



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 November 2025
EMA/CHMP/348962/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ Minutes for the meeting on 03 November 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 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 ongoing 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 the 03 November 2025 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of the 03 November 2025 meeting will be adopted at the November 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 in person and remotely on 3-5 November 2025.
- Minutes of the BWP meeting held remotely on 8-10 September 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).

2.1.3. Call for interest for a new Quality Innovation Group (QIG) member

Call for interest for nomination of a new QIG member. Required area of expertise: biological quality domain.

Nominations, including application form and CV, should be sent to the Agency by 02 December 2025.

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

Action: For information

The CHMP noted the call for interest for a new QIG member.

2.2. Quality Working Party (QWP)

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

2.2.1. Q&A on complex or novel manufacturing process - Revised

Revised Q&A to support use of the revised Variation Classification Guideline.

Adopted by the QWP/BWP in October 2025.

Action: For adoption

The CHMP adopted the revised Q&A on complex or novel manufacturing process to support use of the revised Variation Classification Guideline.

2.2.2. Agenda and Minutes

- Draft Agenda of the QWP meeting to be held remotely on 3-4 November 2025
- Minutes of the QWP meeting held remotely on 8-9 September 2025

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)

Chair: René Anour, Vice-Chair: Niklas Ekman

2.3.1. Agenda and Minutes

- Agenda and Minutes of the BMWP meeting held remotely on 16 September 2025

Action: For information

The CHMP noted the agenda and minutes.

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 02 and 10 September 2025
- Draft agenda of the NcWP meeting to be held remotely on 04-05 November 2025

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. CMDh question to NcWP/NS-OEG

Action: For adoption

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

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. CMDh questions to NcWP

Action: For adoption

The CHMP adopted the CMDh questions to NcWP.

3.1.5. CMDh questions to NcWP

Action: For adoption

The CHMP adopted the CMDh questions to NcWP.

3.1.6. Call for interest for a new NcWP member

Call for interest for nomination of a new NcWP member, following the departure of a NcWP member.

Nominations should be sent to the Agency by the 16 January 2026. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

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

Action: For information

The CHMP noted the call for interest for a new NcWP member.

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

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

3.2.1. Biennial report

The 3Rs Working Party Biennial Report 2023/2024 has been drafted in accordance with the NC Domain Workplan. This is the first report on the 3Rs activities of the Agency since the 3RsWP was established in 2022. It describes the working party's activities and achievements over its first two full years of operation and demonstrates the Agency's continued commitment to fostering the 3Rs in medicines development.

Action: For information

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 on 11 September 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. Extension of the call for interest for new MWP members on Modelling & Simulation expertise

Nominations should be sent to the Agency by 21 November 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 register as EMA expert and submit a new DOI.

Nominations are planned for the December 2025 CHMP PROM meeting.

Action: For information

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

4.1.4. Permanent call for interest for new members of the Methodology Operational Expert Groups: Biostatistics OEG, Modelling and Simulation OEG & Clinical Pharmacology OEG

MWP would like to open the call for additional Biostatistics OEG and Modelling and Simulation OEG members due to an increase in workload.

Nominations should be sent to the Agency, with a clear description in the subject line for which OEG the member is being nominated.

Any nomination shall be accompanied by:

1. A brief recommendation from the CHMP member/alternate supporting the nomination
2. A detailed CV to support the expertise required
3. A confirmation from the expert confirming his/her availability to participate to the meetings, as well as to take Rapporteurship(s) for tasks relevant to his/her expertise, if applicable
4. An up-to-date declaration of interest that confirms that the expert can be part of the Working Party.

All nominations will be evaluated by MWP and submitted to CHMP for endorsement.

Action: For information

The CHMP noted the call for interest for additional Biostatistics OEG, Modelling and Simulation OEG and Clinical Pharmacology OEG members.

4.1.5. Nomination of new Clinical Pharmacology OEG members

MWP kindly requests CHMP members to endorse the nominations to the Clinical Pharmacology OEG.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new Clinical Pharmacology OEG members.

4.1.6. [Guideline on predictive biomarker assay development in the context of medicinal product lifecycle](#)

The guideline is presented to CHMP and other WPs for initial consultation and comments.

Experts: Jörg Engelbergs, Olga Kholmanskikh

Action: For discussion

The CHMP noted and shared comments on the guideline on predictive biomarker assay development in the context of medicinal product lifecycle.

4.1.7. [Guideline on Non-Inferiority and equivalence comparisons](#)

MWP is updating the guidance on non-inferiority and equivalence comparisons, in line with the published concept paper: [Concept Paper on the Development of a Guideline on Non-Inferiority and Equivalence Comparisons](#). The guideline is presented to CHMP for adoption for a 6-month public consultation.

Action: For adoption

The CHMP adopted the updated guidance on non-inferiority and equivalence comparisons for 6 months public consultation.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

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

5.1.1. [Concept Paper on Parkinson Disease](#)

The concept paper on Parkinson disease is presented to the CHMP for adoption for a 6-month public consultation.

Expert: Mario Miguel Rosa

Action: For adoption

The CHMP adopted the concept paper on Parkinson disease for a 4-month public consultation.

5.2. Cardiovascular Working Party (CVSWP)

No topics

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Agenda

- Agenda of the Oncology ESEC webinar on lymphoma to be held remotely on 30 January 2026

Action: For information

The CHMP noted the agenda.

5.4. Rheumatology and Immunology Working Party (RIWP)

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

5.4.1. Call for nomination for RIWP Chair

The mandate of the RIWP Chair, Caroline Auriche, will expire on 25 January 2026.

Nominations should be sent to the Agency by 12 January 2026. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

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

Action: For endorsement

The CHMP endorsed the call for nomination for RIWP Chair.

5.4.2. Revision of the guideline for Acute Respiratory Distress Syndrome

The final revision of the guideline for Acute Respiratory Distress Syndrome is presented to the CHMP for adoption after a 3-month public consultation.

CHMP: Janet Koenig

Action: For adoption

The CHMP adopted the revision of the guideline for Acute Respiratory Distress Syndrome

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 Philadelphy, Vice-chair: Viktoriia Starokozhko

5.7.1. Agenda

- Agenda of the HaemWP meeting held remotely on 30 - 31 October 2025

Action: For information

The CHMP noted the agenda.

5.7.2. EMA workshop on immunoglobulins meeting report

- Meeting report of the EMA workshop on immunoglobulins held remotely on 5 March 2025

CHMP: Daniela Philadelphly

Action: For information

The CHMP noted the meeting report of the EMA workshop on immunoglobulins.

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

No topics

6. Patients, Healthcare Professionals and Consumers

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

No topics

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. ICH Expert Working Group for ICH E20 - Guideline on adaptive designs for clinical trials- appointment of expert(s)

Call launched via MWP to appoint an expert to the Expert Working Group to draft the ICH E20 guideline on adaptive designs for clinical trials.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the appointment of the expert to the Expert Working Group to draft the ICH E20 guideline on adaptive designs for clinical trials.

7.1.2. ICH Expert Working Group for ICH M16 – Guideline on Structured Product Quality submissions – appointment of expert(s)

Following a call launched via the Network Data Steering Group, as to complement knowledge of the already appointed QWP expert for this new ICH Expert Working Group to draft the abovementioned guideline.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the appointment of the expert to the Expert Working Group to draft the ICH M16 guideline on Structured Product Quality submissions.

7.2. Guideline Consistency Group (GCG)

Chair: Elita Poplavska

7.2.1. Nomination of a new member to the GCG

Nomination of a new member to the GCG.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Vilma Petrikaite (LT) as new member to the GCG.

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 27-30 October 2025.

Action: For information

The CHMP noted the summary of recommendations and advice of the PRAC meeting held on 27-30 October 2025.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi, Vice-Chairs: Pierre Demolis, Ewa Balkowiec Iskra

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 27-30 October 2025
- Draft Table of Decisions of the SAWP meeting held as a hybrid meeting on 27-30 October 2025

Action: For information

The CHMP noted the agenda and the table of decisions.

10.1.3. SAWP composition re-nomination

Action: For information

The CHMP noted the SAWP composition re-nomination.

A call for interest for nomination of SAWP members and alternates will be launched in November 2025.

Nominations should be sent to the Agency by 30 January 2025. Candidates are kindly asked to submit an application form and a brief updated CV in support of their candidature.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 12 November 2025

Action: For endorsement

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 21 November 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 topic was postponed to the December 2025 CHMP PROM 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. IMAAVY - Nipocalimab - EMEA/H/C/006379

Janssen Cilag International; treatment of generalised Myasthenia Gravis

Scope: Re-adoption of the Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

The Committee re-adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the updated CHMP assessment report.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. IRIS update

Updates on the IRIS portal.

Action: For information

The CHMP noted the updates on the IRIS portal.

12.3. EMA Health Threat Plan

Incident and crisis preparedness and management plan, i.e. a set of structures, processes and measures foreseen by EMA to prepare for and respond to incidents and crises in the area of health threats to humans and related medicinal products. The aim of this document is to provide general guidance to EMA staff and experts to define the necessary activities of the Agency in preparation for and in response to emerging health threats and (potential) public health emergencies and to enhance coordination and efficiency of implementation. Animal health threats are excluded from the scope, except to the extent that they may pose a threat to human health.

It is intended for publication on the EMA website under Public Health Threats replacing the older version that was lastly revised in 2022-2023.

Action: For information

The CHMP noted the updates of the EMA Health Threat Plan.

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 restrictions applicable to this meeting	
Daniela Philadelphy	Member	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Lyubina Racheva Todorova	Member	Bulgaria	No restrictions applicable to this meeting	
Gergana Lazarova	Alternate	Bulgaria	No restrictions applicable to this meeting	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Member	Cyprus	No interests declared	
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	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member (Vice-Chair)	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Nicolas Beix	Alternate	France	No interests declared	
Janet Koenig	Member	Germany	No interests declared	
Martin Mengel	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No restrictions applicable to this meeting	
Vilma Petrikaite	Member	Lithuania	No restrictions applicable to this meeting	
Larisa Gorobets	Alternate	Lithuania	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 interests declared	
John Joseph Borg	Member	Malta	No restrictions applicable to this meeting	
Peter Mol	Member	Netherlands	No restrictions applicable to this meeting	
Patrick Vrijlandt	Alternate	Netherlands	No restrictions applicable to this meeting	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No restrictions applicable to this meeting	
Ewa Balkowiec Iskra	Member	Poland	No restrictions applicable to this meeting	
Fatima Ventura	Member	Portugal	No restrictions applicable to this meeting	
Paulo Paixão	Alternate	Portugal	No restrictions applicable to this meeting	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Carolina Prieto Fernandez	Member	Spain	No interests declared	
Antonio Gomez-Outes	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Carla Torre	Co-opted member	Portugal	No restrictions applicable to this meeting	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Joerg Engelbergs	Expert	Germany	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Stine Kjörup Boserup	Expert	Denmark	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No restrictions applicable to this meeting	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Nicolas Lee	Expert	Ireland	No participation in discussion, final deliberations and voting on:	5.1.13. - EMA/VR/000028807 3
A representative from the European Commission attended the meeting.				
Meeting run with support from relevant EMA staff.				

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