



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 January 2025
EMA/CHMP/510871/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 04 November 2024

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

04 November 2024, 13:00–15:00, virtual meeting

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 04 November 2024 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of the 04 November 2024 meeting will be adopted at the November 2024 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

2.1.1. Nomination of new Biological Quality ESEC experts

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

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new experts to join the Biological 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. Agenda and minutes

- Agenda of the QWP meeting to be held remotely on 4-5 November 2024
- Minutes of the QWP meeting held in person on 9-11 September 2024

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).

2.3. 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 23 September 2024

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 meeting held remotely on Aug / Sept 2024
- Draft agenda of the meeting to be held virtually on Nov 2024

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. CMDh question to NcWP/NS-OEG

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

3.1.3. NcWP/NS-OEG response to CMDh question

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

3.1.4. NcWP/NS-OEG response to CMDh question

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

3.1.5. NcWP/NS-OEG response to CMDh question

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

3.1.6. NcWP/NS-OEG response to CMDh question

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

3.1.7. NcWP/NS-OEG response to CMDh question

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

3.1.8. NcWP/NS-OEG response to CMDh question

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

3.1.9. NcWP/NS-OEG response to CMDh question on

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

3.1.10. Nomination of new member for the NS-OEG

Following the request for nominations for the NS-OEG in September 2024, the NcWP is nominating two new members of the NS-OEG.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination for two new members of the NS-OEG.

3.1.11. New Approach Methodologies ESEC webinar agenda

- Agenda of the Non-clinical (NC) New Approach Methodologies (NAMs) ESEC webinar held on 16 October 2024

Action: For information

The CHMP noted the agenda.

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

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

3.2.1. 3RsWP – OEG - Batch release testing meeting agenda

- Agenda of the Batch release testing (BRT) OEG meeting held on 18 October 2024

Action: For information

The CHMP noted the agenda.

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 virtual MWP meeting held on 6 September 2024

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of Methodology ESEC experts

Nomination of EMA staff and new experts to enter the Methodology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of EMA staff and new experts to enter the Methodology European Specialised Expert Community (ESEC).

4.1.3. Endorsement of Methodology Domain Governance Composition

Request to CHMP members for endorsement for the proposed composition of the Methodology Domain Governance.

MWP Chair: Christian B. Roes

Action: For endorsement

The CHMP endorsed the proposed composition of the Methodology Domain Governance.

4.1.4. Endorsement of updated - Methodology ESEC Mandate

Request to CHMP to endorse the updated Methodology ESEC Mandate (October 2024), which now includes exclusion criteria for joining ESEC.

MWP Chair: Christian B. Roes

Action: For endorsement

The CHMP endorsed the updated Methodology ESEC Mandate (October 2024), which now includes exclusion criteria for joining ESEC.

The CHMP was informed that to be part of the ESEC, the expert needs to be included in the European expert list, for which he/she will need to provide their CV and a declaration of interest (DoI) in line with the EMA policy on handling of competing interests of scientific committees' members and experts. Experts that have current direct interests in the pharmaceutical industry, i.e. current employment, current involvement in repurposing as champion, current consultancy (except if consultancy for individual products), current strategic advisory role (except if strategic advisory role for individual products) or current financial interests, would be excluded from ESEC membership.

4.1.5. Product-Specific Guidelines

Draft guidelines for 3-month public consultation:

- Aprepitant hard capsules 80 mg, 125 mg, 80 mg + 125 mg (combination) product-specific bioequivalence guidance (EMA/495648/2024).

Expert: Audrey Sultana

- Paclitaxel (nanoparticle albumin-bound) powder for suspension for infusion 5mg/ml product-specific bioequivalence guidance (EMA/418520/2024).

Expert: Carolien Versantvoort

The CHMP adopted the draft guidelines for 3-month public consultation. Final guidelines after 3-month public consultation:

- Budesonide gastro-resistant hard capsules 3 mg and gastro-resistant granules 9 mg (EMA/219288/2024); prolonged release tablets, 9 mg (EMA/219378/2024); and gastro-resistant hard capsules 3 mg (EMA/219393/2024). No comments received so draft version will be published as final.

Expert: Karin Kundler

- Tolvaptan tablets with the dose range 7.5, 15 and 30 mg and tolvaptan tablets with the dose range 15, 30, 45, 60 and 90 mg product-specific bioequivalence guidance (EMA/CHMP/254395/2024).

Expert: Marc Maliepaard

- Methylphenidate prolonged-release tablet 18 mg, 27 mg, 36 mg and 54 mg and modified release capsule 5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg product-specific bioequivalence guidance (EMA/94136/2024) and Overview of comments (EMA/479935/2024).

Expert: Paulo Paixão

- Nilotinib hard capsules 50, 150 and 200 mg product-specific bioequivalence guidance (EMA/518671/2023) and Overview of comments (EMA/479330/2024).

Expert: Carolien Versantvoort

- Trametinib film-coated tablet 0.5 and 2mg product-specific bioequivalence guidance (EMA/CHMP/41624/2023) and Overview of comments (EMA/339228/2024).

Expert: Carolien Versantvoort

Action: For adoption

The CHMP adopted the final guidelines for publication on the EMA website.

4.1.6. [Q&A on the need for bioequivalence studies with acid reducing agents](#)

To date the EMA product-specific bioequivalence guidelines (PSBGL) have been published referencing to the salt, polymorphic form and hydration/solvation state of the drug substance used in the formulation of the reference medicinal product. In response to a request from CMDh, the PSBGL Drafting Group with input from QWP has developed a Q&A on the conditions where even if a published PSBGL does not explicitly highlight this, an additional bioequivalence study with concomitant treatment of a Proton-Pump Inhibitor (PPI) as an acid reducing agent is in principle necessary to demonstrate bioequivalence.

Expert: Carolien Versantvoort

Action: For adoption

The CHMP adopted the Q&A on the need for bioequivalence studies with acid reducing agents.

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. [Agenda and Minutes](#)

- Final Agenda and Draft Minutes for CVS WP meeting held on 20 Sept 2024

Action: For information

The CHMP noted the agenda and minutes.

5.2.2. [Concept Paper on the need for revision of the addendum on weight control in children to the guideline on clinical evaluation of medicinal products used in weight control](#)

Update to the Addendum to align with the Guideline for adults (where appropriate) and to reflect recent developments in this rapidly evolving field with respect to approval of new medicinal products for weight management as well as clinical practice guidelines. The Concept Paper will be released for 3 months public consultation.

Action: For adoption

The CHMP adopted the Concept Paper on the need for revision of the addendum on weight control in children to the guideline on clinical evaluation of medicinal products used in weight control. The document will be published for 3 months public consultation.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Oncology ESEC webinar on Bladder Cancer

- List of speakers for the proposed webinar to take place on 6th December 2024

Action: For information

The CHMP noted the list of speakers for the Oncology ESEC webinar on Bladder Cancer.

5.3.2. Agenda and minutes

- Agenda of the ONCWP meeting on the 23 October – teams meeting
- Minutes of the ONCWP meeting of the 25 September, face to face meeting

Action: For information

The CHMP noted the agenda and minutes.

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. Nomination of new member to the VWP

Nomination of new VWP member.

Action: For endorsement

The CHMP endorsed Sol Ruiz as new member to the VWP.

5.6.2. Workplan of the VWP

Workplan of the VWP for CHMP adoption to be released for public consultation.

VWP Chair: Mair Powell

Action: For adoption

The CHMP adopted the workplan of the VWP for one month public consultation.

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 M15 Draft Guideline on General Principles for Model-informed Drug Development – Step 2b

The ICH M15 Expert Working Group has completed a draft guideline covering the general principles and good practices for the use of MIDD and will harmonise expectations regarding documentation standards, model development, data used in the analysis, model assessment, and its applications. The document is presented for adoption for a 3-month public consultation.

Action: For adoption

The CHMP adopted the ICH M15 Draft Guideline on General Principles for Model-informed Drug Development – Step 2b. The document will be published for a 3-month public consultation.

7.1.2. ICH E6 (R3) Draft Guideline on Good Clinical Practice Annex 2 – Step 2b

The ICH E6 (R3) Expert Working Group has completed a draft guideline on Good Clinical Practice Annex 2. The document is presented for adoption for a 3-month public consultation.

Action: For adoption

The CHMP adopted ICH E6 (R3) Draft Guideline on Good Clinical Practice Annex 2 – Step 2b. The document will be published for a 3-month public consultation.

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

Chair: Ulla Wändel Liminga

Summary of recommendations and advice of PRAC meeting held on 28-31 October 2024.

Action: For information

The CHMP noted the summary of recommendations and advice.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

9.1.1. Revision of variations guidelines

Revision of variations guidelines.

Action: For discussion

The CHMP noted the revision of variations guidelines. The CHMP members were invited to send outstanding comments until the end of the week.

9.1.2. RWD chapter of the Data Quality Framework

Data Quality Framework for EU medicines regulation: application to Real-World Data – document for public consultation.

Action: For adoption

The CHMP noted the RWD chapter of the Data Quality Framework. The CHMP members were invited to send comments until the end of the November CHMP plenary.

9.2. CHMP organisation/templates

9.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP learnings will be discussed in the CHMP November plenary.

9.2.2. GIREX - Group for Internal Rules on Extensions of Clock Stops

Update on requests for extensions of clock stops for ongoing procedures.

Action: For adoption

The CHMP adopted the update on requests for extensions of clock stops for ongoing procedures. See point 11.2 and 11.3.

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 from 28-31 October 2024 meeting held by Webex
- Draft Table of Decisions from 28-31 October 2024 meeting held by Webex

Action: For information

The CHMP noted the agenda and table of decisions.

10.1.3. Call for expression of interest for nomination of SAWP members

Call for expression of interest for nomination of a SAWP member's replacement, following planned departure of Andrea Laslop (with Martin Walter as alternate) and to complete the SAWP composition.

Required areas of expertise: Biosimilars, Non-clinical, Ophthalmology, Pulmonology, Internal Medicine and Neurology.

Applications should be sent to the SAWP Secretariat by Wednesday, 20 November 2024.

The new SAWP members and their alternates' starting date will immediately follow their nomination by the December PROM meeting, on 2 December 2024.

Action: For information

The CHMP noted the call for expression of interest.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 18 November 2024.

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 20 November 2024.

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 22 November 2024.

Action: For adoption

The CHMP endorsed the meeting.

10.2.4. ITF meeting

Meeting date: 16 December 2024.

Action: For adoption

The CHMP endorsed the meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Bruno Sepodes

Action: For information

11.2. Ivermectin/Albendazole - Ivermectin / Albendazole - Article 58 - EMEA/H/W/005186

prevention and treatment of lymphatic filariasis, and soil-transmitted helminths infections.

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in October 2024.

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 30.05.2024.

The CHMP agreed to the request by the applicant requesting an extension to the clock stop

to respond to the list of outstanding issues adopted in October 2024.

11.3. Tuzulby (previously Arxbium) - Methylphenidate hydrochloride - PUMA - EMEA/H/C/005975

treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years of age and over.

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in October 2024.

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 08.06.2023.

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 October 2024.

11.4. WS2551 Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/WS2551/0043 Kalydeco - Ivacaftor - EMEA/H/C/002494/WS2551/0121

Vertex Pharmaceuticals (Ireland) Limited; treatment of cystic fibrosis.

Rapporteur: Peter Mol, Co-Rapporteur: Finbarr Leacy

Scope: update on procedure

Action: For discussion

The CHMP noted the update on the procedure.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

13. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Bruno Sepodes	Chair	Portugal	No interests declared	
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 interests declared	
Gergana Lazarova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	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	
Boje Kvorning Pires Ehmsen	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member/Vice-Chair	Finland	No restrictions applicable to this meeting	
Johanna Lähtenvuo	Alternate	Finland	No interests declared	
Jean-Michel Race	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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Finbarr Leacy	Alternate	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Martine Trauffer	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Peter Mol	Member	Netherlands	No interests declared	
Patrick Vrijlandt	Alternate	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Fatima Ventura	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 interests declared	
Andreja Kranjc	Alternate	Slovenia	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 interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Carolien Versantvoort	Expert	Netherlands	No interests declared	
Rhea Fitzgerald	Expert	Ireland	No interests declared	
Sofia Trantza	Expert	Greece	No interests declared	
Pierre Demolis	Expert	France	No interests declared	
Ana Maria Imedio	Expert	Spain	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	

Experts were evaluated against the agenda topics or activities they participated in.