



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 March 2025
EMA/CHMP/96050/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 17 March 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.



Table of contents

1.	Agenda and Minutes	4
1.1.	Welcome and declarations of interest of members, alternates and experts.....	4
1.2.	Adoption of agenda.....	4
1.3.	Adoption of the minutes	4
2.	Quality Domain	4
2.1.	Biologics Working Party (BWP)	4
2.2.	Quality Working Party (QWP)	5
2.3.	Biosimilar Medicinal Product Working Party (BMWP)	6
3.	Non-Clinical Domain	6
3.1.	Non-Clinical Working Party (NcWP).....	6
3.2.	Joint 3Rs Replacement, Reduction and Refinement Working Party (3Rs)	8
4.	Methodology Domain	8
4.1.	Methodology Working Party (MWP).....	8
5.	Clinical Domain	9
5.1.	Central Nervous System Working Party (CNSWP)	9
5.2.	Cardiovascular Working Party (CVSWP)	9
5.3.	Oncology Working Party (ONCWP)	10
5.4.	Rheumatology and Immunology Working Party (RIWP).....	10
5.5.	Infectious Disease Working Party (IDWP).....	10
5.6.	Vaccines Working Party (VWP).....	10
5.7.	Haematology Working Party (HaemWP)	10
5.8.	Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEG).....	11
6.	Patients, Healthcare Professionals and Consumers	11
6.1.	Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)	11
7.	Harmonisation and consistency groups	12
7.1.	International Council on Harmonisation (ICH)	12
7.2.	Guideline Consistency Group (GCG).....	12
7.3.	Summary of product characteristics Advisory Group	13
8.	Joint groups and collaboration with other Scientific committees	13
8.1.	Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)	13
8.2.	Collaboration with other Scientific committees	13
8.3.	Collaboration with Inspections	13

9.	Regulatory/Organisational matters	13
9.1.	Regulatory Issues/new legislation	13
9.2.	CHMP organisation/templates	13
10.	Product development support	14
10.1.	Scientific Advice Working Party (SAWP).....	14
10.2.	Innovation Task Force	15
11.	Product related topics	15
11.1.	Preview CHMP Plenary.....	15
11.2.	Nirogacestat - Orphan - EMEA/H/C/006071.....	15
12.	Any Other Business	16
12.1.	Rapporteurships	16
12.2.	Revision of EMA policy 0044 on handling of competing interests.....	16
12.3.	New EU fee regulation	16
13.	List of Participants	17

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 17 March 2025 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of 17 March 2025 meeting will be adopted at the March 2025 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

2.1.1. Guideline on the quality aspects of mRNA vaccines

Draft guideline on the quality aspects of mRNA vaccines for adoption for a 6-month public consultation.

Expert: Elena Grabski

Action: For adoption

The CHMP adopted the draft guideline on the quality aspects of mRNA vaccines for adoption for a 6-month public consultation.

2.1.2. BWP Vaccines Quality Operational Expert Group (BV-OEG) Influenza

EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2025/2026. Report from the BV-OEG to the BWP.

Expert: Koen Brusselmans

Action: For discussion

The CHMP noted report from the BV-OEG to the BWP. The EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2025/2026 will be included in the CHMP March plenary meeting for adoption.

2.1.3. BWP Concept paper for the PMF Scientific requirement guideline revision

Concept paper for the revision of PMF Scientific requirement guideline for adoption for a 3-month public consultation.

Expert: Irene Saugar

Action: For adoption

The CHMP adopted Concept paper for the revision of PMF Scientific requirement guideline for adoption for a 3-month public consultation.

2.1.4. Agenda and minutes

- Draft Agenda of the BWP meeting to be held in person on 17-19 March 2025
- Minutes of the BWP meeting held remotely on 20-22 January 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. Agenda and minutes

- Draft Agenda of the QWP meeting to be held in person on 17-19 March 2025
- Minutes of the QWP meeting held remotely on 20-21 January 2025

Action: For information

The CHMP noted the agenda and minutes.

2.2.2. 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).

2.3. 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 3 February 2025

Action: For information

The CHMP noted the agenda and minutes.

2.3.2. Reflection paper on a tailored clinical approach in biosimilar development

Presentation of a final draft for discussion and MS comments.

BMWP Chair and Vice-Chair: René Anour and Niklas Ekman

Action: For endorsement

The CHMP endorsed the reflection paper on a tailored clinical approach in biosimilar development for a 6-months public consultation.

3. Non-Clinical Domain

3.1. Non-Clinical Working Party (NcWP)

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

3.1.1. Nomination of New Approach Methodologies ESEC experts

Nomination of new experts to join the New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new experts to join the New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC).

3.1.2. Agenda and minutes

- Minutes of the meeting held remotely on 21 and 22 January 2025
- Draft agenda of the meeting to be held in person on 18 and 19 March 2025

Action: For information

The CHMP noted the agenda and minutes.

3.1.3. Call for interest for two NcWP members - ongoing

Call for interest for the nomination of two NcWP members' replacement

Nominations should be sent to the Agency by 31 March 2025. 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 2025 CHMP PROM meeting.

Action: For information

The CHMP noted the call for interest for the nomination of two NcWP members' replacement.

3.1.4. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.5. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.6. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.7. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.8. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.9. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.10. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.11. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.12. NcWP response to CHMP/CMDh question

Action: For adoption

The CHMP adopted the NcWP response to CHMP/CMDh question.

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

- Draft minutes of virtual 3RsWP meeting held on 4 and 5 Feb 2025
- Draft agenda for the 2025 Annual Stakeholder meeting to be held on 2 April 2025

Action: For information

The CHMP noted the agenda and minutes.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Agenda and minutes

- Agenda and minutes of the MWP meeting held remotely 7, 21 November and 5, 19 December 2024

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of new Methodology ESEC experts

Nomination of new experts to enter the Methodology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new experts to enter the Methodology European Specialised Expert Community (ESEC).

4.1.3. Reflection Paper on RWE –Revision

Present the main changes introduced to the reflection paper on use of RWD in NIS to generate RWE for regulatory purposes after the public consultation.

CHMP: Carla Torre

Action: For adoption

The CHMP adopted the updated reflection paper on RWD in non-interventional studies (NIS) to generate RWE for regulatory purposes including the revisions made after the public consultation.

4.1.4. CMDh questions to QWP/MWP

Action: For adoption

The CHMP adopted the CMDh questions to QWP/MWP.

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. Agenda and Table of Decisions

- Agenda from CVS WP meeting held virtually on 6 Feb 2025
- Draft Table of Decisions from CVS WP meeting held virtually on 6 Feb 2025

Action: For information

The CHMP noted the agenda and table of decisions.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Cancer drug development for older adults

- Draft agenda of the 'EMA/EORTC meeting (with participation of SIOG): Cancer treatments for older adults - how to optimise and tailor anticancer agents?' meeting to be held in person and virtually on 9 April 2025

Action: For information

The CHMP noted the agenda of the 'EMA/EORTC meeting (with participation of SIOG): Cancer treatments for older adults - how to optimise and tailor anticancer agents?' meeting.

5.3.2. Cancer Medicines Pathfinder

Update on pathfinder stakeholder task force on centralised procedure.

Action: For information

The CHMP noted the update on pathfinder stakeholder task force on centralised procedure.

The CHMP will be kept informed on the developments of this initiative.

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 Philadelphia

5.7.1. Agenda

- Draft agenda for the Blood cluster meeting to be held virtually on 21 March 2025

Action: For information

The CHMP noted the agenda.

5.7.2. Call for nominations for HAEWP Chair

The mandate of the HAEWP Chair Daniela Philadelphia will expire on 12 June 2025.

Nominations should be sent to the Agency by 16 May 2025. 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 May 2025 CHMP Plenary meeting.

Action: For information

The CHMP noted the call for nominations for HAEWP Chair.

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. Updates to Rules of Procedure and mandates for PCWP and HCPWP

Presentation on updates to Rules of Procedures and mandates for PCWP and HCPWP.

Action: For adoption

The CHMP adopted the updated rules of procedures and mandates for PCWP and HCPWP.

6.1.2. Agenda and minutes

- Meeting summary of the PCWP/HCPWP and all eligible organisations meeting held on 20 Nov 2024
- Draft Agenda of the PCWP-HCPWP meeting to be held on 1-2 April 2025

Action: For information

The CHMP noted the agenda and minutes.

6.1.3. Draft Reflection Paper on Patient Experience Data

A drafting group composed of members from EMA committees (CHMP, COMP, PDCO, PRAC and CAT) and selected WPs (SAWP, ONCWP, PCWP, HCPWP) has drafted a reflection paper (RP) on Patient Experience Data.

The RP provides a framework for discussion and clarifies in particular areas where scientific knowledge is fast evolving or regulatory experience is limited. The Reflection Paper is complementary to the ICH guidance work and is not intended to be a methodological guidance.

Action: For information

The CHMP noted the information provided on the Draft Reflection Paper on Patient Experience Data.

CHMP members were invited to send comments on the Draft Reflection Paper.

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. ICH M13B Draft Guideline on bioequivalence for immediate-release solid oral dosage forms - additional strengths biowaiver – Step 2b

The ICH M13 Expert Working Group has completed a draft guideline intended to provide recommendations on obtaining waivers of bioequivalence (BE) studies for one or more additional strengths of a drug product in an application where *in vivo* BE has been demonstrated for at least one of the strengths. The document is presented for adoption for a 3-month public consultation.

Action: For adoption

The CHMP adopted the ICH M13B Draft Guideline on bioequivalence for immediate-release solid oral dosage forms - additional strengths biowaiver – Step 2b for a 3-month public consultation.

7.1.2. ICH E22: “General Considerations for Patient Preference Studies”; Draft Technical Document: internal consultation

The ICH E22 guideline focuses on general considerations for patient preference studies (PPS) to inform drug development and related decisions for pharmaceutical products. The guideline aims to optimise the use of patient preference information using a globally harmonised framework

Action: For discussion

The CHMP noted the ICH E22: “General Considerations for Patient Preference Studies”; Draft Technical Document: internal consultation.

CHMP members were invited to send comments on the Draft Technical Document.

7.2. Guideline Consistency Group (GCG)

Chair: Kristina Dunder

7.2.1. Call for nomination of GCG members

Nominations should be sent to the Agency by 25 April 2025. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

The call is launched because of the expiry of the mandate of the current GCG members on 13 June 2025.

CHMP: Kristina Dunder

Action: For information

The CHMP noted the call for nomination of GCG members.

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 PRAC meeting held on 10-13 March 2025.

Action: For information

The CHMP noted the summary of recommendations and advice.

8.3. Collaboration with Inspections

8.3.1. Joint GCP Inspectors- Assessors virtual meeting

Announcement and request for topics of the annual, virtual joint GCP inspectors-CHMP/assessors meeting, 8 May, 10.00-12.00 CET.

Action: For information

The CHMP noted the announcement and request for topics of the annual, virtual joint GCP inspectors-CHMP/assessors meeting.

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 topic was postponed to the March CHMP plenary.

9.2.2. 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 two requests for extension of clock stops for ongoing procedures. See points 11.2 and 11.3.

9.2.3. Committee Meeting Dates for 2027-2028

Proposed committee meeting dates for the period of 2027-2028.

Action: For information

The CHMP noted the proposed committee meeting dates for the period of 2027-2028.

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 10-13 March 2025 SAWP meeting
- Draft Table of Decisions from 10-13 March 2025 SAWP meeting

Action: For information

The CHMP noted the agenda and table of decisions.

10.1.3. Nomination of new SAWP members and respective alternates

Nomination of new SAWP members and respective alternates' replacement.

Nomination(s) received

The new SAWP members and his/her alternates starting date is as of 7–10 April 2025.

Action: For endorsement

The CHMP endorsed the nomination of Agnieszka Przybyszewska as member and Lauren Myles as alternate (IE), Viktoriia Starokozhko as member and Taina Mattila as alternate (NL).

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 21 March 2025

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 28 March 2025

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

11.2. Nirogacestat - Orphan - EMEA/H/C/006071

Springworks Therapeutics Ireland Limited; treatment of desmoid tumours

Scope: Update of the procedure; Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues adopted in December 2024.

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 27.06.2024.

The CHMP did not agree to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in December 2024.

Inavolisib - EMEA/H/C/006353 treatment of adult patients with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues adopted in February 2025

Action: For adoption

List of Outstanding issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

The CHMP did not agree to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in February 2025.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Revision of EMA policy 0044 on handling of competing interests

The main changes in the revision of policy 0044, the updated declaration of interests form and the next steps for experts will be presented.

Action: For information

The CHMP noted the main changes in the revision of policy 0044, the updated declaration of interests form and the next steps for experts.

12.3. New EU fee regulation

The new EU fee regulation to be presented at the CHMP.

Action: For information

The CHMP noted the information provided on the new EU fee regulation.

13. List of Participants

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 interests declared	
Daniela Philadelphia	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
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	
Emilia Mavrokordatou	Member	Cyprus	No interests declared	
Katerina Savvidou	Alternate	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 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	
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	
Jayne Crowe	Member	Ireland	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	5.1.9. SARCLISA - Isatuximab - EMEA/H/C/004977 /II/0035
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
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 interests declared	
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	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 interests declared	
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	
René Anour	Expert	Austria	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Hilke Zander	Expert	Germany	No interests declared	
Nicolas Lee	Expert	Ireland	No restrictions applicable to this meeting	
Pierre Demolis	Expert	Iceland	No interests declared	
Christoph Furtmann	Expert	Germany	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Irene Saugar Gomez	Expert	Spain	No interests declared	
Ana Maria Imedio	Expert	Spain	No interests declared	
Juan Ignacio Bedoya Ponte	Expert	Spain	No restrictions applicable to this meeting	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Harald Enzmann	Expert	Germany	No interests declared	
Susanna Hausmann	Expert	Germany	No interests declared	
Martina Weise	Expert	Germany	No restrictions applicable to this meeting	

A representative from the European Commission attended the meeting.

Meeting run with support from EMA staff.

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