10 February 2023
EMA/CHMP/42378/2023 Rev.1
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 13 February 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

13 February 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

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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 February 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 February 2023 PROM minutes.

1.2. Adoption of agenda

CHMP PROM agenda for 13 February 2023 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 13 February 2023 meeting will be adopted at the February 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

Sol Ruiz's last term as BWP chair will expire in February 2023. A call for nomination for a new BWP chair was launched during the December 2022 PROM meeting. Nominations should be sent to the Agency by **10 February 2023**.

Action: For information

2.1.2. Agenda and Minutes

- Draft agenda of the BWP meeting to be held F2F on 13-15 February 2023
- Final minutes of the BWP meeting held via Webex on 5-7 December 2022

Action: For information

2.2. Quality Working Party (QWP)

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

2.2.1. Agenda and Minutes

- Final agenda and minutes for QWP-CT meeting held virtually on 18 January 2023

Action: For information

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz, Niklas Ekman

2.3.1. Call for nominations for the BMWP members - extended till 28 February 2023

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

Nominations should be sent to the Agency **by 28 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. Action: For information 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

- Draft minutes for the NcWP meeting held virtually on 11 and 18 January 2023
- Draft agenda for the NcWP meeting to be held virtually on 14-15 February 2023

Action: For information

3.1.2. CMDh questions to NcWP on new nitrosamines

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

- N-nitroso-2,6-pipecoloxilidide
- N-nitroso-valaciclovir (impurity C)

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

Action: For adoption

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

Chairs: Sonja Beken, Sarah Adler-Flindt

3.2.1. Agenda and minutes

- Draft minutes for the 3RsWP meeting held virtually on 23 November 2022
- Draft agenda for the 2-day face-to-face 3RsWP plenary meeting on 28 February and 1 March 2023. The first day will be dedicated to a targeted stakeholder meeting to be held in a virtual setting.

Action: For information

3.2.2. 3RsWP expert attendance to EDQM-EPAA conference on pyrogenicity testing

This international conference jointly hosted by the EDQM, Council of Europe, and the European Partnership for Alternative Approaches to Animal Testing (EPAA), European Commission, will shed light on how the European Pharmacopoeia is, after 50 years of loyal – but animal-based – service, withdrawing the rabbit pyrogen test (RPT) from its texts. Scientific progress has delivered new and humane methods (the in vitro monocyte-activation test, or MAT) and, together with the EPAA, the EDQM wishes to present how the transition to the MAT and the challenges encountered in the process are being successfully managed in the pharmaceutical world.

Sonja Beken, chair of the 3RsWP, will be delivering the 3RsWP regulatory perspective on the pyrogenicity testing based on the strategic vision towards the regulatory acceptance of new alternative methods from the EMA Regulatory Science strategy 2025 and 3RsWP 3-year workplan which has already been endorsed by CHMP.

Action: For Endorsment

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Nomination of Methodology ESEC experts

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

Action: For endorsement

4.1.2. Nomination of Methodology Modelling & Simulation Operational Expert Group (MSOEG)

Nomination by MWP of the experts to enter the Modelling and Simulation Operational Expert Group (MSOEG).

Please send your nominations to the Agency by **8 February 2023**.

Action: For endorsement

4.1.3. Nomination of Methodology Biostatistics Operational Expert Group (BSOEG)

Nomination by MWP of the experts to Biostatistics Operational Expert Group (BSOEG).

Please send your nominations to the Agency by **8 February 2023**.

Action: For endorsement

4.1.4. Agenda and Minutes

- Final Agenda and Minutes for MWP meeting held by teleconference on 19 January 2023

Action: For information

4.2. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

4.2.1. MWP (PKWP) response to CMDh questions on lapatinib product-specific bioequivalence guidance (PSBGL)

CMDh sent a query for MWP (PKWP) input in November 2022 in the context of two ongoing MAAs via DCP for lapatinib containing products regarding the acceptability of the supporting bioequivalence studies and the lapatinib PSBGL.

PKWP (MWP) has discussed the issue in the meantime and agreed a response.

Action: For adoption

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. Agenda and Minutes

- Final Agenda and Minutes for CVS WP meeting held by teleconference on 2 February 2023

Action: For information

5.2.2. Nomination of Cardiovascular ESEC experts

Update on the ongoing call of experts to enter the Cardiovascular European Specialised Expert Community (ESEC).

Action: For endorsement

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

Nomination(s) received

Action: For endorsement

5.3.2. Proposed Oncology ESEC webinar on AML (Acute Myeloid Leukaemia)

3rd Oncology ESEC webinar is proposed on AML following the same organisation of the 2 webinars. PDCO representative will also be invited together with external paediatric experts. Tentative date of the webinar: 17-03-2023.

Action: For endorsement

5.3.3. Agenda and Minutes

- Agenda of the ONCWP meeting held by teleconference on 13 January 2023
- Minutes of the ONCWP meeting held by teleconference on 25 November 2022

Action: For information

5.4. Rheumatology and Immunology Working Party (RIWP)

Chair: Caroline Auriche Benichou

5.4.1. Call for nominations for the RIWP Vice-Chair

Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Nominations should be sent to the Agency **by 13 March 2023**. Proposed candidates must be already members of the RIWP.

Elections will take place at the March 2023 CHMP Plenary meeting.

Action: For endorsement

5.5. Action: For information 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: Juan Garcia Burgos (EMA)

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

6.1.1. Agenda and minutes

- Agenda from the PCWP and HCPWP meeting to be held on 03 March 2023
- Minutes from the PCWP and HCPWP meeting held virtually on 15 November 2022

Action: for information

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 06-09 February 2023.

Action: For information

8.2.2. CMDh proposal regarding mutagenic impurity in products containing Tenofovir Disoproxil

Proposed letter to all MAHs.

Action: For endorsement

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. Readers Guidance template

Introduction of tick boxes for RWD/RWE as possibly included in the product dossier and possible request for research questions with the support of EMA.

See also 12.2.

CHMP: Johann Lodewijk Hillege

Action: For adoption

9.2.2. CHMP co-opted membership

Launch of a call for nominations for a CHMP co-opted member with biostatistics/clinical trial methodology expertise.

Nominations may include persons who have been nominated as alternates in the Committee. Nominations should be accompanied by a recommendation specifying the competence. Where possible, a detailed CV to support the specific expertise required should be included, although reference may also be made to the information held by the EMA with respect to the European Expert List, which includes information on areas of expertise and a CV for each expert.

Nominations should be sent to the CHMP secretariat by **15 February 2022.** The election is planned during the February 2023 plenary meeting.

Nomination(s) received

Action: For information

9.2.3. CHMP meeting calendar

Logistics of 3-day remote CHMP plenary meeting in April 2023.

Action: For information

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

Final 5-year update of informal working instructions for MNATs.

CHMP: Outi Mäki-Ikola

Action: For adoption

9.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

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

10.1.2. Agenda and Table of Decisions

- Agenda from 06-09 February 2023 meeting held by Webex
- Draft Table of Decisions from 06-09 February 2023 meeting held by Webex

Action: For information

10.1.3. Revised SAWP mandate

SAWP mandate, revision 17

Action: For adoption

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 22 February 2023

Action: For adoption

10.2.2. ITF meeting

Meeting date: 02 March 2023

Action: For adoption

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

11.2. glofitamab - Orphan - EMEA/H/C/005751; epcoritamab - Orphan - EMEA/H/C/005985

Roche Registration GmbH; treatment of diffuse large B-cell lymphoma;

AbbVie Deutschland GmbH & Co. KG; treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Scope: Pre-discussion in view of the adoption of d180 LOI at February plenary

Action: For discussion

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

12.2. Real World Evidence update, including DARWIN EU

This is a quarterly progress update on RWE and the establishment of DARWIN EU. The objective of the presentation is to inform the CHMP of the finalisation of year 1 studies conducted via DARWIN EU, prioritisation and selection of studies and data partners for year 2, and the RWE experience report and new RWE MMD folder.

Action: For information

12.3. OPEN experts – phase 2

Discuss and agree on the process and products to be considered for the expansion of the OPEN scope.

Action: For adoption

12.4. Call for membership of the CHMP drafting group on patient experience data

As a follow-up from the multistakeholder workshop on patient experience data in medicines development and regulatory decision-making that took place in September 2022, the outcomes defined that the Agency will elaborate a reflection paper to provide advice on the best EU approach to generate and collect patient experience data. This action is also included in the CHMP workplan 2023 to be adopted this month.

We are therefore seeking a CHMP representative to take part in the drafting of the reflection paper. The work would take place in 2023, with the aim to have a draft of the paper circulated for public consultation by the end of the year.

Action: For discussion

12.5. Update on collaboration with HTA-bodies

This topic is part of the CHMP Work Plan 2023.

Action: For information

12.6. CHMP strategic, review and learning meeting under the Swedish presidency of the Council of the European Union

Information on the SRLM under the Swedish presidency for the 1st part of 2023.

CHMP: Kristina Dunder

Action: For information