



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2026
EMA/CHMP/110010/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM¹ Minutes for the meeting on 11 May 2026

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

The Chairperson opened the meeting by welcoming all participants. The meeting was held remotely.

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 meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants 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. Restrictions applicable to this meeting are captured in the list of participants included in the minutes. 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.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members, alternates (where applicable) and experts in line with the relevant provisions of the [Rules of Procedure](#). All decisions taken at this meeting were made in the presence of a quorum of members. All opinions, recommendations, decisions and advice were agreed by consensus, unless otherwise specified. The members of the EEA-EFTA States agreed with the recommendation of the CHMP, unless otherwise specified.

1.2. Adoption of agenda

The CHMP adopted the PROM agenda of the 11 May 2026 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of the 11 May 2026 meeting will be adopted at the May 2026 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

2.1.1. Minutes

- Minutes of the BWP meeting held in person on 16-18 March 2026

Action: For information

The CHMP noted the 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. Minutes

- Minutes of the QWP meeting held in person on 16-18 March 2026

Action: For information

The CHMP noted the 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/NcWP joint response to CMDh

Action: For adoption

The CHMP adopted the QWP/NcWP joint response to CMDh.

2.2.4. Call for interest for a new QWP member

Call for interest for nomination of a new QWP member, following a resignation.

Nominations should be sent to the Agency by 5 June 2026.

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

Action: For information

The CHMP noted the call for interest for nomination of a new QWP member.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

No topics

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. Agenda and minutes

- Minutes of the NcWP meeting held in person on 17-18 March 2026
- Draft agenda of the NcWP meeting to be held remotely on 12-13 May 2026

Action: For information

The CHMP noted the agenda and minutes.

3.1.3. Nomination of a new member to the NcWP

Nomination of a new NcWP member following a call for interest in March 2026.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Michal Bencze as a new NcWP member.

3.1.4. Call for interest for two NcWP members temporary replacement

Call for interest for nomination of temporary replacements of two NcWP members due to a prolonged period of absence (expected minimum of 3 months).

Nominations should be sent to the Agency by 5 June 2026.

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

Action: For information

The CHMP noted the call for interest for nomination of two NcWP members temporary replacement.

3.1.5. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to NcWP.

3.1.6. CMDh request to NcWP

Action: For adoption

The CHMP adopted the CMDh request to NcWP.

3.1.7. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to NcWP.

3.1.8. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.9. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.10. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

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

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

3.2.1. Nomination of a 3RsWP member temporary replacement

Nomination of a temporary replacement of a 3RsWP member following a call for interest in March 2026.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Jaana Palomaki as a temporary replacement of a 3RsWP member.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chair: Kit Roes, Vice-Chair: Kristin Karlsson

4.1.1. Agenda and minutes

- Agenda and minutes of the MWP meeting held in person on 18-19 March 2026
- Agenda and minutes of the MWP meetings held remotely on 9 April 2026 and 16 April 2026

Action: For information

The CHMP noted the agendas and minutes.

4.1.2. Concept Paper (CP) on the development of a Reflection Paper (RP) on the use of external controls for evidence generation in regulatory decision making

The CP has updated following the comments from the public consultation and the related workshop held in November 2025.

The proposed updates include clarifications on the role of the estimand framework and target trial emulation in the design of clinical trials and reassure the readers on the need for future guidance on aspects that will not be addressed by this RP. The scope of the RP now also includes reflections on the replication and reproducibility of results.

Following MWP adoption, the CP is presented for CHMP adoption to be published on the EMA website to serve as a reference until the draft RP will be available.

Action: For adoption

The CHMP adopted the Concept Paper (CP) on the development of a Reflection Paper (RP) on the use of external controls for evidence generation in regulatory decision making.

4.1.3. 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).

4.1.4. Product-specific bioequivalence guideline

Draft guideline for 3-month public consultation:

- Semaglutide, 0.25, 0.5, 1 and 2 mg solution for injection in pre-filled pen, 0.25, 0.5, 1, 1.7 and 2.4 mg solution for injection in pre-filled pen and 0.25, 0.5, 1, 1.7 and 2.4 mg FlexTouch solution for injection in pre-filled pen product-specific bioequivalence guidance

Expert: Marc Maliepaard

Action: For adoption

The CHMP adopted the product-specific bioequivalence guideline for a 3-month 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 (CP) on the need for revision of the guideline on the development of medicinal products for the treatment of smoking

The current guideline (CHMP/EWP/369963/05) came into effect in July 2009. The scope is to provide guidance in the definition of treatment goals, study design, outcome measures, and data analysis for new medicinal products developed to treat nicotine dependence in support of an indication for the treatment of tobacco smoking.

The CP on the need to revise the guideline, addressing the lack of guidance related to developing treatment for nicotine addiction beyond smoking, is presented to the CHMP for adoption for a 3-month public consultation.

Experts: Erika Svedlund, Charlotta Löfberg, Darius Matusevicius

Action: For adoption

The CHMP adopted the concept paper on the need for revision of the guideline on the development of medicinal products for the treatment of smoking for a 3-month public consultation.

5.2. Cardiovascular Working Party (CVSWP)

No topics

5.3. Oncology Working Party (ONCWP)

No topics

5.4. Immune and Inflammatory Diseases Working Party (IIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

No topics

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)

PCWP: Co-chair: Juan Garcia Burgos (EMA)

HCPWP: Co-chair: Juan Garcia Burgos (EMA)

6.1.1. Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) 2025-2028 workplan (WP)

The key topics identified in both the joint section and the individual WP sections have been revisited and aligned with the strategic areas outlined in the EMANS 2028. The document is presented for CHMP endorsement.

Action: For endorsement

The CHMP endorsed the 2025-2028 workplan for the PCWP and HCPWP.

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.2. Guideline Consistency Group (GCG)

No topics

7.3. Summary of product characteristics Advisory Group

No topics

8. Joint groups and collaboration with other Scientific committees

8.1. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

No topics

8.2. Collaboration with other Scientific committees

8.2.1. PRAC report to CHMP

PRAC Chair: Ulla Wändel Liminga

Summary of recommendations and advice of the PRAC meeting held on 05-07 May 2026.

Action: For information

The CHMP noted the summary of recommendations and advice of the PRAC meeting held on 05-07 May 2026.

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 discussion

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

9.2.2. Revamp update

Update on the start of the new PI review process for iMAA and extension applications.

Action: For information

The CHMP noted the revamp update.

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

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

10.1.1. Agenda and Outcomes

SAWP Agenda and Outcomes, SAWP presentation for CHMP and List of procedures for discussion at CHMP.

Action: For information

The CHMP noted the agenda and the outcomes table.

10.1.2. Appointment of CHMP peer review for SA

List of procedures for discussion at CHMP

Action: For information

The CHMP noted the appointment of CHMP peer review for SA.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 22 May 2026

Action: For endorsement

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 27 May 2026

Action: For endorsement

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 12 June 2026

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.

11.2. Ixchiq – Chikungunya vaccine (live) - EMEA/H/PSUR/0000327923 – PSUSA/00011058/202511

Valneva Austria GmbH

Rapporteur: Christophe Focke, PRAC Rapporteur: Dirk Mentzer

Scope: Update on the procedure

Action: For information

The CHMP noted the update on the ongoing PSUSA procedure.

11.3. Norucholic acid - Orphan - EMEA/H/C/006515

Dr. Falk Pharma GmbH; treatment of primary sclerosing cholangitis (PSC) in adults

Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in April 2026

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 April 2026.

11.4. Ensitrelvir - EMEA/H/C/006063

treatment of coronavirus disease 2019 (COVID-19)

Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in April 2026

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 April 2026.

11.5. Leriglitzone - Orphan - EMEA/H/C/006693

Minoryx Therapeutics S.L.; treatment of adrenoleukodystrophy

Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in April 2026

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 April 2026.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

No Rapporteurship update was provided.

12.2. Medicinal Products & Technology Pipeline 2026-2028 report

Update

Action: For information

The CHMP noted the Medicinal Products & Technology Pipeline 2026-2028 report.

12.3. Revision of the guideline on good pharmacovigilance practices (GVP) Module VIII on Post-authorisation Safety Studies

This revision is mainly focused on updates of definitions in accordance with Regulation (EU) No 536/2014 and, the Implementation Regulation (EU) 2025/1466 amending Implementing Regulation (EU) No 520/2012; reference to the ICHM14 Guideline for guidance regarding the feasibility assessment, protocol and study report; registration requirements for all non-interventional PASS in the HMA-EMA Catalogue of Real-World Data Studies; replacement of

Appendix I by reference to the ICH-M14 Guideline and the CHMP-MWP Reflection Paper on Use of Real-World Data in Non-Interventional Studies to Generate Real-World Evidence for Regulatory Purposes and the CHMP Guideline on Registry-Based Studies; integration of the GVP Module VIII Addendum I on requirements and recommendations for the submission of information on non-interventional PASS. The document is proposed for CHMP adoption.

Action: For adoption

The CHMP adopted the revised guideline on good pharmacovigilance practices (GVP) Module VIII on Post-authorisation safety studies.

13. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 11 May 2026 CHMP PROM meeting, which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Bruno Sepodes	Chair	Portugal	No restrictions applicable to this meeting	
Daniela Philadelphia	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No 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	
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	
Finbarr Leacy	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Vilma Petrikaite	Member	Lithuania	No restrictions applicable to this meeting	
Larisa Gorobets	Alternate	Lithuania	No interests declared	
Martine Trauffer	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No interests declared	
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	
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	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Christian B. (Kit) Roes	Co-opted member	Netherlands	No restrictions applicable to this meeting	
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	
Jörg Engelbergs	Expert	Germany	No interests declared	
Marc Maliepaard	Expert	Netherlands	No interests declared	
Erika Svedlund	Expert	Sweden	No interests declared	
Charlotta Löfberg	Expert	Sweden	No interests declared	
Christopher Schulze	Expert	Germany	No interests declared	
Dirk Mentzer	Expert	Germany	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Susan Uiterwaal	Expert	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Tina Soon Engraff	Expert	Denmark	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
A representative from the European Commission attended the meeting.				
Meeting run with support from relevant EMA staff.				

Experts' declared interests were evaluated against the topics or activities they participated in.