



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 December 2025
EMA/CHMP/377773/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ Minutes for the meeting on 01 December 2025

Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

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 01 December 2025 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 01 December 2025 meeting will be adopted at the December 2025 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

2.1.1. Q&A on Biological Medicinal products

Additional BWP Q&As from selected BWP learnings on: excipients manufactured using recombinant DNA technology, control of visible particles, routine control of the ADCC activity of monoclonal antibodies, vaccines date of manufacture, deviations in safety related critical in-process controls, potency assignment in reference standard qualification protocols, sample volume for bioburden testing, and acceptable deviation in the active substance content limit of the finished products containing recombinant proteins. A revision

of the Low endotoxin recovery (LER) is also proposed. The document is presented to the CHMP for adoption.

Action: For adoption

The CHMP adopted the Q&A on Biological Medicinal products.

2.1.2. BWP 3-year workplan 2026-2028

Adoption of the 3-year workplan of the BWP as adopted by BWP in November 2025.

Action: For adoption

The CHMP adopted the BWP 3-year workplan.

2.1.3. Call for interest for a new BWP member

Call for interest for nomination of a new BWP member, following the resignation of a member.

Nominations should be sent to the Agency by 09 January 2026.

Nominations will take place at the January 2026 CHMP PROM meeting.

Action: For information

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

2.1.4. Agenda and Minutes

- Draft Agenda of the BWP meeting to be held remotely on 1-3 December 2025.
- Minutes of the BWP meeting held remotely on 6-8 October 2025.

Action: For information

The CHMP noted the agenda and minutes.

2.1.5. Nomination of new Biologics Quality ESEC experts

Nomination of new experts to join the Biologics Quality European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new experts to join the Biologics Quality European Specialised Expert Community (ESEC).

2.2. Quality Working Party (QWP)

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

2.2.1. [Guideline on stability testing for applications for variations to a marketing authorisation \(EMA/CHMP/QWP/441071/2011- Rev.3\)](#)

Administrative revision of the guideline to reflect the variation classification codes of the revised Variation Guidelines (Annex) and remove references to the Veterinary medicinal products.

Action: For adoption

The CHMP adopted the revised guideline on stability testing for applications for variations to a marketing authorisation.

2.2.2. [Guideline on quality of radiopharmaceuticals \(EMA/CHMP/QWP/363827/2025\)](#)

Revision of the guideline to further clarify a number of issues that have been the subject of non-harmonised interpretations, to address some issues not covered or poorly detailed in the current guideline, and to provide guidance on new issues raised after recent developments and new practices in the field of radiopharmaceuticals. The revised guideline is presented to the CHMP for adoption for a 4-month public consultation.

Action: For adoption

The CHMP adopted the revised guideline on quality of radiopharmaceuticals for a 4-month public consultation.

2.2.3. [QWP 3-year workplan 2026-2028](#)

Adoption of the 3-year workplan of the QWP as adopted by QWP in November 2025.

Action: For adoption

The CHMP adopted the QWP 3-year workplan.

2.2.4. [Guideline on the Development and Manufacture of Synthetic Peptides \(EMA/CHMP/CVMP/QWP/367182/2025\)](#)

The guideline is presented for CHMP adoption following the 6 months public consultation.

Action: For adoption

The CHMP adopted the guideline on the Development and Manufacture of Synthetic Peptides.

2.2.5. [Q&A on post approval change management protocols \(PACMP\) \(EMA/CHMP/CVMP/QWP/586330/2010 -Rev1\)](#)

Revision of the Q&A to support implementation of the revised Variation Regulation and Guidelines. This revised Q&A is presented to the CHMP for adoption.

Action: For adoption

The CHMP adopted the revised Q&A on PACMP.

2.2.6. Agenda and Minutes

- Draft Agenda of the QWP meeting to be held remotely on 1-2 December 2025.
- Minutes of the QWP meeting held in-person on 6-8 October 2025.

Action: For information

The CHMP noted the agenda and minutes.

2.2.7. Nomination of new Chemical Quality ESEC experts

Nomination of new experts to join the Chemical Quality European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new experts to join the Chemical Quality European Specialised Expert Community (ESEC).

2.2.8. CMDh question to QWP and NcWP

Action: For adoption

The CHMP adopted the CMDh question to QWP and NcWP.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: René Anour, Vice-Chair: Niklas Ekman

2.3.1. Agenda and Minutes

- Agenda and Minutes of the BMWP meeting held remotely on 20 October 2025.

Action: For information

The CHMP noted the agenda and minutes.

2.3.2. BMWP 3-year workplan 2026-2028

Adoption of the 3-year workplan of the BMWP as adopted by BMWP in November 2025.

Action: For adoption

The CHMP adopted the BMWP 3-year workplan.

2.4. Quality Innovation Group (QIG)

2.4.1. Nomination of Chair of the Quality Innovation Group (QIG)

Nomination of Chair of the QIG as recommended by the Quality Domain Governance.

Action: For endorsement

The CHMP endorsed Marcel Hoefnagel as the Chair of the QIG.

3. Non-Clinical Domain

3.1. Non-Clinical Working Party (NcWP)

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

3.1.1. CMDh question to NcWP/NS-OEG

Action: For adoption

The CHMP adopted the CMDh question to NcWP/NS-OEG.

3.1.2. Agenda and Minutes

- Draft Agenda of the NcWP meeting to be held remotely on 2-3 December 2025.
- Minutes of the NcWP meeting held in-person on 7-8 October 2025.

Action: For information

The CHMP noted the agenda and minutes.

3.1.3. NcWP 3-year workplan 2026-2028

Adoption of the 3-year updated workplan of the non-clinical domain.

Action: For adoption

The CHMP adopted the NcWP 3-year workplan.

3.1.4. CMDh question to QWP and NcWP

Action: For adoption

The CHMP adopted the CMDh question to QWP and NcWP.

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

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

3.2.1. Minutes

- Minutes of the 3Rs meeting held in-person on 19-20 November 2025.

Action: For information

The CHMP noted the minutes.

3.2.2. 3Rs 3-year workplan 2026-2028

Adoption of the 3-year updated workplan of the non-clinical domain.

Action: For adoption

The CHMP adopted the 3Rs 3-year workplan.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chair: Kit Roes, Vice-Chair: Kristin Karlsson

4.1.1. Agenda and Minutes

- Agenda and Minutes of the MWP meetings held remotely on 10 and 23 October 2025.

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of new Methodology ESEC experts

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

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of EMA staff and new experts to join the Methodology European Specialised Expert Community (ESEC).

4.1.3. Nomination of new Biostatistics OEG members

Nomination of new experts to join the Biostatistics Operational Expert Group (OEG).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new experts to join the Biostatistics Operational Expert Group (OEG).

4.1.4. Extension of the call for interest for new MWP members on Modelling & Simulation expertise

Nominations should be sent to the Agency by 31 January 2026.

Nominations are planned for the February 2026 CHMP PROM meeting.

Action: For information

The CHMP noted the extension of the call for interest for new MWP members on Modelling & Simulation expertise.

4.1.5. MWP 3-year workplan 2026-2028

Adoption of the rolling 3-year workplan of the MWP.

Action: For adoption

The CHMP adopted the MWP 3-year workplan.

4.1.6. [Concept paper on the amendments to the guideline on good pharmacogenomic practice](#)

The concept paper outlines the planned amendments to the guideline on good pharmacogenomic practice. The concept paper underwent internal consultation over the summer, and endorsement for a 3-month public consultation period is now sought from CHMP.

Expert: Markus Paulmichl

Action: For adoption

The CHMP adopted the concept paper on the amendments to the guideline on good pharmacogenomic practice for a 3-month public consultation.

4.1.7. [Product-Specific Guidelines](#)

Final guidelines after public consultation:

- Dronedarone film-coated tablets 400 mg product-specific bioequivalence guidance - Revision 1 (EMA/151695/2025 Rev. 1)
- Ledipasvir/sofosbuvir film-coated tablets 45 mg/200 mg and 90 mg/400 mg, coated granules 33.75mg/150mg and 45mg/200mg product-specific bioequivalence guidance - Revision 1 (EMA/151702/2025 Rev. 1)
- Aliskiren film-coated tablets 150 mg and 300 mg product-specific bioequivalence guidance - Revision 1 (EMA/151687/2025 Rev. 1)
- Sirolimus coated tablets 0.5, 1 and 2 mg, oral solution 1 mg/ml product-specific bioequivalence guidance - Revision 1 (EMA/151700/2025 Rev. 1)

Action: For adoption

The CHMP adopted the Product-Specific Guidelines.

4.1.8. [Nomination of a new member to the MWP](#)

Nomination of a new MWP member.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Ramzi Mraidi as new MWP member.

5. [Clinical Domain](#)

5.1. [Central Nervous System Working Party \(CNSWP\)](#)

Chair: Ewa Balkowiec Iskra, Vice-Chair: Marion Haberkamp

5.1.1. Agenda and Minutes

- Agenda and Minutes of the CNSWP meeting held in-person on 25 September 2025.

Action: For information

The CHMP noted the agenda and minutes.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Guideline on clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease of the lower extremities

This guideline replaces the Note for Guidance on clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease (CPMP/EWP/714/98 rev 1). The final Guideline and Overview of External Comments obtained during the 6-months public consultation is presented to the CHMP for adoption.

Expert: Gabriella Passacquale

Action: For adoption

The CHMP adopted the guideline on clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease of the lower extremities.

5.2.2. Agenda and Minutes

- Agenda of the CVSWP meeting held in-person on 14 November 2025.
- Draft Minutes/Table of Decisions of the CVSWP meeting held in-person on 14 November 2025.

Action: For information

The CHMP noted the agenda and minutes/table of decisions.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Nomination of new Oncology ESEC experts

Nomination of a new expert to join the Oncology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of a new expert to join the Oncology European Specialised Expert Community (ESEC).

5.3.2. Agenda and Minutes

- Agenda of the ONCWP meeting held remotely on 26 November 2025.
- Minutes of the ONCWP meeting held in-person on 24 September 2025.

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)

Chair: Sol Ruiz, Vice-Chair: Eleonora G. Wijnans

5.6.1. Agenda and Minutes

- Agenda and Minutes of the VWP meeting held in-person on 23 October 2025.

Action: For information

The CHMP noted the agenda and minutes.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphia, Vice-chair: Viktoriia Starokozhko

5.7.1. Agenda and Minutes

- Minutes of the HaemWP meeting held in-person on 30-31 November 2025.
- Draft Minutes of the Blood cluster TC held remotely on 17 October 2025.
- Draft Agenda of the ad hoc Blood cluster TC to be held remotely on 2 December 2025.

Action: For information

The CHMP noted the agenda and minutes.

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

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)

7.1.1. Report from ICH MC in Singapore

Following the recent ICH meeting, an update is provided to CHMP on progress of relevant ICH discussions and decisions taken, including on guidelines.

CHMP: Bruno Sepodes

Action: For information

The CHMP noted the report from the ICH MC in Singapore.

7.1.2. ICH E22 (draft) – Patient Preference studies

Following the ICH adoption, the draft version of the ICH E22 guideline is presented for CHMP adoption for a 4-month public consultation.

Action: For adoption

The CHMP adopted the draft version of the ICH E22 guideline on Patient Preference studies for a 4-month public consultation.

7.1.3. ICH M11 – Clinical Electronic Structured Harmonised Protocol Template

Following the ICH adoption of the final version of the ICH M11 guideline, the associated CT protocol template and underlying IT technical specifications, the guideline and the template are presented for CHMP adoption. The documents will be implemented 6 months after adoption.

Action: For adoption

The CHMP adopted the ICH M11 guideline and template on Clinical Electronic Structured Harmonised Protocol Template.

7.1.4. Call for expression of interest - ICH Q5E Annex on comparability for ATMPs

Following endorsement of the ICH Recommendations on Cell and Gene Therapy Discussion Group (CGTDG), the group will disband, and the relevant ICH experts will transition to a new guideline expert working group tasked with development of a Q5E annex on comparability for ATMPs. The CHMP appointed experts to the CGTDG are proposed to be nominated to the new EWG.

Action: For endorsement

The CHMP endorsed the expert nomination of Jan Mueller-Berghaus and Andreea Barbu for the ICH Q5E Annex on comparability for ATMPs.

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)

8.1.1. User Guide ASMF Worksharing procedure

Update of the worksharing procedure for the assessment of ASMF with an updated user guide. The document is presented for CHMP adoption, following CMDh and CMDv adoption. QWP has been informed.

Expert: Nienke Rodenhuis

Action: For adoption

The CHMP adopted the update of the worksharing procedure for the assessment of ASMF with an updated user guide.

8.2. Collaboration with other Scientific committees

8.2.1. PRAC report to CHMP

PRAC Chair: Ulla Wändel Liminga

Summary of recommendations and advice of the PRAC meeting held on 24-27 November 2025.

Action: For information

The CHMP noted the summary of recommendations and advice of the PRAC meeting held on 24-27 November 2025.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

9.2. CHMP organisation/templates

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi, Vice-Chairs: Pierre Demolis, Ewa Balkowiec Iskra

10.1.1. Agenda and Outcomes

SAWP Agenda and Outcomes, SAWP presentation for CHMP and List of procedures for discussion at CHMP.

Action: For information

The CHMP noted the agenda and the outcomes table.

10.1.2. Appointment of CHMP peer review for SA

List of procedures for discussion at CHMP

Action: For information

The CHMP noted the appointment of CHMP peer review for SA.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 5 December 2025

Action: For endorsement

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 17 December 2025

Action: For endorsement

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 16 January 2026

Action: For adoption

The CHMP endorsed the meeting.

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

Regular 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 update on Real-world evidence (including DARWIN EU) for regulatory decision making.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Bruno Sepodes

Action: For information

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

11.1.1. REZUROCK - Belumosudil - Orphan - EMEA/H/C/006421

Sanofi Winthrop Industrie; treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy

Scope: Adoption of timetable; Third-party interventions

Action: For adoption

Opinion adopted on 16.10.2025. List of Outstanding Issues adopted on 19.06.2025. List of Questions adopted on 30.01.2025.

The CHMP adopted the procedural timetable and noted the third-party interventions.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Incident management plan

[Revision 2 of the European Medicines Regulatory Network Incident Management Plan for Medicines for Human Use \(IMP-H\)](#) has been published on the EMA website and came into force upon publication. This update incorporates lessons learned from previous incidents, as

well as builds on experience from the COVID-19 pandemic and reflects the changes brought by [Regulation \(EU\) 2022/123](#) including the new process for IMP-H major event management with the involvement of the EU Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG).

Action: For information

The CHMP noted the revision 2 of the European Medicines Regulatory Network IMP-H.

13. List of Participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 01 December 2025 PROM meeting, which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Bruno Sepodes	Chair	Portugal	No restrictions applicable to this meeting	
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 restrictions applicable to this meeting	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	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	
Boje Kvorning Pires Ehmsen	Alternate	Denmark	No interests declared	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member (Vice-Chair)	Finland	No interests declared	
Johanna Lähteenvuio	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Nicolas Beix	Alternate	France	No interests declared	
Janet Koenig	Member	Germany	No interests declared	
Martin Mengel	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No restrictions applicable to this meeting	
Vilma Petrikaite	Member	Lithuania	No restrictions applicable to this meeting	
Larisa Gorobets	Alternate	Lithuania	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martine Trauffer	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No interests declared	
Peter Mol	Member	Netherlands	No restrictions applicable to this meeting	
Patrick Vrijlandt	Alternate	Netherlands	No restrictions applicable to this meeting	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No restrictions applicable to this meeting	
Ewa Balkowiec Iskra	Member	Poland	No restrictions applicable to this meeting	
Fatima Ventura	Member	Portugal	No restrictions applicable to this meeting	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No restrictions applicable to this meeting	
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Carolina Prieto Fernandez	Member	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 interests declared	
Carla Torre	Co-opted member	Portugal	No restrictions applicable to this meeting	
Jan Mueller-Berghaus	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	
Markus Paulmichl	Expert	Austria	No interests declared	
Gabriella Passacquale	Expert	Italy	No interests declared	
Anne H. Buur	Expert	Denmark	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No restrictions applicable to this meeting	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Susanna Uiterwaal	Expert	Netherlands	No interests declared	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Juan Ignacio Bedoya Ponte	Expert	Spain	No restrictions applicable to this meeting	
Meeting run with support from relevant EMA staff.				

Experts' declared interests were evaluated against the topics or activities they participated in.