17 May 2023
EMA/CHMP/229678/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 15 May 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 May 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

CHMP adopted the PROM agenda for 15 May 2023 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 15 May 2023 meeting will be adopted at the May 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 for the BWP meeting to be held virtually on 15-17 May 2023
- Final minutes for the BWP meeting held virtually on 20-22 March 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. Agenda and Minutes

- Final agenda and minutes for QWP-CT meeting held virtually on 19 April 2023

Action: For information

The CHMP noted the agenda and minutes.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

No topics

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

- Draft minutes for the NcWP meeting held virtually on 18-19 April 2023
- Draft agenda for the NcWP meeting to be held virtually on 16-17 May 2023

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. CMDh questions to NcWP on new nitrosamines

The CMDh requests that the NcWP determines the acceptable intake for:

Ciprofloxacin-NO based on lifetime daily exposure including information on the points of departure and methodology used.

The CMDh further requests NcWP to either (1) determine the acceptable intake of Nitrosamine 2-Methyl-1-nitroso-2,3-dihydro-1H-indole based on lifetime daily exposure including information on the points of departure and methodology used, or (2) confirm that Nitrosamine 2-Methyl-1-nitroso-2,3-dihydro-1H-indole can be seen as non-mutagenic and consequently can be controlled as non-mutagenic impurity in accordance with ICH Q3A/B.

Action: For adoption

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

3.1.3. NcWP responses to CMDh on new nitrosamines

NcWP final position on the acceptable intake for n-nitroso-atomoxetine following alignment with international regulatory partners.

Action: For adoption

The CHMP adopted the NcWP final position on the acceptable intake for n-nitroso-atomoxetine.

3.1.4. 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).

Action: For endorsement

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

3.1.5. Upcoming call for nominations of new NcWP member

Following the departure of Louise Bang-Lauritsen at the end of April 2023 the NcWP will launch a call for nomination of a new member.

Action: For information

The CHMP noted the upcoming call for NCWP member nomination.

3.1.6. MAH response to CMDh and EMA regarding the tightening of the limit for CMIC impurity in Tenofovir disoproxil containing products

After CMDh and CHMP consulted NcWP on the potential mutagenicity of CMIC in 2022, EMA and CMDh have sent a letter in March 2023 requesting MAHs of Tenofovir disoproxil containing products to tighten the limit of CMIC according to ICH M7(R2) guideline. EMA has now received a response from a MAH providing arguments for not supporting the new request and limit of 50ppm. EMA is preparing a response after informally consulting the NcWP and discussing the issue with regulatory affairs.

NcWP Chair: Susane-Brendler Schwaab

Action: For information

The CHMP noted the MAH response and the EMA reply to be sent for consultation to NcWP.

3.1.7. NcWP responses to CMDh on Diclofenac

NcWP response to CMDh on questions for labelling for diclofenac and other NSAID gels to minimise environmental exposure.

Action: For adoption

The CHMP adopted the NcWP response to CMDh on questions for labelling for diclofenac and other NSAID gels to minimise environmental exposure.

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

- Draft report following the public session on the 3RsWP work plan and priorities for 2023 held virtually on 28 February 2023
- Final agenda for the 3RsWP meeting to be held virtually on 11 May 2023

Action: For information

The CHMP noted the agenda and minutes.

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 by teleconference on 23 March, 4 April and 20 April 2023

Action: For information

The CHMP noted the agendas and minutes.

4.1.2. Concept Paper on Platform trials

The concept paper on platform trials was published on the EMA website in November 2022 and the public consultation period ended 31 January 2023: Platform trials - Scientific guideline | European Medicines Agency (europa.eu).

Comments from 12 organisations were received. A reply to stakeholders addressing their comments will be published, outlining the comments which will be addressed and others that will likely not be addressed in the Reflection paper.

Action: For endorsement

The CHMP endorsed the concept paper and the reply to stakeholders addressing their comments.

4.1.3. Nomination of Methodology ESEC experts

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

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nominations by MWP of the experts to enter the Methodology European Specialised Expert Community (ESEC).

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

The reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle is presented in draft status for initial PROM discussion. It also relates to the BDSG work plan 2022-2025.

Action: For discussion

The CHMP received a presentation on the draft reflection paper on the use of Artificial Intelligence (AI). CHMP members were invited to send comments until the 19 May. The CHMP will re-discuss the paper for adoption in July.

4.1.5. Draft EMA Q&A on model-based approaches for approval of alternative dosing regimens and routes of administration of (anti- PD-1 and PD-L1) monoclonal antibodies

This Q&A document addresses situations when modelling and simulations of pharmacokinetics (PK) and dose-exposure-response (D-E-R) relationships for efficacy and safety with or without additional clinical studies, can support approval of alternative dosing regimens and routes of administration of (anti PD-1 and PD-L1) monoclonal antibodies.

The Q&A has been initiated based on a request by the Oncology Working Party. It has been drafted by the Modelling and Simulation Working Party and reviewed by the Oncology Working Party, Methodology Working Party, SAWP and GCG.

Action: For adoption

The CHMP adopted the Q&A document that will be published in the EMA website.

4.2. Pharmacokinetics Working Party (PKWP)

No topics

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 member to the CVS ESEC

Nomination of a member to the CVS ESEC.

Action: For endorsement

The CHMP endorsed the nominations by CVSWP of the expert to enter the CVS ESEC. The CHMP was informed that the ESEC TEAMs channel will be launched shortly.

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 experts to enter the Oncology European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nominations by ONCWP of the experts to enter the oncology ESEC.

5.3.2. ONCWP Work plan – Priorities 2023

Updated 3-years rolling plan with priorities for 2023.

Action: For endorsement

The CHMP adopted the updated 3-year workplan for the ONCWP including the priorities for 2023.

5.3.3. ONCWP recommendation on the inclusion of patients with targetable drivers in the indications of PD-1/PD-L1 inhibitors

The ONCWP was asked by the CHMP as to whether to include or exclude patients with targetable oncogenic drivers from the indications of PD-1/PD-L1 inhibitors, in the absence of dedicated studies.

ONCWP Chair: Pierre Demolis

Action: For adoption

The ONCWP discussed whether to include or exclude patients with targetable oncogenic drivers from the indications of PD-1/PD-L1 inhibitors, in the absence of dedicated studies. CHMP received a presentation on the various options.

The ONCWP will refine the final wording and share it with the ONCWP/ESEC. The final wording will be reflected in the CHMP learnings.

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)

PCWP: Co-chair: Marko Korenjak (ELPA)

HCPWP: Co-chair: Rosa Giuliani (ESMO)

6.1.1. Agenda and meeting summary

- Agenda of the upcoming PCWP/HCPWP joint meeting to be held by Webex 28 June 2023
- Agenda of the upcoming HCPWP meeting to be held by Webex 28 June 2023
- Agenda of the upcoming PCWP meeting to be held by Webex 27 June 2023
- Meeting Summary of the PCWP/HCPWP joint meeting with all eligible organisations held by Webex on 3 March 2023

Action: For information

The agendas and minutes were noted.

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. ICH E6(R3) – Good Clinical Practice

Revision 3 of ICH E6 includes revised overarching GCP principles and provisions for application of these principles to clinical trials. The document is tabled for adoption and proposed to be subsequently released for a 4-months public consultation.

Action: For adoption

The CHMP adopted the ICH E6(R3) – Good Clinical Practice. The document will be released for a 4-months public consultation.

7.1.2. ACT EU PA04 – Multi-stakeholder Workshop on ICH E6 R3 July 2023

To inform the CHMP on the upcoming ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 (R3) - Public Consultation which will take place on 13-14 July 2023.

Action: For information

The CHMP noted the upcoming ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 to be held on 13-14 July 2023.

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 8-11 May 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. Co-rapporteur Day 95 Assessment

Recent discussions at EMA took place to open the Day 95 Co-rapporteur AR to COVID applications and ATMPs.

Action: For discussion

The CHMP agreed to go ahead and open the Day 95 Co-rapporteur Assessment to COVID applications.

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. Format of OEs during CHMP meetings

Information on the new arrangement and format of oral explanations (OEs) during CHMP plenary meetings in order to enhance the experience.

Action: For information

The CHMP was informed on the new format of the OEs during the CHMP plenary meetings. Companies will have an enhanced experienced being able to see both the live video feeds of other participants and the presentation slides.

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 10-12 May 2023 meeting held by Webex
- Draft Table of Decisions from 10-12 May 2023 meeting held by Webex

Action: For information

The CHMP noted the agenda and the table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 22 May 2023

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 24 May 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. Preparation of oncology product-related discussions

CHMP: Harald Enzmann

Action: For discussion

The CHMP Chair presented a proposal on how to better prepare for the oncology product-related discussions.

11.3. eribulin - EMEA/H/006134

Scope: Request for a clock stop extension to respond to the list of questions adopted in February 2023.

Action: For adoption

List of Questions adopted on 23.02.2023.

The CHMP agreed on a clock-stop extension to respond to the list of questions adopted in February 2023.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Report on experience with RWE studies to support EMA scientific committees

Present the main findings of the report on the experience with RWE studies to support regulatory decision making. The report evaluates the opportunities and challenges of regulator led studies, and outlines lessons learned from the ongoing pilots on RWE and provides recommendations.

Action: For discussion

The CHMP received a presentation on the main findings of the report on the experience with regulator-led RWE studies to support regulatory decision making. CHMP members were encouraged to review the learnings and recommendations included on the report and provide comments by the designated deadline. An update on DARWIN EU was also provided.

12.3. Call for CHMP members sponsoring geriatric medicines strategy

The 2023 CHMP workplan (sect. 1.3.1) outlines the CHMP activities under the Geriatric Medicines strategy, which are being restarted after BCP.

The following members are identified in the workplan: CHMP topic leader: Andrea Laslop Other contributors: Bruno Sepodes; Martine Trauffler; Sabine Mayrhofer; Carla Torre; Mario Miguel Rosa (SAWP); Elina Rönnemaa (SAWP).

A short presentation on the restart of the activities will be given. The CHMP is requested to confirm/nominate members interested in the topic. A new call for external experts to support activities when requested by CHMP will also be launched.

Action: For endorsement

The CHMP noted the update on the work plan topic.

12.4. Business Pipeline Report

Business Pipeline – 3-year forecast report.

Action: For information

The CHMP received a presentation on the business pipeline and 3-year forecast report until 2025.

12.5. Short video explaining the work of CHMP

In the margins of the May CHMP plenary there will be filming for a very short video explaining the work of the CHMP to lay audience. The CHMP Chairs agreed to be filmed and if any CHMP member would like to participate please contact the CHMP secretariat.

Action: For information

The CHMP noted the expected video recording and CHMP members volunteered to participate.

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 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	
Margareta Bego	Member	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:	concizumab - EMEA/H/C/005938 Esperoct - turoctocog alfa pegol - EMEA/H/C/004883/X/0016 Sogroya - somapacitan - Orphan - EMEA/H/C/005030/X/0006/G
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	
Armando Genazzani	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Alexandra Branchu	Alternate	Luxembourg	No restrictions applicable to this meeting	
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	
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	
Maria Concepcion Prieto Yerro	Member	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:	Imjudo - tremelimumab - EMEA/H/C/006016/II/0001
Carla Torre	Co-opted member	Portugal	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Nora Cascante Estepa	Expert	Germany	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Martijn van Gils	Expert	Netherlands	No interests declared	
Carla Herberts	Expert	Netherlands	No interests declared	
Vincent Gazin	Expert	France	No interests declared	
Gabriel Westman	Expert	Sweden	No interests declared	
Luca Santi	Expert	Italy	No restrictions applicable to this meeting	
Martina Perini	Expert	Italy	No restrictions applicable to this meeting	
Line Praest Lauridsen	Expert	Denmark	No restrictions applicable to this meeting	
Deidre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Carolina Prieto Fernandez	Expert	Spain	No interests declared	
Matea Cartolano	Expert	Germany	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Flora Musuamba Tshinanu	Expert	Belgium	No restrictions applicable to this meeting	
Pierre Demolis	Expert	France	No interests declared	
Mette Tranholm	Expert	Denmark	No interests declared	
Kit Roes	Expert	Netherlands	No participation in discussion, final deliberations and voting on:	masitinib
Meeting run with support from relevant EMA staff.				

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