13 January 2023
EMA/CHMP/953415/2022 Rev.1
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 16 January 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

16 January 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 PReparatory and Organisational Matters (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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PROM meeting to be held on 13 January 2023. 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 are also considered. See January 2023 PROM minutes.

1.2. Adoption of agenda

CHMP PROM agenda for 16 January 2023 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of 16 January 2023 meeting will be adopted at the January 2023 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz, Sean Barry

2.1.1. Call for nomination for the BWP Chair

BWP Chair Sol Ruiz's last term will expire in February 2023. A call of nomination for a new BWP Chair was launched during December 2022 PROM meeting. Nominations should be sent to the Agency by **10 February 2023**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

The election will take place at the February 2023 CHMP plenary meeting.

Action: For information

2.1.2. Nomination of new alternate

Nomination of new BWP alternate to replace Grzegorz Kontny representing Poland.

Action: For endorsement

2.1.3. Nomination of new member and alternate

Nomination of new BWP member and BWP alternate to replace member Heidi Meyer and alternate Matthias Renner representing Germany.

Action: For endorsement

2.1.4. BWP Workplan 2023

The workplan has been agreed by the BWP and is presented to the CHMP for adoption.

Action: For adoption

2.1.5. Agenda and Minutes

- Draft agenda of the 16-18 January 2023 meeting to be held via Webex
- Final minutes of the 3-4 November 2022 meeting held via Webex

Action: For information

2.2. Quality Working Party (QWP)

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

2.2.1. Call for nomination for the QWP Chair

QWP Chair Blanka Hirschlerova's first term will expire in February 2023. A new call of nomination for a QWP chair was launched during December 2022 PROM meeting. The election is scheduled at the January 2023 CHMP Plenary meeting.

Nominations received

Action: For information

2.2.2. QWP Core Team Agenda & Minutes

- Final agenda and minutes for QWP-CT meeting held by webex on 7 December 2022

Action: For information

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Vice-Chair: Niklas Ekman

2.3.1. Call for nominations for BMWP members

Call for nominations for members of the BMWP following the stepping down of 4 members. The BMWP will welcome candidates with expertise primarily in quality and clinical assessment of biosimilars including PK aspects.

Nominations should be sent to the Agency by **10 February 2023**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Action: For information

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)

Chairs: Susanne Brendler-Schwaab, Karen van Malderen

3.1.1. Agenda and minutes

- Final minutes of NcWP meeting with EMA and industry stakeholders held on 4 October 2022
- Draft minutes for the NcWP meeting held virtually on 6-7 December 2022
- Draft agenda for the NcWP meeting to be held virtually on 18 January 2023

Action: For information

3.1.2. Non-clinical domain workplan – priorities 2023

The 3-year workplan including priorities for 2023 was endorsed by the NcWP on 7 December 2022.

Action: For adoption

3.1.3. CMDh questions to NcWP on new nitrosamines

The CMDh requests that the NcWP determines the acceptable intake for

- N-nitroso-atomoxetine - With regards to N-nitroso-atomoxetine, the CMDh also puts the following question forward to the NcWP: Is the life-long intake (AI) of 573 ng/day Nitrosoatomoxetin for Strattera (atomoxetin HCl) as proposed by the MAH acceptable?
- N-nitroso-atenolol (to be added to the group of beta-blockers for which the AI has already been requested)
- N-nitroso-desmethyl-tripelennamine
- N-nitroso-p-chloro-benzylamino-pyridine and N-nitroso-desmethyl-chloropyramine

based on lifetime daily exposure including information on the points of departure and methodology used.

Additional question:

- For N-nitroso-desmethylazithromycin, the CMDh requests the NcWP to confirm that N-nitroso-desmethylazithromycin can be seen as non-mutagenic and consequently can be controlled as non-mutagenic impurity in accordance with ICH Q3A/B.

Action: For adoption

3.1.4. NcWP recommendations for implementing SEND data in the European regulatory review

The Clinical Data Interchange Standards Consortium (CDISC), a non-profit organisation, developed the Standard for Exchange of Nonclinical Data (SEND) to harmonise the way pharmaceutical companies and contract research organisations (CROs) could submit electronic data to Regulatory Agencies. In 2020 a working group consisting of few NCAs was formed with the goal of evaluating the potential benefits and limitations of implementing SEND visualisation in the regulatory review process. The outcome of the pilot phase has been discussed at the NCWP and the group has made some recommendations to EMA. Peter van Meer, member of the NcWP and topic lead for the pilot project, will present the main conclusions from this project together with the recommendations from the NcWP to EMA.

NcWP expert: Peter van Meer

Action: For discussion

3.1.5. New nomination in the ERA Drafting Group

Nomination of an additional expert for the drafting group for the revision of the Guideline on Environmental Risk Assessment (ERA) of medicinal products for human use (EMEA/CHMP/SWP/4447/00 Rev. 1).

Action: For endorsement

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

Chairs: Sonja Beken, Sarah Adler-Flindt

3.2.1. Non-clinical domain workplan – priorities 2023

The 3-year workplan including priorities for 2023 was endorsed by the 3Rs Working Party on 23 November 2022 (see 3.1.2).

Action: For adoption

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Call for Nominations for Modelling and Simulation Operational Expert Groups

Launch of Call for Nominations to Biostatistics and Modelling and Simulation Operational Expert Groups.

Nominations should be sent to the Agency. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Action: For endorsement

4.1.2. Agenda and minutes

- Final Agenda & minutes for MWP meeting held by teleconference on 08 December 2022

Action: For information

4.2. Biostatistics Operational Expert Group (BOEG)

No topics

4.3. Modelling and Simulation Operational Expert Group (MSOEG)

No topics

4.4. 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)

Chairs: Alar Irs, Patrick Vrijlandt

5.2.1. Paediatric Addendum on the guidelines on clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease

This is an addendum to the Guideline on clinical investigation of medicinal products for the treatment of venous thromboembolic disease (EMA/CHMP/41230/2015) [1] and the two guidelines for prophylaxis of venous thromboembolism (VTE) in surgical (EMA/CHMP/325170/2012 Rev.2) [2] and non-surgical adult patients (EMA/CPMP/EWP/6235/04 Rev. 1) [3] and should be read in conjunction with these guidelines. This addendum includes guidance on paediatric clinical medicine development, highlighting paediatric specific issues and differences from the treatment and prophylaxis of venous thromboembolism in adults.

Action: For adoption

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Nomination of Oncology ESEC experts

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

Action: For endorsement

5.3.2. Upcoming MAA in Oncology

Presentation of the upcoming MAA in Oncology for 2023 based on the business pipeline data to identify specific need for additional Oncology ESEC experts and topics for upcoming webinars.

Action: For discussion

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo, Vice Chair: Maja Sommerfelt Grønvold

5.5.1. IDWP Work Plan

The Infectious Disease Working Party work plan was endorsed by IDWP on 10 January 2023.

IDWP Chair & Vice-Chair: Maria Jesus Fernandez Cortizo, Maja Sommerfelt Grønvold

Action: For adoption

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. Guideline on Clinical evaluation of new vaccines (EMEA/CHMP/VWP/164653/2005)

This guideline is for final adoption after public consultation and GCG review.

VWP Chair: Mair Powell

Action: For adoption

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Minutes

- Draft minutes of the Blood cluster held by teleconference on 04 November 2022

Action: For information

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 M13 - Bioequivalence for orally administered immediate-release (IR) solid oral dosage forms (Step 2b)

Following ICH sign-off, this document is proposed for CHMP's endorsement and to be subsequently released for a 4-months public consultation period.

Action: For adoption

7.1.2. ICH Q9(R1) – Quality risk management (Step 5)

Following ICH sign-off of this final revised guideline, this document is proposed for CHMP's endorsement and to be subsequently published with an enforcement date 6 months after publication.

Action: For adoption

7.1.3. ICH S1B(R1) – Addendum to testing for carcinogenicity for pharmaceuticals

Following CHMP adoption of the revised ICH S1B(R1) in September 2022, and in preparation for its enforcement in March 2023, SAWP and NCWP are likely to be approached by Applicant's seeking to receive agreement for not performing a 2-year rat carcinogenicity study, as the new guideline allows under specific cases. A dedicated workflow for SA/PA procedures, including a consultation of NCWP by default is proposed.

Action: For information

7.2. Guideline Consistency Group (GCG)

Chair: Kristina Dunder

7.2.1. Reader's Guidance for GCG review

A short Reader's Guidance has been prepared by the GCG, which the authors of documents are to provide at the start of the GCG review in order to facilitate the review process.

Chair: Kristina Dunder

Action: For information

7.3. Summary of product characteristics Advisory Group

7.3.1. Information on immunogenicity in the SmPC

Overview on the information of immunogenicity in the SmPC and proposals for consistency following learnings proposal in 2022.

Action: For discussion

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 28 November - 03 December 2022.

Action: For information

8.2.2. Call for joint CHMP/PDCO members

The paediatric legislation foresees 5 joint CHMP/PDCO members and alternates to be appointed by CHMP into PDCO. CHMP is asked to express interest to step into a joint CHMP/PDCO membership position for the next 3-year term.

Action: For information

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

9.2.2. CHMP Co-rapporteur critique

Update and proposal to the CHMP.

Action: For information

9.2.3. Practical working instructions for Multinational assessment Teams (MNATs)

5-year update of guidance.

CHMP: Outi Mäki-Ikola

Action: For discussion

9.2.4. CHMP Co-opted membership

The CHMP co-opted member position of Christian Gartner became vacant as he was nominated as the new CHMP alternate representing Austria. The CHMP should decide on whether a new co-opted member should be appointed and if so, on the required specific complementary scientific expertise. Afterwards a call for nominations will be launched.

Action: For discussion

9.2.5. CHMP Work Plan 2023

Following changes in CHMP Lead for topic CHMP workplan 2023 - Strengthening the assessment of Companion Diagnostics in the Work-plan, re-adoption of the CHMP Work Plan for 2023 from the version adopted during December 2022 plenary meeting. Members are encouraged to volunteer as contributors for this activity by contacting EMA.

Action: For adoption

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

10.1.1. Appointment of CHMP peer review for SA

Action: For information

10.1.2. Agenda and Table of Decisions

- Agenda from 09-12 January 2023 meeting held face-to-face
- Draft Table of Decisions from 09-12 January 2023 meeting held face-to-face

Action: For information

10.1.3. SAWP mandate revision

SAWP mandate revision 17 to be adopted at PROM on 13 February 2023.

Action: For information

10.1.4. SAWP composition re-nomination

Call for expression of interest to propose names for the SAWP members and associated alternates to be appointed by the CHMP to be launched on 16 January 2023.

Please send your nominations to the Agency by **15 February 2023** EOB.

Action: For information

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 26 January 2023

Action: For adoption

10.2.2. ITF meeting

Meeting date: 3 February 2023

Action: For adoption

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

11.2. Buvidal - buprenorphine - EMEA/H/C/004651/II/0017

Camurus AB

Rapporteur: Peter Kiely, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Tiphaine Vaillant

Scope: "To add the new therapeutic indication of treatment of moderate to severe chronic pain in patients with opioid dependence. As a consequence, sections 4.1, 4.2, 4.5, 5.1 and 6.6 of the SmPC and sections 1, 3 and Instruction for use of the PL are updated accordingly. The updated RMP version 2.1 has also been submitted."

Letter by the applicant requesting an extension to the clock stop to respond to the request for supplementary information adopted in June 2022.

Action: For adoption

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

12.2. Diabetes Drafting Group - Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus - (CPMP/EWP/1080/00)

Update on the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus (CPMP/EWP/1080/00) further to the comments received at the public consultation.

CHMP: Kristina Dunder

Action: For adoption

12.3. CHMP communications to EMA's stakeholders

Overview of CHMP communications and process flow.

Action: For information

12.4. Q&A "Is the monitoring of bioequivalence clinical trials mandatory?"

Q&A "Is the monitoring of bioequivalence clinical trials mandatory?" published on EMA corporate website – Q&A: Good clinical practice (GCP) | European Medicines Agency (europa.eu) please refer to B.16. A further clarification document: *Assessment of the adequacy of monitoring information in bioequivalence clinical trials* drafted.

CHMP: Jayne Crowe

Action: For adoption