EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 October 2022
EMA/CHMP/855932/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP)

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

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

31 October 2022, 09:00–16:30, 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.

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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

The CHMP adopted the 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

The CHMP noted the agenda and the minutes.

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

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

The CHMP adopted the Reflection paper on criteria to be considered for the evaluation of new active substance (NAS) status of biological substances for public consultation.

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

The CHMP noted the agenda.

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

The CHMP noted the agenda and the minutes.

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

The CHMP endorsed the Nomination of Marcel Hoefnagel as chair of the QIG as recommended by the Quality Domain Governance.

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

The CHMP noted the agenda and the minutes.

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

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

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

The CHMP adopted the NcWP responses to CMDh on new nitrosamines.

3.1.4. NcWP responses to CHMP on new nitrosamines

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

- nitrosamine impurity present in a new pharmaceutical

Action: For adoption

The CHMP adopted the NcWP responses to CHMP on new nitrosamine.

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

The CHMP noted the agenda and the minutes.

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

The CHMP endorsed Sonja Beken to represent CHMP at the events stated above.

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

The CHMP noted the agenda and the minutes.

4.1.2. Concept Paper on Platform trials

This concept paper set 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

The CHMP adopted the Concept Paper on Platform trials for public consultation.

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

The CHMP noted the agenda and the minutes.

5.3. Oncology Working Party (ONCWP)

Chairs: 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

The CHMP noted the agenda and the minutes.

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

The CHMP endorsed the Nomination by ONCWP of expert to enter the Oncology European Specialised Expert Community (ESEC).

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

The CHMP noted update on Oncology ESEC activities.

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

The CHMP endorsed the call for nomination for a member of the CHMP Rheumatology and Immunology Working Party (RIWP).

5.4.2. Agenda and minutes

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

Action: For information

The CHMP noted the agenda and the minutes.

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

This topic was not covered and was postponed.

5.7. Haematology Working Party (HaemWP)

Chairs: Daniela Philadelphy

5.7.1. Agenda

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

Action: For information

The CHMP noted the agenda.

5.7.2. HaemWP 3-year workplan

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

Action: For adoption

The CHMP adopted the HaemWP 3-year workplan.

5.7.3. Nomination of new member

Nomination of a new member to replace Viktoriia Starokozhko.

Action: For adoption

The CHMP adopted the Nomination of Ita Walsh (previous BPWP) to replace Viktoriia Starokozhko as new member of the HaemWP.

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

The CHMP noted the agenda and the minutes.

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

The CHMP noted the summary of recommendations and advice.

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

CHMP noted recommendations for designating orphan conditions in Inherited Retinal Dystrophies.

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

CHMP noted the reflection on the Legal Basis under Article 10(3) – Hybrid Applications and endorsed proposed general learnings.

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. 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

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

9.2.3. CHMP face-to-face meetings 2023

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

Action: For information

CHMP noted the Plan of the CHMP plenary face to face and hybrid meetings for 2023.

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

CHMP noted the appointment of CHMP peer review for Scientific Advice.

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

The CHMP noted the agenda and the table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 09 November 2022

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 14 November 2022

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 18 November 2022

Action: For adoption

The CHMP endorsed the meeting.

10.2.4. ITF meeting

Meeting date: 24 November 2022

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. 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

The CHMP noted the COVID-19 ongoing and upcoming procedures.

11.3. Report on eligibility

Ad-hoc report on eligibility to the centralised procedure

Action: For adoption

The CHMP adopted the Ad-hoc report on eligibility to the centralised procedure.

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.

The CHMP noted the status of this application.

12. Any Other Business

12.1. Rapporteurships

Update

Action: For information

The CHMP noted the update.

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

CHMP noted the establishment of the DARWIN EU Coordination Centre and its structure and mission.

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

CHMP noted the Public Consultation on the Good Practice Guide and Data Quality Framework.

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

The CHMP endorsed the proposal to create a CDx peer group for Consultation procedure on Companion Diagnostic.

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	
Andrea Laslop	Member	Austria	No interests declared	
Daniela Philadelphy	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	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:	Draft Agenda of November CHMP plenary meeting: Sogroya - somapacitan - 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	
Konstantina Alexopoulou	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Armando Genazzani	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Paula Boudewina van Hennik	Alternate	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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
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	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Blanca Garcia-Ochoa	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Christian Gartner	Co-opted member	Austria	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Kristina Bech Jensen	Expert	Denmark	No interests declared	
Christian B. (Kit) Roes	Expert	Netherlands	No participation in discussion, final deliberations and voting on:	Draft Agenda of November CHMP plenary meeting: sodium phenylbutyrate / ursodoxicoltaurine - EMEA/H/C/005901
Sabine Mayrhofer	Expert	Germany	No interests declared	
Irene Bachmann	Expert	Germany	No interests declared	
Maria Victoria Tudanca Pacios	Expert	Spain	No restrictions applicable to this meeting	
Eva Malikova	Expert	Slovakia	No interests declared	
Mats Ökvist	Expert	Norway		
Hatice Canan Bayar	Expert	Norway	No interests declared	
Luca Santi	Expert	Italy	No restrictions applicable to this meeting	
Meeting run with support from relevant EMA staff.				

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