



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 October 2021
EMA/CHMP/562180/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 04 October 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

04 October 2021, 09:00–17:30, 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 PReparatoy and Organisational Matter (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 04 October 2021 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of 04 October 2021 meeting will be adopted at the October 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. Annual meeting with committee members (Patients/HCP and Chairs)

Feedback from the Annual meeting with committee members (Patients/HCP and Chairs) which took place on 1st October 2021.

CHMP: Harald Enzmann

Action: For information

CHMP was informed on the topics discussed related to the Annual meeting with committee members (Patients/HCP and Chairs).

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by Webex on 12-14 July 2021
- Draft agenda for BWP meeting to be held by Webex on 4-6 October 2021

Action: For information

CHMP noted agenda and minutes.

2.2.2. Nomination of new BWP member and alternate

Nomination of new BWP member following the resignation of Maeve Lally representing Ireland.

Nomination of new BWP alternate replacing Agnes Mambole-Dema representing France.

Action: For endorsement

CHMP endorsed the nomination of new BWP member Sean Barry following the resignation of Maeve Lally representing Ireland.

CHMP endorsed the nomination of new BWP alternate Sandra Lopes replacing Agnes Mambole-Dema representing France.

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Minutes

- Final minutes from QWP Core Team meeting held by teleconference on 8 September 2021
- Final minutes for QWP meeting held by Webex on 25-27 May 2021

Action: For information

CHMP noted the minutes.

2.3.2. QWP responses to CMDh questions on medicinal product monographs

Recently Ph. Eur. includes Monographs on Medicinal Products containing chemically defined active substances. This has resulted in several questions from MAHs on how to comply with these monographs. QWP provides responses to CMDh on this topic.

Action: For adoption

CHMP adopted QWP responses to CMDh questions on medicinal product monographs.

2.4. Safety Working Party (SWP)

Chairs: Jan Willem Van der Laan/Susanne Brendler-Schwaab

2.4.1. Minutes

- Final minutes for SWP meeting held by teleconference on 19 July 2021.

Action: For information

CHMP noted the minutes.

2.4.2. CMDh question on novel nitrosamine in methylphenidate

The CMDh requests the SWP to determine the acceptable intake for Nitrosomethylphenidate based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

CHMP adopted CMDh question on novel nitrosamine in methylphenidate.

2.4.3. Election of the SWP chair

Jan Willem van der Laan's second term (after the introduction of a maximum of two 3-year terms in the RoP) will expire on 18 October 2021. Elections will take place at the October CHMP plenary. Candidatures received

Action: For information

CHMP noted the upcoming elections.

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 26 May 2021
- Agenda for BMWP meeting held by Webex on 22 September 2021

CHMP noted 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 Table of decisions

- Agenda of the MSWP meeting held by Webex on 22 September 2021
- Table of decisions of the MSWP meeting held by Webex on 2 September 2021
- Draft Table of decisions of the MSWP meeting held by Webex on 22 September 2021

Action: For information

CHMP noted agenda, minutes and 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)

3.5.1. Agenda

- Agenda of the ONCWP meeting held by Webex on 22 September 2021

Action: For information

CHMP noted the agenda.

3.5.2. Reflection paper on the use of measurable residual disease (MRD) as a clinical endpoint in multiple myeloma (MM) studies - (EMA/554633/2021)

Final draft version of reflection paper on the use of measurable residual disease as a clinical endpoint in multiple myeloma studies. Reflection paper is intended for publication after adoption.

Action: For adoption

CHMP noted the Reflection paper on the use of measurable residual disease (MRD) as a clinical endpoint in multiple myeloma (MM) studies.

3.6. Rheumatology/Immunology Working Party (RIWP)

No topics

3.7. Vaccines Working Party (VWP)

No topics

3.8. Scientific Advisory Groups (SAGs)

3.8.1. Appointment of SAG Oncology (SAG-O) Chair and Vice-chair

Appointment of SAG Oncology (SAG-O) Chair and Vice-Chair based on outcome of the election organised by the SAG, in accordance to the SAG-O rules of procedure.

Action: For endorsement

The CHMP endorsed the appointment of Julio Delgado as SAG-Oncology chair.

At present, no SAG Oncology Vice-Chair was elected due to lack of candidates. Election of the Vice -Chair will be repeated at later stage.

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 Guideline E21 on General principles on planning and designing pharmacoepidemiological studies that utilize real-world data for safety assessment of a medicine

Action: For adoption

CHMP endorsed the PRAC proposal to nominate Annalisa Capuano (EC Co-opted PRAC Member) as EMA/EC representative for the drafting of ICH Guideline E21 on General principles on planning and designing pharmacoepidemiological studies that utilize real-world data for safety assessment of a medicine.

5.1.2. ICH E8(R1) step 5 - General considerations for clinical studies

ICH E8(R1) step 5 - General considerations for clinical studies final version for adoption. Once the sign-off by the E8(R1) Regulatory experts is completed, the Regulatory Members of the Assembly will be invited to adopt as final under Step 4 this document, which would subsequently be published on the ICH public website.

Action: For adoption

CHMP adopted ICH E8(R1) step 5 - General considerations for clinical studies final version. This document will now be published on the EMA website. Enforcement of this guideline is planned 6 months after publication.

5.1.3. ICH New Topics

Introduction to new ICH Topics.

Action: For information

CHMP noted ICH topic.

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)

Chairs: Ellen-Margrethe Vestergaard/Susanne Brendler-Schwaab

No topics

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

Chair: Nienke Rodenhuis

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 27-30 September 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. Pharmaceutical Strategy –Revision of general pharmaceutical acts

Update from CHMP contact points on the Revision of general pharmaceutical acts.

CHMP: Harald Enzmann

Action: For information

CHMP was updated with the current CHMP contact points on Revision of general pharmaceutical acts.

7.1.2. EMA pre-submission meetings –proposal for streamlined interactions

CHMP advice is sought on potential joint meetings with the Rapporteurs.

Action: For discussion

CHMP noted proposal on the EMA pre-submission meetings proposals for streamlined interactions.

CHMP members were encouraged to join the EMA pre-submission meeting working group. Interested members can participate on this exercise by contacting by 15 October 2021.

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

First experience of the implementation of Co-Rapp Critique in initial marketing authorisation applications.

Action: For discussion

CHMP discussed first experience of the implementation of Co-Rapp Critique in initial marketing authorisation applications.

7.2.3. 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 discussion

This topic was postponed for discussion during the October CHMP plenary meeting.

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Agenda and Table of decisions

- Agenda from 27-30 September 2021 SAWP meeting held by Webex
- Draft Table of decisions from 27-30 September SAWP meeting held by Webex

Action: For information

CHMP noted agenda and table of decisions.

8.1.2. Appointment of CHMP peer review for SA

List of procedures for discussion.

Action: For information

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

8.1.3. Nomination of new member and alternate

Nomination of new SAWP member. and alternate

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

Action: For endorsement

CHMP endorsed Nomination of new SAWP member Hrefna Guðmundsdóttir and alternate Sif Ormarsdóttir (IS).

8.1.4. 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 departure of Ferran Torres (alternate Rosalía Ruano Camps).

Required areas of expertise: rare diseases (esp. neurological and metabolic), ATMPs, statistics, clinical pharmacology, internal medicine, endocrinology, gynaecology.

CHMP noted the call for interest for nomination of a replacement SAWP member following departure of Ferran Torres (alternate Rosalía Ruano Camps), timelines of the process and the required areas of expertise.

8.1.5. 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 7 January 2022.

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

Action: For information

CHMP noted the call for nominations for Scientific Advice Working Party Chair and upcoming elections. The deadline was moved to early December (deadline for submission of nominations by 3rd December 2021, Elections to take place at 13-16 December CHMP plenary meeting) instead of the initial proposed timeline in the CHMP PROM December Agenda (election expected in January) in order to allow a longer hand-over period between the current and new SAWP chair. The call for interest will also be circulated via email.

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 18 October 2021

Action: For adoption

CHMP endorsed the meeting.

8.2.2. ITF meeting

Meeting date: 21 October 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 list of COVID-19 ongoing and upcoming procedures.

9.1.3. COVID-19 vaccine (recombinant, adjuvanted) - EMEA/H/C/005754

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

Scope: Presentation to CHMP Rolling Review (RR)1 on non-clinical

Action: For discussion

CHMP was updated with the status of this application.

9.1.4. vacopan - Orphan - EMEA/H/C/005523

Vifor Fresenius Medical Care Renal Pharma France; Treatment of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)

Scope: Update on the status of this application

Action: For information

CHMP was updated with the status of this application.

10. Any Other Business

10.1.1. EMA press releases: presentation and discussion

Presentation to inform of current practice for COVID-19 public communications and activities to coordinate such information within the EU Regulatory Network.

Action: For discussion

CHMP noted EMA press releases and public communications for COVID-19 and presented activities to coordinate such information within the EU Regulatory Network.

10.1.2. EMA new emergency notification system FACT24

The previous notification system, RapidReach, has been decommissioned. The FACT24 system allows the Agency to send out emergency alerts to all members and alternates in the event of a crisis situation, disruption to business-critical infrastructure or other emergency event.

Action: For information

CHMP noted the new EMA emergency notification system FACT24 with comment to explore re-sending the registration email as the original email was confused by some member with a potential phishing email.

10.1.3. EMA lessons learned from COVID-19 pandemic

An update on the current status of and considerations identified in the ongoing exercise of EMA lessons learned from the COVID-19 pandemic.

Action: For information

CHMP noted the update on the current status of and considerations identified in the ongoing exercise of EMA lessons learned from the COVID-19 pandemic and welcome the alignment with the SUPRA initiative.

10.1.4. Nitrosamines Multidisciplinary Expert Group (NMEG)

Update on Rifampicin nitrosamine contamination: preparation for follow -up meeting on 15 October (after January 2021 NMEG).

Action: For information

CHMP noted the update on Rifampicin nitrosamine contamination

10.1.5. Supplementary Urgency Procedures for Regulatory Assessment (SUPRA)

Update on the progress of SUPRA initiative which is currently part of the CHMP WP 2021. Feedback from Workshop which took place on 22nd September 2021.

Action: For information

CHMP noted the update on the progress of SUPRA initiative and the feedback from workshop.

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	
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	
Kirstine Moll Harboe	Alternate	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 Lähteenvuio	Alternate	Finland	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	
Konstantinos Markopoulos	Member	Greece	No interests declared	
Eleftheria Nikolaidi	Alternate	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
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	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	
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Adriana Ammassari	Expert - via WebEx*	Italy	No interests declared	
Mette Tranholm	Expert - via WebEx*	Denmark	No interests declared	
Deirdre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Yuansheng Sun	Expert - via WebEx*	Germany	No interests declared	
Kristina Karlsson	Expert - via Webex*	Sweden	No restrictions applicable to this meeting	
Andreas Kirisits	Expert - via WebEx*	Austria	No interests declared	
Maria Victoria Tudanca Pacios	Expert - via Webex*	Spain	No restrictions applicable to this meeting	
Paula Contreras Alarcón	Expert - via WebEx*	Spain	No participation in discussion, final deliberations and voting on:	Skyrizi - risankizumab - EMEA/H/C/004759/II/0014
Elisabeth Øya	Expert - via WebEx*	Norway	No interests declared	
Svein Rune Andersen	Expert - via WebEx*	Norway	No interests declared	
Charlotta Bergquist	Expert - via WebEx*	Sweden	No interests declared	
Helena Faust	Expert - via WebEx*	Sweden	No interests declared	
Jessica Mwinyi	Expert - via WebEx*	Sweden	No interests declared	
Annette Lommel	Expert - via WebEx*	Germany	No interests declared	
Violette Dirix	Expert - via WebEx*	Belgium	No interests declared	
Heidi Meyer	Expert - via WebEx*	Germany	No interests declared	
Anja Schiel	Expert - via WebEx*	Norway	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