



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2023
EMA/459840/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 10 July 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

10 July 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.



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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 10 July 2023 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 10 July 2023 meeting will be adopted at the July 2023 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry

2.1.1. Concept Paper on the revision of the Guideline on Radiopharmaceuticals Based on Monoclonal Antibodies

Concept paper for adoption by CHMP for 3-month public consultation.

Action: For adoption

The CHMP adopted the Concept Paper on the revision of the Guideline on Radiopharmaceuticals Based on Monoclonal Antibodies for 3-month public consultation.

2.1.2. Agenda and Minutes

- Draft agenda of the BWP meeting to be held virtually on 10-12 July 2023
- Final minutes of the BWP meeting held virtually on 15-17 May 2023

Action: For information

The CHMP noted the agenda and minutes.

2.2. Quality Working Party (QWP)

Chair: Blanka Hirschlerova, Vice-Chairs: Marie-Hélène Sabinotto, Laivi Saaremäe

2.2.1. Concept Paper on the revision of the Guideline on Radiopharmaceuticals

Concept paper for adoption by CHMP for 3-month public consultation.

Action: For adoption

The CHMP adopted the Concept Paper on the revision of the Guideline on Radiopharmaceuticals for 3-month public consultation.

2.2.2. Agenda and Minutes

- Final agenda and minutes for QWP-CT meeting held virtually on 14 June 2023
- Final minutes of the QWP meeting held virtually on 6-8 March 2023

Action: For information

The CHMP noted the agenda and minutes.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: vacant, Vice-Chair: Niklas Ekman

2.3.1. Agenda and Minutes

- Final agenda for BMWP meetings held virtually on 5 April and 31 May 2023
- Final minutes of the BMWP meetings held virtually on 8 March, 5 April and 31 May 2023

The CHMP noted the agenda and 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. CMDh questions to NcWP on new nitrosamines

The CMDh requests that the NcWP determines the acceptable intake for N-nitroso-landiolol based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

The CHMP endorsed the CMDh questions to NcWP on new nitrosamines.

3.1.2. Agenda and Minutes

- Draft minutes for the NcWP meeting held face-to-face on 13-14 June 2023
- Draft agenda for the NcWP meeting to be held virtually on 11-12 July 2023

Action: For information

The CHMP noted the agenda and minutes.

3.1.3. 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 Non-clinical and New Approach Methodologies ESEC experts.

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

- Adopted minutes for the 3RsWP meeting held virtually on 11 May 2023
- Adopted agenda for the 3RsWP meeting held virtually on 19 June 2023

Action: For information

The CHMP noted the agenda and minutes.

3.2.2. Request to MAHs – information on animal use in LD₅₀ testing

Presentation of a draft letter to MAHs of botulinum neurotoxin containing products. This action was initiated in response to a petition submitted to EMA by an animal welfare organisation

Action: For endorsement

The CHMP endorsed the letter to Botulinum Product MAHs.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chair: Kit Roes, Vice-Chair: Kristin Karlsson

4.1.1. Agenda and Minutes

- Final agenda and minutes for MWP meeting held virtually on 1 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 to enter the Methodology European Specialised Expert Community (ESEC).

Action: For endorsement

The CHMP endorsed the nomination by MWP of EMA staff to enter the Methodology European Specialised Expert Community (ESEC).

Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

The AI reflection paper was presented to CHMP PROM in May 2023 and has since been revised following discussion with the European Commission on medical devices and scope, and a GCG review. Following adoption, the paper will be released for public consultation

Action: For endorsement

The CHMP adopted the reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle for public consultation.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

Chair: Andre Elferink, Vice-Chair: Ewa Balkowiec Iskra

5.1.1. Nomination of members to the CNS ESEC

Nomination of ESEC members.

Action: For endorsement

The CHMP endorsed the nomination of members to the CNS ESEC.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Nomination of a new member to the CV ESEC

Nomination of ESEC member.

Action: For endorsement

The CHMP endorsed the nomination of a member to the CV ESEC.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Agenda and Minutes

- Agenda for the ONCWP meeting held virtually on 17 May and 16 June 2023
- Minutes for the ONCWP meeting held virtually on 19 April and 17 May 2023

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)

No topics

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 report to CHMP

Summary of the ICH bi-annual meeting in Vancouver, Canada (09-13 June).

CHMP: Bruno Sepodes

Action: For information

The CHMP noted the Summary of the ICH bi-annual meeting in Vancouver, Canada (09-13 June).

7.1.2. ICH Cell and Gene Therapy Discussion Group – appointment of experts

Following a call launched via CAT and BWP, CHMP is requested to appoint two experts to the new ICH discussion group which will serve as a technical discussion forum for issues related to ICH harmonisation efforts in the field of CGT products.

CHMP: Bruno Sepodes

Action: For adoption

The CHMP endorsed Jan Mueller-Berghaus CAT/CHMP (DE, PEI) and Niamh Curran CAT/BWP (HPRA) as ICH representatives to ICH Cell and Gene Therapy Discussion Group (CGTDG).

7.2. Guideline Consistency Group (GCG)

No topics

7.3. Summary of product characteristics Advisory Group

Chair: Kristina Dunder

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 03-06 July 2023

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. EMA/CMDh concept paper on update to variations framework for EC

CHMP to be updated on the EMA/CMDh concept paper to variations framework for EC.

Action: For information

The CHMP was informed of the progress regarding the new variation regulation framework and the next steps.

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. CHMP AR Revamp Project

Adoption of D80 nonclinical and D80 clinical AR templates; discussion of implementation plan.

CHMP: Johann Lodewijk Hillege

Action: For discussion

The CHMP adopted the D80 nonclinical and D80 clinical AR templates. The CHMP endorsed the implementation plan. Training sessions will be organised in September for assessors before the new templates become effective. A Pilot using the new templates will be started in October 2023.

9.2.3. OPEN update

The EMA piloted the OPEN initiative during the COVID-19 public health emergency, to support international collaboration in the evaluation and supervision of COVID-19

medicines. WHO took part in the pilot, which contributed to protecting public health across the world. The CHMP noted the extended scope of OPEN in June 2023 based on a review of the pilot's first year, to cover medicines intended to help combat Antimicrobial resistance; designated under the PRIME: priority medicines scheme (temporarily excluding advanced therapy medicinal products), and other products that address a high unmet medical need; intended to address public health threats and public health emergencies.

Action: For information

The EMA clarified the principles applying to OPEN experts: OPEN experts invited to comment during the CHMP evaluation as any other EU MS; OPEN experts are not contributing to CHMP conclusions during the final benefit-risk decision; OPEN experts participate in ETF (when applicable) and CHMP meetings only.

The open products will be highlighted in the CHMP agendas and minutes and EPARs will reflect that the product was assessed under the OPEN framework.

The CHMP noted the revised Q&A and CHMP OPEN partners playbook.

9.2.4. October PROM date

Proposal to have the October 2023 PROM meeting on Thursday after the CHMP plenary.

Action: For information

The CHMP noted and agreed on the proposed date for the October PROM meeting to be held on Thursday 12 October 2023 after the CHMP plenary.

9.2.5. CHMP members participation and voting

According to the current rules of procedure of Scientific Committees, in non-emergency situations, Committee members or, in its absence, their alternates (if applicable) should attend F2F meetings in person;

Remote participation will not count for the purposes of calculating the quorum and voting; hence, if neither the member nor the alternate (if applicable) is able to participate in person and wishes to exert its right to vote, a proxy should be given to another Committee member.

Action: For information

The CHMP was reminded of the current rules of procedure of Scientific Committees, in non-emergency situations and to arrange a proxy as needed.

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 03–06 July 2023 meeting held face-to-face.
- Draft Table of Decisions from 03–06 July 2023 meeting held face-to-face.

Action: For information

The CHMP noted the agenda and the table of decisions.

10.1.3. Scientific Advice Working Party (SAWP) call for interest for nomination of replacement SAWP member

Call for interest for nomination of a replacement SAWP member following resignation of Peter Mol.

Required areas of expertise: Cardiovascular medicine, Endocrinology/ diabetes/ metabolic diseases, Oncology, Haematology.

Action: For endorsement

The CHMP endorsed the nomination of André Elferink as SAWP member and Serena Marchetti as SAWP alternate.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 23 August 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 29 August 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. Update on COVID-19

Action: For information

The CHMP noted the update on COVID-19.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Update on the raw data pilot

The fourth regulatory procedure for the clinical trials raw data pilot has been selected.

It is an extension of MAA due to the introduction of new route of administration, pre-filled syringe, grouped with an extension of indication to treatment of the GPP in adolescents and adults.

Action: For information

The CHMP noted the update on the regulatory procedure for the clinical trials raw data pilot.

12.3. Preparation of oncology product-related discussions

Action: For discussion

The CHMP agreed with the proposed way forward regarding the preparation of oncology product-related discussions.

12.4. Control options for nitrosamines

Updated Q&A.

Action: For adoption

The CHMP adopted via written procedure the revision to the EMA and CMDh Question and Answer document on nitrosamine impurities in human medicinal products.

12.5. Call for interest in Network Subject Matter Expert role for the Clinical Trial Navigator product team

This is a call for expression of interest to join the Clinical Trial Navigator (CTN) team in the role of Network Subject Matter Expert (SME). The work of this team will be run using the [Agile principles and the Scaled Agile Framework \(SAFe\) approach](#).

NCA experts may express their interest in this role by completing the relevant form and e-mailing it by Friday 21 July 2023.

All nominations received will be reviewed against the requirements as defined in the call for interest and the EMA Portfolio Board, in dialogue with the HMA representatives in the Network Portfolio Advisory Group, will determine the most suitable candidates.

Action: For information

The CHMP noted the call for interest in Network Subject Matter Expert role for the Clinical Trial Navigator product team.

13. List of Participants

| Name | Role | Member State or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda and for which restrictions apply |
|-----------------------------|-----------|-----------------------------|--|---|
| Harald Enzmann | Chair | Germany | No interests declared | |
| Daniela Philadelphly | 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 | |
| Selma Arapovic Dzakula | Alternate | Croatia | No interests declared | |
| Helena Panayiotopoulou | Member | 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 | |
| Aaron Sosa Mejia | Alternate | Denmark | No participation in final deliberations and voting on: | Esperoct - turoctocog alfa pegol - EMEA/H/C/004883/X/0016 |
| 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 | |
| Anastasia Mountaki | Alternate | Greece | No interests declared | |
| Robert Porszasz | Member | Hungary | No interests declared | |
| Beata Maria Jakline Ullrich | Alternate | Hungary | No interests declared | |
| Finbarr Leacy | Alternate | Ireland | No interests declared | |
| Armando Genazzani | Member | Italy | No interests declared | |
| Vilma Petrikaite | Member | Lithuania | No interests declared | |
| Martine Trauffler | Member | Luxembourg | No interests declared | |
| Alexandra Branchu | Alternate | Luxembourg | No restrictions applicable to this meeting | |
| John Joseph Borg | Member | Malta | No interests declared | |
| Johann Lodewijk Hillege | Member | 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 and 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 |
| 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 | |
| Maria Concepcion Prieto Yerro | Member | Spain | No interests declared | |
| 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 participation in discussion, final deliberations and voting on: | Beyfortus - nirsevimab - EMEA/H/C/005304/II/0005 Imfinzi - durvalumab - EMEA/H/C/004771/II/0057 |
| 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 | |
| Sol Ruiz | Co-opted member | Spain | No interests declared | |
| Vincent Gazin | Expert | France | No interests declared | |
| Nora Cascante Estepa | Expert | Germany | No interests declared | |
| Sabine Mayrhofer | Expert | Germany | No interests declared | |
| Irene Bachmann | Expert | Germany | No interests declared | |
| Tina Soon Engraff | Expert | Norway | No interests declared | |
| Patrick Vrijlandt | Expert | Netherlands | No interests declared | |
| Kristina Bech Jensen | Expert | Denmark | No interests declared | |
| Paula Contreras Alarcón | Expert | Spain | No participation in discussion, final deliberations and voting on: | epcoritamab - Orphan - EMEA/H/C/005985 bimatoprost - EMEA/H/C/005916 Skyrizi - risankizumab - EMEA/H/C/004759/X/0033 |
| Deidre Mannion | Expert | Denmark | No restrictions applicable to this meeting | |
| Sarah Adler-Flindt | Expert | Germany | No interests declared | |
| Susanne Brendler-Schwaab | Expert | Germany | No interests declared | |
| Gabriel Westman | Expert | Sweden | No interests declared | |

| Name | Role | Member State or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda and for which restrictions apply |
|---|------|-----------------------------|---|---|
| Meeting run with support from relevant EMA staff. | | | | |

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