



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2026
EMA/CHMP/81517/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM¹ Minutes for the meeting on 13 April 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 13 April 2026 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of the 13 April 2026 meeting will be adopted at the April 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 remotely on 16-18 February 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. Revision 3 of EU Annex I to ICH Q3C Guideline on impurities: guideline for residual solvents (EMA/CHMP/ICH/82260/2006)

In 2024, the QWP agreed on the revision of Annex I of (V)ICH Q3C, which was published in 2013, in order to address inconsistent interpretation of the text related to the chapter 'Specifications for class 1 solvents'. During the revision, minor updates to the rest of the text were also implemented. The revised Annex I was adopted by the QWP in March 2026, and it is now presented for CHMP adoption for a 1.5-month public consultation.

Expert: Ivica Malnar

Action: For adoption

The CHMP adopted the revision 3 of EU Annex I to ICH Q3C Guideline on impurities: guideline for residual solvents for a 1.5-month public consultation.

2.2.2. Overview of comments received on the draft "Guideline on the Development and Manufacture of synthetic peptides"

The final "Guideline on the Development and Manufacture of synthetic peptides" has been adopted by the CHMP in December 2025 and published on the EMA website. The overview of comments on the draft guideline has been adopted by the QWP in March 2026 and is intended for CHMP adoption and subsequent publication.

Action: For adoption

The CHMP adopted the overview of comments received on the draft "Guideline on the Development and Manufacture of synthetic peptides".

2.2.3. Q&A on reduced testing of starting materials (Quality of medicines questions and answers: Part 2)

The Q&A was revised based on chapter 5 of EU GMP and Article 28 of the Commission Implementing Regulation (EU) 2025/2091. The update aims to enhance clarity versus skip testing. The proposed amendment was adopted during the March 2026 QWP meeting, and it is intended for CHMP adoption for subsequent publication.

Action: For adoption

The CHMP adopted the Q&A on reduced testing of starting materials (Quality of medicines questions and answers: Part 2).

2.2.4. Q&A on implementation of Ph. Eur. Medicinal Product Monographs

The proposed administrative updates, including revisions to outdated references and coding adjustments aligned with the new Variations Classification Guideline, have been adopted during the March 2026 QWP meeting. The Q&A is intended for CHMP adoption for subsequent publication.

Action: For adoption

The CHMP adopted the Q&A on implementation of Ph. Eur. Medicinal Product Monographs.

2.2.5. Minutes

- Minutes of the QWP meeting held remotely on 16-17 February 2026

Action: For information

The CHMP noted the minutes.

2.2.6. 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).

2.2.7. CMDh request to QWP

Action: For adoption

The CHMP adopted the CMDh request to QWP.

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 2 March 2026

Action: For information

The CHMP noted the agenda and minutes.

2.3.2. Biosimilar reflection paper – implementation

Implementation of the Biosimilar tailored approach.

Action: For endorsement

The CHMP endorsed the implementation of the Biosimilar tailored approach.

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 remotely on 17-18 February 2026
- Draft agenda of the NcWP meeting to be held remotely on 14-15 April 2026

Action: For information

The CHMP noted the agenda and minutes.

3.1.3. CMDh question to NcWP/NS-OEG

Action: For adoption

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

3.1.4. CMDh Letter to CHMP (NcWP)

Action: For adoption

The CHMP adopted the CMDh Letter to CHMP (NcWP).

3.1.5. NcWP response to the M12QA-tDG

Action: For adoption

The CHMP adopted the NcWP response to the M12QA-tDG.

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

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

3.2.1. Agenda

- Agenda of the 3RsWP meeting held in-person on 31 March and 1 April 2026

Action: For information

The CHMP noted the agenda.

3.2.2. Call for interest for a 3RsWP member temporary replacement (deadline extended)

The call for interest for nomination of a temporary replacement of a 3RsWP member is extended.

Nominations should be sent to the Agency by 17 April 2026

Nominations are planned for the May 2026 CHMP PROM meeting.

Action: For information

The CHMP noted the extended deadline for the call for interest for nomination of a 3RsWP member temporary replacement.

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

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. Nomination of new Methodology MSOEG expert

Nomination of a new expert to join the Methodology Modelling and Simulation Operational Expert Group (MSOEG).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of a new expert to join the Methodology Modelling and Simulation Operational Expert Group (MSOEG).

4.1.4. Product-specific bioequivalence guideline

Draft guideline for 3-month public consultation:

- Tafamidis soft gelatine capsules 20 mg and 61 mg product-specific bioequivalence guidance (EMA/73948/2026).

Experts: Carolien Versantvoort, Sara Camilleri

Action: For adoption

The CHMP adopted the product-specific bioequivalence guideline for a 3-month public consultation.

4.1.5. Q&A on EMA Guidance on the use of Real-World Data (RWD)

The document was developed under the umbrella of MWP and aims to address questions raised by stakeholders during public consultations of several regulatory documents related to the use of RWD. Following consultation with CHMP, PRAC, SAWP, PDCO, CAT and COMP, the updated Q&A is presented for CHMP adoption.

CHMP: Carla Torre

Action: For adoption

The CHMP adopted the Q&A on EMA Guidance on the use of Real-World Data.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

No topics

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Call for interest for new CVSWP members

Call for interest for nomination of two new CVSWP members.

Nominations should be sent to the Agency by 11 May 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 new CVSWP members.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Nomination of new Oncology ESEC experts

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

Nomination(s) received

Action: For endorsement

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

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)**

Chair: Sol Ruiz, Vice-Chair: Eleonora G. Wijnans

5.6.1. Nomination of a new member to the VWP

Nomination of a new non-clinical VWP member following a call for interest in January 2026.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Brigitte Tiesjema as a new VWP member.

5.7. **Haematology Working Party (HaemWP)**

Chair: Daniela Philadelphia, Vice-chair: Viktoriia Starokozhko

5.7.1. Call for interest for a new HAEMWP member

Call for interest for nomination of a new HAEMWP member.

Nominations should be sent to the Agency by 24 April 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 HAEMWP member.

5.7.2. Scientific Article on 'Dysimmune Inflammatory Neuropathies (DINs): A Narrative Literature Review and Patient Perspectives'

Information on the above-mentioned draft article.

Action: For information

The CHMP noted the scientific article on 'Dysimmune Inflammatory Neuropathies (DINs): A Narrative Literature Review and Patient Perspectives'.

5.7.3. Haematology ESEC webinar on bone marrow failure

The remote webinar will take place on 5 June 2026 (14:00-15:30).

CHMP: Daniela Philadelphia

Action: For information

The CHMP noted the upcoming Haematology ESEC webinar on bone marrow failure.

5.7.4. [EMA workshop on the challenges in drug development, regulation and clinical practice in immune thrombocytopenia](#)

This remote workshop will take place on 30 June 2026 (14h-18h) with the aim to have a multi-stakeholder's perspective on the challenges in drug development, regulation and clinical practice in immune thrombocytopenia. The workshop outcomes will inform the next update of the [Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia](#).

Action: For information

The CHMP noted the upcoming [EMA workshop on the challenges in drug development, regulation and clinical practice in immune thrombocytopenia](#).

5.7.5. Minutes

- Draft minutes of the Blood cluster meeting held remotely on 13 March 2026

Action: For information

The CHMP noted the 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

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 07-10 April 2026.

Action: For information

The CHMP noted the summary of recommendations and advice of the PRAC meeting held on 07-10 April 2026.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

9.2. CHMP organisation/templates

9.2.1. Initial marketing authorisation applications assessment timetables revised

As agreed at the December 2025 CHMP plenary meeting, the standard assessment timetables for initial marketing authorisation applications have been revised.

The EMA external Q&A and the procedural timetables as of May start date have been updated and published accordingly.

Action: For information

The CHMP noted the EMA external Q&A and procedural timetables update.

9.2.2. Nominated Proxy

Lyubina Racheva Todorova (BG) gave a proxy to Outi Mäki-Ikola (FI) for the entire duration of the meeting.

Aris Angelis (GR) gave a proxy to Margareta Bego (HR) for the entire duration of the meeting.

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: 29 April 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.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

No Rapporteurship update was provided.

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 13 April 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	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Member	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	
Outi Mäki-Ikola	Member (Vice-Chair)	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Nicolas Beix	Alternate	France	No interests declared	
Janet Koenig	Member	Germany	No interests declared	
Martin Mengel	Alternate	Germany	No interests declared	
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	
Ruth Kieran	Alternate	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	
Alexandra Branchu	Alternate	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No restrictions applicable to this meeting	
Peter Mol	Member	Netherlands	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Patrick Vrijlandt	Alternate	Netherlands	No restrictions applicable to this meeting	
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	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
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	
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	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No interests declared	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Nicolas Lee	Expert	Ireland	No participation in discussion, final deliberations and voting on:	3.1.3. EMEA/H/C/006498 ; 3.1.9. EMEA/H/C/006539 ; 5.1.12. EMA/VR/00003171 59; 9.1.3. EMA/VR/00003254 84
Ivica Malnar	Expert	Croatia	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Carolien Versantvoort	Expert	Netherlands	No interests declared	
Ulla Wändel Liminga	Expert	Sweden	No interests declared	
Nienke Rodenhuis	Expert	Netherlands	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.