



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 March 2024
EMA/CHMP/174396/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ Minutes for the meeting on 11 March 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

11 March 2024, 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 11 March 2024 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 11 March 2024 meeting will be adopted at the March 2024 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Francesca Luciani

2.1.1. Agenda and Minutes

- Draft Agenda of the BWP meeting to be held virtually on 11-13 March 2024
- Minutes of the BWP meeting held virtually on 15-17 January 2024

Action: For information

The CHMP noted the agenda and minutes.

2.1.2. Call for nomination of new member to the BWP

Following the resignation of a BWP member, a call for nomination of a new member is being launched. Applications should be sent by 5 April 2024. The CHMP will endorse the new member in its April PROM.

Action: For information

The CHMP noted the launch of a call for nomination of new member to the BWP.

2.1.3. Call for nomination of new vice-chair to the BWP

Following the resignation of the current Vice-Chair, the position is now vacant. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Nominations should be sent by 17 April 2024. The election will take place at the April 2024 CHMP Plenary Meeting.

Action: For information

The CHMP noted the launch of a call for nomination of new vice-chair to the BWP.

2.2. Quality Working Party (QWP)

Chair: Blanka Hirschlerova, Vice-Chairs: Marie-Hélène Sabinotto, Nicholas Lee

2.2.1. EMA (QWP) Final Analysis on TiO₂

EMA (QWP) final feedback to the EU Commission request to evaluate the feasibility of alternatives to replace titanium dioxide (TiO₂) in medicinal products and its possible impact on medicines' availability.

Action: For adoption

The CHMP adopted the EMA final feedback to the EU Commission request to evaluate the feasibility of alternatives to replace titanium dioxide (TiO₂) in medicinal products and its possible impact on medicines' availability. The document was updated taking into consideration the feedback received from industry stakeholders.

2.2.2. Agenda and Minutes

- Draft Agenda of the QWP meeting to be held in person on 11-13 March 2024
- Minutes of the QWP meeting held remotely on 15-16 January 2024

Action: For information

The CHMP noted the agenda and minutes.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

No topics

2.4. Quality Innovation Group (QIG)

Chair: Marcel H. N. Hoefnagel

2.4.1. Report from Second QIG Listen and Learn Focus Group meeting with stakeholders

This is the report from the second QIG LLFG meeting organized to discuss with stakeholders the application of digital novel technologies to manufacturing and quality control testing; in particular, process models and digital twins, as well as artificial intelligence (AI) and machine learning for GMP applications. It captures the challenges identified, proposed solutions and proposed follow-up actions (which include the development of guidance on process models – see 2.4.2).

Action: For information

The CHMP noted the report from the second QIG LLFG with stakeholders.

2.4.2. QIG preliminary considerations on process models

During the interactions with stakeholders, including the two QIG Listen and Learn Focus Group meetings held in 2023, it was highlighted the need for more specific regulatory guidance on process models to facilitate their implementation.

For this purpose, the QIG has captured its current thinking on the QIG preliminary considerations on process models. The document has been released for public consultation. In addition, stakeholders were invited to submit abstracts/case studies for discussion at the first 2024 QIG LLFG meeting in June (which will focus on this topic). The learnings from the LLFG will be used to progress on this area and serve for future guidance development.

Action: For information

The CHMP noted the QIG preliminary considerations on process models.

3. Non-Clinical Domain

3.1. Non-Clinical Working Party (NcWP)

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

3.1.1. Reflection paper on the data requirements for intravenous iron-based nano-colloidal products developed with reference to an innovator medicinal product

Following the CHMP discussion at the February 2024 Plenary Meeting, it is proposed to discuss the next steps and both the NcWP and QWP involvement. This is based on the recent scientific advices' experience obtained.

Action: For discussion

The CHMP agreed to consult both the NcWP and QWP. Upon consultation of the WPs a strategy will be defined on how to progress the reflection paper discussions.

3.1.2. Nomination of new member to the NcWP

Following the departure of Javier de Cristobal in October 2023, the NcWP is nominating a new member.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new member of the NcWP.

3.1.3. Minutes

- Minutes of the NcWP meeting held remotely on 9 and 17 January 2024

Action: For information

The CHMP noted the minutes.

3.1.4. CMDh questions to NcWP

Action: For adoption

The CHMP adopted the CMDh question to the NcWP.

3.1.5. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to the NcWP.

3.1.6. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to the NcWP.

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

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

3.2.1. Agenda and Minutes

- Agenda and draft minutes of the Batch Release Testing Operational Expert Group (BRT OEG) kick-off meeting held remotely on 16 February 2024

Action: For information

The CHMP noted the agenda and minutes.

3.2.2. Annual stakeholder meeting and public session

The 3RsWP will hold its second annual stakeholder meeting on 20 and 21 March 2024. Participants will include industry and trade associations, animal welfare organisations, research consortia and EU agencies. The meeting will start with a virtual public session on 20 March 2023, 09:00-09:45 Amsterdam time (CET), which will be broadcast and is open to all stakeholders. The aim of the public session is to present the 3RsWP work plan and priorities for 2024 and to give an opportunity to stakeholders to comment and provide their views on the working party's activities. The link to the event can be found [here](#).

Action: For information

The CHMP noted the information on the event and CHMP members were encouraged to join.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Christian B. Roes, Kristin Karlsson

4.1.1. Agenda and Minutes

- Agenda and minutes of the MWP meeting held remotely on 11 January 2024

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of Methodology ESEC experts

Nomination 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 of the new members of the Methodology European Specialised Expert Community (ESEC).

4.1.3. Methodology ESEC Mandate – Wording Revision

The MWP kindly requests the CHMP endorsement on the revised wording of the Methodology ESEC mandate, including reference to the Specialised Interest Areas (SIAs) which is aligned to the mandate, objectives, and rules of procedure for the Working Parties, Operational Expert Groups, and Drafting Groups.

Action: For endorsement

The CHMP endorsed the proposed revised wording of the Methodology ESEC mandate. The mandate will be published on the EMA website.

4.1.4. [MWP Stakeholder Interaction Meeting 2023 – Report](#)

Following the opening of the public consultation on the draft Methodology Working Party (MWP) Work Plan for 2024, a virtual MWP stakeholder interaction meeting took place on 7 December 2023 to discuss the main comments received during the public consultation and to clarify questions raised by stakeholders.

The report summarises the topics discussed during this stakeholder interaction meeting and should be published on the EMA website after CHMP endorsement.

Action: For information

The CHMP noted the report on the MWP Stakeholder Interaction Meeting 2023.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

No topics

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. [Paediatric addendum to the guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension](#)

Concept paper on the need for revision of the Paediatric addendum to the guideline on the treatment of pulmonary arterial hypertension (EMA/CHMP/213972/2010) was released for public consultation until 30 September 2023. Draft Guideline is planned to be developed in 2024. Next steps include the proposal for the SAG CVS meeting to be discussed.

The List of Questions to SAG CVS and the call for nominations of experts:

- (1) Paediatric cardiologists experienced in echocardiography and specialising in treatment of children with PAH; and (2) cardiologists experienced in echocardiography and in treatment of adults with PAH. to join the SAG CVS are proposed for adoption.

CHMP: Patrick Vrijlandt

Expert: Clemens Mittmann

Action: For adoption

The CHMP endorsed the proposed steps for development of the paediatric addendum to the draft guideline on clinical investigation of medicinal products for the treatment of pulmonary

arterial hypertension. The CHMP adopted the LoQ to the SAG CSV and endorsed the call for nominations of experts to join the SAG CVS.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis

5.3.1. Nomination of Oncology ESEC Experts

Nomination of new members to enter the Oncology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new members of the Oncology European Specialised Expert Community (ESEC).

5.3.2. Agenda and Minutes

- Agenda of the ONCWP meeting held on 6 March 2024
- Minutes of the ONCWP meeting held remotely on 14 February 2024

Action: For information

The CHMP noted the agenda and minutes.

5.3.3. Upcoming Cancer Medicines Forum Workshop

The EMA and EORTC are co-chairing the Cancer Medicines Forum (CMF) which objective is to integrate the work of the academic sector into the regulatory decision-making process by acting as a unique channel between the regulator and academic clinical research.

The deliverables of the CMF are aimed at supporting policy decisions to facilitate treatment optimisation in Europe with a focus on post-licensing questions based on clinically relevant endpoints for patients in the healthcare setting.

The CMF will be reporting its observations and preliminary solutions to address treatment optimisation at a hybrid workshop to be held at the EMA on 5 April 2024 under the Auspices of the EU Belgian Presidency.

Action: For discussion

The CHMP noted the information on the upcoming Cancer Medicines Forum (CMF) Workshop.

5.3.4. Joint EMA/EORTC Soft Tissue and Bone Sarcoma and QoL Workshop

The joint EMA/EORTC soft tissue and bone sarcoma workshop was held on 12 January 2024 as well as the joint EMA/EORTC workshop on 'How can patient-reported outcomes (PRO) and health-related quality of life (HRQoL) data inform regulatory decisions?'.
Discussions on the next steps follow these 2 workshops.

Action: For discussion

The CHMP noted the information on the Joint EMA/EORTC Soft Tissue and Bone Sarcoma and QoL Workshops.

5.4. Rheumatology and Immunology Working Party (RIWP)

Chair: Caroline Auriche-Benichou, Vice-Chair: Karolina Törneke

5.4.1. Reflection Paper on Regulatory Requirements for the Development of Medicinal Products for Non-Alcoholic Steatohepatitis (NASH)

The reflection paper was discussed in January and February PROM. Further updates are proposed based on the discussions.

Expert: Elmer Schabel

Action: For adoption

The CHMP adopted the reflection paper on Regulatory Requirements for the Development of Medicinal Products for Non-Alcoholic Steatohepatitis (NASH). The reflection paper will be published on the EMA website.

5.4.2. Guideline on the requirements for demonstrating therapeutic equivalence between orally inhaled products (OIP) for asthma and chronic obstructive pulmonary disease (COPD)

This is the second revision of the CHMP Guideline formerly called "Guideline on the requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of asthma and chronic obstructive pulmonary disease (COPD) in adults and for use in the treatment of asthma in children and adolescents". It addresses the requirements for demonstration of therapeutic equivalence (TE) between orally inhaled products containing the same active moiety(ies).

Expert: Karolina Törneke

Action: For adoption

The CHMP adopted the second revision of the "Guideline on the requirements for demonstrating therapeutic equivalence between orally inhaled products (OIP) for asthma and chronic obstructive pulmonary disease (COPD)". The document will be published for a 6-month public consultation.

5.5. Infectious Disease Working Party (IDWP)

5.5.1. Call for nomination of new member to the IDWP

Following the departure of Lourdes Rodriguez Rojas, the IDWP is launching a call for nomination of a new member.

Action: For information

The CHMP endorsed the call for nomination of new IDWP members.

5.6. Vaccines Working Party (VWP)

No topics

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Agenda

- Agenda of the Blood Cluster TC held remotely on 8 March 2024
- Agenda of the EMA/FDA bilateral meeting on Haematology to be held remotely on 15 March 2024

Action: For information

The CHMP noted the agenda and 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)

No topics

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 04-07 March 2024

Action: For information

The CHMP noted the summary of recommendations and advice.

8.2.2. Guideline on quality, non-clinical, and clinical requirements for investigational ATMPs in clinical trials

Guideline revised after the public consultation and overview of comments. For publication for a second 2-months public consultation.

CAT Chair: Ilona G. Reischl

Action: For adoption

The CHMP adopted the revised "Guideline on quality, non-clinical, and clinical requirements for investigational ATMPs in clinical trials". The document will be published for a 2-month public consultation.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

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. [Group for Internal Rules on Extensions of Clock Stops - Outcome](#)

Report on outcomes and proposals to the CHMP.

Information about the key outcome, a template letter for requests of clock stop extensions. Proposal to update the current CHMP guidance to be considered in the future.

Action: For adoption

The CHMP received a report on the outcomes from the Group for Internal Rules on Extensions of Clock Stops. The CHMP agreed to adhere to the current CHMP guidance more strictly. In addition, the CHMP agreed to implement a new template for the request of the clock stop extension to be used by applicants and MAHs. It will be published on the EMA website and applicable as of 1 April. The pre/post authorisation guidance will be updated accordingly.

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 appointment of CHMP peer review for SA.

10.1.2. [Agenda and Table of Decisions](#)

- Agenda from the meeting held on 04-07 March 2024
- Draft Table of Decisions from the meeting held on 04-07 March 2024

Action: For information

The CHMP noted the agenda and table of decisions.

10.1.3. [Call for expression of interest for new SAWP members](#)

Call for expression of interest for nomination of a SAWP member replacement following planned departure of Sheila Killalea. The deadline is extended to Thursday, 4 April 2024.

Call for expression of interest for nomination of a SAWP member replacement following planned departure of Kerstin Wickström.

Required areas of expertise:

- Ophthalmology
- Pulmonology
- Immunology
- Internal Medicine
- Oncology
- Infectious Diseases
- Biosimilars

Applications should be sent by Thursday, 11 April 2024, EoB.

The new SAWP members and their alternates' starting date will immediately follow their nomination by the April CHMP PROM (15 April 2024).

Action: For information

The CHMP noted the launch of a new call for nomination of new members to the SAWP.

10.2. Innovation Task Force

10.2.1. ITF Briefing meeting

Meeting date: 25 March 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF activities for the year 2023

Overview of the activities within the Innovation Task Force in 2023.

Action: For information

The CHMP noted the overview of the Innovation Task Force activities in 2023.

10.3. Real-world evidence (including DARWIN EU) for regulatory decision making

Monthly touchpoint to explore emerging research questions at the time of pre-submission meetings and provide updates on the development of DARWIN EU, upcoming trainings and workshops and report on study requests received as well as planned/completed RWD studies. CHMP members will have an opportunity to raise RWD study proposals.

Action: For discussion

The CHMP noted the updates on Real-World Evidence, including DARWIN EU, upcoming events and the ongoing and completed RWD studies. The overview of upcoming pre-submission meetings as an opportunity to identify RWD research questions was welcome and proposals for improvement (type of application and availability of data) were noted.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

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

12. Any Other Business

12.1. Rapporteurships

Update

Action: For information

The CHMP noted the update.

12.2. Health Threats and ETF Update

Action: For information

The CHMP noted the Health Threats and ETF updates.

12.3. IncreaseNet - Joint Action on Capacity Building

Presentation on-the-job training program mainly focused on the CP procedures.

CHMP: Andreja Kranjc

Expert: Anna Nickel

Action: For information

The CHMP noted the presentation on "IncreaseNet - Joint Action on Capacity Building".

The CHMP members were invited to send comments on the proposal by 22 March.

12.4. EU NTC Training Webinar - Regulatory/HTA Interface

On 2 May 2024, an EU NTC training webinar on the regulatory/HTA interface under the HTA Regulation will be held. EMA would like to raise awareness within the wider regulatory network, whilst extending the target audience also to HTA colleagues, given the mutual learnings in view of the future collaborations. The agenda will cover an overview of the new HTA Regulation, outline of collaboration between regulators and HTAs under the new legal framework, followed by mutual learning about the respective assessment scopes. The webinar will be delivered by colleagues from the EC, HTAs and regulatory network and EMA respectively.

Action: For information

The CHMP noted the information on the upcoming EU NTC Training Webinar on the regulatory/HTA interface.

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	
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	
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 restrictions applicable to this meeting	Awikli - Insulin icodec - EMEA/H/C/005978
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	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	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
HjalTI Kristinsson	Alternate	Iceland	No interests declared	

Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Martine Trauffer	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No restrictions applicable to this meeting	Dupixent - Dupilumab - EMEA/H/C/004390/II/0081 Kevzara - Sarilumab - EMEA/H/C/004254/II/0044
John Joseph Borg	Member	Malta	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	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
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	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Thadeus Bao Quan Nguyen	Expert	Denmark	No interests declared	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Karolina Törneke	Expert	Sweden	No interests declared	
Anna Nickel	Expert	Germany	No interests declared	

Elmer Schabel	Expert	Germany	No interests declared	
Ilona G. Reischl	Expert	Austria	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Clemens Mittmann	Expert	Germany	No interests declared	
Marta Marcelino	Expert	Portugal	No interests declared	
Dina Lopes	Expert	Portugal	No interests declared	
Luka Kosec	Expert	Slovenia	No interests declared	
Lina Čačić	Expert	Croatia	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Milena Peraita Ezcurra	Expert	Spain	No interests declared	

Meeting run with support from relevant EMA staff.

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