



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 May 2025
EMA/CHMP/158851/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 12 May 2025

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 12 May 2025 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 12 May 2025 meeting will be adopted at the May 2025 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

2.1.1. Revision of the Questions and Answers for Plasma Master File (PMF) Holders on PMF requirements

This revised Q&A describes the approach to be applied in the evaluation of the compliance of BE/BCs registered in PMF applications, with the aim to improve and harmonise the PMF content at submission and consequently to streamline the PMF certification and evaluation timelines.

Expert: Jens Reinhardt

Action: For adoption

The CHMP adopted the revised PMF Q&A.

2.1.2. [Agenda and minutes](#)

- Draft Agenda of the BWP meeting to be held remotely on 12-14 May 2025
- Minutes of the BWP meeting held in-person on 17-19 March 2025

Action: For information

The CHMP noted the agenda and minutes.

2.1.3. [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).

2.1.4. [Questions and Answers \(Q&A\) on phasing out the rabbit pyrogen test](#)

Publication of Guidance/Q&A on Phasing out of the rabbit pyrogen test (RPT).

Action: For adoption

The CHMP adopted the Q&A on phasing out the rabbit pyrogen test.

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 12-13 May 2025
- Minutes of the QWP meeting held in-person on 17-19 March 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).

2.2.3. QWP/MWP response to CMDh questions

Action: For adoption

The CHMP adopted the QWP/MWP response to CMDh questions.

2.2.4. Call for interest for two new QWP members

Call for interest for nomination of two QWP members' replacement, following the resignation of one QWP member and the retirement of one QWP member.

Nominations should be sent to the Agency by 20 June 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 July 2025 CHMP PROM meeting.

Action: For information

The CHMP noted the call for interest for two new QWP members.

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 31 March 2025

Action: For information

The CHMP noted the agenda and minutes.

2.3.2. Draft BMWP 3-year Work Plan 2026-2028

Initial draft BMWP 3-year work plan 2026-2028 for interested parties' consultation.

Action: For information

The CHMP noted the draft BMWP work plan 2026-2028.

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

3.1.2. Agenda and minutes

- Minutes of the NcWP meeting held remotely on 18 - 19 March 2025.
- Draft agenda of the NcWP meeting to be held in person on 13 - 14 May 2025.

Action: For information

The CHMP noted the agenda and minutes.

3.1.3. Call for nominations – NAMs ESEC subgroup

To meet the needs of the network and establish an integrated network of assessors, EMA will create a subgroup of non-clinical assessors within the Non-clinical NAMs ESEC who wish to follow, in listening mode, the NCWP monthly meetings.

Action: For information

The CHMP noted the call for nominations of the Non-clinical NAMs ESEC subgroup.

3.1.4. 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. Call for nominations for 3RsWP Chair and Vice-chair

The mandate of the 3RsWP Chair Sonja Beken and Vice-chair Sarah Alder-Flindt will expire on 04 September 2025.

Nominations should be sent to the Agency by 6 July 2025. 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 July 2025 CHMP Plenary meeting.

Action: For endorsement

The CHMP endorsed the call for nominations for 3RsWP Chair and Vice-chair.

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 6, 20-21 March and 3 April 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. Product-Specific Guidelines

Revised guidelines in line with ICH M13A for 3-month public consultation:

- Aliskiren film-coated tablet 150 mg and 300 mg product-specific bioequivalence guidance (EMA/151687/2025 Rev. 1*).
- Carglumic acid dispersible tablets 200 mg product-specific bioequivalence guidance (EMA/151691/2025 Rev. 1*).
- Dronedarone film-coated tablets 400 mg product-specific bioequivalence guidance (EMA/151695/2025 Rev. 1*).
- Ledipasvir/sofosbuvir film-coated tablet 45 mg/200 mg and 90 mg/400 mg, coated granules 33.75mg/150mg and 45mg/200mg product-specific bioequivalence guidance (EMA/151702/2025 Rev. 1*).

Revised guidelines in line with ICH M13A for publication:

- Acenocoumarol tablet 1 mg and 4 mg product-specific bioequivalence guidance (EMA/CHMP/512475/2020 Rev. 1*).
- Apixaban film-coated tablet 2.5 and 5 mg product-specific bioequivalence guidance (EMA/151689/2025 Rev. 1*).
- Asenapine sublingual tablets 5 and 10 mg product-specific bioequivalence guidance (EMA/151690/2025 Rev. 1*).

- Dabigatran etexilate hard capsule 75 mg, 110 mg and 150 mg product-specific bioequivalence guidance (EMA/151692/2025 Rev. 1*).
- Metformin immediate-release film-coated tablets 500, 850 and 1000 mg and 1000 mg/5ml oral solution product-specific bioequivalence guidance (EMA/CHMP/591346/2022/Rev. 1*).
- Oseltamivir hard capsules 30, 45 and 75 mg, powder for oral suspension 6 mg/ml and 12 mg/ml product-specific bioequivalence guidance (EMA/151698/2025/Rev. 1*).
- Prasugrel film-coated tablets 5 mg and 10 mg product-specific bioequivalence guidance (EMA/151699/2025/Rev. 2*).
- Sirolimus coated tablets 0.5, 1 and 2 mg, oral solution 1 mg/ml product-specific bioequivalence guidance (EMA/151700/2025 Rev. 1*).
- Ursodeoxycholic acid capsule 250 mg, film-coated tablet 150 mg, 300 mg, 450 mg, 500 mg, 600 mg and suspension 50mg/ml (250mg/5ml) product-specific bioequivalence (EMA/CHMP/559890/2021/Rev. 1*).

Expert: Carolien Versantvoort

Action: For adoption

The CHMP adopted the revised Product-Specific Guidelines, 4 ahead of a 3-month public consultation before final adoption.

4.1.4. [MWP/QWP joint response to CMDh question](#)

Action: For adoption

The CHMP adopted the MWP/QWP joint response to CMDh question.

4.1.5. [MWP response to CMDh question](#)

Action: For adoption

The CHMP adopted the MWP response to CMDh question.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

Chair: Ewa Balkowiec Iskra

5.1.1. [Call for nominations for CNSWP Vice-chair](#)

Following the election of Ewa Balkowiec-Iskra as the CNSWP Chair at the April 2025 CHMP plenary meeting, the Vice-chair position is now vacant.

Nominations should be sent to the Agency by 12 July 2025. 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 July 2025 CHMP Plenary meeting.

Action: For endorsement

The CHMP endorsed the call for nominations for CNSWP Vice-chair.

5.2. Cardiovascular Working Party (CVSWP)

No topics

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Call for nominations for ONCWP Vice-chair

The mandate of the ONCWP Vice-chair Olli Tenhunen will expire on 20 July 2025.

Nominations should be sent to the Agency by 12 July 2025. 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 July 2025 CHMP Plenary meeting.

Action: For endorsement

The CHMP endorsed the call for nominations for ONCWP Vice-chair.

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

Chair: Maja Sommerfelt Grønvold

5.5.1. Call for nominations for IDWP Vice-chair - extended

Following the election of Maja Sommerfelt Grønvold as the IDWP Chair at the April 2025 CHMP plenary meeting, the Vice-chair position is now vacant and the call for nominations has been extended.

Nominations should be sent to the Agency by 12 June 2025. 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 June 2025 CHMP Plenary meeting.

Action: For endorsement

The CHMP endorsed the extension of the call for nominations for IDWP Vice-chair.

5.6. Vaccines Working Party (VWP)

Chair: Sol Ruiz

5.6.1. Call for nominations for VWP Vice-chair

Following the election of Sol Ruiz as the VWP Chair at the April 2025 CHMP plenary meeting, the Vice-chair position is now vacant.

Nominations should be sent to the Agency by 12 July 2025. 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 July 2025 CHMP Plenary meeting.

Action: For endorsement

The CHMP endorsed the call for nominations for VWP Vice-chair.

5.7. Haematology Working Party (HaemWP)

No topics

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 E21 Draft Guideline on inclusion of pregnant and breastfeeding individuals in clinical trials – Step 2b

The ICH E21 Expert Working Group has completed a draft guideline covering inclusion and/or retention of pregnant and/or breastfeeding individuals in clinical trials and facilitate the generation of robust clinical data that allow for evidence-based decision making on the safe and effective use of medicinal products by these individuals and their healthcare providers (HCPs). The document is presented for adoption for a 4-month public consultation.

Action: For adoption

The CHMP adopted the ICH E21 Draft Guideline on inclusion of pregnant and breastfeeding individuals in clinical trials – Step 2b for a 4-month public consultation.

7.1.2. Update on ICH E11A implementation activities

Update about the ongoing activities related to the implementation of ICH E11A across the network, including feedback on the development of training material at ICH level.

Action: For information

The CHMP noted the update on ICH E11A implementation activities and the call of interest for one CHMP member to join the implementation group.

7.2. Guideline Consistency Group (GCG)

Chair: Kristina Dunder

7.2.1. Nomination of new members to the GCG

Nomination of new members to join the GCG.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Andreas Kirisits (SAWP member), Anna Vikerfors (SAWP member), Elita Poplavska (CHMP member), Janet Koenig (CHMP member), Maria Grazia Evandri (CHMP member) to join the GCG.

7.2.2. Call for nominations for GCG Chair

The mandate of the GCG Chair Kristina Dunder will expire on 11 July 2025.

Nominations should be sent to the Agency by 28 May 2025. 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 June 2025 CHMP Plenary meeting.

Action: For endorsement

The CHMP endorsed the call for nominations for GCG Chair.

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 05-08 May 2025.

PRAC Chair: Ulla Wändel Liminga

Action: For information

The CHMP noted the summary of recommendations and advice.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. 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 a request for extension of a clock-stop for an ongoing procedure. See point 11.

9.2.2. CHMP co-opted membership

The 3-year co-opted member mandate for Sol Ruiz comes to an end on 21.07.2025. Her area of expertise is Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies).

The nomination procedure foresees that the CHMP should decide on their areas of expertise in order to proceed with the nominations.

The election is anticipated at the June 2025 plenary meeting.

Action: For endorsement

The CHMP endorsed the call for the nomination of co-opted member.

9.2.3. Mandate, objectives, and rules of procedure for WPs under the domains

A high-level mandate for all working parties (WPs) under the domains has been developed in line with the new operational model for the WPs.

Action: For discussion

The CHMP discussed the high-level mandate for all working parties (WPs) under the domains developed in line with the new operational model for the WPs.

9.2.4. Medicinal Products and Technology Pipeline 3 – Year Outlook Report

Updated list of MAAs, Line Extensions and Type II variations expected in 2025-2027.

Action: For information

The CHMP noted the updated list of MAAs, Line Extensions and Type II variations expected in 2025-2027.

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 of the SAWP meeting held remotely on 05-08 May 2025
- Draft Table of Decisions of the SAWP meeting held remotely on 05-08 May 2025

Action: For information

The CHMP noted the agenda and table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 15 May 2025

Action: For endorsement

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 23 May 2025

Action: For endorsement

The CHMP endorsed the meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Outi Mäki-Ikola

Action: For information

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

11.2. Teduglutide - EMEA/H/C/006564

treatment of Short Bowel Syndrome

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

Action: For adoption

List of Questions adopted on 27.02.2025.

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

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Provision of information to support Joint Clinical Assessment (JCA)

Outcome report on the discussion and development of guidance on exchange of information between EMA and the HTA secretariat in the context of Joint Clinical Assessments (JCA) for medicinal products under Regulation (EU) 2021/2282. CHMP: Margareta Bego

Action: For information

The CHMP noted the development of initial guidance regarding information from the centralised procedure to be shared in support of Joint Clinical Assessments (JCA).

13. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Daniela Philadelphia	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	
Emilia Mavrokordatou	Member	Cyprus	No interests declared	
Katerina Savvidou	Alternate	Cyprus	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	
Jean-Michel Race	Alternate	France	No restrictions applicable to this meeting	
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 Trauffer	Member	Luxembourg	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	3.3.10. Teplizumab - PRIME - EMEA/H/C/005496 ; 5.1.4. Dupixent - Dupilumab - EMA/VR/00002487 78
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	
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	
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	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No restrictions applicable to this meeting	
Line Præst Lauridsen	Expert	Denmark	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
Nicolas Lee	Expert	Ireland	No restrictions applicable to this meeting	
Carolien Versantvoort	Expert	Netherlands	No interests declared	
Juan Iganacio Bedoya Ponte	Expert	Spain	No restrictions applicable to this meeting	
Enrique Blanco Cortina	Expert	Spain	No restrictions applicable to this meeting	

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.