



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2025
EMA/CHMP/464338/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM¹ minutes for the meeting on 07 October 2024

Chair: Bruno Sepodes

07 October 2024, 09:00–16:00, virtual meeting

Disclaimers

Some of the information contained in this document is considered commercially confidential or sensitive and therefore not disclosed.

Of note, agendas and minutes are working documents primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

¹ The CHMP PROM is a meeting to discuss CHMP organisational matters and other topics in preparation for the CHMP Plenary meeting. It is a virtual meeting, which usually takes place on Monday before the CHMP Plenary meeting. CHMP members, working party chairs and national experts together with EMA staff are participating in this forum. Depending on the nature of the issue and availability of documents and experts some PROM topics can be discussed at the CHMP Plenary.



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)	5
2.4.	Quality Innovation Group (QIG)	6
2.5.	Formulation Expert Group (FEG).....	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)	7
4.	Methodology Domain	7
4.1.	Methodology Working Party (MWP).....	7
5.	Clinical Domain	8
5.1.	Central Nervous System Working Party (CNSWP)	8
5.2.	Cardiovascular Working Party (CVSWP)	8
5.3.	Oncology Working Party (ONCWP)	8
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	11
7.1.	International Council on Harmonisation (ICH)	11
7.2.	Guideline Consistency Group (GCG).....	12
7.3.	Summary of product characteristics Advisory Group	12
8.	Joint groups and collaboration with other Scientific committees	12
8.1.	Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)	12

8.2.	Collaboration with other Scientific committees	12
9.	Regulatory/Organisational matters	12
9.1.	Regulatory Issues/new legislation	12
9.2.	CHMP organisation/templates	12
10.	Product development support	13
10.1.	Scientific Advice Working Party (SAWP).....	13
10.2.	Innovation Task Force	13
10.3.	Real-world evidence (including DARWIN EU) for regulatory decision making	14
11.	Product related topics	14
11.1.	Preview CHMP Plenary.....	14
11.2.	Belzutifan- EMEA/H/C/005636	14
11.3.	Insulin human – EMEA/H/C/006011	15
11.4.	Trabectedin - EMEA/H/C/006433.....	15
11.5.	Nuvaxovid– COVID-19 vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0078.....	15
11.6.	Givinostat - Orphan - EMEA/H/C/006079.....	15
12.	Any Other Business	16
12.1.	Rapporteurships	16
12.2.	Update on the raw data pilot	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 07 October 2024 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of 07 October 2024 meeting were adopted at the January 2025 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry

2.1.1. Q&As from BWP learnings

Q&As from selected BWP learnings for adoption (batch 2)

Expert: Martijn Van der Plas

Action: For adoption

The CHMP adopted the Q&As from selected BWP learnings.

2.1.2. Nomination of new Biological Quality ESEC experts

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

Nomination(s) received

Action: For endorsement

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

2.1.3. Agenda and Minutes

- Minutes of the BWP meeting held remotely on 15-17 July 2024
- Agenda of the BWP meeting to be held F2F on 7-9 October 2024

Action: For information

The CHMP noted the agenda and minutes.

2.2. Quality Working Party (QWP)

Chair: Blanka Hirschlerova, Vice-Chairs: Marie-Hélène Sabinotto, Laivi Saaremäe

2.2.1. Q&A on Ph. Eur. chapter 2.2.46 / flexibility in analytical test procedures

Q&A on Ph. Eur. chapter 2.2.46 / flexibility in analytical test procedures.

CHMP: Blanka Hirschlerova

Action: For adoption

The CHMP adopted the Q&A on Ph. Eur. chapter 2.2.46 on flexibility in analytical test procedures. The Q&A will be published on the EMA website.

2.2.2. Agenda and minutes

- Agenda of the QWP meeting to be held remotely on 7-8 October 2024
- Minutes of the QWP meeting held remotely on 15-16 July 2024

Action: For information

The CHMP noted the agenda and minutes.

2.2.3. 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)

No topics

2.4. Quality Innovation Group (QIG)

No topics

2.5. Formulation Expert Group (FEG)

No topics

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 meeting held remotely on 16 and 17 July 2024
- Draft agenda of the meeting to be held F2F on 8, 9 October 2024

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Nomination of new member for the NcWP

Following the departure of Fernando Mendez Hermina at the end of July 2024, the NcWP is nominating a new member.

Nomination(s) received

Action: for endorsement

The CHMP endorsed the nomination of the new members for the NcWP.

3.1.3. Call for two new NcWP members

Mikael Andersson and Fabienne Gaugaz will leave the NcWP, thus a new call for 2 members is launched.

Action: for information

The CHMP noted the call for two new NcWP members.

3.1.4. Call for expertise for ICH E14/S7B IWG kick-off meeting

In March 2024 a new concept paper was endorsed to address round 2 of Q&A. Thus, additional experts with background in oligonucleotides and biologicals are needed.

Expert: Sonja Beken

Action: for information

The CHMP noted the call for expertise for ICH E14/S7B IWG kick-off meeting.

3.1.5. NcWP response to CMDh question

Action: for adoption

The CHMP noted the NcWP 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. Agenda and Minutes

- Adopted minutes of the meeting held virtually on 21-22 May 2024.
- Agenda of the meeting held in person on 24-25 September 2024.

Action: For information

The CHMP noted the agenda and minutes.

3.2.2. Call for nomination of CHMP/CVMP Joint 3Rs Working Party (3RsWP) members (deadline extended)

The call for nomination of two additional members of the 3RsWP will be experts' representatives of the human or veterinary areas and may also be members of the Non-Clinical Working Party (NCWP), Safety Working Party-Veterinary (SWP-V), Immunologicals Working Party-Veterinary (IWP), Biologics Working Party (BWP) and Efficacy Working Party-Veterinary (EWP-V).

The deadline for nominations is 18 October.

Action: For information

The CHMP noted the extended deadline of the call for nomination of CHMP/CVMP Joint 3Rs Working Party (3RsWP) members.

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 virtual MWP meeting held on 4 July 2024

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of Methodology ESEC experts

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

Nomination(s) received

Action: For endorsement

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

4.1.3. Nomination of new Methodology Biostatistics OEG experts

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

Nomination(s) received

MWP Chair: Christian B. Roes

Action: For endorsement

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

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. Revision of the Guideline on Clinical Investigation of Medicinal Products for the Treatment of Peripheral Arterial Occlusive Disease of the Lower Extremities

The CVS WP elaborated the 'Revision 2' of the Guideline on Peripheral Arterial Occlusive Disease in line with plans in CVS WP Work Plan. Draft guideline to be released for public consultation 4Q 2024. The document is presented for adoption for a 6-months public consultation.

Expert: Gabriella Passacquale

Action: For adoption

The CHMP adopted the revised Guideline on Clinical Investigation of Medicinal Products for the Treatment of Peripheral Arterial Occlusive Disease of the Lower Extremities for 6-months public consultation.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Concept Paper on the clinical evaluation of therapeutic radiopharmaceuticals in oncology

There is currently no guidance provided on specificities of therapeutic radiopharmaceuticals. The concept paper presents key ideas about therapeutic radiopharmaceuticals to systematically incorporate personalised dosimetry-based treatment planning into their clinical development programs. These key concepts will be further elaborated in the future guideline with the purpose of optimising the safety and efficacy of therapeutic radiopharmaceuticals.

Experts: Anna Sundlöf, Serena Marchetti

Action: For adoption

The CHMP adopted the Concept Paper on the clinical evaluation of therapeutic radiopharmaceuticals in oncology.

5.3.2. Planning of next Oncology ESEC webinars, Oncology workshops and events

Planned Oncology ESEC webinars (end of 2024 – 2025), Oncology workshops (2025) and events (such as the planned 19th November 2024 paediatric conversations on cancer)

Action: For discussion

The CHMP noted the planned Oncology ESEC webinars, Oncology workshops (2025) and events.

EMA presented the planned Oncology ESEC webinars for 2024 specifically the breast cancer webinar which was held on 27th September where the meeting invitation has been extended to HTA assessors. The bladder cancer webinar planned on 6th December 2024. The Oncology ESEC webinars planned for 2025 are planned for prostate cancer, lung cancer, colorectal and pancreatic.

The joint EMA/International Myeloma Society (IMS) workshop (follow-up) took place on 18th October 2024. The CMF meeting took place on 1st October and the next one will be on 16th December where learned societies will be asked to come forward with the identification of treatment optimisation questions.

The planned Oncology workshops for 2025 were also presented and are currently planned for sarcoma (rare cancers), therapeutic radiopharmaceuticals, cancer in elderly patients, clinical endpoints in oncology (incorporating the estimand framework) and CMF workshop with industry.

The next Conversations on Cancer will be on paediatric and is planned on 19th November 2024.

5.3.3. Agenda

- Agenda of the virtual ONCWP meeting which was held on 25 September 2024

Action: For information

The CHMP noted the agenda.

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. IDWP Webinars

A series of webinars is organised by the CHMP Infectious Disease Working Party (IDWP) on anti-infective agents, including antibacterial, anti-tuberculosis, antifungal, and antiviral agents.

Action: For information

The CHMP noted the series of webinars that is organised by the CHMP Infectious Disease Working Party (IDWP) on anti-infective agents, including antibacterial, anti-tuberculosis, antifungal, and antiviral agents.

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. Call for expression of interest for a new VWP member

The VWP proposes a call for nominations of 1 additional member

The following areas of expertise are requested:

- Non-clinical models for vaccines, specifically experience in assessing the non-clinical studies intended to support immunogenicity and efficacy
- Clinical studies
- Quality aspects and manufacturing of vaccines
- Pharmacovigilance and monitoring of vaccines
- Paediatric development of vaccines

The deadline for nominations is 13 October.

Action: For endorsement

The CHMP endorsed the call for nominations 1 additional VWP member.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphia

5.7.1. Nomination of new Haematology ESEC member

Nomination of new Haematology ESEC member.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new Haematology ESEC member.

5.7.2. Agenda

- Draft agenda of the Haematology working party meeting to be held face-to-face on 25-26 October 2024
- Draft agenda of the Blood cluster meeting to be held virtually on 18th October 2024

Action: For information

The CHMP noted the agenda and minutes.

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

5.8.1. Renewal of SAG mandate

Renewal of SAG mandate/call for nomination of experts for the 5 therapeutic SAGs (Neurology, Oncology, Vaccines, Infectious Diseases and Cardiovascular Issues).

Action: For information

The CHMP noted the call for nomination of experts for the 5 therapeutic SAGs (Neurology, Oncology, Vaccines, Infectious Diseases and Cardiovascular Issues).

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. Nomination of replacement quality expert for ICH Q1/Q5C

QWP has put forward an expert to participate in the ICH working group Q1/Q5 drafting the guidance document.

Nomination(s) received

Action: For information

The CHMP noted the participation of an expert working group Q1/Q5 drafting the guidance document.

7.1.2. Nomination of expert for ICH M4Q(R2)

Quality working party has put forward an expert to participate in the ICH working group M4Q(R2) drafting the guidance document.

Nomination(s) received

Action: For information

The CHMP noted the participation of an expert in the ICH working group M4Q(R2) drafting the guidance document.

7.2. Guideline Consistency Group (GCG)

No topics

7.3. Summary of product characteristics Advisory Group

No topics

8. Joint groups and collaboration with other Scientific committees

8.1. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

No topics

8.2. Collaboration with other Scientific committees

8.2.1. PRAC report to CHMP

Chair: Ulla Wändel Liminga

Summary of recommendations and advice of PRAC meeting held on 30 September-03 October 2024.

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 endorsed the proposed learnings.

9.2.2. CHMP Revamp

CHMP adoption of the new Revamp Overview template.

CHMP: Daniela Philadelphy

Action: For adoption

The CHMP adopted the new Revamp Overview template.

9.2.3. Consultation of SAGs/AHEGs by CHMP

CHMP awareness and discussion on the running of SAG/AGEG meetings.

CHMP: Filip Josephson

Action: For discussion

The CHMP discussed possible ways to improve the SAG/AGEG meetings.

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 30 September- 03 October 2024 meeting held by Webex
- Draft Table of Decisions from 30 September- 03 October 2024 meeting held by Webex

Action: For information

The CHMP noted the agenda and table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 09 October 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 11 October 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 16 October 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.4. ITF meeting

Meeting date: 21 October 2024

Action: For adoption

The CHMP endorsed the meeting.

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

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

Action: For discussion

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

11.2. Belzutifan- EMEA/H/C/005636

treatment of adult patients with advanced renal cell carcinoma (RCC) and treatment of adult patients with von Hippel-Lindau (VHL) disease

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2024.

Action: For adoption

List of questions adopted on 19.09.2024

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues.

11.3. Insulin human – EMEA/H/C/006011

treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2024.

Action: For adoption

List of questions adopted on 19.09.2024

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues.

11.4. Trabectedin - EMEA/H/C/006433

treatment of soft tissue sarcoma and combination with PLD treatment of relapsed platinum-sensitive ovarian cancer

Scope: Letter by the applicant requesting an additional extension to the clock stop to respond to the list of outstanding issues adopted in September 2024.

Action: For adoption

List of outstanding issues adopted on 19.09.2024

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues.

11.5. Nuvaxovid– COVID-19 vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0078

Novavax CZ a.s. prevention of COVID-19

Rapporteur: Patrick Vrijlandt

Action: For adoption

Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0071/G

Action: For adoption

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

11.6. Givinostat - Orphan - EMEA/H/C/006079

Italfarmaco S.p.A.; treatment of Duchenne muscular dystrophy (DMD)

Scope: Letter by the applicant requesting an additional extension to the clock stop to respond to the list of outstanding issues adopted in September 2024.

Action: For adoption

List of outstanding issues adopted on 19.09.2024

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Update on the raw data pilot

Update on the interim proof-of-concept raw data pilot, exploring access and analysis of electronically structured individual patient data from clinical trials in medicines evaluation. Initial pilot insights/learnings and recommendations arising from pilot participants' feedback collected halfway through the pilot were shared at CHMP/SAWP SRLM meeting in June. Information on new pilot procedures and next steps with dissemination of the interim pilot report will be shared.

Action: For information

The CHMP noted the update on the raw data pilot.

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	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Lyubina Racheva Todorova	Member	Bulgaria	No interests declared	
Gergana Lazarova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Alternate	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
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	
Finbarr Leacy	Alternate	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Martine Trauffer	Member	Luxembourg	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	4.2.1. Kevzara - Sarilumab - EMEA/H/C/004254/X/0043/G 5.1.5. Dupixent - Dupilumab - EMEA/H/C/004390/II/0081 5.1.6. Dupixent - Dupilumab - EMEA/H/C/004390/II/0083
John Joseph Borg	Member	Malta	No interests declared	
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	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Antonio Gomez-Outes	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Anna Sundlöv	Expert	Sweden	No restrictions applicable to this meeting	
Ana Maria IMEDIO	Expert	Spain	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Adriana Ammassari	Expert	Italy	No interests declared	
Annette Lommel	Expert	Germany	No interests declared	
Celine Jumeau	Expert	France	No interests declared	
Elsa Grangier	Expert	France	No interests declared	

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