27 October 2022
EMA/CHMP/832725/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 31 October 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

31 October 2022, 09:00–16:00, virtual meeting/room 08-A

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.

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

1.2. Adoption of agenda

CHMP PROM agenda for 31 October 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 31 October 2022 meeting will be adopted at the November 2022 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz, Sean Barry

2.1.1. Agenda and minutes

- Agenda from the BWP meeting to be held virtually on 3-4 November 2022
- Minutes from the BWP meeting held virtually on 5-7 September 2022

Action: For information

2.1.2. Reflection paper on criteria to be considered for the evaluation of new active substance (NAS) status of biological substances

A drafting group has been working on this draft reflection paper which is presented for adoption. Following CHMP adoption, the draft reflection paper will be published for a 6-month public consultation.

CHMP: Sol Ruiz

Action: For adoption

2.2. Quality Working Party (QWP)

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

2.2.1. Agenda

- Final Agenda and minutes for QWP-CT meeting held by teleconference on 5 October 2022

Action: For information

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz, Niklas Ekman

2.3.1. Agenda and minutes

- Agenda from the BMWP meeting held virtually on 21 September 2022
- Minutes from the BMWP meeting held virtually on 21 September 2022

Action: For information

2.4. Quality Innovation Group (QIG)

Chair(s): vacant

2.4.1. Nomination of Chair of the Quality Innovation Group (QIG)

Nomination of a chair of the QIG as recommended by the Quality Domain Governance following the implementation of the new working party model.

Action: For adoption

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 face-to-face on 4-5 October 2022, including annual stakeholders meeting
- Draft agenda for the NcWP meeting to be virtually on 3-4 November 2022
- Draft minutes for the EMA/FDA non-clinical oncology cluster teleconference held virtually on 18 October 2022

Action: For information

3.1.2. CMDh questions to NcWP on new nitrosamines

CMDh requests that the NcWP determines the acceptable intake for the following nitrosamines based on lifetime daily exposure including information on the points of departure and methodology used.

- N-nitrosophenylephrine
- N-nitrosopramipexole

- N-Nitrosoreboxetine

Action: For adoption

3.1.3. NcWP responses to CMDh on new nitrosamines

Following CMDh's request the NcWP determined the acceptable intake for the following nitrosamines based on lifetime daily exposure including information on the points of departure and methodology used.

- N-nitroso-paroxetine
- N-nitroso-diethanolamine
- N-nitroso-mefenamic acid

Action: For adoption

3.1.4. NcWP responses to CHMP on new nitrosamines

Following CHMP request the NcWP determined the acceptable intake for a new nitrosamine based on lifetime daily exposure including information on the points of departure and methodology used.

- nitrosamine impurity present in a new pharmaceutical form

Action: For adoption

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

Chairs: Sonja Beken, Sarah Adler-Flindt

3.2.1. Agenda

- Draft agenda of the first 3RsWP meeting to be held virtually on 23 November 2022

Action: For information

3.2.2. EMA/CHMP representation

- Request from 3RsWP chair, Sonja Beken, to represent EMA at the EPAA (European Partnership for Alternative Approaches to Animal Testing) Annual Conference 2022: Accelerating the Transition to Animal-Free, Sustainable Innovation scheduled on 15 November 2022 in Brussels
- Request from 3RsWP chair, Sonja Beken, to represent EMA at the EPAA December Steering Committee Meeting on 2 December 2022

Sonja Beken will be delivering EMA strategic vision towards the regulatory acceptance of new alternative methods based on the EMA Regulatory Science strategy 2025 and 3RsWP 3-year workplan which has already been endorsed by CHMP. The request has been approved by EMA management.

Action: For endorsement

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Agenda and minutes

- Final agendas & minutes for MWP meetings held by teleconference on 8 and 22 September and F2F meeting held on 10-11 October 2022

Action: For information

4.1.2. Concept Paper on Platform trials

This concept paper sets out the objectives and strategy for the development of a Reflection paper on Platform trials. It will complement instead of replacing existing (Points to consider on multiplicity issues in clinical trials, CPMP/EWP/908/99) or upcoming documents (Guideline on multiplicity issues in clinical trials, EMA/CHMP/44762/2017). The aim of the reflection paper is to clarify the regulatory position on e.g. multiplicity and adaptive designs in platform trials, and to introduce a consolidated terminology. The concept paper is proposed for public consultation until 31 January 2023.

MWP Chair: Kit Roes

Action: For adoption

4.2. Biostatistics Operational Expert Group (BOEG)

No topics

4.3. Modelling and Simulation Operational Expert Group (MSOEG)

No topics

4.4. Real World Data Operational Expert Group (RWDOEG)

No topics

4.5. 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. Agenda and minutes

- Agenda from the CVS WP meeting held virtually on 22 September 2022
- Minutes from the CVS WP meeting held virtually on 22 September 2022

Action: For information

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis

5.3.1. Agenda and minutes

- Agenda from the ONCWP meeting held virtually on 19 October 2022
- Minutes from the ONCWP meeting held virtually on 13 July 2022

Action: For information

5.3.2. Nomination of Oncology ESEC experts

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

Action: For endorsement

5.3.3. Update on Oncology ESEC activities

EUNTC Webinar – Challenges in drug development, regulation and clinical practice in DLBCL - Friday 25 November, 14.00-15.30.

Action: For information

5.4. Rheumatology and Immunology Working Party (RIWP)

Chair(s): vacant

5.4.1. Call for nomination for an expert as member of the CHMP Rheumatology and Immunology Working Party (RIWP)

Following the leave of a RIWP member, a call for nomination of a new member for the RIWP is launched. Nominations should be sent to the Agency **by 25 November 2022**.
Endorsement of the new member by the CHMP is planned to take place at December PROM.

Action: For endorsement

5.4.2. Agenda and minutes

- Agenda and minutes from the RIWP meeting held virtually on 17 October 2022

Action: For information

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. VWP 3-year workplan

The 3-year VWP workplan was endorsed by the VWP on 28 September 2022.

Action: For adoption

5.7. Haematology Working Party (HaemWP)

Chairs: Daniela Philadelphy

5.7.1. Agenda

- Draft agenda of the Blood cluster to take place on the 4 November 2022

Action: For information

5.7.2. HaemWP 3-year workplan

The 3-year HaemWP workplan was endorsed by the HaemWP on 27 October 2022.

Action: For adoption

5.7.3. Nomination of new member

Nomination of a new member to replace Viktoriia Starokozhko.

Action: For adoption

5.8. Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEGs)

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 15 November 2022
- Minutes from the PCWP and HCPWP meeting held virtually on 22 September 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 23 October – 26 October 2022

Action: For information

8.2.2. COMP: Conditions for orphan designation in Inherited retinal diseases

Chair: Violeta Stoyanova-Beninska

Update on finalised recommendation for designating orphan conditions in Inherited Retinal Diseases, following Expert consultation and COMP consideration. A three-pronged approach will be available to the COMP including, a broad-based approach, gene-specific approach or isolated conditions where appropriate.

Action: For information

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

9.1.1. Reflection on Legal Basis under Article 10(3) – Hybrid Applications

Reflection on the application of Legal Basis under Article 10(3) – Hybrid Applications for consideration as general learning.

CHMP: Kristina Dunder, Martina Weise, Andrea Laslop

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. Onboarding Programme for CHMP members and alternates

Proposed programme for on-boarding new CHMP members, alternates or co-opted members to the work of the CHMP.

Action: For discussion

9.2.3. CHMP face-to-face meetings 2023

Plan of the CHMP plenary FtF and hybrid meetings for 2023.

Action: For information

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 the 24-27 October 2022 meeting held by Webex
- Draft Table of Decisions from the 24-27 October 2022 meeting held by Webex

Action: For information

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 09 November 2022

Action: For adoption

10.2.2. ITF meeting

Meeting date: 14 November 2022

Action: For adoption

10.2.3. ITF meeting

Meeting date: 18 November 2022

Action: For adoption

10.2.4. ITF meeting

Meeting date: 24 November 2022

Action: For adoption

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

11.2. COVID-19 ongoing and upcoming procedures

List of currently ongoing and upcoming (imminently, i.e. expected within the next 2 months) applications for COVID-19 vaccines and therapeutics.

Action: For information

11.3. Report on eligibility

Ad-hoc report on eligibility to the centralised procedure

Action: For adoption

11.4. Zejula - niraparib - EMEA/H/C/004249/II/0033, Orphan

GlaxoSmithKline (Ireland) Limited

Rapporteur: Ingrid Wang, PRAC Rapporteur: Jan Neuhauser

Scope: Update on the status of this application. "Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning and add MDS/AML to the list of adverse

drug reactions (ADRs) with frequency common and update of section 5.1 based on final results from NOVA study (213356); this is a Phase 3 Randomized Double-Blind Trial of Maintenance with Niraparib Versus Placebo in Patients with Platinum Sensitive Ovarian Cancer. In addition, the MAH also took this opportunity to update sections 4.4 and 4.6 to update information on contraception based on EMA and CTFG recommendations. The Package Leaflet is updated accordingly. The RMP version 6 has also been submitted."

Action: For information

Request for Supplementary Information adopted on 19.05.2022, 10.02.2022.

12. Any Other Business

12.1. Rapporteurships

Update

Action: For information

12.2. Introduction to the DARWIN EU Coordination Centre

This is a quarterly progress update on the establishment of the DARWIN EU Coordination Centre. The objective of the presentation will be to introduce the Coordination Centre representatives and continue raising awareness about DARWIN EU and Real World Evidence. CHMP members will also have an opportunity to ask question to the Coordination Centre representatives.

Action: For information

12.3. Public Consultation on Good Practice Guide and Data Quality Framework

This is a presentation on the following documents: The Good Practice Guide for the use of the Metadata Catalogue and the Data Quality Framework. These two documents are now available for public consultation on the EMA website and CHMP members can familiarise with them and raise any questions. The Good Practice Guide provides a guide to help regulators, data holders, and other interested stakeholders to use the catalogue which will replace the currently available ENCePP catalogue. The Data Quality Framework, on the other side, aims at setting out the principles to assess and measure the data quality across multiple use cases applicable to the use of data within medicine regulation in the European Network.

Action: For information

12.4. Consultation procedure on Companion Diagnostic (CDx) - Proposal for a CDx peer group

This proposal is to set up a CHMP Peer group on companion diagnostics to review assessment reports, identify procedure overarching issues and isolate general principles.

CHMP: Paula Boudewina van Hennik

Action: For discussion