26 February 2026
EMA/CHMP/37145/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] Minutes for the meeting on 16 February 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 16 February 2026 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of the 16 February 2026 meeting will be adopted at the February 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 1-3 December 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. Guideline on the Chemistry of Active Substances (H) - Revision

The guideline was revised following the "Sartans Lessons Learned" exercise and subsequent referrals to cover expectations for "cohort of concern" impurities, principally nitrosamines, during product development.

Action: For adoption

The CHMP adopted the revised guideline on the chemistry of active substances.

2.2.2. Minutes

- Minutes of the QWP meeting held remotely on 1-2 December 2025

Action: For information

The CHMP noted the 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. Q&A on the Implementation of 3DP Technology (Additive Manufacturing Technology) for Solid Oral Dosage Forms

The Q&A document was developed to provide guidance on Quality and Good Manufacturing Practice (GMP) requirements to support the use of 3DP technology in pharmaceutical manufacturing of solid oral dosage forms. The Q&A has already been endorsed by QWP, QIG and GMDP IWG.

Action: For adoption

The CHMP adopted the Q&A on the Implementation of 3DP Technology (Additive Manufacturing Technology) for Solid Oral Dosage Forms.

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 in-person on 11-12 December 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. 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 2-3 December 2025
- Draft agenda of the NcWP meeting to be held remotely on 17-18 February 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 launched in November 2025.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Gaja Lesnicar Pucko as a new NcWP member.

3.1.4. Nomination of a NcWP member temporary replacement

Nomination of a temporary replacement of a NcWP member.

Nomination(s) received

Action: For endorsement

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

3.1.5. Concept paper on the development of a reflection paper on the non-clinical development and evaluation of microbiome-based medicinal products

Following implementation of the GCG comments, the draft concept paper on the development of a reflection paper on the non-clinical development and evaluation of microbiome-based medicinal products is presented for CHMP adoption for a 2-month public consultation.

Expert: Violaine Francois

Action: For adoption

The CHMP adopted the concept paper on the development of a reflection paper on the non-clinical development and evaluation of microbiome-based medicinal products for a 2-month public consultation.

3.1.6. CMDh question to NcWP/NS-OEG

Action: For adoption

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

3.1.7. CMDh question to NcWP/NS-OEG

Action: For adoption

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

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 response to CMDh request

Action: For adoption

The CHMP adopted the NcWP response to CMDh request.

3.1.10. NcWP response to CMDh request

Action: For adoption

The CHMP adopted the NcWP response to CMDh request.

3.1.11. Concept paper on the development of a reflection paper on proof-of-concept data supporting the development of anti-cancer products in paediatric patients

Following implementation of the GCG comments, the draft concept paper on the development of a reflection paper on proof-of-concept data supporting the development of anti-cancer products in paediatric patients is presented for CHMP adoption for a 2-month public consultation.

Expert: Karen van Malderen

Action: For adoption

The CHMP adopted the concept paper on the development of a reflection paper on proof-of-concept data supporting the development of anti-cancer products in paediatric patients for a 2-month public consultation.

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

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

3.2.1. Agenda and Minutes

- Minutes of the 3RsWP meeting held in-person on 19-20 November 2025
- Agenda of the 3RsWP meeting held remotely on 28-29 January 2026

Action: For information

The CHMP noted the agenda and minutes.

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 meetings held remotely on 22 January and 5 February 2026

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of new Methodology MSOEG expert

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

Nomination(s) received

Action: For endorsement

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

4.1.3. Nomination of new Methodology BSOEG expert

Nomination of a new expert to join the Methodology Biostatistics Operational Expert Group (BSOEG).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of a new expert to join the Methodology Biostatistics Operational Expert Group (BSOEG).

4.1.4. 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).

4.1.5. Product-specific bioequivalence guidelines

Final guidelines after public consultation:

- Melatonin prolonged-release tablets 2 mg product-specific bioequivalence guidance (EMA/226444/2025) and Overview of comments received after public consultation (EMA/32320/2026).
- Eltrombopag film-coated tablets 12.5 mg, 25 mg, 50 mg, 75 mg and powder for oral suspension 25 mg product-specific bioequivalence guidance (EMA/226445).
  No comments received so the draft guidance is considered as final.

Action: For adoption

The CHMP adopted the product-specific bioequivalence guidelines.

4.1.6. Clinical Pharmacology Q&A – ICH M13A review

To complete the review in line with ICH M13A and the EMA considerations regarding the implementation of ICH M13A on bioequivalence for immediate-release solid oral dosage forms, the CP-OEG has reviewed the product-specific bioequivalence related Clinical Pharmacology Q&As Section 4 of Clinical pharmacology and pharmacokinetics: questions and answers.

Expert: Carolien Versantvoort

Action: For adoption

The CHMP adopted the revised Clinical Pharmacology Q&A.

4.1.7. MWP response to CMDh Questions

Action: For adoption

The CHMP adopted the MWP response to CMDh questions.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

Chair: Ewa Balkowiec-Iskra, Vice-Chair: Marion Haberkamp

5.1.1. Nomination of a new member to the CNSWP

Nomination of a new CNSWP member, following a call for interest launched in January 2026.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of Georgios Aislaitner as a new CNSWP member.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Table of Decisions

- Table of Decisions of the CVSWP meeting held remotely on 5 February 2026

Action: For information

The CHMP noted the table of decisions.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.4. Rheumatology and Immunology Working Party (RIWP)

Chair: Caroline Auriche Benichou, Vice-Chair: Karolina Törneke

5.4.1. Guideline on the clinical investigation of medicinal products for the treatment of cystic fibrosis

The revised Guideline on the clinical investigation of medicinal products for the treatment of cystic fibrosis is presented to the CHMP for adoption for a 6-month public consultation.

Expert: Caroline Auriche Benichou

Action: For adoption

The CHMP adopted the guideline on the clinical investigation of medicinal products for the treatment of cystic fibrosis for a 6-month public consultation.

5.4.2. Changing the name of RIWP to IIWP (Working Party for Immune and Inflammatory Diseases)

To align the title of the Working Party more closely with its broader scope and activities (including also therapeutic areas such as respiratory, gastrointestinal and dermatological diseases) the WP proposes to amend its name to IIWP (Working Party for Immune and Inflammatory Diseases).

Action: For endorsement

The CHMP endorsed the change of the name of RIWP to IIWP.

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, Vice-chair: Viktoriia Starokozhko

5.7.1. Agenda

- Agenda of the ad hoc Blood cluster meeting held remotely on 3 February 2026

Action: For information

The CHMP noted the agenda.

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

5.8.1. Scientific Advisory Group on Immune and Inflammatory Diseases (SAG IMM)

Draft list of nominated experts.

Action: For adoption

The CHMP adopted the nominated experts for the SAG IMM.

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 E11A implementation activities

Update on implementation activities of ICH E11A guideline, use case development by the ICH E11A working group and formation of a temporary OEG under MWP.

Action: For information

The CHMP noted the update on the ICH E11A implementation activities.

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 09-12 February 2026.

Action: For information

The CHMP noted the summary of recommendations and advice of the PRAC meeting held on 09-12 February 2026.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

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: 27 February 2026

Action: For endorsement

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 6 March 2026

Action: For endorsement

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 20 March 2026

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 updates on 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.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Clinical Domain Workplan 2026-2028

The workplan provides a high-level framework and strategic direction for the activities that will be undertaken by the Clinical Domain over a three-year period, outlining key objectives and priority areas for all therapeutic areas. This domain workplan is implemented as of 2026.

Action: For endorsement

The CHMP noted the Clinical Domain priorities for 2026 and the Clinical Domain Workplan 2026-2028.

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 16 February 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 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	
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	
Nicolas Beix	Alternate	France	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	
Finbarr Leacy	Member	Ireland	No interests declared	
Ruth Kieran	Alternate	Ireland	No interests declared	
Elita Poplavska	Member	Latvia	No restrictions applicable to this meeting	
Vilma Petrikaite	Member	Lithuania	No restrictions applicable to this meeting	
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 DoI	Topics for which restrictions apply
John Joseph Borg	Member	Malta	No restrictions applicable to this meeting	
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	
Paulo Paixão	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No restrictions applicable to this meeting	
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Carolina Prieto Fernandez	Member	Spain	No interests declared	
Antonio Gomez-Outes	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No interests declared	
Carla Torre	Co-opted member	Portugal	No restrictions applicable to this meeting	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Nicolas Lee	Expert	Ireland	No restrictions applicable to this meeting	
Karen van Malderen	Expert	Belgium	No interests declared	
Violaine Francois	Expert	Belgium	No interests declared	
Marianne Schmidt	Expert	Denmark	No interests declared	
Carolien Versantvoort	Expert	Netherlands	No interests declared	
Pierre Demolis	Expert	Iceland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Caroline Auriche Benichou	Expert	Iceland	No interests declared	
Juan Ignacio Bedoya Ponte	Expert	Spain	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No restrictions applicable to this meeting	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
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.