24 February 2022
EMA/CHMP/97882/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 14 February 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

14 February 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 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

Table of contents

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 the 14 February 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 14 February 2022 meeting will be adopted at the February 2022 CHMP plenary.

2. Non therapeutic-area-specific working parties

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

PCWP: Co-chair: Kaisa Immonen, Co-chair: Juan Garcia Burgos (EMA)

HCPWP: Co-chair: Ulrich Jaeger, Co-chair: Juan Garcia Burgos (EMA)

2.1.1. Agenda and meeting summary

- Meeting Summary of the PCWP/HCPWP joint meeting with all eligible organisations held by Webex on 24 November 2021
- Draft Agenda of the upcoming PCWP/HCPWP joint meeting to be held by Webex 2 and 3 March 2022

Action: For information

CHMP noted the agenda and the meeting summary.

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Agenda and minutes

- Final minutes for the BWP meeting held by Webex on 6-8 December 2021
- Draft agenda for the BWP meeting to be held by Webex on 14-16 February 2022

Action: For information

CHMP noted the agenda and the 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 19 January 2022

Action: For information

CHMP noted the minutes.

2.4. Safety Working Party (SWP)

Chairs: Susanne Brendler-Schwaab/Günter Waxenecker

2.4.1. Minutes

- Minutes from SWP meeting held by Webex on 13 December 2021

Action: For information

CHMP noted the minutes.

2.4.2. CMDh Question to SWP regarding medicinal products with genotoxic potential

SWP answered questions from CMDh in 2020 on how to deal with the duration of contraception after completion of a therapy using potentially genotoxic medicines. Member states are now receiving variations with regards to these recommendations. CMDh proposed an amendment to the published Q&A.

Action: For adoption

CHMP adopted the CMDh question to SWP regarding medicinal products with genotoxic potential.

2.4.3. CMDh request on the acceptable intake for nitrosamine N-nitroso diisopropanolamine

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

Action: For adoption

CHMP adopted the CMDh request on the AI for the nitrosamine N-nitroso diisopropanolamine containing medicinal product.

2.4.4. CMDh request on the acceptable intake for nitrosamine Nitroso-STG-19

CMDh request to SWP to determine the acceptable intake for Nitroso-STG-19 (7-Nitroso-3-(trifluoromethyl)-5,6,7,8-tetrahydro[1,2,4]triazolo-[4,3- a]pyrazine) based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

CHMP adopted the CMDh request on the AI for the nitrosamine Nitroso-STG-19.

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 Table of Decisions

- Table of Decisions for MSWP meeting held by teleconference on 14 January 2022
- Agenda for MSWP meeting to be held by teleconference on 02 February 2022

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)

No topics

3. Therapeutic-area-specific working parties and SAGs

3.1. Blood Products Working Party (BPWP)

No topics

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. Agenda

- Agenda of the ONCWP meeting held by Webex on 10 February 2022

Action: For information

CHMP noted the agenda. In addition, members were informed on the progress of the call for nominations for the ONCWP under the new Working Party Operating model. Nominations for the ONCWP have been received and there will be a proposal of composition that will be brought to CHMP for confirmation or modification. In addition, an European Specialised Expert Community (ESEC) will be set up, for which a call will be launched once the working party has been established.

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)

No topics

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 07-10 February 2022.

Action: For information

The CHMP noted the summary of recommendations and advice.

6.3.2. Joint CHMP-PDCO membership

CHMP members are invited to express interest for the joint CHMP-PDCO membership as required by the Paediatric Regulation. Candidatures should be submitted until 4 March 2020.

Action: For information

The CHMP noted the invitation to express interest for the joint CHMP-PDCO membership as required by the Paediatric Regulation.

6.3.3. EMA Advice on the designation of antimicrobials reserved for treatment of certain infections in humans

Regulation (EU) 2019/6 on veterinary medicinal products allows the European Commission to adopt implementing acts designating antimicrobials or groups of antimicrobials to be reserved for the treatment of certain infections in humans only. These antimicrobials (antibiotics, antivirals, antifungals and anti-protozoals) shall not be used in any animals under any circumstances. The CVMP, with assistance from colleagues at ECDC, EFSA and external experts, prepared advice for the Commission on this topic.

Action: For discussion

CHMP noted the EMA advice on the designation of antimicrobials reserved for treatment of certain infections in humans.

7. Regulatory/Organisational matters

7.1. Regulatory Issues/new legislation

7.1.1. Revision of the Pharmaceutical legislation

Follow-up on implementation of Pharmaceutical Strategy.

Action: For information

CHMP noted the follow-up on the implementation of Pharmaceutical Strategy.

7.2. CHMP organisation/templates

7.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

CHMP endorsed the proposed learnings.

7.2.2. CHMP Co-rapporteur critique

Experience of the implementation of Co-Rapporteur critique in initial marketing authorisation applications.

Action: For discussion

CHMP noted the reminder to provide feedback through the circulated survey on the experience on the implementation of the Co-Rapporteur critique in initial marketing authorisation applications.

7.2.3. Presentation of the CPAS group (Classification of Post-Authorisation Studies)

Presentation of the mandate of the CPAS.

Action: For discussion

CHMP noted the presentation of the mandate of the CPAS group (Classification of Post-Authorisation Studies).

7.2.4. Accelerating Clinical Trials in the EU (ACT EU)

Accelerating Clinical Trials in the EU (ACT EU) is an EC-HMA-EMA co-led initiative that aims to optimise the environment for clinical research in Europe. This business change initiative will use the momentum of the Clinical Trials Regulation to further promote the conduct of bigger and better clinical trials. This session will outline the initiative's priorities for 2022-2023.

Action: For information

CHMP noted the scope and priorities that will be considered as part of the Accelerating Clinical Trials in the EU (ACT EU).

7.2.5. New Working Parties Operating Model (WOM)

Call for nominations and 3-year workplans for workings parties in clinical (excluding ONCWP), non-clinical and methodology domain.

Progressing in the implementation of the WOM, the CHMP is presented with the call for nominations and drafts 3-year workplans for workings parties in clinical (excl. ONCWP), non-clinical and methodology domain.

Clinical domain

- Central Nervous System Working Party (CNSWP)
- Cardiovascular Woking Party (CSSWP)
- Haematology Working Party (HAEMWP)
- Infectious Disease Working Party (IDWP)
- Rheumatology and Immunology Working Party (RIWP)
- Vaccines Working Party (VWP)

Non-Clinical domain

- Non-Clinical Working Party (NCWP)
- Joint 3Rs Working Party (J3RsWP)

Methodology domain

- Methodology Working Party (MWP)

Action: For adoption

CHMP adopted the call for nominations and 3-year workplans for workings parties in clinical (excluding ONCWP – see January 2020 PROM minutes), non-clinical and methodology domains.

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 status for CHMP peer review appointment for Scientific Advice.

Please note there is only one procedure from the SAWP to be discussed/presented at the February 2022 CHMP meeting. This is a qualification procedure and the CHMP reviewers have been confirmed already, hence there will be no call for CHMP reviewers this time.

8.1.2. Scientific Advice Working Party (SAWP) call for interest for nomination of a replacement SAWP member

Call for interest for nomination of a replacement SAWP member following change of role of Paolo Foggi (alternate Cristina Migali).

Required areas of expertise: oncology, genetic disorders (focus on metabolic and neurological ones), infectious diseases, clinical trial methodology and/or pharmacoepidemiology.

Applications including application form and CV (for both member and alternate positions) should be sent to the Agency by March 2022.

The new SAWP member and his/her alternate starting date will immediately follow their nomination by the CHMP PROM (14 March 2022).

Action: For information

CHMP noted the call for interest for nomination of a replacement SAWP member following change of role of Paolo Foggi (alternate Cristina Migali).

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 14 February 2022

Action: For information

CHMP endorsed the meeting.

8.2.2. ITF meeting

Meeting date: 09 March 2022

Action: For information

CHMP endorsed the meeting.

9. Product related topics

9.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

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

9.2. 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.

9.3. Covid-19 Vaccine (recombinant) – EMEA/H/C/005754/000

Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.

Scope: Rolling review 3rd interim opinion

Action: For information

The CHMP noted the closure of the 3rd cycle of rolling review.

10. Any Other Business

10.1. Update on proof-of-concept raw data pilot

Update on the proof-of-concept raw data pilot. The pilot, which is expected to start in summer 2022, will analyse individual patient data (raw data) from selected marketing authorisation applications. The pilot aims to generate relevant learnings about accessing and analysing raw data during the assessment process.

The proof-of-concept raw data pilot is part of EMA's Lifecycle Regulatory Submissions Raw Data project, which is focusing on utilising raw data to support regulatory decision making and was listed as an action in CHMP's work plan for 2022.

Action: For discussion

CHMP noted the next steps and plan for the proof-of-concept raw data pilot. CHMP endorsed the initiative.

10.2. CHMP additional experts

CHMP members and experts needs, extend of attendance and participation to CHMP meetings.

Action: For discussion

CHMP noted the information on the CHMP members and experts needs, extend of attendance and participation to CHMP meetings.

10.3. Structured guidance on reflection of use of extrapolation - development of an assessor's guidance template

This document reflects on the published reflection paper on the use of extrapolation of efficacy and safety data in the development of medicines, with a focus on paediatrics.

Action: For adoption

CHMP adopted the structured guidance on reflection of use of extrapolation - development of an assessor's guidance template.

10.4. Rapporteurships

Update

Action: For information

CHMP noted the update.

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	
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	
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	
Janet Koenig	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Armando Genazzani	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Elita Poplavska	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No participation in final deliberations and voting	COVID-19 vaccines
Martine Trauffler	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	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	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting	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	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Elisabeth Øya	Expert - via WebEx*	Norway	No interests declared	
Luca Santi	Expert - via WebEx*	Italy	No restrictions applicable to this meeting	
Martina Perini	Expert - via WebEx*	Italy	No restrictions applicable to this meeting	
Line Præst Lauridsen	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
Mette Steen Tranholm	Expert - via WebEx*	Denmark	No interests declared	
Deirdre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Kristin Karlsson	Expert - via WebEx*	Sweden	No restrictions applicable to this meeting	
Paula Contreras Alarcon	Expert - via WebEx*	Spain	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert - via WebEx*	Spain	No restrictions applicable to this meeting	
Paolo Foggi	Expert - via WebEx*	Italy	No interests declared	
Gerard Moulin	Expert - via WebEx*	France	No interests declared	
Irene Bachmann	Expert - via WebEx*	Germany	No interests declared	
Nora Cascante Estepa	Expert - via WebEx*	Germany	No interests declared	
Sabine Mayrhofer	Expert - via WebEx*	Germany	No interests declared	
Meeting run with the help of EMA staff				

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