



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 January 2026
EMA/CHMP/11604/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ Minutes for the meeting on 19 January 2026

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

The Chairperson opened the meeting by welcoming all participants. The meeting was held remotely.

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 meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants 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. Restrictions applicable to this meeting are captured in the list of participants included in the minutes. 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.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members, alternates (where applicable) and experts in line with the relevant provisions of the [Rules of Procedure](#). All decisions taken at this meeting were made in the presence of a quorum of members. All opinions, recommendations, decisions and advice were agreed by consensus, unless otherwise specified. The members of the EEA-EFTA States agreed with the recommendation of the CHMP, unless otherwise specified.

1.2. Adoption of agenda

The CHMP adopted the PROM agenda for the 19 January 2026 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of the 19 January 2026 meeting will be adopted at the January 2026 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

2.1.1. PRAC request for BWP advice

Action: For adoption

The CHMP adopted the PRAC request for BWP advice.

2.1.2. Nomination of a new member to the BWP

Nomination of a new BWP member, following a call for nomination launched at the December 2025 PROM, subsequent to the resignation of a member.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Darija Kos as new BWP member.

2.1.3. Agenda and Minutes

- Draft agenda of the BWP meeting to be held remotely on 19-21 January 2026.
- Minutes of the BWP meeting held remotely on 3-5 November 2025.

Action: For information

The CHMP noted the agenda and minutes.

2.1.4. 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).

2.1.5. Alert limits of guideline on epidemiological data on blood transmissible infections

Draft Revision of Chapter 9 on alert limits of the guideline on epidemiological data on blood transmissible infections (EMA/CHMP/BWP/548524/2008 rev 2).

Expert: Marja van de Bovenkamp

Action: For adoption

The CHMP adopted the revision of the alert limits of the guideline on epidemiological data on blood transmissible infections.

2.2. Quality Working Party (QWP)

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

2.2.1. Q&A to provide technical and procedural guidance on the use of titanium dioxide (TiO₂) as colourant in medicines (EMA/CHMP/CVMP/QWP/360415/2022)

Following the Staff Working Document on the use of titanium dioxide in medicinal products published by the EC in August 2025, the QWP has revised the document following the new views of the EC that the use of titanium dioxide as a colourant in medicinal products, as

provided for in Regulation (EU) 2022/63 amending Regulation (EC) No 1333/2008, should be maintained.

Action: For adoption

The CHMP adopted the Q&A to provide technical and procedural guidance on the use of titanium dioxide (TiO₂) as colourant in medicines.

2.2.2. [Q&A: how to use a CEP in the context of a Marketing Authorisation Application \(MAA\) or a Marketing Authorisation Variation \(MAV\) \(EMA/CHMP/CVMP/QWP/5/2024\)](#)

The proposed administrative updates, including revisions to outdated references and coding adjustments aligned with the new Variations Classification Guideline, have been adopted during the December QWP meeting.

Action: For adoption

The CHMP adopted the Q&A on how to use a CEP in the context of a Marketing Authorisation Application (MAA) or a Marketing Authorisation Variation (MAV).

2.2.3. [Quality of medicines Q&A: Part 1 and Part 2](#)

The proposed administrative updates primarily address coding revisions in accordance with the new Variations Classification Guideline, updates to certain outdated references, and minor corrections such as spelling adjustments and hyperlink updates. The amendments to the Q&As have been presented at the December QWP meeting, and the comments provided have been duly implemented. The updates have been adopted by QWP in writing.

Action: For adoption

The CHMP adopted the Quality of medicines Q&A: Part 1 and Part 2.

2.2.4. [Q&A regarding co-processed excipients used in solid oral dosage forms \(H&V\)](#)

The Q&A summarises the dossier (Module 3) requirements for co-processed excipients. It has been reviewed and updated taking into consideration the stakeholder comments. In December 2025, it has been endorsed by the IWG and adopted by the QWP. The Q&A is now planned for CHMP adoption.

Expert: Tina Visholm Jensen

Action: For adoption

The CHMP adopted the Q&A regarding co-processed excipients used in solid oral dosage forms (H&V), which has also been endorsed by CVMP.

2.2.5. [Agenda and Minutes](#)

- Draft agenda of the QWP meeting to be held remotely on 19-20 January 2026
- Minutes of the QWP meeting held remotely on 3-4 November 2025

Action: For information

The CHMP noted the agenda and minutes.

2.2.6. 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).

2.2.7. Q&A on the use of product lifecycle management (PLCM) document

New Q&A to support the use of the PLCM. PLCM is one of the lifecycle management tools foreseen by the revised Variation Regulation (Article 6a Additional regulatory tools), and the revised Annex of the Variations Guidelines (chapter Q.I.e & Q.II.g Additional Regulatory Tools), and facilitates global harmonisation of post-approval CMC changes.

Action: For adoption

The CHMP adopted the Q&A on the use of the PLCM.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

No topics

2.4. Quality Innovation Group (QIG)

2.4.1. Nomination of a new member to the QIG

Nomination of a new QIG member, following a call for nomination launched at the November 2025 PROM.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Silvia Vogl as new QIG member.

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

- Minutes of the NcWP meeting held remotely on 4-5 November 2025
- Draft agenda of the NcWP meeting to be held remotely on 20-21 January 2026

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Reflection paper on the qualification of non-mutagenic impurities (NMI)

This reflection paper outlines the current thinking on recommended approaches for evaluating the safety of NMIs in chemically synthesised pharmaceuticals (to be considered where appropriate for combination products). The principles and methodologies discussed are intended to support the qualification of new or elevated impurity levels which are specified at levels that exceed existing ICH Q3A/B QTs, particularly when such impurities are identified after completion of non-clinical toxicology studies. In addition, this paper complements the approaches described in ICH M3(R2) for evaluating the safety of impurities during clinical development. Its aim is to supplement existing guidelines — specifically ICH Q3A(R2) and Q3B(R2)— by proposing alternative, non-animal strategies for the qualification of NMIs.

The reflection paper has been updated taking into consideration the comments received during the public consultation. The final reflection paper has been endorsed by the NcWP in December 2025 and GCG comments have been implemented. The CHMP is requested to endorse the publication of the final reflection paper.

Experts: Marianne Schmidt, Susanne Brendler-Schwaab

Action: For adoption

The CHMP adopted the reflection paper on the qualification of NMI.

3.1.3. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to NcWP.

3.1.4. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

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

No topics

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 meeting held in-person on 25-26 September 2025.
- Agenda and minutes of the MWP meetings held remotely on 6 November, 4 December and 18 December 2025.

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. [Reminder of the 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 will take place at the February 2026 CHMP PROM meeting.

Action: For information

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

4.1.3. [Concept paper for the development of a Guideline on the use of Bayesian methods in clinical development](#)

The current MWP workplan includes the development of guidance on the use of Bayesian statistics in clinical trials. This concept paper motivates the need for guidance on the topic and outlines key aspects that will be covered. The document is presented to the CHMP for endorsement for a 3-month public consultation.

Expert: Peter van de Ven

Action: For adoption

The CHMP adopted the concept paper for the development of a Guideline on the use of Bayesian methods in clinical development for a 3-month public consultation.

4.1.4. [Concept paper on the revision of the Guideline on Clinical Evaluation of Diagnostic agents and its appendix 1 on imaging agents](#)

The current MWP workplan includes the revision of the Guideline on Clinical Evaluation of Diagnostic agents and its appendix 1 on imaging agents. This concept paper outlines key aspects that will be covered in the revised guideline. The document is presented to the CHMP for endorsement for a 3-month public consultation.

Expert: Sofia Kapanadze

Action: For adoption

The CHMP adopted the concept paper on the revision of the Guideline on Clinical Evaluation of Diagnostic agents and its appendix 1 on imaging agents for a 3-month public consultation.

4.1.5. [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 to join the Methodology European Specialised Expert Community (ESEC).

4.1.6. Methodology ESEC experts

Update on the list of active experts of the Methodology ESEC.

Action: For information

The CHMP noted the update on the list of active experts of the Methodology ESEC.

4.1.7. CMDh Question to MWP

Action: For adoption

The CHMP adopted the CMDh Question to MWP.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

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

5.1.1. Call for interest for a new CNSWP member

Call for interest for nomination of a new CNSWP member.

The expertise required is within the field of neurology and psychiatry, in accordance with the published workplan. It would be particularly beneficial if the proposed candidates had experience in development of guidelines and are current or recent members of guideline drafting groups.

Nominations should be sent to the Agency by 09 February 2026. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

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

Action: For information

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

5.1.1. Concept paper on the development of a Guideline on clinical investigation of medicinal products in the treatment of Myasthenia Gravis

The purpose of the proposed concept paper is to provide recommendations on the clinical investigation of medicinal products in the treatment of Myasthenia Gravis. The document is presented to the CHMP for endorsement for a 6-month public consultation.

Expert: Taina Mattila

Action: For adoption

The CHMP adopted the concept paper on the development of a Guideline on clinical investigation of medicinal products in the treatment of Myasthenia Gravis for a 6-month public consultation.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Reflection Paper on investigation and assessment of cardiovascular safety of anticancer medicinal products

The purpose of the proposed Reflection Paper (RP) is to provide recommendations for the planning, collection of data and evaluation of cardiovascular (CV) safety of anticancer medicinal products considering specific issues that apply to the oncology setting with respect to type of medicinal products applied, patients and trials designs. The Concept Paper for this RP was published in 2025. The RP was developed in collaboration between the CVSWP and the ONCWP. The document is presented to the CHMP for endorsement for a 6-month public consultation.

CHMP: Antonio Gómez Outes

Expert: Gabriella Passacquale

Action: For adoption

The CHMP adopted the reflection paper on investigation and assessment of cardiovascular safety of anticancer medicinal products for a 6-month public consultation.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Nomination of new Oncology ESEC experts

Nomination of new experts 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).

5.4. Rheumatology and Immunology Working Party (RIWP)

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

5.4.1. Call for nominations for RIWP Vice-Chair

The mandate of the RIWP Vice-chair Karolina Törneke will expire on 29 March 2026.

Nominations should be sent to the Agency by 19 March 2026. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Elections will take place at the March 2026 CHMP plenary meeting.

Action: For endorsement

The CHMP endorsed the call for nominations for RIWP Vice-Chair.

5.4.2. Minutes

- Minutes of the RIWP meeting held in-person on 27-28 November 2025.

Action: For information

The CHMP noted the minutes.

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. Call for interest for a new VWP member

Call for interest for nomination of a new non-clinical VWP member.

Nominations should be sent to the Agency by 28 February 2026. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

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

Action: For information

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

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphia, Vice-chair: Viktoriia Starokozhko

5.7.1. Agenda

- Draft agenda of the ad hoc Blood cluster TC held remotely on 2 December 2025 and follow-up on 18 December 2025.

Action: For information

The CHMP noted the agenda.

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)

7.1.1. ICH Expert Working Group for ICH guideline on Natural history studies and registry data to advance rare disease drug development– appointment of experts

Following a call launched, CHMP is requested to appoint experts for a new ICH Expert Working Group to draft the ICH guideline on Natural history studies and registry data to advance rare disease drug development.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of experts to the ICH Expert Working Group for ICH guideline on Natural history studies and registry data to advance rare disease drug development.

7.1.2. ICH E6(R3) Guideline for good clinical practice Annex 2

Following the EU public consultation on ICH E6 annex 2 from November 2024 to February 2025, the document has been revised to address comments received. An update is provided to CHMP on the revision ahead of finalisation of the document by the Annex 2 Expert Working Group.

Expert: Gabriele Schwarz

Action: For information

The CHMP noted the update on the ICH E6(R3) Guideline for good clinical practice Annex 2.

7.1.3. ICH M15 Guideline on general principles for model-informed drug development

Following the finalisation of ICH M15 guideline, the document is presented for CHMP adoption. The guideline will be implemented 6 months after adoption.

Action: For adoption

The CHMP adopted the ICH M15 Guideline on general principles for model-informed drug development.

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

PRAC Chair: Ulla Wändel Liminga

Summary of recommendations and advice of the PRAC meeting held on 12-15 January 2026.

Action: For information

The CHMP noted the summary of recommendations and advice of the PRAC meeting held on 12-15 January 2026.

8.2.2. Mandate of Novel therapies & technologies ESEC

Setting up a novel therapies & technologies European Specialised Expert Communities (ESEC) in the veterinary domain.

Action: For information

The CHMP noted the mandate of Novel therapies & technologies ESEC.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. CHMP co-opted membership

The 3-year co-opted member mandate for Bruno Delafont comes to an end on 26.03.2026. His area of expertise is Biostatistics and clinical trial methodology.

The nomination procedure foresees that the CHMP should decide on their areas of expertise in order to proceed with the nominations.

The election is anticipated at the February 2026 plenary meeting.

Action: For endorsement

The CHMP endorsed the call for the nomination of a co-opted member and agreed that the co-opted member position should be filled again. CHMP was invited to provide input on the areas of expertise

9.2.2. CHMP Workplan 2026

Draft CHMP workplan for 2026.

CHMP: Bruno Sepodes

Action: For discussion

The CHMP noted the update on the CHMP workplan for 2026.

9.2.3. GIREX - Group for Internal Rules on Extensions of Clock Stops

Update on requests for extensions of clock stops for ongoing procedures. See also point 11.

Action: For adoption

The CHMP discussed the requests for extensions of clock stops for ongoing procedures. See point 11.

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: 21 January 2026.

Action: For endorsement

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 22 January 2026.

Action: For endorsement

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 3 February 2026.

Action: For endorsement

The CHMP endorsed the meeting.

10.2.4. ITF meeting

Meeting date: 4 February 2026.

Action: For endorsement

The CHMP endorsed the meeting.

10.2.5. EC Request for EMA scientific opinion

Action: For discussion

The topic was postponed for the January CHMP plenary meeting.

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. Furosemide - PUMA - EMEA/H/C/006617

treatment of all conditions requiring diuresis due to mechanical obstruction or venous insufficiency.

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in July 2025.

Action: For adoption

The Committee did not agree to the request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in July 2025.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The topic was postponed for the January CHMP plenary meeting.

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 19 January 2026 PROM meeting, which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics 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	
Gergana Lazarova	Alternate	Bulgaria	No restrictions applicable to this meeting	
Margareta Bego	Member	Croatia	No interests declared	
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	
Outi Mäki-Ikola	Member (Vice-Chair)	Finland	No interests declared	
Johanna Lähteenvu	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	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
Finbarr Leacy	Alternate	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Elita Poplavska	Member	Latvia	No restrictions applicable to this meeting	
Vilma Petrikaite	Member	Lithuania	No restrictions applicable to this meeting	
Alexandra Branchu	Alternate	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No restrictions applicable to this meeting	
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	
Simona Badoi	Member	Romania	No interests declared	
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	
Antonio Gomez-Outes	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 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	
Katrin Buss	Expert	Germany	No interests declared	
Tina Visholm Jensen	Expert	Denmark	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No restrictions applicable to this meeting	
Marianne Schmidt	Expert	Denmark	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Kristin Karlsson	Expert	Sweden	No restrictions applicable to this meeting	
Peter van de Ven	Expert	Netherlands	No restrictions applicable to this meeting	
Maria Grünewald	Expert	Sweden	No interests declared	
Elina Asikanius	Expert	Finland	No restrictions applicable to this meeting	
Sofia Kapanadze	Expert	Germany	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Taina Mattila	Expert	Netherlands	No interests declared	
Gabriele Schwarz	Expert	Germany	No interests declared	
A representative from the European Commission attended the meeting.				
Meeting run with support from relevant EMA staff.				

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