31 October 2023
EMA/CHMP/571146/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft PROM[1] Minutes for the meeting on 30 October 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

30 October 2023, 09:00–16:00, 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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 30 October 2023 meeting.

1.3. Adoption of the minutes

The CHMP PROM Minutes of the 30 October 2023 meeting will be adopted at the November 2023 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Francesca Luciani

2.1.1. Agenda and Minutes

- Draft agenda of the BWP meeting to be held via WebEx on 30-31 October 2023
- Final minutes of the BWP meeting held via WebEx on 2-4 September 2023

Action: For information

The CHMP noted the agenda and minutes.

2.1.2. Nomination for a member of BWP

Following the call for nominations launched in October for a BWP member, the Quality Domain selection panel has recommended the new BWP member to be endorsed by CHMP at the November plenary meeting.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the BWP member.

2.2. Quality Working Party (QWP)

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

2.2.1. Guideline on the use of near infrared spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations

Addendum defining the scope of an NIRS procedure (H+V). The updated document will be published for a short public consultation.

Action: For adoption

The CHMP adopted the addendum to the guideline on the use of near infrared spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations. The document will be released for 1-month public consultation.

2.2.2. Q&A on implementation of Ph. Eur. Medicinal Product Monographs (MPM)

This Q&A has been prepared by QWP to provide guidance to applicants on the implementation of Ph. Eur. MPM and address the issues identified.

Action: For adoption

The CHMP adopted the Q&A for publication on the EMA website.

2.2.3. Minutes

- Final minutes of the QWP meeting on 4-5 September 2023

Action: For information

The CHMP noted the minutes.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: René Anour, Vice-Chair: Niklas Ekman

2.3.1. Minutes

- Final minutes of the BMWP meeting on 15 September 2023

Action: For information

The CHMP noted the minutes.

2.4. Quality Innovation Group (QIG)

No topics

2.5. Formulation Expert Group (FEG)

No topics

3. Non-Clinical Domain

3.1. Non-Clinical Working Party (NcWP)

Chair: Susanne Brendler-Schwaab, Vice-Chair: Karen van Malderen

3.1.1. Agenda and Minutes

- Minutes for the NcWP meeting held face-to-face on 3-4 October 2023, including session with interested parties
- Agenda for the NcWP meeting to be held virtually on 26 October and 31 October 2023
- Minutes of Non-clinical oncology cluster EMA-FDA-meeting held on 5 October 2023
- Agenda of the Non-clinical and new approach methodologies ESEC Kick-off meeting held on 18 October 2023

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Nomination of Non-clinical and New Approach Methodologies ESEC experts

Nomination by NcWP of the experts to enter 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 the experts to enter the Non-clinical and New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC).

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

No topics

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Agenda and Minutes

- Final agenda and minutes for MWP meeting held virtually on 5 October 2023

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of Methodology ESEC experts

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

4.1.3. Endorsement of Draft Methodology Work Plan 2024

Action: For endorsement

The CHMP endorsed the Draft Methodology Work Plan 2024.

4.1.4. Guideline on Data Quality Frameworks

Methodology Working Party and Big Data Steering Group joint guideline on Data Quality Frameworks.

Action: For adoption

The CHMP adopted the Methodology Working Party and Big Data Steering Group joint guideline on Data Quality Frameworks.

4.1.5. Reflection Paper on the use of real-world data

Reflection paper on the use of real-world data to generate real-world evidence in non-interventional studies.

CHMP: Carla Torre, Expert: Xavier Kurz

Action: For discussion

The CHMP noted the reflection paper on the use of real-world data to generate real-world evidence in non-interventional studies. CHMP members were invited to send comments by 13 November.

4.1.6. Final product-specific guidelines after public consultation

The following guidelines all finished public consultation on 30 September 2023. No comments were received on any and so it is proposed that the drafts for consultation are adopted as the final versions without any changes.

- Lurasidone film-coated tablets, 18.5, 37 and 74 mg product-specific bioequivalence guidance (EMA/39336/2023)

Rapporteur: Erika Fredriksson/Elin Lindhagen

- Bosutinib film-coated tablets, 100, 400 and 500 mg product-specific bioequivalence guidance (EMA/590937/2022)

Rapporteur: Jutta Dedorath/Katalina Mettke

- Metformin immediate-release film-coated tablets 500, 850 and 1000 mg product-specific bioequivalence guidance (EMA/591346/2022)

Rapporteur: Jutta Dedorath/Katalina Mettke

- Fampridine prolonged-release tablet 10 mg product-specific bioequivalence guidance (EMA/39346/2023)

Rapporteur: Paulo Paixao

- Pirfenidone film-coated tablets 267, 537 and 801 mg and hard capsules 267 mg product-specific bioequivalence guidance (EMA/901584/2022)

Rapporteur: Audrey Sultana

Action: For adoption

The CHMP adopted the final product-specific guidelines. The documents will be published on the EMA website.

4.1.7. CMDh question to MWP – bioequivalence requirements for lenalidomide

Issues have arisen in procedures at CMDh on dissolution and bioequivalence study conditions for lenalidomide.

Action: For adoption

The CHMP endorsed the CMDh question to MWP.

4.1.8. Implementation strategy of ICH guideline M10 on bioanalytical method validation

A strategy has been developed to address specific considerations relating to the timing of studies and the validation of bioanalytical methods to enable the practical implementation in the European Union of ICH M10 - Guideline on Bioanalytical methods validation (EMA/CHMP/ICH/172948/2019). It is intended to provide guidance for Marketing Authorisation (MA) Applicants and MA Holders, CROs, as well as Regulators. As such, a two-month public consultation is foreseen.

Expert: Alfredo Garcia-Arieta

Action: For adoption

The CHMP adopted the implementation strategy of ICH guideline M10 on bioanalytical method validation for 2-month public consultation.

4.1.9. Adoption of the Concept Paper on Non-inferiority and equivalence trials

Adoption of the concept paper on non-inferiority and equivalence trials for endorsement for public consultation.

Expert: Norbert Benda

Action: For adoption

The CHMP adopted the concept paper on non-inferiority and equivalence trials for public consultation.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

Chair: André Elferink

5.1.1. Revision 3 of the Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders

Action: For adoption

The CHMP adopted the Revision 3 of the Guideline on Clinical Investigation of Medical Products in the Treatment of Epileptic Disorders. The document will be published on the EMA website.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Agenda and Minutes

- Draft minutes for CVS WP meeting held virtually on 21 Sep 2023
- Final agenda for CVS WP meeting held virtually on 21 Sep 2023

Action: For information

The CHMP noted the agenda and minutes.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Nomination of Oncology ESEC experts

Nomination by Oncology WP of new experts to enter the Oncology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new ESEC Oncology experts.

5.3.2. EMA/EORTC workshop on sarcomas

Proposal to have an EMA/EORTC workshop on 12 January 2024.

Action: For discussion

The CHMP noted the proposal to have an EMA/EORTC workshop on sarcomas on 12 January 2024.

5.3.3. EMA/EORTC workshop on QoL

Proposal to have an EMA/EORTC workshop in February/March 2024.

Action: For discussion

The CHMP noted the proposal to have an EMA/EORTC workshop on quality of life (QoL) in March 2024.

5.4. Rheumatology and Immunology Working Party (RIWP)

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

5.4.1. Q&A on replacement of propellants

Q&A on replacement of propellants.

Expert: Karolina Törneke

Action: For adoption

The CHMP adopted the Q&A on replacement of propellants. The document will be published on the EMA website.

5.4.2. Nomination of two new drafting group members (ARDS-DG) by the RIWP

Action: For information

The CHMP noted the nomination of two new drafting group members (ARDS-DG) by the RIWP.

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

5.7.1. Agenda and Minutes

- Draft agenda for HAEMWP WP meeting on 16 and 17 November 2023

Action: For information

The CHMP noted the agenda.

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

No topics

6. Patients, Healthcare Professionals and Consumers

6.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

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

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

6.1.1. Update on Patient Experience Data (PED)

PED is a key priority in the regulatory Science Strategy and Network Strategy to 2025. This presentation will provide an update on actions agreed at the workshop in Sep 2022. In particular, it will focus on the development of a reflection paper on the EU approach to collect and analyse PED and on the update of the AR template to include a dedicated section on PED.

Action: For information

The CHMP received a presentation on the actions agreed at the PED workshop, in particular the CHMP work plan deliverables. The CHMP was updated on the ongoing progress on the development of the reflection paper on the EU approach to collect and analyse PED in the EU. The CHMP experts will be incorporated to the drafting group. The CHMP noted the updated sections included in the CHMP AR, in particular the dedicated section on PED.

6.1.2. Agenda and Minutes

- Draft agenda for the Joint PCWP/HCPWP meeting to be held face-to-face on 14-15 November 2023

Action: For information

The CHMP noted the agenda.

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

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 23-26 October 2023.

Action: For information

The CHMP noted the summary of recommendations and advice.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

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 endorsed the proposed learnings.

9.2.2. Guidance on SmPC section 5.1

Summary of responses from HCPWP and updated guidance on SmPC section 5.1

CHMP: Patrick Vrijlandt

Action: For adoption

The CHMP adopted the draft Guidance on SmPC section 5.1 for circulation to assessors through CHMP and other relevant committees and groups (e.g. SmPC Advisory Group) for

testing by assessors within the coming months, before formal adoption and publication early 2024.

9.2.3. CHMP co-opted membership

Launch of a call for nominations for a CHMP co-opted member with expertise on quality, safety, and efficacy of biological medicinal products with specific emphasis on vaccines, advanced therapies and biosimilars.

Nominations should be sent to the CHMP Secretariat by **1 November 2023**. The election is planned during the November 2023 plenary meeting.

Action: For information

The CHMP noted the launch of a call for nominations for a CHMP co-opted member with expertise on quality, safety, and efficacy of biological medicinal products with specific emphasis on vaccines, advanced therapies and biosimilars.

9.2.4. Eligibility

Following the request by CHMP, a presentation on eligibility case-studies and the future EU pharma legislation is planned.

Action: For information

The CHMP noted the presentation on eligibility case studies and the future EU pharma legislation.

9.2.5. WebEx update

Action: For information

The CHMP noted the update on WebEx meetings.

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 23-26 October 2023 meeting held by WebEx
- Draft Table of Decisions from 23-26 October 2023 meeting held by WebEx

Action: For information

The CHMP noted the agenda and table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 16 November 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 24 November 2023

Action: For adoption

The CHMP endorsed the meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

The CHMP Chair flagged some procedures on the agenda of the upcoming plenary.

11.2. Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0058/G

Novavax CZ, a.s.

Rapporteur: Patrick Vrijlandt

Update on procedure

Action: For discussion

Scope: quality variation

The CHMP discussed the Nuvaxovid/II/0058/G quality variation.

12. Any Other Business

12.1. Rapporteurships

Update

Action: For information

The CHMP noted the update.

12.2. Health Threats and ETF 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
Harald Enzmann	Chair	Germany	No interests declared	
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 interests declared	
Margareta Bego	Member	Croatia	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	
Aaron Sosa Mejia	Alternate	Denmark	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Janet Koenig	Alternate	Germany	No interests declared	
Konstantina Alexopoulou	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	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 participation in final deliberations and voting on:	COVID-19 vaccines
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Carolina Prieto Fernandez	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 restrictions applicable to this meeting	
Carla Torre	Co-opted member	Portugal	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Thadeus Bao Quan Nguyen	Expert	Denmark	No interests declared	
Mette Steen Tranholm	Expert	Denmark	No interests declared	
Karolina Törneke	Expert	Sweden	No interests declared	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert	Spain	No restrictions applicable to this meeting	
Xavier Kurz	Expert	Belgium	No interests declared	
Luca Santi	Expert	Italy	No restrictions applicable to this meeting	
Martina Perini	Expert	Italy	No restrictions applicable to this meeting	
Alfredo García-Arieta	Expert	Spain	No interests declared	
Nicolas Lee	Expert	Ireland	No restrictions applicable to this meeting	
Joep Bergers	Expert	Netherlands	No interests declared	
Marjolijn Schalk	Expert	Netherlands	No interests declared	
Helena Back	Expert	Sweden	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
André Elferink	Expert	Netherlands	No interests declared	
Meeting run with support from relevant EMA staff.				

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