



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 October 2023
EMA/568436/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 12 October 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

12 October 2023, 14:00–18:00, 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 12 October 2023 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 12 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 F2F on 2-4 October 2023
- Final minutes of the BWP meeting held via Webex on 10-12 July 2023

Action: For information

The CHMP noted the agenda and minutes.

2.1.2. Call for nomination for an expert as member of the CHMP Biologics Working Party (BWP)

Following the leave of a BWP member, a call for nomination of a new member for the BWP is launched.

Nominations should be sent by 25 October 2023. Endorsement of the new member by the CHMP is planned to take place at November PROM.

Action: For information

The CHMP noted the call for nomination for an expert as member of the CHMP Biologics Working Party (BWP).

2.2. Quality Working Party (QWP)

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

2.2.1. Agenda and Minutes

- Draft Agenda of the QWP meeting on 5-6 October 2023
- Final minutes of the QWP meeting on 26-28 June 2023

Action: For information

The CHMP noted the agenda and minutes.

2.2.2. Guideline on the Development and Manufacture of Synthetic Peptides

This guideline addresses specific aspects regarding the manufacturing process, characterisation, specifications and analytical control for synthetic peptides not covered by other guidelines; it also contains requirements related to conjugation, to medicinal product development, to synthetic peptide development using biological peptides as European reference medicinal product, and to clinical trial applications (human products only). It was authored by a drafting group and is part of the QWP work plan. The draft guideline is to be released for 6-month public consultation.

Action: For adoption

The CHMP adopted the Guideline on the Development and Manufacture of Synthetic Peptides to be released for 6-month public consultation.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

No topics

2.4. Quality Innovation Group (QIG)

Chair: Marcel Hoefnagel

2.4.1. Q&A on the use of X-ray sterilisation processes for SUS used in biopharmaceutical manufacturing

QIG has drafted a Q&A on the use of X-ray sterilisation processes for Single Use Systems (SUS) used in biopharmaceutical manufacturing. This Q&A has been agreed by QWP, BWP, QIG, and GMDP IWG at their September 2023 meetings. Final version is now presented for adoption.

Expert: Marcel Hoefnagel

Action: For adoption

The CHMP adopted the Q&A on the use of X-ray sterilisation processes for SUS used in biopharmaceutical manufacturing. The Q&A document will be published on the EMA website.

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 virtually on 29 August and 5 September 2023
- Agenda for the NcWP meeting to be held face-to-face on 3-4 October 2023, including session with interested parties

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

3.1.3. Appendix 1 to Nitrosamines Q&A: Acceptable intakes established for N-nitrosamines

October 2023 update.

Action: For information

The CHMP noted the Appendix 1 to Nitrosamines Q&A: Acceptable intakes established for N-nitrosamines.

3.1.4. [CMDh request to NcWP on Doxycycline](#)

CMDh has requested advice to the NcWP on the potential genotoxicity of doxycycline.

Action: For adoption

The CHMP endorsed the CMDh request to NcWP for advice on the potential genotoxicity of doxycycline.

3.1.5. [CMDh request to NcWP on Lorazepam](#)

CMDh has requested advice from NcWP on the safety of combined use of excipients benzyl alcohol, propylene glycol, and polyethylene glycol (PEG 400) in children under 12 years of age.

Action: For adoption

The CHMP endorsed the CMDh request to NcWP.

3.1.6. [CMDh follow-up request to NcWP on Diclofenac](#)

CMDh has requested the NcWP to reconsider the wording of the proposed information on disposal in the PI for topical medicinal products containing diclofenac.

Action: For information

The CHMP endorsed the CMDh request to NcWP.

3.1.7. [Revision 19 of the Q&A for marketing authorisation holders/applicants on the CHMP Opinion for the Art. 5\(3\) of Regulation \(EC\) No 726/2004 referral on nitrosamine impurities in human medicinal products](#)

Update of Answer to Question 10.

Action: For adoption

The CHMP adopted the Revision 19 of the Q&A for marketing authorisation holders/applicants on the CHMP Opinion for the Art. 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products. The Q&A will be published on the EMA website.

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](#)

- Final minutes for the 3RsWP meeting held virtually on 19 June 2023
- Agenda for the 3RsWP meeting held virtually on 19 September 2023

Action: For information

The CHMP noted the agenda and minutes.

3.2.2. [Call for nominations - Batch Release Testing OEG](#)

- Deadline for nominations extended to 30 November 2023

Action: For information

The CHMP noted the extension of the deadline of the call for nominations for the Batch Release Testing Operational Experts Group (BRT OEG).

3.2.3. [Concept paper on the revision of the Guideline on the principles of regulatory acceptance of 3Rs \(replacement, reduction, refinement\) testing approaches](#)

The 3RsWP is proposing to revise the "guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches". For this purpose, the 3RsWP has drafted a concept paper which explains the proposed amendments to the guideline which include new terminology in line with the recent developments regarding 3Rs methods. Furthermore, the revised guideline will also include annexes with acceptance criteria related to specific contexts of use. The concept paper will be published for a 3-month public consultation. This work is part of the Non-clinical domain 3-year work plan, and the 3RsWP is seeking endorsement from CHMP.

Action: For adoption

The CHMP adopted the concept paper on the revision of the Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches for a 3-month public consultation.

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 13 July 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. Nomination of Methodology BSOEG experts

Nomination by MWP of EMA staff and new experts to enter the Methodology Biostatistics Operational Experts Group.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination by MWP of EMA staff and new experts to enter the Methodology Biostatistics Operational Experts Group.

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

Topic postponed for the November PROM meeting.

4.1.5. ICH M15 MIDD Guideline

Internal review. The objective of this guideline is to outline general MIDD principles and describe recommended practices with respect to planning, conduct, reporting, interpretation, and alignment on the impact on regulatory decision-making.

Action: For information

The CHMP noted the internal review on the ICH M15 MIDD Guideline.

4.1.6. CMDh question to MWP and QWP regarding in-vitro dissolution of modified release products in release media containing alcohol

CMDh has requested combined advice from MWP and QWP on dissolution requirements with alcohol added and considering the existing Quality Q & A (Quality of medicines: Part 2) 'Specific types of product - Need for in vitro dissolution studies with alcohol for modified-release oral products including opioid drug products.'

Action: For adoption

The CHMP endorsed the CMDh question to MWP and QWP.

4.1.7. CMDh question to MWP – CMDh referral

CMDh requests advice from MWP on the requirements for bridging to the literature based on in vitro dissolution data only for gastro-resistant products in the context of an ongoing referral procedure for gastro-resistant capsules. This procedure concerns an application for marketing authorisation according to Article 10a of Directive 2001/83/EC (well-established use application) via the decentralised procedure.

Action: For adoption

The CHMP endorsed the CMDh question to MWP.

4.1.8. [CMDh question to MWP on bridging requirements for well-established use applications](#)

During the July 2023 CMDh plenary, MSs were presented with the outcome of a questionnaire on data requirements for well-established use applications, in particular, which bridging studies are considered needed. The responses to this survey clearly showed a different interpretation/implementation of the requirements.

The CMDh requests the MWP to provide guidance on data requirements for well-established use applications, in particular, which bridging studies are needed.

Action: For adoption

The CHMP endorsed the CMDh question to MWP.

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. [Nomination of new members to the CVS ESEC](#)

Nomination of new ESEC CVS members.

Action: For endorsement

The CHMP endorsed the nomination of new ESEC CVS members.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. [Nomination of new members to the Oncology ESEC](#)

Nomination of new ESEC Oncology members.

Action: For endorsement

The CHMP endorsed the nomination of new ESEC Oncology members.

5.3.2. [Agenda and Minutes](#)

- Agenda of the ONCWP meeting held on 20 September 2023
- Minutes of the ONCWP TC meeting held virtually on 12 July 2023

Action: For information

The CHMP noted the agenda and minutes.

5.3.3. Guideline on the clinical evaluation of anticancer medicinal products – Revision 6

Guideline (Rev. 6) on the clinical evaluation of anticancer medicinal products following GCG review and adoption of the ONCWP.

Experts: Pierre Demolis, Olga Kholmanskikh Van Crieelingen

Action: For adoption

The topic was discussed in the October CHMP Plenary Meeting.

5.3.4. Guidance for assessors

Action: For adoption

The CHMP adopted the guidance for assessors.

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. Concept paper on the revision of the Non-clinical and Clinical Module of the influenza vaccines guideline

The revised guideline will address some aspects of the non-clinical and clinical development of new influenza vaccine that are not covered by the current version. This will guide applicants of innovative influenza vaccines through their product development to licensure. The revised version will also address post-approval issues including changes in strains and the collection of vaccine effectiveness data.

All amendments foreseen will contribute to addressing the need for safe and effective influenza vaccines including those used during zoonotic flu outbreaks taking new scientific knowledge and lessons learned from the Covid-19 pandemic into account.

Action: For adoption

The CHMP adopted the concept paper on the revision of the Non-clinical and Clinical Module of the influenza vaccines guideline to be released for 3-month public consultation.

5.6.2. Concept paper on the development of an addendum to the Guideline on clinical development of vaccines on clinical trials for vaccines for immunocompromised individuals

The Guideline on clinical evaluation of vaccines EMEA/CHMP/VWP/164653/05 Rev. 1 (3) did not include detailed guidance on the design of clinical trials to assess the safety, immunogenicity and efficacy of vaccines in immunocompromised individuals because these individuals are commonly excluded from the clinical trials conducted before the first licensure of new vaccines to avoid confounding of the immunogenicity and efficacy data.

The scope of this revision is to provide such guidance for studies in immunocompromised subpopulations to support regulatory decisions and to ideally identify alternative doses and/or regimens that could provide adequate levels of protection against infectious diseases in these vulnerable people.

This new guidance document will be annexed as an addendum to the body of the main Guideline on Clinical evaluation of new vaccines, whose revision started in 2018 and ended in February 2023 due to the COVID-19 pandemic and related BCP.

Action: For adoption

The CHMP adopted the concept paper on the development of an addendum to the guideline on clinical development of vaccines on clinical trials for vaccines for immunocompromised individuals to be released for 3-month public consultation.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphly

5.7.1. Guideline on the clinical requirements for non-replacement prophylactic therapy in congenital haemophilia A and B

The purpose of this guideline is to provide applicants and regulators with harmonised requirements for applications for marketing authorisation of non-replacement therapies for haemophilia A and B. Guideline for adoption by CHMP for 6-month public consultation.

Rapporteur: Daniela Philadelphly

Action: For adoption

The CHMP adopted the guideline on the clinical requirements for non-replacement prophylactic therapy in congenital haemophilia A and B to be released for 6-month public consultation.

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 September 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

Topic was postponed to the November PROM meeting.

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 25-28 September 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. Companion diagnostics (CDx)

The Companion Diagnostics Expert group has updated the frequently asked questions on medicinal products development and assessment involving companion diagnostic (CDx).

Experts: Joerg Engelbergs, Olga Kholmanskikh

Action: For endorsement

The CHMP endorsed the update on the FAQ on medicinal products development and assessment involving companion diagnostic (CDx). The updated document will be published on the EMA website.

9.2.3. Presentation of the Classification of Post-Authorisation Studies (CPAS)

Following the request by CHMP in July CHMP, a presentation on the CPAS activities, case studies and examples is planned.

Action: For discussion

The CHMP noted the presentation of the Classification of Post-Authorisation Studies (CPAS).

9.2.4. Proposal to review the rules for granting companies extended clock-stops

Call for expression of interest from the members of the Committee. Expressions of interest to be sent by 20 October.

Action: For discussion

A focus group to review the rules for granting companies extended clock-stops will be established. Nominations should be sent by 20 October 2023.

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 list.

10.1.2. Agenda and Table of Decisions

- Agenda from 25-28 September 2023 meeting held by WebEx
- Draft Table of Decisions from 25-28 September 2023 meeting held by WebEx

Action: For information

The CHMP noted the agenda and table of decisions.

10.2. Innovation Task Force

No topics

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.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. IRIS updates

Updates on the development of IRIS to CHMP and PRAC – Variations, Art. 61(3), and MA Transfers into IRIS.

Action: For information

The CHMP noted the presentation on IRIS developmental updates, in particular Variations, Art. 61(3), and MA Transfers into IRIS. The presentation was followed by a demo on how to access the procedures and a Q&A session.

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 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	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	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	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	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
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	
Paolo Gasparini	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Martine Trauffler	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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Bruno Sepodes	Member (Vice-Chair)	Portugal	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	
Dorota Distlerova	Alternate	Slovakia	No interests declared	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Carolina Prieto Fernandez	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No participation in discussion, final deliberations and voting on:	Imfinzi - durvalumab - EMEA/H/C/004771/II/0057 Beyfortus - nirsevimab - EMEA/H/C/005304/II/0005
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Trine Sidonia Jensen	Expert	Denmark	No restrictions applicable to this meeting	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Paula Contreras Alarcón	Expert	Spain	No participation in discussion, final deliberations and voting on:	rezafungin - Orphan - EMEA/H/C/005900 bimatoprost - EMEA/H/C/005916 Skyrizi - risankizumab - EMEA/H/C/004759/X/0033
Luca Santi	Expert	Italy	No restrictions applicable to this meeting	
Olga Kholmanskikh Van Criekingen	Expert	Belgium	No interests declared	
Michal Zwienka	Expert	Slovakia	No interests declared	
Joerg Engelbergs	Expert	Germany	No interests declared	
Mair Powell	Expert	Ireland	No interests declared	
Sonja Beken	Expert	Belgium	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	

Meeting run with support from relevant EMA staff.

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