EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2026
EMA/CHMP/61737/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] Minutes for the meeting on 16 March 2026

Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

Disclaimers

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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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Table of contents

1. Agenda and Minutes 4
1.1. Welcome and declarations of interest of members, alternates and experts 4
1.2. Adoption of agenda 4
1.3. Adoption of the minutes 4
2. Quality Domain 4
2.1. Biologics Working Party (BWP) 4
2.2. Quality Working Party (QWP) 5
2.3. Biosimilar Medicinal Product Working Party (BMWP) 6
3. Non-Clinical Domain 6
3.1. Non-Clinical Working Party (NcWP) 6
3.2. Joint 3Rs Replacement, Reduction and Refinement Working Party (3Rs) 7
4. Methodology Domain 8
4.1. Methodology Working Party (MWP) 8
5. Clinical Domain 9
5.1. Central Nervous System Working Party (CNSWP) 9
5.2. Cardiovascular Working Party (CVSWP) 9
5.3. Oncology Working Party (ONCWP) 10
5.4. Immune and Inflammatory Diseases Working Party (IIWP) 10
5.5. Infectious Disease Working Party (IDWP) 10
5.6. Vaccines Working Party (VWP) 10
5.7. Haematology Working Party (HaemWP) 10
5.8. Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEG) 11
6. Patients, Healthcare Professionals and Consumers 11
6.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP) 11
7. Harmonisation and consistency groups 12
7.1. International Council on Harmonisation (ICH) 12
7.2. Guideline Consistency Group (GCG) 12
7.3. Summary of product characteristics Advisory Group 12
8. Joint groups and collaboration with other Scientific committees 12
8.1. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG) 12
8.2. Collaboration with other Scientific committees 12
9. Regulatory/Organisational matters 13
9.1. Regulatory Issues/new legislation 13

9.2. CHMP organisation/templates 13
10. Product development support 13
10.1. Scientific Advice Working Party (SAWP) 13
10.2. Innovation Task Force 14
11. Product related topics 14
11.1. Preview CHMP Plenary 14
11.2. Diazoxide choline - Orphan - EMEA/H/C/006576 14
12. Any Other Business 14
12.1. Rapporteurships 14
13. List of participants 15

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 March 2026 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of the 16 March 2026 meeting will be adopted at the March 2026 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

2.1.1. BWP Vaccines Quality Operational Expert Group (BV-OEG) Influenza

EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2026/2027. Draft Report from the BV-OEG to the BWP.

Expert: Koen Brusselmans

Action: For information

The CHMP noted the EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2026/2027.

2.1.2. Minutes

- Minutes of the BWP meeting held remotely on 19-21 January 2026

Action: For information

The CHMP noted the 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).

2.2. Quality Working Party (QWP)

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

2.2.1. Minutes

- Minutes of the QWP meeting held remotely on 19-20 January 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. CMDh request to QWP

Action: For adoption

The CHMP adopted the CMDh request to QWP.

2.2.4. Quality Domain Update

Overview of recent paper evaluating major objections over the last decade and trends in quality relevant to CHMP.

Action: For information

The CHMP noted the quality domain update.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: René Anour, Vice-Chair: Niklas Ekman

2.3.1. Draft Reflection paper on a tailored clinical approach in biosimilar development

BMWP has prepared the final draft of the Reflection Paper, following extensive drafting with network colleagues and a stakeholder workshop in 2025.

Experts: René Anour, Niklas Ekman

Action: For adoption

The CHMP adopted the Draft Reflection paper on a tailored clinical approach in biosimilar development. A summary of the consultation process and comments received was also provided.

2.3.2. Agenda and Minutes

- Agenda and Minutes of the BMWP meeting held remotely on 2 February 2026

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

- Minutes of the NcWP meeting held remotely on 20-21 January 2026
- Draft agenda of the NcWP meeting to be held in-person on 17-18 March 2026

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Call for interest for a new NcWP member

Call for interest for nomination of a new NcWP member, following the departure of a member.

Nominations should be sent to the Agency by 24 April 2026. 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 May 2026 CHMP PROM meeting.

Action: For information

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

3.1.3. Presentation from the Nitrosamine Safety-OEG (NSOEG) on the 2025 achievements

The NSOEG would like to inform the CHMP on their achievements in 2025 and the plans for 2026.

Expert: Marianne Schmidt

Action: For information

The CHMP noted the NSOEG 2025 achievements and plans for 2026.

3.1.4. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to NcWP.

3.1.5. CMDh question to NcWP/NS-OEG

Action: For adoption

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

3.1.6. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.7. 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. Call for interest for a 3RsWP member temporary replacement

Call for interest for nomination of a temporary replacement of a 3RsWP member.

Nominations should be sent to the Agency by 27 March 2026.

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

Action: For information

The CHMP noted 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 remotely on 5 March 2026

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of new Methodology BSOEG expert

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

Nomination(s) received

Action: For endorsement

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

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. Data Quality Framework RWD chapter

The "Data Quality Framework for EU medicines regulation: application to Real-World Data" (RW-DQF) is a deliverable of the Network Data Steering Group (NDSG) and has been adopted by the MWP and the Guideline Consistency Group (GCG). This will be the second version of the guideline, following public consultation in 2023, and is presented for CHMP adoption.

Action: For adoption

The CHMP adopted the Data Quality Framework for EU medicines regulation: application to Real-World Data chapter.

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 endorsement by MWP, the document will be presented to PRAC, CHMP and SAWP

Action: For information

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

4.1.6. Product-specific bioequivalence guideline

Draft guideline for a 3-month public consultation:

- Liraglutide 6 mg/mL solution for injection in pre-filled pen product-specific bioequivalence guidance (EMA/58489/2026).

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 on the need for revision of the Guideline on clinical investigation of medicinal products for the treatment of amyotrophic lateral sclerosis

The current guideline, from 2016, predates some recent developments in the field. Since the first version, new diagnostic criteria and tools for patient phenotyping have been developed, the standard of care has evolved which could impact the design of studies, methodological aspects on the design of efficacy studies in ALS should be addressed as well as the potential role of biomarkers in the drug development in ALS. The document is presented to the CHMP for adoption for a 6-month public consultation.

Action: For adoption

The CHMP adopted the concept paper on the need for revision of the Guideline on clinical investigation of medicinal products for the treatment of amyotrophic lateral sclerosis for a 6-month public consultation.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Draft Paediatric Addendum to the Guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension

CVSWP has prepared the draft of the Paediatric Addendum, addressing points raised in the Concept Paper: the role of invasive haemodynamic data, the implication of modelling and simulation approaches, the definition of endpoints reflecting time to clinical worsening and the role of additional endpoints like echocardiography, PROs and biomarkers. A stakeholders meeting was organised to support this revision in 2024. The document is presented to the CHMP for adoption for a 6-month public consultation.

CHMP: Patrick Vrijlandt

Expert: Clemens Mittmann

Action: For adoption

The CHMP adopted the draft Paediatric Addendum to the Guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension for a 6-month public consultation.

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)

No topics

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy, Vice-chair: Viktoriia Starokozhko

5.7.1. Agendas

- Draft agenda of the Blood cluster meeting to be held remotely on 13 March 2026
- Draft agenda of the Non-malignant Haematology cluster meeting to be held remotely on 13 March 2026

Action: For information

The CHMP noted the agendas.

5.7.2. Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg) (EMA/CHMP/BPWP/496692/2023 rev 2)

The revised Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration is presented to the CHMP for final adoption following the public consultation.

Expert: Claudia Grammiccioni

Action: For adoption

The CHMP adopted the revised Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration.

5.7.3. Revised core SmPC for human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg) (EMA/CHMP/BPWP/143744/2011 rev.2)

The revised core SmPC for human normal immunoglobulin for subcutaneous and/or intramuscular administration is presented to the CHMP for final adoption following the public consultation.

Expert: Claudia Grammiccioni

Action: For adoption

The CHMP adopted the revised core SmPC for human normal immunoglobulin for subcutaneous and/or intramuscular administration.

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 09-12 March 2026.

Action: For information

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

8.2.2. Guideline on declaration of herbal substances/preparations in (traditional) herbal medicinal products

Following HMPC revision, the Guideline on declaration of herbal substances/preparations in (traditional) herbal medicinal products, is presented for adoption for a 3-month public consultation.

Expert: Kristine Hvolby

Action: For adoption

The CHMP adopted the guideline on declaration of herbal substances/preparations in (traditional) herbal medicinal products for a 3-month public consultation.

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 11.2.

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.

10.1.3. Virtual workshop on Geographic Atrophy endpoints

European Medicines Regulatory Network (EMRN) workshop on Geographic Atrophy endpoints which will take place on 29 April.

Action: For information

The CHMP noted the upcoming virtual workshop on Geographic Atrophy endpoints.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 27 March 2026

Action: For endorsement

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 17 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.

11.2. Diazoxide choline - Orphan - EMEA/H/C/006576

Soleno Therapeutics Europe Limited; treatment of adult and paediatric patients with Prader-Willi syndrome (PWS)

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

Action: For adoption

List of Outstanding Issues adopted on 26.02.2026. List of Questions adopted on 18.09.2025.

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 February 2026.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

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 March 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	
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	
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	
Hrefna Gudmundsdottir	Member	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	

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	
Martine Trauffler	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	
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	
Koen Brusselmans	Expert	Belgium	No interests declared	
René Anour	Expert	Austria	No interests declared	
Claudia Gramiccioni	Expert	Italy	No interests declared	
Kristine Hvolby	Expert	Denmark	No interests declared	
Quan Thadeus Bao Nguyen Jakobsen	Expert	Denmark	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
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	
Susanne Brendler-Schwaab	Expert	Germany	No restrictions applicable to this meeting	
Marianne Schmidt	Expert	Denmark	No interests declared	
Clemens Mittmann	Expert	Germany	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.