11 November 2021
EMA/CHMP/620080/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 03 November 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

03 November 2021, 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.

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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 03 November 2021 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of 03 November 2021 meeting will be adopted at the November 2021 CHMP plenary

2. Non therapeutic-area-specific working parties

2.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

No topics

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by teleconference on 6-8 September 2021
- Draft agenda for BWP meeting to be held by teleconference on 3-5 November 2021

Action: For information

CHMP noted the agenda and minutes.

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Minutes

- Final minutes from QWP Core Team meeting held by teleconference on 6 October 2021

Action: For information

CHMP noted the minutes.

2.4. Safety Working Party (SWP)

Chair: Susanne Brendler-Schwaab

2.4.1. Minutes

- Final minutes from SWP meeting held by teleconference on 13 September 2021

Action: For information

CHMP noted the minutes.

2.4.2. Chloramphenicol containing eye drops and revision of the Annex of the guideline on excipients labelling for boric acid

Minor update on the Annex of the EMA excipient guideline for boric acid and borates.

Action: For adoption

CHMP adopted the update on the Annex of the EMA excipient guideline for boric acid and borates.

2.4.3. CMDh request on the AI for the nitrosamine N-Nitrosodi-n-propylamine (NDPA)

CMDh question to SWP to determine the acceptable intake for nitrosamine N-Nitrosodi-n-propylamine (NDPA) based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

CHMP adopted the CMDh question to SWP to determine the acceptable intake for nitrosamine N-Nitrosodi-n-propylamine (NDPA) based on lifetime daily exposure including information on the points of departure and methodology used. The answer is expected for silent adoption during the November CHMP plenary.

2.4.4. CHMP question to SWP for a new nitrosamine impurity in Rasagilene

CHMP question to SWP to determine the acceptable intake for N-nitroso rasagilene based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

CHMP adopted the CMDh question to SWP to determine acceptable intake for N-nitroso rasagilene based on lifetime daily exposure including information on the points of departure and methodology used.

2.4.5. CMDh request on the AI for the nitrosamine N-nitrosotrimetazidine and N-nitroso-piperazine

CMDh question to SWP to determine the acceptable intake for N-nitrosotrimetazidine and N-nitroso-piperazine based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

CHMP adopted the CMDh question to SWP to determine acceptable intake for N-nitrosotrimetazidine and N-nitroso-piperazine based on lifetime daily exposure including information on the points of departure and methodology used.

2.4.6. Call for nomination for the election of the SWP vice chair

Susanne Brendler-Schwaab (DE) left her position as SWP vice-chair to undertake the SWP chair position following election at the October 2021 CHMP meeting. Nominations for a new SWP vice-chair should be sent together with a CV and a brief motivation letter by 30 November 2021.

Action: For information

CHMP noted the call for nomination.

2.5. Biosimilar Medicinal Product Working Party (BMWP)

No topics

2.6. Biostatistics Working Party (BSWP)

No topics

2.7. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

2.7.1. Agenda and minutes

- Agenda of the MSWP meeting held by Webex on 20 October 2021.
- Draft Table of Decisions of the MSWP meeting held by Webex on 20 October 2021.

Action: For information

CHMP noted the agenda and the table of decisions.

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

2.9.1. Product-specific guidelines

Draft product-specific guidelines for public consultation for a 3-month public consultation.

- Enzalutamide product-specific bioequivalence guidance (EMA/CHMP/371467/2021)
- Olaparib product-specific bioequivalence guidance (EMA/CHMP/371470/2021)
- Ibrutinib product-specific bioequivalence guidance (EMA/CHMP/371445/2021)

Action: For adoption

CHMP adopted the draft Enzalutamide product-specific bioequivalence guidance (EMA/CHMP/371467/2021) for a 3-month public consultation.

CHMP adopted the draft Olaparib name product-specific bioequivalence guidance (EMA/CHMP/371470/2021) for a 3-month public consultation.

CHMP adopted the draft Ibrutinib product-specific bioequivalence guidance (EMA/CHMP/371445/2021) for a 3-month public consultation.

2.9.2. CMDh question to CHMP (PKWP) on ibuprofen oral lyophilisate versus film coated tablets and oral suspension

Request from CMDh for PKWP input relating to the ibuprofen product-specific guideline.

Action: For adoption

CHMP adopted the CMDh question to CHMP (PKWP) on ibuprofen oral lyophilisate versus film coated tablets and oral suspension with no further comments.

3. Therapeutic-area-specific working parties and SAGs

3.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

3.1.1. Agenda and minutes

- Final minutes of the Blood cluster TC held on 4 June 2021
- Agenda of the Blood cluster held on 29 October 2021
- Final minutes of the meeting held with the plasma industry associations (PPTA/IPFA) on 10 June 2021

Action: For information

CHMP noted the agenda and minutes.

3.2. Central Nervous System Working Party (CNSWP)

No topics

3.3. Cardiovascular Working Party (CVSWP)

No topics

3.4. Infectious Diseases Working Party (IDWP)

No topics

3.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

3.5.1. Minutes

- Agenda of the ONCWP meeting held on 15 October 2021
- Final minutes of ONCWP meeting held via Webex on 22 September 2021

Action: For information

CHMP noted the agenda and minutes.

3.6. Rheumatology/Immunology Working Party (RIWP)

No topics

3.7. Vaccines Working Party (VWP)

No topics

3.8. Scientific Advisory Groups (SAGs)

No topics

4. Drafting groups

4.1. Excipients Drafting Group

No topics

4.2. Gastroenterology Drafting Group (GDG)

No topics

4.3. Geriatric Expert Group (GEG)

No topics

4.4. Radiopharmaceuticals Drafting Group (RadDG)

No topics

4.5. Respiratory Drafting Group (RDG)

No topics

5. Harmonisation and consistency groups

5.1. International Council on Harmonisation (ICH)

5.1.1. Nomination of experts for ICH groups

ICH E6 (R3) Good clinical practice. The EMA proposes that the current Regulatory Chair role for this ICH WG is transitioned by May 2022.

Action: For information

CHMP noted transition of the Regulatory Chair role for ICH E6 (R3) Good clinical practice by May 2022.

5.2. Guideline Consistency Group (GCG)

No topics

5.3. Summary of product characteristics Advisory Group

No topics

6. Joint groups and collaboration with other Scientific committees

6.1. Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of medicinal products (J 3RsWG)

No topics

6.2. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

No topics

6.3. Collaboration with other Scientific committees

6.3.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 25-28 October 2021.

Action: For information

The CHMP noted the Summary of recommendations and advice.

7. Regulatory / Organisational matters

7.1. Regulatory Issues / new legislation

7.1.1. Update on the Companion Diagnostics (CDx) consultation procedure

To provide an update on interactions of CHMP-CAT-EMA experts with Notified Bodies (NBs) to develop the NB consultation procedure on CDx suitability with EMA. Comments to be provided by 17 November 2021.

Action: For discussion

CHMP noted the update on the Companion Diagnostics (CDx) consultation procedure with further comments/question on which situations NB will consult EMA or national competent authorities. It is clarified that Medicinal products (MPs) falling under mandatory scope of the CP will need a consultation on the CDx with EMA. For other MPs, the consultation should be with the competent authority authorising or reviewing the MP application of concern for use with the CDx. Therefore, for all products submitted and/or authorised through the optional scope of the CP, the EMA will also have to be consulted for the CDx consultation.

7.2. CHMP organisation / templates

7.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

7.2.2. CHMP endorsed the proposed learnings. CHMP Co-Rapporteur Critique

Update on Co-Rapporteur critique review.

Action: For adoption

7.2.3. CHMP noted the experience on the implementation of Co-Rapp Critique in initial marketing authorisation applications. CHMP PROM dates for 2022-2024

Proposed dates for the CHMP PROM meetings for 2022-2024 to be reviewed by the CHMP. Comments are welcome and should be sent to the Agency by 5th of November.

Action: For information

CHMP noted the proposed PROM dates for 2022-2024.

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Appointment of CHMP peer review for SA

Action: For information

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

8.1.2. SAWP Rules of Procedure

Revised rules of procedure of SAWP for adoption by the CHMP.

Action: For adoption

CHMP endorsed the revised SAWP rules of procedure.

8.1.3. Nomination of new member and alternate to the Scientific Advice Working Party

Nomination of new SAWP member and alternate

The required areas of expertise: Cardiovascular, Endocrinology, Diabetes, Nephrology, Internal medicine, Immunology, Clinical pharmacology.

Additional nomination of alternate member to Fernando de Andrés-Trelles to fill the vacant position from the departure of Blanca García-Ochoa Martín.

Action: For endorsement

CHMP endorsed the nomination of the new SAWP member Rosalía Ruano Camps and alternate Bruno Delafont.

CHMP endorsed the nomination of Ivana Haunerová as alternate member to Fernando de Andrés-Trelles to fill the vacant position from the departure of Blanca García-Ochoa Martín.

8.1.4. Call for nominations for Scientific Advice Chair

The mandate of Scientific Advice Working Party Chair Anja Schiel will expire on 28 February 2022.

Nominations should be sent to the Agency by 3 December 2021.

Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Elections will take place at the 13–16 December 2021 CHMP Plenary meeting.

Action: For information

CHMP noted the call for nomination.

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 12th November 2021

Action: For adoption

CHMP endorsed the meeting.

8.2.2. ITF meeting

Meeting date: 15th November 2021

Action: For adoption

CHMP endorsed the meeting.

8.2.3. ITF meeting

Meeting date: 16th November 2021

Action; For adoption

CHMP endorsed the meeting.

8.2.4. ITF meeting

Meeting date: 22nd November 2021

Action: For adoption

CHMP endorsed the meeting.

8.2.5. ITF meeting

Meeting date: 24th November 2021

Action: For adoption

CHMP endorsed the meeting.

9. Product related topics

9.1.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

The CHMP chair flagged some procedures on the agenda of the upcoming plenary.

9.1.2. 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

CHMP noted the Covid-19 ongoing and upcoming procedures.

10. Any Other Business

10.1.1. Call for interest for nomination of CHMP members to join Advisory Group on Raw Data and Lifecycle Regulatory Submissions

Call for interest for nomination of CHMP members to join Advisory Group on Raw Data in order to assist the design of the future proof-of-concept raw data pilot.

EMA's Lifecycle Regulatory Submissions Raw Data project is focusing on utilising raw data to generate evidence for better and more efficient regulatory decision making.

This project is part of the Data Analytics Programme also known as the Agency's vehicle for evolving to data-driven medicines regulation and constitutes one of the priority recommendations of the EMA-HMA Big Data Taskforce.

Interested members should contact the Agency by 10 November 2021.

Action: For information

CHMP noted the call for interest for nomination.

10.1.2. Call for interest for nomination of CHMP members to join the subgroup "GCP inspection outcomes in support of B/R evaluation".

Call for interest for nomination of CHMP members to join the subgroup "GCP inspection outcomes in support of B/R evaluation".

The purpose of this project is to review current inspection procedures to enhance Inspector assessor information flow and understanding (Inspection request and findings) and consider appropriateness of the current guidance "Points to consider on GCP inspection findings and the benefit-risk balance".

Interested members should contact directly by 12 November 2021.

Action: For information

CHMP noted the call for interest for nomination.

10.1.3. Real World Evidence initiatives and planning for the future

To present the initiatives that EMA and the network are undertaking to strengthening decision-making with the use of RWE. To update on the pilot that has started with the Scientific Advice Working Party and to introduce the pilot aimed to be started with CHMP next year.

Action: For information

CHMP noted the update on Real World Evidence initiatives and planning for the future. The training curricula has been adopted, and in 2022 the delivery of training will be rolled-out to the EU Regulatory Network including through the engagement of external training partners.

10.1.4. Routine GCP inspections

No more Routine GCP inspections were requested since the start of the Covid-19 pandemic due to travel restrictions and lack of resources. Proposal to re-start requesting routine GCP inspections. Pilot phase to start in November.

Action: For information

CHMP noted update on the pilot to re-start requesting routine GCP inspections.

10.1.5. OPEN Experts pilot review

The OPEN Pilot (Opening our Procedures at EMA to Non-EU authorities), started in December 2020 to allow experts from 5 Non-EU Regulatory Authorities (Australia – TGA, Canada – Health Canada, Japan – MHLW/PMDA, Switzerland – Swissmedic, and WHO) to attend and contribute to EMA's CHMP and ETF meetings. A survey will be sent to the Committees, Applicants/MAHs, Non-EU regulators and EMA to review this initiative.

Action: For discussion

CHMP noted OPEN Experts pilot review project and agreed for the survey to target all CHMP/ETF members.

11. 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	
Ilko Getov	Member	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Ondřej Slanař	Member	Czechia	No restrictions applicable to this meeting	
Tomas Radimersky	Alternate	Czechia	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Jan Sjöberg	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No participation in final	COVID-19 vaccines

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
			deliberations and voting on	
Martine Trauffler	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Ingrid Wang	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
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	
Francisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	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	
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	
Nora Cascante Estepa	Expert - via WebEx*	Germany	No interests declared	
Sabine Mayrhofer	Expert - via WebEx*	Germany	No interests declared	
Irene Bachmann	Expert - via WebEx*	Germany	No interests declared	
Susanne Høpner Rasmussen	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Meera Varma	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Deirdre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Susanne Brendler-Schwaab	Expert - via WebEx*	Germany	No interests declared	
Dominique Masset	Expert - via WebEx*	France	No interests declared	
Maria Grazia Evandri	Expert - via WebEx*	Italy	No interests declared	
Carolien Versantvoort	Expert - via WebEx*	Netherlands	No interests declared	
Alfredo García-Arieta	Expert - via WebEx*	Spain	No interests declared	
Yseult Brun	Expert - via WebEx*	France	No interests declared	
Anja Schiel	Expert - via WebEx*	Norway	No interests declared	
Helene Blok	Expert - via WebEx*	Netherlands	No interests declared	
Paolo Foggi	Expert - via WebEx*	Italy	No interests declared	
Paula Contreras Alarcón	Expert - via WebEx*	Spain	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert - via Webex*	Spain	No restrictions applicable to this meeting	
Eva Maria Pérez Sacristán	Expert - via WebEx*	Spain	No interests declared	
Joerg Engelbergs	Expert - via WebEx*	Germany	No interests declared	
Adriana Ammassari	Expert - via WebEx*	Italy	No interests declared	
Thalia Marie Estrup Blicher	Expert - via WebEx*	Denmark	No participation in discussion, final deliberations and voting on	semaglutide - EMEA/H/C/005422 semaglutide - EMEA/H/C/004174/X/0021
Meeting run with the help of EMA staff				

*Experts were evaluated against the product(s) they have been invited to talk about