08 September 2025
EMA/CHMP/266703/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] Minutes for the meeting on 08 September 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 the 08 September 2025 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of the 08 September 2025 meeting will be adopted at the September 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 8-10 September 2025
- Minutes of the BWP meeting held remotely on 10-12 June 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 8-9 September 2025
- Minutes of the QWP meeting held remotely on 11-12 June 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. Call for interest for one new BMWP member

Call for interest for nomination of a new BMWP member, following the retirement of one member.

Nominations should be sent to the Agency by 03 October 2025. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

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

Action: For information

The CHMP noted the call for interest for nomination of a new BMWP member, following the retirement of one member.

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 Non-clinical and New Approach Methodologies ESEC experts

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

Nomination(s) received

Action: For endorsement

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

3.1.2. CMDh question to NcWP/NS-OEG

Action: For adoption

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

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

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

3.2.1. Minutes

- Minutes of the 3Rs Working party meeting held remotely on 20-21 May 2025

Action: For information

The CHMP noted the minutes.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Agenda and minutes

- Agenda and Minutes of the MWP meetings held remotely on 26 June and 17 July 2025.

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of new Methodology ESEC experts

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

Nomination(s) received

Action: For endorsement

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

4.1.3. Call for interest for new MWP members on Modelling & Simulation expertise

Call for interest for nomination of new MWP members with expertise and experience in Modelling & Simulation, following the departure of a MWP member.

Nominations should be sent to the Agency by 17 October 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 November 2025 CHMP PROM meeting.

Action: For information

The CHMP noted the call for interest for nomination of new MWP members with expertise and experience in Modelling & Simulation.

4.1.4. New standing Clinical Pharmacology OEG (replacing the tDG –XMWP- PSBGLS group)

As part of the MWP and within the new structure of the Working Party Model (WOM), endorsement is sought to transition the Product Specific Bioequivalence Guidelines temporary drafting group into a standing Clinical Pharmacology Operational Expert Group. This transition will widen the scope of the group and its expertise.

Action: For endorsement

The CHMP endorsed the new standing Clinical Pharmacology OEG (replacing the tDG –XMWP- PSBGLS group).

4.1.5. Nomination of Clinical Pharmacology OEG members

Proposed transfer and endorsement of members of the tDG-XMWP-PSBGLs to the Clinical Pharmacology OEG.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the transfer and nomination of members of the tDG-XMWP-PSBGLs to the Clinical Pharmacology OEG.

4.1.6. Call for interest for new Clinical Pharmacology OEG members

Call for interest for nomination of new Clinical Pharmacology OEG members, following the endorsement of the new standing CP OEG. The OEG is looking to incorporate 3 to 6 new members.

Nominations should be sent to the Agency by 28 September 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.

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

Action: For information

The CHMP noted the call for interest for nomination of new Clinical Pharmacology OEG members, following the endorsement of the new standing CP OEG.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

Chair: Ewa Balkowiec Iskra

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 and minutes

- Minutes of the ONCWP meeting held remotely on 4 June 2025.
- Agenda and Minutes of the ONCWP meeting held remotely on 2 July 2025.

Action: For information

The CHMP noted the agenda and minutes.

5.4. Rheumatology and Immunology Working Party (RIWP)

Chair: Caroline Auriche Benichou

5.4.1. Guideline on clinical investigation of medicinal products for the treatment of psoriatic arthritis

The revised guideline on clinical investigation of medicinal products for the treatment of psoriatic arthritis is presented for CHMP adoption for a 6–month public consultation.

Expert: Anna Vikerfors

Action: For adoption

The CHMP adopted the revised guideline on clinical investigation of medicinal products for the treatment of psoriatic arthritis for a 6–month public consultation.

5.4.2. Concept paper on clinical investigation of medicinal products for the treatment of idiopathic pulmonary fibrosis

The concept paper on clinical investigation of medicinal products for the treatment of idiopathic pulmonary fibrosis is presented for CHMP adoption for a 3–month public consultation.

Expert: Agnieszka Przybyszewska

Action: For adoption

The CHMP adopted the concept paper on clinical investigation of medicinal products for the treatment of idiopathic pulmonary fibrosis for a 3–month public consultation.

5.5. Infectious Disease Working Party (IDWP)

Chair: Maja Sommerfelt Gronvold

5.5.1. Guideline on the clinical evaluation of medicinal products intended for treatment of hepatitis B

This is the first revision of the guideline on the clinical evaluation of medicinal products intended for the treatment of hepatitis B (CHMP/EWP/6172/03). The document is presented to the CHMP for adoption for a 6-month public consultation.

Action: For adoption

The CHMP adopted the guideline on the clinical evaluation of medicinal products intended for the treatment of hepatitis B (CHMP/EWP/6172/03) for a 6-month public consultation.

5.6. Vaccines Working Party (VWP)

Chair: Sol Ruiz

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Minutes

- Minutes of the Blood cluster meeting held remotely on 27 June 2025
- Minutes of the ad hoc non-malignant haematology meeting held remotely on 27 June 2025

Action: For information

The CHMP noted the minutes.

5.7.2. Nomination of new Haematology ESEC expert

Nomination of a new expert to join the Haematology European Specialised Expert Community (ESEC).

Nomination(s) received

CHMP: Daniela Philadelphy

Action: For endorsement

The CHMP endorsed the nomination of a new expert to join the Haematology European Specialised Expert Community (ESEC).

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

No topics

6. Patients, Healthcare Professionals and Consumers

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

PCWP Co-chair: Juan Garcia Burgos (EMA)

HCPWP Co-chair: Juan Garcia Burgos (EMA)

6.1.1. Draft reflection paper on Patient Experience Data (PED)

A multidisciplinary drafting group including representatives from PCWP and HCPWP but also many other WPs and committees has drafted a reflection paper on patient experience data. The document is presented to the CHMP (in parallel to PRAC) for adoption for a 4-month public consultation.

Action: For discussion

The CHMP noted the update on the draft reflection paper on Patient Experience Data (PED). The reflection paper will be adopted at the September 2025 CHMP plenary meeting.

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. ICH E2D(R1) Adoption of Guideline on post-approval safety data: definitions and standards for management and reporting of individual case safety reports – Step 5

Following the finalisation of the guideline by the expert working group, CHMP adoption of Step 5 is requested. The guideline will be implemented 6 months after adoption.

Action: For adoption

The CHMP adopted the ICH E2D(R1) Guideline on post-approval safety data: definitions and standards for management and reporting of individual case safety reports – Step 5.

7.1.2. ICH M14 Adoption of Guideline on general principles on planning, designing, analysing, and reporting of non-interventional studies that utilise Real-World Data for safety assessment of medicines – Step 5

Following the finalisation of the guideline by the expert working group, CHMP adoption of Step 5 is requested. The guideline will be implemented 6 months after adoption.

Action: For adoption

The CHMP adopted the ICH M14 Guideline on general principles on planning, designing, analysing, and reporting of non-interventional studies that utilise Real-World Data for safety assessment of medicines – Step 5

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

Summary of recommendations and advice of the PRAC meeting held on 01-04 September 2025.

PRAC Chair: Ulla Wändel Liminga

Action: For information

The CHMP noted the summary of recommendations and advice of the PRAC meeting held on 01-04 September 2025.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. GIREX - Group for Internal Rules on Extensions of Clock Stops

Update on requests for extensions of clock-stops for ongoing procedures. See also point 11.

Action: For adoption

The CHMP discussed the requests for extensions of clock-stops for ongoing procedures. See point 11.

9.2.2. Mandate, objectives and rules of procedure for Working Parties under the domains

The Mandate, objectives, and rules of procedure for working parties under the quality, non-clinical, methodology, clinical and veterinary domains is now final included for CHMP endorsement.

Action: For endorsement

The CHMP endorsed the Mandate, objectives, and rules of procedure for working parties under the quality, non-clinical, methodology, clinical and veterinary domains.

9.2.3. CHMP workplan 2025

Status update on the CHMP Workplan 2025.

CHMP: Bruno Sepodes

Action: For information

The CHMP noted the update on the CHMP workplan 2025.

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 and draft Table of Decisions of the SAWP meeting held remotely on 01-04 September 2025

Action: For information

The CHMP noted the agenda and draft table of decisions.

10.1.3. SAWP CTCG pilot for consolidated advice

Interim report on pilot after 1 year.

SAWP Chair: Paolo Foggi

Experts: Marianne Lunzer, Monique Al

Action: For information

The CHMP noted the update on the SAWP CTCG pilot for consolidated advice.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 12 September 2025

Action: For endorsement

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 23 September 2025

Action: For endorsement

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 3 October 2025

Action: For endorsement

The CHMP endorsed the meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Bruno Sepodes

Action: For information

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

11.1.1. ACELLULAR PERTUSSIS VACCINE - EMEA/H/C/006304

indicated as active booster immunization against *pertussis* of persons aged 11 years onwards and passive protection against *pertussis* in early infancy following maternal immunization during pregnancy

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

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 14.11.2024.

Action: For adoption

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

11.1.2. Midazolam - EMEA/H/C/005657

conscious sedation before and during diagnostic or therapeutic procedures with or without local anaesthesia and premedication before induction of anaesthesia

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in June 2025.

List of questions adopted on 19.06.2025.

Action: For adoption

The CHMP did not agree to the request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in June 2025.

11.1.3. Midazolam - EMEA/H/C/005658

treatment of prolonged, acute, convulsive seizures in adults, adolescents, children and toddlers (from 2 years of age).

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in June 2025.

List of questions adopted on 19.06.2025.

Action: For adoption

The CHMP did not agree to the request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in June 2025.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update

12.2. Health Threats and ETF Update

Action: For information

The topic has been postponed.

12.3. IncreaseNet - Joint Action on Capacity Building

Update on the on-the-job training and coaching program with a focus on centralised procedures.

Expert: Anna Nickel

Action: For information

The CHMP noted the update on the on-the-job training and coaching program with a focus on centralised procedures.

12.4. Participation in FDA Project Orbis as Observer

As part of the strengthened collaboration between EMA and FDA, EMA is currently running a pilot with the aim to determine the type of interaction and potential benefits of EMA participation in project ORBIS as observer.

Action: For information

The CHMP noted the information on the participation in the FDA Project Orbis as an observer.

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	
Christian Gartner	Alternate	Austria	No interests declared	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No restrictions applicable to this meeting	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Katerina Savvidou	Alternate	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Boje Kvorning Pires Ehmsen	Alternate	Denmark	No interests declared	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member (Vice-Chair)	Finland	No interests declared	
Johanna Lähteenvuo	Alternate	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	
Hjalti Kristinsson	Alternate	Iceland	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	
Larisa Gorobets	Alternate	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No interests declared	
Peter Mol	Member	Netherlands	No restrictions applicable to this meeting	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	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
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	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No restrictions applicable to this meeting	
Jana Klimasová	Alternate	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	
Bruno Delafont	Co-opted member	France	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	
Valerie Lescrainier	Expert	Belgium	No interests declared	
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	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Nicolas Lee	Expert	Ireland	No participation in discussion, final deliberations and voting on:	3.3.6. Alpelisib - Orphan - EMEA/H/C/006539 ; 3.3.7. Onasemnogene abeparvovec - Orphan - ATMP - EMEA/H/C/006498 ; 5.1.10. Tafinlar – Dabrafenib -

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				EMA/VR/0000271728
Paolo Foggi	Expert	Italy	No interests declared	
Hemme Hijma	Expert	Netherlands	No restrictions applicable to this meeting	
Anna Vikerfors	Expert	Sweden	No interests declared	
Maja Sommerfelt Gronvold	Expert	Norway	No interests declared	
Anna Nickel	Expert	Germany	No interests declared	
Agnieszka Przybyszewska	Expert	Ireland	No restrictions applicable to this meeting	
Marianne Lunzer	Expert	Austria	No interests declared	
Monique Al	Expert	Netherlands	No interests declared	
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.