12 May 2023
EMA/CHMP/194942/2023 Rev.1
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda 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

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 15 May 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 May 2023 PROM minutes.

1.2. Adoption of agenda

CHMP 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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).

Action: For endorsement

5.3.2. ONCWP Work plan – Priorities 2023

Updated 3-years rolling plan with priorities for 2023.

Action: For endorsement

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

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

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

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

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

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

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. 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

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

Action: For information

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 22 May 2023

Action: For adoption

10.2.2. ITF meeting

Meeting date: 24 May 2023

Action: For adoption

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

11.2. Preparation of oncology product-related discussions

CHMP: Harald Enzmann

Action: For discussion

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.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

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

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

12.4. Business Pipeline Report

Business Pipeline – 3-year forecast report.

Action: For information

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