



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2021
EMA/CHMP/724020/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 06 December 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

06 December 2021, 11:00–17:30, 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 06 December 2021 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 06 December 2021 meeting will be adopted at the December 2021 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 minutes

- Meeting summary of the PCWP-HCPWP joint meeting held by teleconference on 21-22 September 2021.
- Draft agenda of the annual PCWP-HCPWP joint meeting with all Eligible organisations held by teleconference on 24 November 2021.

Action: For information

CHMP noted the agenda and minutes.

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by teleconference on 4-6 October 2021
- Draft agenda for BWP meeting to be held by teleconference on 6-8 December 2021

Action: For information

CHMP noted the agenda and minutes.

2.2.2. Nomination of new alternate to the BWP

Nomination of new BWP alternate replacing Sean Barry representing Ireland.

Action: For endorsement

CHMP endorsed the nomination of Sarah Gilgunn replacing Sean Barry as BWP alternate representing Ireland.

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Minutes

- Final minutes for QWP meeting held by teleconference on 22-23 September 2021.
- Final minutes for the Joint QWP-IWG meeting held by teleconference on 22 September 2021

Action: For information

CHMP noted the minutes.

2.3.2. Quality Innovation Group (QIG) – Survey to stakeholders

A Survey to stakeholders was developed to inform and support the establishment of the Quality Innovation Group (QIG) within the quality domain. The output of this survey will complement the feedback gathered in preparation of the Regulatory Science to 2025 strategic reflection, identify any subsequent developments, and inform the priorities and expertise requirements for the QIG membership.

Action: For information

CHMP noted the plans for establishment of the Quality Innovation Group (QIG) and the survey to stakeholders which will be launched to that effect. CHMP requested an update on the general implementation plan for the working parties. Launch for call for nominations was initially planned for Dec 2021/January 2022. EMA will follow up on this and the WOM implementation plan will be covered during the December CHMP plenary meeting.

2.4. Safety Working Party (SWP)

Chairs: Susanne Brendler-Schwaab

2.4.1. Minutes

- Final minutes for SWP virtual meeting held on 4-5 October 2021.

Action: For information

CHMP noted the minutes.

2.4.2. Update on call for nominations for 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. The election of the SWP vice-chair is planned for December 2021 plenary meeting.

Nominations received

Action: For information

CHMP noted the call for nominations.

2.4.3. Nomination of new member to the SWP

Nomination of new SWP member replacing Sortvik Nilssen representing Norway.

Action: For endorsement

CHMP endorsed the nomination of Anne Soleng replacing Laila Sortvik Nilssen as SWP member representing Norway.

2.4.4. Nomination of new member to the SWP

Following the election of Susanne Brendler-Schwaab as SWP chair, the German membership became vacant. Nomination of a new SWP member representing Germany.

Action: For endorsement

CHMP endorsed the nomination of Roland Froetschl as SWP member representing Germany.

2.5. **Biosimilar Medicinal Product Working Party (BMWP)**

Chair: Elena Wolff-Holz

2.5.1. Agenda and minutes

- Final minutes for BMWP meeting held by Webex on 22 September 2021.
- Agenda for BMWP meeting held by Webex on 17 November 2021.

Action: For information

CHMP noted the agenda and minutes.

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 24 November 2021.
- Final minutes for MSWP meeting held by Webex on 24 November 2021.

Action: For information

CHMP noted the agenda and minutes.

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

2.9.1. Product-specific guidelines

EMA: Kevin Blake

Draft product-specific guidelines for public consultation.

- Ursodeoxycholic acid product-specific bioequivalence guidance (EMA/CHMP/559890/2021)
- Liposomal amphotericin B product-specific bioequivalence guidance (EMA/CHMP/559889/2021)

Action: For adoption

CHMP adopted -both specific bioequivalence guidance for public consultation.

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

Response from PKWP to request from CMDh for PKWP input relating to the ibuprofen product-specific guideline (EMA/CHMP/356876/2017) and requirements for T_{max} .

Action: For adoption

CHMP adopted the PKWP response to CMDh question on ibuprofen oral lyophilisate versus film coated tablets and oral suspension.

2.9.3. PKWP response to CMDh question on bioequivalence waiver for oily parenteral (i.m.) solutions

PKWP response to CMDh request for PKWP input on bioequivalence waiver for an oily parenteral (i.m.) solution to clarify if viscosity, and/or what other in vitro comparative, data are needed to demonstrate comparable physicochemical characteristics of oily solutions, sufficient to support a biowaiver.

Action: For adoption

CHMP adopted the PKWP response to CMDh question on bioequivalence waiver for oily parenteral (i.m.) solutions.

2.9.4. Request for CHMP/EMA external representation

Request from PKWP Chair Carolien Versantvoort to represent CHMP/EMA at the Marbach Castle International Drug-Drug Interaction (DDI) Workshop 29–31 May 2021 regarding the EMA DDI Guideline and ICH M12.

Action: For endorsement

CHMP endorsed that the PKWP Chair Carolien Versantvoort represents CHMP/EMA at the Marbach Castle International Drug-Drug Interaction (DDI) Workshop.

3. Therapeutic-area-specific working parties and SAGs

3.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

3.1.1. Minutes

- Final minutes of the Blood cluster held by teleconference on 29 October 2021.

Action: For information

CHMP noted the minutes.

3.1.2. Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) (EMA/CHMP/BPWP/94033/2007 rev. 4)

Update of the guideline in order to provide recommendation to use immunoglobulins for the treatment of measles pre and post-exposure prophylaxis for susceptible persons in whom active immunisation is contraindicated or not advised.

Action: For adoption

CHMP adopted the guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg).

3.1.3. Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg) (EMA/CHMP/BPWP/94038/2007 Rev. 6)

Update of the guideline in order to provide recommendation to use immunoglobulins for the treatment of measles pre and post-exposure prophylaxis for susceptible persons in whom active immunisation is contraindicated or not advised.

Action: For adoption

CHMP adopted the guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg).

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)

Chair: Maria Cortizo

3.4.1. Product Information of the HIV products

Update of the Product Information of the HIV products in what refers to the risk of transmission of HIV either due to sexual activity or breastfeeding.

Action: For adoption

CHMP noted the update of the Product Information of the HIV products CHMP requested additional information before adoption.

3.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

3.5.1. Agenda and minutes

- Agenda of the ONCWP meeting held by Webex on 19 November 2021.
- Minutes of the ONCWP meeting held by Webex on 15 October 2021.

Action: For information

CHMP noted the agenda and minutes.

3.5.2. Therapeutic indication of the SmPC of Multiple Myeloma products

Guidance on the wording of the therapeutic indication under section 4.1 of the SmPC of Multiple Myeloma products.

Action: For adoption

CHMP noted the guidance on therapeutic indication of the SmPC of Multiple Myeloma products and provided comments for consideration prior adoption.

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. ICH report from November 2021 Virtual meeting (Vancouver, Canada)

Presentation and written report with information on the topics discussed during the last ICH Assembly meeting held virtually on 17-18 November 2021.

Action: For adoption

CHMP noted the written report of the ICH Assembly meeting held virtually on 17-18 November 2021.

5.1.2. ICH Q9(R1) – Quality Risk Management

Step2b - ICH Q9(R1) to be adopted for a public consultation until 15 March 2022.

Action: For adoption

The CHMP adopted the guideline Step2b - ICH Q9(R1) for a public consultation until 15 March 2022.

5.1.3. ICH new topic proposal

ICH new topic proposal to be adopted for submission to ICH.

Action: For adoption

CHMP adopted the ICH new topic proposal.

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 29 November–2 December 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

EMA guidance on CDx consultation and CHMP/CAT AR CDx template have been reviewed at the November meeting. Comments received are taken into account. Public consultation is planned in January 2022.

Action: For adoption

CHMP noted the update on the Companion Diagnostics (CDx) consultation procedure.

CHMP adopted the documents for release for public consultation.

7.1.2. Guideline on the acceptability of names for human medicinal products processed through the centralised procedure, Revision 7 (EMA/CHMP/287710/2014)

Updated version of the NRG guideline. The draft guideline is brought to the CHMP for adoption prior to a 3-month external consultation.

Action: For adoption

CHMP adopted the guideline on the acceptability of names for human medicinal products processed through the centralised procedure, Revision 7 (EMA/CHMP/287710/2014).

7.1.3. Revision of the Pharmaceutical legislation

Follow up on new Pharmaceutical Strategy.

Action: For information

CHMP noted the update on the revision of the Pharmaceutical Legislation. CHMP organisation/templates.

7.1.4. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola **Action:** For discussion

CHMP endorsed the proposed.

7.1.5. CHMP Work Plan 2022

Discussion on draft CHMP Work Plan 2022. CHMP members are invited to send comments by 10 December 2021.

Action: For discussion

CHMP noted the draft CHMP Work Plan 2022. CHMP members are invited to send comments by 10 December 2021. Member are encouraged to volunteer as CHMP leads or CHMP contributors for the different initiatives.

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Update on call for nominations for Scientific Advice Chair

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

Nomination(s) received

Action: For information

CHMP noted the update on the call for nominations for the Scientific Advice Chair.

8.1.2. Qualification procedures in 2021 - Digital technologies

Overview of qualification procedures from Scientific Advice (SA) involving digital technologies received by the Agency in 2021. This activity is being performed within the context of the CHMP Workplan 2021.

Action: For information

This topic has been postponed and was not covered during the meeting.

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 10 December 2021

Action: For adoption

This topic has been postponed. Adoption of this meeting will take place during the December CHMP plenary meeting.

8.2.2. ITF meeting

Meeting date: 15 December 2021

Action: For adoption

This topic has been postponed. Adoption of this meeting will take place during the December CHMP plenary 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. Introduction to the Lifecycle Regulatory Submissions Metadata Project

The purpose of the project is to deliver effective generation of evidence in support of benefit/risk decision making from data-driven interrogation of scientific information within regulatory submissions.

Action: For information

This topic has been postponed and was not covered during the meeting.

10.1.2. Management of shortages of CAPs

Description of the processes for handling shortages of CAPs, including the review of DHPCs and (Co)-Rapporteurs involvement as well as the EU SPOC Network (single points of contact in NCAs for shortages).

Action: For information

CHMP noted the processes for handling shortages of CAPs and the expected involvement of (Co)-Rapporteurs.

10.1.3. Nitrosamines Multidisciplinary Expert Group (NMEG) on metformin

Follow-up to 1 December 2020 meeting on metformin and considerations for any potential subsequent NMEG.

Action: For information

CHMP noted the follow-up to the 1 December 2020 meeting from the Nitrosamines Multidisciplinary Expert Group (NMEG) on metformin.

10.1.4. Initial experience on OPEN Pilot

The OPEN Pilot started in December 2020 to allow experts from 5 non-EU regulatory Authorities (Australia TGA, Health Canada, Japan MHLW/PMDA, Switzerland, Swissmedic and WHO) to attend and contribute the EMA's CHMP and WTF meetings.

EMA would like to share with the Committee the first reflections on initial experience and plans to better define with CHMP how the pilot could be moving forward.

Action: For information

CHMP noted the initial experience on the OPEN pilot and plans to further strengthen international scientific assessments.

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	
Tomas Radimersky	Alternate	Czechia	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Thalia Marie Estrup Blicher	Alternate	Denmark	No restrictions applicable to this meeting	
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	
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	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jan Sjöberg	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Armando Genazzani	Member	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No participation in final deliberations and voting on	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	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Grzegorz Cessak	Alternate	Poland	No participation in final deliberations and voting on	COVID-19 vaccines
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	
Dorota Distlerova	Alternate	Slovakia	No interests declared	
Kristina Nadrah	Member	Slovenia	No restrictions applicable to this meeting	
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
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	
Katalina Mettke	Expert - via WebEx*	Germany	No interests declared	
Carolien Versantvoort	Expert - via WebEx*	Netherlands	No interests declared	
Alfredo García-Arieta	Expert - via WebEx*	Spain	No interests declared	
Hilke Zander	Expert - via WebEx*	Germany	No interests declared	
Vincent Gazin	Expert - via WebEx*	France	No interests declared	
Sabine Mayrhofer	Expert - via WebEx*	Germany	No interests declared	
Nora Cascante Estepa	Expert - via WebEx*	Germany	No interests declared	
Maria Jesus Fernández Cortizo	Expert - via WebEx*	Spain	No interests declared	
Kristina Bech Jensen	Expert - via WebEx*	Denmark	No interests declared	
Deirdre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Michal Zwiewka	Expert - via WebEx*	Germany	No interests declared	
Lukas Malte Aguirre Davila	Expert - via WebEx*	Germany	No interests declared	
Elena Wolff-Holz	Expert - via WebEx*	Germany	No interests declared	
Jacqueline Kerr	Expert - via WebEx*	Germany	No interests declared	
Paolo Foggi	Expert - via WebEx*	Italy	No interests declared	
Adriana Ammassari	Expert - via WebEx*	Italy	No interests declared	
Maria Grazia Evandri	Expert - via WebEx*	Italy	No interests declared	
Anja Schiel	Expert - via WebEx*	Norway	No interests declared	
Martina Schuessler-Lenz	Expert - via WebEx*	Germany	No interests declared	
Charlotte Geluk	Expert - via WebEx*	Swissmedic	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