14 April 2025
EMA/137922/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 14 April 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 14 April 2025 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 14 April 2025 meeting will be adopted at the April 2025 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

2.1.1. Agenda and minutes

- Draft Agenda of the BWP meeting to be held remotely on 14-16 April 2025
- Minutes of the BWP meeting held remotely on 17-19 February 2025

Action: For information

The CHMP noted the agenda and minutes.

2.1.2. 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 remotely on 14-15 April 2025
- Minutes of the QWP meeting held remotely on 17-18 February 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 March 2025

Action: For information

The CHMP noted the agenda and minutes.

2.4. Quality Innovation Group (QIG)

Chair: Marcel Hoefnagel

2.4.1. Listen and Learn Focus Group (LLFG) meeting

Report of the 4th LFFG meeting on Platform Technologies held remotely on 19-20 November 2024.

Action: For information

The CHMP noted the report of the 4th LFFG meeting on Platform Technologies.

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 18 - 19 February 2025
- Draft agenda of the NcWP meeting to be held remotely on 15 and 16 April 2025

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Nominations of two new members to the NcWP

Nomination of two new members following a call for interest in December 2024 and January 2025 and debate with the selection committee.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Peter Theunissen (NL) and Alan Sanh (FR) to the NcWP.

3.1.3. Nomination of a new Non-Clinical Working Party - Nitrosamines OEG expert

Nomination of a new expert to join the NcWP - Nitrosamines Operational Expert Group (OEG)

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of a new expert to join the NcWP - Nitrosamines Operational Expert Group (OEG).

3.1.4. CMDh question to NcWP/NS-OEG

Action: For adoption

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

3.1.5. Revision of the Q&A for marketing authorisation holders / applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products

Update of Question 10 and 22 of the Q&A for marketing authorisation holders / applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products to clarify the applicable AI limit to different administration routes and accepted in vivo study type and to include guidance to amend the shelf-life and storage conditions.

Action: For adoption

The CHMP adopted the revised Q&A. The document will be published on the EMA website.

3.1.6. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

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

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

3.2.1. 3RsWP annual stakeholder (IP) meeting

3RsWP held its annual stakeholder (IP) meeting on 02 and 03 April.

On Day 1, as part of the plenary, a virtual public session was held. During this session, the chair presented the 3RsWP work plan and stakeholders were given the opportunity to comment and provide views. The recording of the session is available on the event page.

Action: For information

The CHMP noted the information on the 3RsWP annual stakeholder (IP) meeting.

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 23 January, 6 and 20 February 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 Methodology BSOEG experts

Nomination of a new expert to join the Methodology Biostatistics Operational Expert Group (BSOEG).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of a new expert to join the Methodology Biostatistics Operational Expert Group (BSOEG).

4.1.4. Nomination of two new members of the MWP

Nomination of two new members following a call for interest in January 2025 and debate with the selection committee.

Nomination(s) received

CHMP: Finbarr Leacy

Action: For endorsement

The CHMP endorsed the nomination of Wolfgang Jacquet (BE) and Laszlo Tothfalusi (HU) to the MWP.

4.1.5. Call for interest for new MWP members

Call for interest for nomination of new MWP members, following the departure of a MWP member. Expertise and experience in Artificial Intelligence (with a particular interest in pharmacovigilance) is being sought.

Nominations should be sent to the Agency by 01 June 2025. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise and a downloaded copy of their DoI or to fill in the DoI file available in the survey if not registered yet as EMA expert.

Nominations will take place at the June 2025 CHMP PROM meeting.

Action: For information

The CHMP noted the call for interest for nomination of new MWP members.

4.1.6. Concept Paper on a Guideline on investigation of drug interactions in the gastrointestinal tract

The ICH-M12 guideline covers pharmacokinetic drug interactions involving metabolic enzymes and transporters but does not cover those occurring in the upper gastrointestinal tract (e.g., food effect, gastric pH changes or complex formation). With the planned withdrawal of the EMA's guideline on drug interactions, a new guideline is proposed to prevent a regulatory gap and update recommendations on gastrointestinal drug interactions.

MWP is proposing a Concept Paper on a Guideline on investigation of drug interactions in the gastrointestinal tract for adoption by CHMP before publication. There will be no public consultation.

Action: For adoption

The CHMP adopted the Concept Paper on a Guideline on investigation of drug interactions in the gastrointestinal tract.

4.1.7. Product-Specific Guidelines

Final guideline after public consultation:

- Dabrafenib hard capsule 50 and 75 mg product-specific bioequivalence guidance (EMA/CHMP/39771/2023) and Overview of comments (EMA/339228/2024).

  Expert: Carolien Versantvoort

Revised guidelines in line with ICH M13A for publication:

- Dolutegravir film-coated tablets 10 mg, 25 mg and 50 mg product-specific bioequivalence guidance (EMA/CHMP/356874/2017 Rev. 1).
- Ibuprofen oral use immediate release formulations 200–800 mg product-specific bioequivalence guidance (EMA/CHMP/356876/2017 Rev.2).
- Paracetamol oral use immediate release formulations product-specific bioequivalence guidance (EMA/CHMP/356877/2017 Rev.2).
- Tadalafil film-coated tablets 2.5 mg, 5 mg, 10 mg and 20 mg product-specific bioequivalence guidance (EMA/CHMP/315234/2014 Rev.3).
- Levothyroxine tablets 12.5 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg and 200 mcg (and additional strengths within the range) product-specific bioequivalence guidance (EMA/CHMP/176098/2020 Rev. 1).
- Lurasidone film-coated tablets 18.5, 37 and 74 mg 4 product-specific bioequivalence guidance (EMA/CHMP/39336/2023 Rev. 1).
- Memantine film-coated tablets 5, 10, 15 and 20 mg, oral solution 5 mg product-specific bioequivalence guidance (EMA/CHMP/315243/2014 Rev. 1).
- Posaconazole oral suspension 40 mg/ml product-specific bioequivalence guidance (EMA/CHMP/315247/2014 Rev. 1).
- Repaglinide tablets 0.5, 1 and 2 mg product-specific bioequivalence guidance (EMA/CHMP/675842/2014 Rev. 1).

- Voriconazole tablets 50, 200 mg and powder for oral suspension 40 mg/ml product-specific bioequivalence guidance (EMA/CHMP/315236/2014 Rev. 1).

Action: For adoption

The CHMP adopted the Product-Specific Guidelines.

4.1.8. 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)

No topics

5.2. Cardiovascular Working Party (CVSWP)

No topics

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Call for nominations for ONCWP Vice-Chair

The mandate of the ONCWP Vice-Chair Olli Tenhunen will expire on 21 July 2025.

Nominations should be sent to the Agency by 13 June 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 June 2025 CHMP Plenary meeting.

Action: For endorsement

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

5.3.2. Concept Paper on the revision of the Guideline on the evaluation of anticancer medicinal products and its appendices

The concept paper outlines the reasons for revising the "Guideline on the Clinical Evaluation of Anticancer Medicinal Products" (Revision 7). The primary driver for the revision is the need to align the guideline with recent regulatory and scientific developments, including the implementation of the estimands framework introduced by the ICH E9(R1) addendum.

Additionally, Revision 7 will introduce updates such as the inclusion of haematological cancer sections, improvements to guidance on single-arm trials, and revisions to regulatory standards in adjuvant, neoadjuvant, and perioperative settings. A comprehensive review of Appendix 4 on condition-specific guidance, is also planned. Structural changes will streamline information to avoid overlap and enhance clarity.

ONCWP is proposing a Concept Paper on the revision of the guideline on the evaluation of anticancer medicinal products and its appendices for adoption by CHMP.
The document will be published for 3-months public consultation after CHMP adoption.

Action: For adoption

The CHMP adopted the Concept Paper on the revision of the Guideline on the evaluation of anticancer medicinal products and its appendices.

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo, Vice-Chair: Maja Sommerfelt Gronvold

5.5.1. Nomination of three new members of the IDWP

Nomination of three new members following a call for interest in January and February 2025 and debate with the selection committee.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Roel Van Loock (BE), Bettina Klug (DE) and Ingrid Schellens (NL) to the IDWP.

5.6. Vaccines Working Party (VWP)

No topics

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. EMA's Plasma master file (PMF)

Expert group comments "ECDC guidelines on the prevention of donor-derived transmission of HIV through substances of human origin".

Action: For information

The CHMP noted the information on the EMA's Plasma master file (PMF).

5.7.2. Blood cluster minutes

- Minutes of the blood cluster meeting held remotely on 21 March 2025

Action: For information

The CHMP noted the minutes.

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

No topics

6. Patients, Healthcare Professionals and Consumers

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

No topics

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. ICH Q1 Draft Guideline on stability testing of drug substances and drug products – Step 2b

The ICH Q1 Expert Working Group has completed a draft guideline that outlines the stability data expectations for drug substances and drug products. ICH Q1 is a consolidated revision that supersedes ICH Q1A-F and Q5C guidelines and provides additional guidance on principles relating to stability. The document will be published for 3-months public consultation after CHMP adoption.

Action: For adoption

The CHMP adopted the ICH Q1 Draft Guideline on stability testing of drug substances and drug products – Step 2b.

7.2. Guideline Consistency Group (GCG)

Chair: Kristina Dunder

7.2.1. Call for interest for new GCG members

At the March 2025 CHMP PROM meeting, a call for interest for new GCG members was launched, following the expiry of the mandate of the current GCG members on 13 June 2025.

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.

Action: For information

The CHMP noted the call for interest for new GCG members.

7.3. Summary of product characteristics Advisory Group

7.3.1. Summary of product characteristics Advisory Group (SmPC AG) Q180 on the structure of section 4.2

Summary of recommendations and advice following the PRAC meeting held on 7-10 April 2025.

The SmPC AG with the support of QRD has prepared a Q&A to clarify the structure of section 4.2, to avoid confusion between the subsections on Posology, Special population, Paediatric population and method of administration.

Action: For adoption

The CHMP discussed the SmPC AG Q180 proposal on the structure of section 4.2.

7.3.2. Nomination of a new member to the SmPC AG

Nomination of a new member, following the departure of Anna Baumann.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Paul Pirson (DE) to the SmPC AG.

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 7-10 April 2025.

Action: For information

The CHMP noted the summary of recommendations and advice.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP noted the proposed learnings.

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 of the SAWP meeting held as a hybrid meeting on 07-10 April 2025
- Draft Table of Decisions of the SAWP meeting held as a hybrid meeting on 07-10 April 2025

Action: For information

The CHMP noted the agenda and table of decisions.

10.1.3. Revision of SAWP mandate (rev.19)

SAWP mandate has been revised to introduce the option to have two vice-chairs for adoption at the April 2025 CHMP PROM meeting.

Action: For adoption

The CHMP adopted the revised SAWP mandate (rev.19).

10.1.4. Call for nominations for a second SAWP Vice-Chair

As endorsed by the CHMP at its March 2025 plenary meeting, the SAWP is launching a call for a second Vice-Chair.

Nominations should be sent to the Agency by 2 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 endorsement

The CHMP endorsed the call for nominations for a second SAWP Vice-Chair.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 15 April 2025

Action: For endorsement

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 updates on the development of real-world evidence (including DARWIN EU) for regulatory decision making and highlighted the worth of complementing the assessment with the results from the studies.

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. Colistimethate sodium (CMS) – EMEA/H/A-5(3)/1524

Various MAHs

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Ewa Balkowiec Iskra

Scope: Request for a timetable extension

Action: For adoption

Review of the ratio of polymyxins E1 and E2 in colistin starting material and of the (sulfomethylation) composition profile of CMS finished product.

List of outstanding issues adopted on 21.03.2024, 22.02.2024. List of questions adopted on 22.06.2023.

The CHMP adopted a revised timetable:

Submission of PK study protocol (as per Question 1): 31 March 2025

Rapporteurs' joint assessment report circulated to CHMP: 30 April 2025

CHMP discussion: 22 May 2025

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. EMANS (EU medicines agencies' network strategy) to 2028

EMA and Heads of Medicines Agencies (HMA) have published their joint EU medicines agencies' network strategy to 2028 (EMANS), following its recent adoption by the HMA and the EMA Management Board. The strategy is a comprehensive update of the five-year strategy which was developed to cover the period 2021 to 2025 (EMANS 2025). It will guide the European medicines regulatory network over the next few years to meet the challenges ahead, including preparing for, and responding to, public health emergencies and threats and further changes to the technological and regulatory landscape. It aligns with the EU's ongoing revision of its pharmaceutical legislation and lays the groundwork for its implementation.

Action: For information

The CHMP noted the EU medicines agencies' network strategy (EMANS) to 2028.

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 Philadelphy	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	
Gergana Lazarova	Alternate	Bulgaria	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	
Outi Mäki-Ikola	Member (Vice-Chair)	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Jean-Michel Race	Alternate	France	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	
Finbarr Leacy	Alternate	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No restrictions applicable to this meeting	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Larisa Gorobets	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No restrictions applicable to this meeting	
Peter Mol	Member	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Patrick Vrijlandt	Alternate	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No restrictions applicable to this meeting	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Paulo Paixão	Alternate	Portugal	No interests declared	
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	
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 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	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Christoph Furtmann	Expert	Germany	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Thadeus Bao Quan Nguyen	Expert	Denmark	No interests declared	
Christian (Kit) Roes	Expert	Netherlands	No participation in discussion, final deliberations and voting on:	5.1.12. Keytruda – Pembrolizumab - EMA/VR/0000245108; 9.1.9. Zostavax - shingles (herpes zoster) vaccine (live) EMEA/H/C/000674
Susanne Brendler-Schwaab	Expert	Germany	No restrictions applicable to this meeting	
Marcel Hoefnagel	Expert	Netherlands	No interests declared	
Pierre Demolis	Expert	Iceland	No interests declared	
Maria Jesus Fernandez Cortizo	Expert	Spain	No restrictions applicable to this meeting	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Juan Bedoya Ponte	Expert	Spain	No participation in discussion, final	8.1.1. - Lurbinectedin – H0006673

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			deliberations and voting on:	
Enrique Blanco Cortina	Expert	Spain	No restrictions applicable to this meeting	
Meeting run with support from EMA staff.				

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