in discussion, final deliberations and voting on: | 5.1.8. fexinidazole - EMEA/H/W/002320/II/0016 |
| John Joseph Borg | Member | Malta | No interests declared | |
| Helen Vella | Alternate | Malta | No interests declared | |
| Peter Mol | Member | Netherlands | No interests declared | |
| Patrick Vrijlandt | Alternate | Netherlands | No interests declared | |
| Ingrid Wang | Member | Norway | No interests declared | |
| Eva Skovlund | Alternate | Norway | No interests declared | |
| Ewa Balkowiec Iskra | Member | Poland | No interests declared | |
| Grzegorz Cessak | Alternate | Poland | No participation in final deliberations and voting on: | COVID-19 vaccines |
| Bruno Sepodes | Member (Vice-Chair) | Portugal | No interests declared | |
| Fatima Ventura | Alternate | Portugal | No participation in final deliberations and voting on: | COVID-19 vaccines |
| Simona Badoi | Member | Romania | No interests declared | |
| Dana Gabriela Marin | Alternate | Romania | No interests declared | |
| Name | Role | Member State or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
| Frantisek Drafi | Member | Slovakia | No interests declared | |
| Dorota Distlerova | Alternate | Slovakia | No interests declared | |
| Kristina Nadrah | Member | Slovenia | No restrictions applicable to this meeting | |

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|-------------------------------|-------------------|------------------------------------|--|--|
| Andreja Kranjc | Alternate | Slovenia | No interests declared | |
| Maria Concepcion Prieto Yerro | Member | Spain | No interests declared | |
| Carolina Prieto Fernandez | Alternate | Spain | No interests declared | |
| Kristina Dunder | Member | Sweden | No interests declared | |
| Filip Josephson | Alternate | Sweden | No interests declared | |
| Bruno Delafont | Co-opted member | France | No restrictions applicable to this meeting | 9.1.8. ticagrelor - EMEA/H/C/001241/II/0061 3.3.5. Capivasertib - EMEA/H/C/006017 |
| Carla Torre | Co-opted member | Portugal | No interests declared | |
| Jan MuellerBerghaus | Co-opted member | Germany | No interests declared | |
| Blanka Hirschlerova | Co-opted member | Czechia | No interests declared | |
| Sol Ruiz | Co-opted member | Spain | No interests declared | |
| Dagmar Stará | EC Representative | European Commission | | |
| Vincent Gazin | Expert | France | No interests declared | |
| Nora Cascante Estepa | Expert | Germany | No interests declared | |
| Sabine Mayrhofer | Expert | Germany | No interests declared | |
| Irene Bachmann | Expert | Germany | No interests declared | |
| Susanne BrendlerSchwaab | Expert | Germany | No interests declared | |
| Tina Soon Engraff | Expert | Denmark | No interests declared | |
| Martijn Van der Plas | Expert | Netherlands | No interests declared | |
| Luca Santi | Expert | Italy | No restrictions applicable to this meeting | |
| Martina Perini | Expert | Italy | No restrictions applicable to this meeting | |
| Deirdre Mannion | Expert | Denmark | No restrictions applicable to this meeting | |
| Name | Role | Member State or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
| Charlotte Hejl | Expert | Denmark | No restrictions applicable to this meeting | |
| Tina Soon Engraff | Expert | Denmark | No interests declared | |
| Kristina Bech Jensen | Expert | Denmark | No interests declared | |
| Paula Contreras Alarcón | Expert | Spain | No restrictions applicable to this meeting | |

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