



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 September 2021
EMA/CHMP/499778/2021
Human Medicines Division

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

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

06 September 2021, 09:00–14:00, 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 for 06 September 2021.

1.3. Adoption of the minutes

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

- Draft agenda from joint PCWP/HCPWP meeting to be held by WebEx on 21-22 September 2021

Action: For information

The CHMP noted the agenda.

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by WebEx on 14-16 June 2021
- Draft agenda for BWP meeting to be held by WebEx on 6-8 September 2021

Action: For information

The CHMP noted the agenda and minutes.

2.2.1. Call for nomination for the election of the BWP vice chair

Nanna Aaby Kruse (DK) has resigned from her position as BWP vice-chair following the September 2021 meeting. Nominations should be sent with a CV and a brief motivation letter by 6 October 2021.

Action: For information

The CHMP noted the call for nomination.

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Agenda and minutes

- Final minutes from QWP Core Team meeting held by teleconference on 14 July 2021
- Draft agenda for QWP meeting to be held by WebEx on 22-24 September 2021

Action: For information

The CHMP noted the agenda and minutes.

2.4. Safety Working Party (SWP)

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

2.4.1. Workshop on Nitrosamine Impurities in Human Drugs

The workshop will address the Safety Assessment of Potential Risks Associated with Nitrosamine Impurities in Human Drugs and will take place on 20-21 September 2021. Day 1 will address aspects related to hazard identification whereas day 2 will cover elements related to risk assessment.

Action: For information

The CHMP noted the information on the workshop.

2.4.2. Minutes

- Final minutes for SWP meeting held by teleconference on 21 June 2021

Action: For information

The CHMP noted the minutes.

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)

No topics

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

2.9.1. Product-specific guidelines

Revision of product-specific guidelines - Abiraterone acetate product-specific bioequivalence guidance.

Action: For adoption

The CHMP noted the update of the guideline to recommend studies in male volunteers as contraindicated in women who are or may potentially be pregnant. The CHMP adopted the revised guideline.

2.9.2. PKWP response to CMDh request on pirfenidone tablet formulations

Updated response following discussion of draft at CHMP PROM 12 July 2021.

Action: For adoption

The CHMP adopted the updated PKWP response to CMDh and endorsed that the response may be published in form of a question and answer document.

2.9.3. PKWP response to CMDh request on tadalafil orodispersible tablet

PKWP response to CMDh regarding input on bioequivalence requirements for tadalafil orodispersible tablet.

Action: For adoption

The CHMP adopted the PKWP response to CMDh and endorsed that the response may be published in form of a question and answer document.

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)

No topics

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 Guideline Q3C on Residual solvents
- ICH Guideline Q3D on Elemental impurities

Action: For adoption

The CHMP endorsed experts for ICH groups for the guidelines Q3C on Residual solvents and Q3D on Elemental impurities. Ivica Malnar from (HR) was endorsed for ICH Q3C and Kristofer Olofsson (SE) for ICH Q3D.

5.1.2. ICH M7(R2) - Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk

Step2b - ICH M7(R2) guideline and addendum to be adopted for a 60-day public consultation.

These updated documents include: Identified Acceptable intake levels (Permitted daily intake levels) for the following selected known mutagenic impurities: Acetaldehyde; Formaldehyde; 1,2-Dibromoethane; Epichlorohydrin; Ethyl bromide; Styrene; Vinyl Acetate. In addition, the guideline is updated with a new classification of anti-HIV therapeutics as medicines for life-long treatment, with impact on AI levels. These two draft documents are proposed for adoption and release for a 60-day public consultation.

Action: For adoption

The CHMP adopted the guideline for a 60-day public consultation.

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 30/08-02/09 2021.

Action: For information

The CHMP noted the report.

7. Regulatory / Organisational matters

7.1. Regulatory Issues / new legislation

No topics

7.2. CHMP organisation / templates

7.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP noted that there were no CHMP learnings for discussion this month.

7.2.2. Report from Scientific Coordination Board meeting (SciCoBo) meeting

Report from Scientific Coordination Board meeting (SciCoBo) meeting.

CHMP: Harald Enzmann

Action: For information

7.2.3. The CHMP noted the report from the Scientific Coordination Board meeting. Pilot – Relaunch of face to face Scientific Committee Meetings

Next steps on the relaunch of face to face Scientific Committee Meetings.

Action: For discussion

The CHMP was informed about the expected set-up for returning to Committee face to face meetings. By 10 September the members will receive a survey on their likely attendance in person to the CHMP meeting scheduled 8-11 November. The outcome will be discussed with the CHMP chair for agreement whether the November plenary goes ahead as face-to-face or fully remote meeting.

7.2.4. CHMP rules of procedure - update

Adoption of changes to the CHMP rules of procedure.

Action: For adoption

The CHMP adopted the rules of procedure by consensus.

7.2.5. Election of new CHMP chairperson

Harald Enzmann has served as Chair of the CHMP since 21 September 2018 and his first 3-year mandate will shortly come to an end.

The election of a new Chairperson will take place at the end of the September 2021 CHMP plenary meeting as previously communicated to the Committee.

Candidates for the position of CHMP Chair are now invited to indicate their interest in standing for this position. Although candidates can express their interest until the start of the September 2021 CHMP meeting, we would appreciate receiving nominations **by Wednesday, 8 September 2021** EOB to facilitate preparation of the meeting.

Candidates should declare their interest by circulating a letter, indicating their intention to stand, together with a motivation for so doing, as well as a brief résumé to the EMA

Any questions regarding the election can be addressed.

Action: For information

The CHMP noted the call for nomination.

7.2.6. [Template updates for PAMs procedures](#)

Presentation on the draft update to the PAMs procedures templates.

Action: For adoption

The CHMP adopted the updated templates for PAM procedures.

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

The CHMP noted the report.

8.1.2. [Scientific Advice Working Party \(SAWP\) Products Related](#)

Qualification Opinion

Action: For discussion

The CHMP discussed the IMI-PREFER Qualification Opinion for silent adoption at October CHMP plenary meeting.

8.1.3. [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 Kolbeinn Gudmundsson (alternate Hrefna Guðmundsdóttir).

Action: For information

The CHMP noted the call for nominations.

8.2. Innovation Task Force

8.2.1. ITF meeting:

Meeting date: 20th September 2021

Action: For adoption

The CHMP endorsed the meeting.

8.2.2. Amendment of ITF webpage to focus on 3Rs innovative methods

Information on the amendment of ITF webpage to focus on 3Rs innovative methods.

Action: For information

The CHMP noted the update on the amendment of the ITF webpage.

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

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

9.1.3. BRILIQUE – Ticagrelor - EMEA/H/C/001241/II/0049

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC
Rapporteur: Menno van der Elst

Scope: Extension of indication to include, in co-administration with acetylsalicylic acid (ASA), the prevention of stroke in adult patients with acute ischaemic stroke or transient ischaemic attack (TIA), based on the final results of study D5134C00003 (THALES), a phase III, international, multicentre, randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of ticagrelor and ASA compared with ASA in the prevention of stroke and death in patients with acute ischaemic stroke or transient ischaemic attack; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13 of the RMP has also been submitted.

Request by the applicant for an extension of the clock stop to respond to the request for supplementary information adopted in June 2021.

Action: For adoption

Request for Supplementary Information adopted on 24.06.2021, 28.01.2021, 17.09.2020.

The CHMP agreed to the request by the applicant for an extension of the clock stop to respond to the request for supplementary information adopted in June 2021.

9.1.4. Teriparatide Cinnagen - teriparatide - EMEA/H/C/005543

Treatment of osteoporosis

Scope: Request by the applicant for an extension to the clock stop to respond to the list of questions adopted in March 2021.

Action: For adoption

List of Questions adopted on 25.03.2021.

The CHMP did not agree with the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in March 2021.

9.1.5. Nouryant - istradefylline - EMEA/H/C/005308

Kyowa Kirin Holdings B.V.; indicated as an adjunctive treatment to levodopa-based regimens in patients with Parkinson's disease

Scope: Draft timetable, call for re-examination rapporteurs

Action: For information

New active substance (Article 8(3) of Directive No 2001/83/EC)

Opinion adopted on 22.07.2021. List of Outstanding Issues adopted on 25.02.2021. List of Questions adopted on 30.04.2020.

The CHMP noted the draft timetable and call for re-examination rapporteurs.

9.1.6. Nexviadyme - avalglucosidase alfa - Orphan - EMEA/H/C/005501

Genzyme Europe BV; for long-term enzyme replacement therapy for the treatment of patients with Pompe disease.

Scope: Notification of re-examination, draft timetable, call for re-examination rapporteurs

Action: For information

Known active substance (Article 8(3) of Directive No 2001/83/EC)

Opinion adopted on 23.07.2021. List of Outstanding Issues adopted on 20.05.2021. List of Questions adopted on 28.01.2021.

The CHMP noted the draft timetable and call for re-examination rapporteurs.

9.1.7. Rapporteurship overview

Action: For information

The CHMP noted the update.

10. Any Other Business

10.1.1. Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus Drafting Group

Adoption of the composition of the drafting group to revise the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus.

Action: For adoption

The CHMP adopted the list of experts for the drafting group.

10.1.2. Updated Guideline on registry-based studies

Presentation on the changes made to the Guideline on Registry-based studies following the public consultation.

Action: For adoption

The CHMP noted the update. The publication is foreseen in Q4 2021. The CHMP noted the communication strategy.

10.1.3. Response to Letter from third party

EMA: Stefano Ponzano

Action: For information

The CHMP endorsed the response letter.

10.1.4. EMA Introduction into IRIS for Scientific Committees

EMA training to Committees on IRIS system.

Action: For information

The CHMP was informed about an EMA training to Committees – an introduction to IRIS. It will take place remotely on 17 September, 15:30–17:00. Any interested member/expert should contact the CHMP Secretariat in case they would like to participate.

11. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda 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	
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	
Jean-Michel Race	Alternate	France	No interests declared	
Konstantinos Markopoulos	Member	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	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 Vaccines
Martine Trauffer	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	
Bjorg Bolstad	Member	Norway	No restrictions applicable to this meeting	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda 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 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	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	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	
Carolien Versantvoort	Expert - via Webex*	Netherlands	No interests declared	
Martina Schuessler-Lenz	Expert - via Webex*	Germany	No interests declared	
Maria Victoria Tudanca Pacios	Expert - via Webex*	Spain	No restrictions applicable to this meeting	
Andreas Kirisits	Expert - via WebEx*	Austria	No interests declared	
Joerg Zinserling	Expert - via WebEx*	Germany	No interests declared	
Ole Weis Bjerrum	Expert - via WebEx*	Denmark	No interests declared	
Thomas Lang	Expert - via WebEx*	Austria	No interests declared	
Finbarr Leacy	Expert - via WebEx*	Ireland	No interests declared	
Deirdre Mannion	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	
Trine Jensen	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 for which restrictions apply
Peter Mol	Expert - via WebEx*	Netherlands	No interests declared	
Vincent Gazin	Expert - via WebEx*	France	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