06 October 2025
EMA/CHMP/323082/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] Minutes for the meeting on 06 October 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 06 October 2025 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of the 06 October 2025 meeting will be adopted at the October 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 6-8 October 2025
- Minutes of the BWP meeting held remotely on 14-16 July 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. Guideline on quality aspects of phage therapy medicinal products

The Guideline on quality aspects of phage therapy medicinal products is presented to the CHMP for adoption for a 6-month public consultation.

Expert: Helerin Eiche

Action: For adoption

The CHMP adopted the Guideline on quality aspects of phage therapy medicinal products for a 6-month public consultation.

2.2. Quality Working Party (QWP)

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

2.2.1. Q&A on Skip Testing

Q&A consisting in 6 questions on definition of skip testing, in what situation is allowed, in which situations is no longer allowed, frequency, acceptability for active substances covered by CEPs or ASMFs, and reliability on the tests performed by the ASM by FPM. The document was adopted by QWP at its September meeting and is presented to the CHMP for adoption.

Experts: M. Mehmandoust, E. Cogliandro, N. Filiz, B. Denayer, C. Spiteri

Action: For adoption

The CHMP adopted the Q&A on Skip Testing.

2.2.2. Agenda and Minutes

- Draft Agenda of the QWP meeting to be held in person on 6-8 October 2025
- Minutes of the QWP meeting held remotely on 14-15 July 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).

2.2.4. CMDh question to QWP

Action: For adoption

The CHMP adopted the CMDh question to QWP.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: René Anour, Vice-Chair: Niklas Ekman

2.3.1. Nomination of a new BMWP member

Nomination of a new BMWP member, following a call for nomination launched in September 2025, subsequent to the retirement of one member.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Martina Weise (DE) and Norén Caroline (SE) as new BMWP members, subsequent to the retirement of one member and in anticipation of the retirement of a second member.

2.3.2. Agenda and Minutes

- Agenda and Minutes of the BMWP meeting held remotely on 23 June 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

- Draft agenda of the NcWP meeting to be held in-person on 7-8 October 2025
- Minutes of the NcWP meeting held remotely on 2 and 9 September 2025

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Reflection paper on non-human primates in safety testing of human medicinal products and opportunities for 3Rs implementation

The reflection paper on non-human primates in safety testing of human medicinal products and opportunities for 3Rs implementation is presented to the CHMP for adoption for a 3-month public consultation.

Experts: Peter Theunissen, Peter van Meer

Action: For adoption

The CHMP adopted the reflection paper on non-human primates in safety testing of human medicinal products and opportunities for 3Rs implementation for a 3-month public consultation.

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

Update of Question 22 of the Q&A for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products to clarify the timeframe of applicability of the interim limit during CAPA implementation. The document is presented to the CHMP for adoption.

Action: For adoption

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

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 MWP meeting held remotely on 28 August 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 member on Real World Data expertise

Call for interest for nomination of new MWP member with expertise in Real-World Evidence, following the departure of a member. Candidates must demonstrate scientific and regulatory competencies relevant to real-world data, biostatistics and pharmacoepidemiology and experience with real-world data sources, pharmacoepidemiology, biostatistics, and regulatory assessment of non-interventional studies.

Nominations should be sent to the Agency by 21 November 2025.

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

Action: For information

The CHMP noted the call for interest for nomination of a new MWP member with expertise in Real-World Evidence.

4.1.4. Call for interest for new Clinical Pharmacology OEG members - extension

MWP requests an extension of the call for nominations launched at the September 2025 PROM meeting until 21 October 2025 and thus to postpone the nominations to the November 2025 CHMP PROM meeting.

Action: For endorsement

The CHMP endorsed the extension to the call for interest for new Clinical Pharmacology OEG members.

4.1.5. Clarification on the 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 was 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 information

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

4.1.6. Guiding Principles of Good Artificial Intelligence Practice in Drug Development

The EMRN, through an MWP temporary drafting group, has been collaborating with FDA to develop a set of foundational principles for the responsible use of AI in medicines' lifecycle. The principles – and a supporting preamble – have been endorsed by the MWP. The principles are presented to CHMP for adoption.

Expert: Joerg Zinserling

Action: For adoption

The CHMP adopted the Guiding Principles of Good Artificial Intelligence Practice in Drug Development.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

Chair: Ewa Balkowiec Iskra

5.1.1. Agenda

- Agenda of the CNSWP meeting held on 25 September 2025

Action: For information

The CHMP noted the agenda.

5.1.2. 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 topic was postponed to the November CHMP PROM meeting.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Agenda and Minutes

- Agenda and table of decisions of the CVSWP meeting held in-person on 25 September 2025

Action: For information

The CHMP noted the agenda and table of decisions.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Cancer Medicines Forum workshop Agenda

Draft Agenda of the Cancer Medicines Forum workshop to be held remotely and in-person on 14 November 2025

Action: For information

The CHMP noted the agenda of the Cancer Medicines Forum workshop.

5.3.2. Agenda

- Agenda of the ONCWP meeting held on 24 September 2025

Action: For information

The CHMP noted the agenda.

5.4. Rheumatology and Immunology Working Party (RIWP)

Chair: Caroline Auriche Benichou

5.4.1. Nomination of a new member to the RIWP

Nomination of a new RIWP member, following a call for nomination launched in July 2025, subsequent to the departure of two former members.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Karoline Buhre (DE) and Agnieszka Przybyszewska (IE) as new RIWP members, subsequent to the departure of two former members.

5.4.2. Concept paper on a paediatric update on the Guideline on the development of new medicinal products for the treatment of Ulcerative colitis

The concept paper on a paediatric update on the Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis is presented for CHMP adoption for a 2-month public consultation.

Experts: Joost Romme, Karijn Pijnenburg-Kleizen

Action: For adoption

The CHMP adopted the concept paper on a paediatric update on the Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis for a 2-month public consultation.

5.4.3. Concept paper on a paediatric update on the Guideline on the development of new medicinal products for the treatment of Crohn’s Disease

The concept paper on a paediatric update on the Guideline on the development of new medicinal products for the treatment of Crohn’s Disease is presented for CHMP adoption for a 2-month public consultation.

Experts: Joost Romme, Karijn Pijnenburg-Kleizen

Action: For adoption

The CHMP adopted the concept paper on a paediatric update on the Guideline on the development of new medicinal products for the treatment of Crohn’s Disease for a 2-month public consultation.

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

5.7.1. Agenda and Minutes

- Draft agenda of the HaemWP meeting to be held in-person on 30-31 October 2025
- Minutes of the ad hoc meeting on non-malignant haematology held remotely on 17 June 2025

CHMP: Daniela Philadelphy

Action: For information

The CHMP noted the agenda and minutes.

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

No topics

6. Patients, Healthcare Professionals and Consumers

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

No topics

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

No topics

7.2. Guideline Consistency Group (GCG)

No topics

7.3. Summary of product characteristics Advisory Group

7.3.1. Nomination of a new member to the SmPC AG

Nomination of a new PRAC representative, following the departure of the SmPC AG member.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Amelia Cupelli (IT) as new PRAC representative.

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 29 September-02 October 2025.

PRAC Chair: Ulla Wändel Liminga

Action: For information

The CHMP noted the summary of recommendations and advice of the PRAC meeting held on 29 September-02 October 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.

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 29 September-02 October 2025

Action: For information

The CHMP noted the agenda and draft table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 8 October 2025

Action: For endorsement

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 20 October 2025

Action: For endorsement

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 31 October 2025

Action: For endorsement

The CHMP endorsed the meeting.

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

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

Action: For discussion

The CHMP noted the information provided on the 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 and members flagged some procedures on the agenda of the upcoming plenary.

11.1.1. Blarcamesine - EMEA/H/C/006475

treatment of Alzheimer's disease and dementia

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

Action: For adoption

List of Outstanding Issues adopted 18.09.2025. List of Questions adopted on 25.04.2025.

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 September 2025.

11.1.2. Camcevi – Leuprorelin - EMA/X/0000258054

Accord Healthcare S.L.U.

Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to add a new strength of 21 mg for Leuproelin prolonged-release suspension for injection pre-filled syringe, for subcutaneous (SC) administration.

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

List of Question adopted on 24.07.2025.

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 July 2025.

11.1.3. Doxecitine / Doxribtimine - PRIME - Orphan - EMEA/H/C/005119

UCB Pharma; indicated for the treatment of paediatric and adult patients with thymidine kinase 2 deficiency (TK2d) with an age of symptom onset on or before 12 years

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

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 27.03.2025.

Action: For adoption

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 September 2025.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update

12.2. Code of conduct of the European Medicines Agency

Provisions for members and experts of EMA Scientific Committees.

The Code of conduct is published on the EMA website and a news item was posted at the time of the Management Board's endorsement.

Action: For information

The CHMP noted the information provided on the Code of conduct of the European Medicines Agency.

12.3. Nitrosamines Multidisciplinary Expert Group (NMEG)

Feedback and Minutes of the NMEG meeting held on 26 September 2025.

NMEG Chair: Priscilla Schoondermark

Action: For information

The topic was postponed to the October CHMP plenary meeting.

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	
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	
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	
Hrefna Gudmundsdottir	Member	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	
Vilma Petrikaite	Member	Lithuania	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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Patrick Vrijlandt	Alternate	Netherlands	No 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	
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	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Susanna 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:	5.1.18. Scemblix - Asciminib - EMA/VR/0000265010
Peter van Meer	Expert	Netherlands	No restrictions applicable to this meeting	
Kristin Karlsson	Expert	Sweden	No restrictions applicable to this meeting	
Joerg Zinserling	Expert	Germany	No participation in discussion, final	10.3. Real-world evidence (including

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			deliberations and voting on:	DARWIN EU) for regulatory decision making
Pierre Demolis	Expert	Iceland	No interests declared	
Joost Romme	Expert	Netherlands	No interests declared	
Helerin Eiche	Expert	Estonia	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.