20 January 2025
EMA/CHMP/82016/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 20 January 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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 the 20 January 2025 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 20 January 2025 meeting will be adopted at the January 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

- Agenda of the BWP meeting to be held remotely on 20-22 January 2025
- Minutes of the BWP meeting held remotely on 4-6 November 2024

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 the new experts to join the Biological 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

- Agenda of the QWP meeting to be held remotely on 20-21 January 2025
- Minutes of the QWP meeting held remotely on 4-5 November 2024
- Minutes of the joint BWP/QWP/GMDP-IWG meeting held remotely on 25 September 2024
- Minutes of the QWP Interested Parties meeting held remotely on 10 October 2024

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 the 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. BMWP 3-year workplan 2025-2027

Adoption of the 3-year work plan of the Biosimilar Medicinal Products Working Party as adopted by BMWP in December 2024.

Action: For adoption

The CHMP adopted the revised 3-year workplan of the BMWP.

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

3.1.2. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to NcWP.

3.1.3. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.4. Call for interest for one NcWP member

Call for interest for nomination of a NcWP member's replacement

Nominations should be sent to the Agency by the 28 February 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 nomination of a NcWP member

3.1.5. Agenda and Minutes

- Minutes of the NcWP meeting held remotely on 5-6 November 2024
- Draft agenda of the NcWP meeting to be held remotely on 21-22 January 2025

Action: For information

The CHMP noted the agenda and minutes.

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

No topics

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 face-to-face MWP meeting held on 10 October 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 of the new experts of the Methodology European Specialised Expert Community (ESEC).

4.1.3. 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 Clinical Pharmacology, particularly in bioequivalence, biowaivers, PK and generics / hybrids is being sought.

Nominations should be sent by 21 March 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 April 2025 CHMP PROM meeting.

Action: For information

The CHMP noted the call for interest for nomination of new MWP members, following the departure of a MWP member.

4.1.4. Concept paper on the development of a Guideline on assessment and reporting of mechanistic models used

Endorsement on the final Concept paper on the development of a Guideline on assessment and reporting of mechanistic models used for public consultation. The document will be published for 3-months public consultation.

Action: For endorsement

The CHMP endorsed the Concept paper on the development of a Guideline on assessment and reporting of mechanistic models used for public consultation.

4.1.5. 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: Andre Elferink, Vice-Chair: Ewa Balkowiec Iskra

5.1.1. Nomination of a new member for the CNSWP

Nomination of a new member.

Nomination(s) received

Action: For endorsement

The CHMP agreed to postpone this topic to February PROM

5.1.2. Guideline on clinical investigation of medicinal products in the treatment of depression

The Guideline on clinical investigation of medicinal products in the treatment of depression is presented for CHMP adoption.

Expert: Marion Haberkamp

Action: For adoption

The CHMP adopted the Guideline on clinical investigation of medicinal products in the treatment of depression.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Minutes

- Draft Minutes of the CVSWP meeting held remotely on 28 November 2024

Action: For information

The CHMP noted the minutes.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Nomination of new Oncology ESEC members to the Oncology Working party

Nomination of new Oncology European Specialised Expert Community (ESEC) members.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of as Oncology European Specialised Expert Community (ESEC) members to the Oncology Working party.

5.3.2. Agenda of the 'How to develop new treatments in ultra-rare sarcomas, as a model for ultra-rare tumours?' meeting

- Draft Agenda of the 'How to develop new treatments in ultra-rare sarcomas, as a model for ultra-rare tumours?' meeting to be held remotely on 31 January 2025.

Action: For information

The CHMP noted the agenda of the 'How to develop new treatments in ultra-rare sarcomas, as a model for ultra-rare tumours?' meeting.

5.4. Rheumatology and Immunology Working Party (RIWP)

Chair: Caroline Auriche Benichou

5.4.1. RIWP 3-year workplan 2025-2027

Adoption of the 3-year workplan of the RIWP and the priorities 2025.

Action: For adoption

The CHMP adopted the 3-year workplan of the RIWP and the priorities 2025.

5.4.2. Establishment of a RIWP drafting group on the paediatric part of the IBD Guidelines (UC/DC) as per workplan

New drafting group on the paediatric part of the IBD Guidelines (UC/DC)

Action: For information

The CHMP noted the establishment of a RIWP drafting group on the paediatric part of the IBD Guidelines (UC/DC) as per workplan.

5.4.3. Agenda and minutes

- Agenda for the RIWP meeting held virtually on 17 December 2024

- Draft Minutes for the RIWP meeting held virtually on 17 December 2024

Action: For information

The CHMP noted the agenda and minutes.

5.5. Infectious Disease Working Party (IDWP)

5.5.1. Nomination of an IDWP member to the Steering Committee of the Forum for Collaborative Research's HIV Prevention Project

Nomination of an IDWP member to join the Steering Committee of the Forum for Collaborative Research's HIV Prevention Project

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of an IDWP member to join the Steering Committee of the Forum for Collaborative Research's HIV Prevention Project.

5.5.2. Call for interest for 2 new IDWP members

Call for interest for nomination of 2 new IDWP members, following the departure of 2 members.

Nominations should be sent to the Agency by 20 February 2025. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise, DoI, endorsement of the nomination by a Committee member or alternate.

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

Action: For information

The CHMP noted the call for interest for nomination of 2 new IDWP members, following the departure of 2 members.

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. VWP 3-year workplan 2025-2027

Adoption of the 3-year workplan of the VWP.

Action: For adoption

The CHMP adopted the 3-year workplan of the VWP.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Agenda of the joint EMA/EC webinar on the European Regulation on substances of Human origin, clinical safety, practice and use of transfusions

- Draft Agenda of the European Regulation on substances of Human origin, clinical safety, practice and use of transfusions webinar to be held remotely on 14 February 2025.

Action: For information

The CHMP noted the agenda of the joint EMA/EC webinar on the European Regulation on substances of Human origin, clinical safety, practice and use of transfusions.

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

5.8.1. SAG mandate renewal and (re)nominations

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

Action: For discussion

The CHMP noted the update of the renewal of SAG mandate/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)

No topics

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 PRAC meeting held on 13-16 January 2025.

Action: For information

The CHMP noted the summary of recommendations and advice.

8.2.2. Guideline on quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials

CAT Chair: Ilona Reischl

The Guideline on quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials (final after second public consultation and GCG comments) has been adopted by CAT and BWP in December 2024 and is presented for CHMP adoption.

Action: For adoption

The CHMP adopted the Guideline on quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials.

8.2.3. Concept paper on the revision of the Guideline on Risk assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling

Outcome of the public consultation comments to the concept paper, prepared by a CHMP/PRAC multi-stakeholders drafting group, on the high-level topics to update the 'CHMP Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling', triggered by PRAC and CHMP work plans for 2024/25.

CHMP: Jan Müller-Berghaus, PRAC Chair: Ulla Wändel Liminga

Action: For discussion

The CHMP supported the drafting group outcome of the public consultation comments to the concept paper on the revision of the Guideline on Risk assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling.

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. 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 adopted the update on requests for extensions of clock stops for ongoing procedures. See point 11.2 and 11.3.

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 13-16 January 2025 meeting held by Webex
- Draft Table of Decisions from 13-16 January 2025 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: 20 January 2025

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 31 January 2025

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 3 February 2025

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 information

The CHMP noted the updates on Real-world evidence (including DARWIN EU) for regulatory decision making.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Bruno Sepodes

Action: For information

The CHMP 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: Letter by the applicant requesting 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 agreed 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.

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

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

Scope: 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, 19.09.2024. List of Questions adopted on 14.12.2023.

The CHMP agreed 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.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Joint HTAb-EMA methodological workshop series: understanding key evidence challenges, managing remaining uncertainties and exploring potential solutions

Reporting back from the technical workshop held on the 25 November 2024, examining three use cases with the aim to:

- Improve mutual understanding between HTA bodies and regulators on key challenges and uncertainties faced with clinical evidence
- Understand how uncertainties at time of assessment are managed from both perspectives
- Identify and explore potential solutions to improve evidence generation and uncertainty management
- Establish the groundwork for future HTA-regulatory collaboration on methodology.

Action: For discussion

The CHMP noted the reporting back from the technical workshop held on the 25 November 2024.

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	
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	
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	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	3.3.5. - EMEA/H/C/006421 5.1.9. 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	Member	Portugal	No restrictions applicable to this meeting	
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	
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	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Pierre Demolis	Expert	Iceland	No interests declared	
Caroline Auriche Benichou	Expert	France	No interests declared	
Ilona Reischl	Expert	Austria	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Susanne Høpner Rasmussen	Expert	Denmark	No interests declared	
Elsa Grangier	Expert	France	No interests declared	
Dierdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No interests declared	
René Anour	Expert	Austria	No interests declared	
Kristin Karlsson	Expert	Sweden	No restrictions applicable to this meeting	
Zane Neikena	Expert	Latvia	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Joerg Engelbergs	Expert	Germany	No interests declared	
Ana Maria Imedio	Expert	Spain	No interests declared	
Marion Haberkamp	Expert	Germany	No interests declared	

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