



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 May 2021
EMA/CHMP/268010/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 10 May 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

10 May 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 Prepratory 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 10 May 2021 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of May 2021 meeting will be adopted at the May 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)

Chairs: Sol Ruiz/Nanna Aaby Kruse

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by Adobe Connect on 15-17 March 2021
- Draft agenda for BWP meeting to be held by WebEx on 10-12 May 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 representing Estonia.

Action: For endorsement

CHMP endorsed the nomination of new BWP alternate Reet Rumvolt representing Estonia.

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Minutes

- Final minutes from QWP Core Team meeting held by teleconference on 14 April 2021

Action: For information

CHMP noted the minutes.

2.3.2. Update on EFSA assessment on TiO₂: Final opinion published

EFSA opinion on TiO₂ has been finalised and published on the 6th of May. A short summary on the main conclusions of the final EFSA opinion will be presented together with the next steps in agreement with DG SANTE.

Action: For information

CHMP was presented in previous PROM meeting in April with the historical background related to the evaluation of TiO₂ and was informed regarding the ongoing assessment by EFSA on TiO₂. During May PROM meeting, CHMP was informed on EFSA opinion on TiO₂ which has been finalised and published on the 6th of May. In order to determine the impact on human and veterinary medicinal products, EC (DG SANTE) will request additional information from EMA. CHMP agreed in asking QWP to provide responses to the request from DG SANTE by 23 July 2021.

2.3.3. CMDh question to QWP on Ph. Eur. Product Monographs

CMDh question to QWP seeking clarification on the compliance with Ph. Eur. Product Monographs on Finished Products containing chemically defined active substances.

Action: For adoption

CHMP adopted CMDh question to QWP seeking clarification on the compliance with Ph. Eur. Product Monographs on Finished Products containing chemically defined active substances with no further comments.

2.4. Safety Working Party (SWP)

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

2.4.1. Agendas and minutes

- Final minutes for SWP meeting held virtually in replacement for face-to-face on 17-18 March 2021
- Draft agenda for ad-hoc SWP meeting with EFSA on TiO₂ to be held by teleconference on 10 May 2021
- Draft agenda for SWP Nitrosamines Interested Party Meeting to be held by teleconference on 31 May 2021

Action: For information

CHMP noted Agendas and 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 Product-specific guidelines

Final product-specific guidelines

- Deferasirox product-specific bioequivalence guidance (EMA/CHMP/472383/2020) and Overview of comments

Action: For adoption

CHMP adopted final Deferasirox product-specific bioequivalence guidance (EMA/CHMP/472383/2020) and Overview of comments with no further comments.

Proposed new product-specific guidelines

- CMDh request to CHMP (PKWP) for new ad-hoc product specific bioequivalence guidelines for ibrutinib, olaparib, enzalutamide, liposomal amphotericin B, ursodeoxycholic acid and lanreotide.

Action: For adoption

CHMP adopted CMDh request to CHMP (PKWP) for new ad-hoc product specific bioequivalence guidelines for ibrutinib, olaparib, enzalutamide, liposomal amphotericin B, ursodeoxycholic acid and lanreotide with no further comments.

2.9.1. Questions from Committees, other Working Parties

- CMDh question to CHMP (PKWP) related to Tapentadol prolonged release capsules

Action: For adoption

CHMP adopted CMDh question to CHMP (PKWP) related to Tapentadol prolonged release capsules 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. Adverse reactions to COVID-19 vaccination and the safety of substances of human origin

ECDC draft recommendations for EMA input.

Action: For discussion

CHMP was presented with ECDC draft recommendations on adverse reactions to COVID-19 vaccination and the safety of substances of human origin. This document aims to address the safety of donors and products of Substances of Human Origin (SoHO) regarding the potential risk of thrombotic and thromboembolic adverse reactions following COVID-19 vaccination of a donor. CHMP member were invited to provide comments. CHMP noted the draft recommendations with no further comments.

3.1.2. Minutes

- Final minutes of the Blood cluster TC on 19 March 2021

Action: For information

CHMP noted the minutes

3.2. Central Nervous System Working Party (CNSWP)

No topics

3.3. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs

3.3.1. Cancelled - Call for nominations for CVS WP chair and CVS WP vice-chair

The call for nomination is cancelled in light of the ongoing EMA Working Party restructuring.

Action: For information

CHMP noted cancellation of call for nominations for CVS WP chair and CVS WP vice-chair with no further comments.

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 and minutes

- Final minutes for ONCWP meeting held by Adobe Connect on 11 March 2021
- Final agenda for ONCWP meeting held by Adobe Connect on 06 May 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)

3.8.1. Participants to the SAG

Update to CHMP on the exclusion criteria and restrictions applicable to participants of SAG.

Action: For discussion

CHMP was presented with a clarification from EMA on the verification of declaration of interests of SAG members and experts and the exclusion criteria and restrictions applied to their participation in SAG meetings. The interests declared by proposed experts are in particular reviewed versus the product under review and its indication as well as versus any rival products for that product in order to determine if the expert is to be excluded or not or if restrictions apply.

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. Adoption of Guidelines

- ICH Q3C(R8) Step 5 - Residual solvents

This updated document contains PDE levels for three solvents: 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol. Implementation foreseen 6 months after publication.

Action: For adoption

CHMP adopted guideline ICH Q3C(R8) Step 5 - Residual solvents with no further comments.

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)

6.3. Collaboration with other Scientific committees

6.3.1. PRAC report to CHMP

Summary of recommendations and advice of PRAC meeting held on 03-06 May 2021.

Action: For information

The CHMP noted the Summary of recommendations and advice.

6.4. Regulatory Issues / new legislation

6.4.1. Procedural guidance for variation for variant update to covid-19 vaccines

Update to CHMP on draft procedural guidance for variation for variant update to covid-19 vaccines. CHMP members are invited to send comments by 24 May 2021.

Action: For information

CHMP noted draft procedural guidance for variation for variant update to covid-19 vaccines with no further comments.

6.5. CHMP organisation / templates

6.5.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

CHMP endorsed the proposed learnings.

6.5.1. Resourcing of Covid-19 applications: Follow up from April CHMP meeting

Update to the CHMP on the progress and next steps on resourcing of Covid-19 applications following discussion at April CHMP meeting.

Action: For discussion

Following discussion in the extraordinary CHMP on the 4th of March, Management Board on 11th of March and PROM on 12th of April, the CHMP was presented with additional description and clarifications on the scenarios where two assessment reports (rapporteur and co-rapporteur assessment reports) for MAA and for post-authorisation line extensions and extension of indications will be needed. CHMP agreed on how to decide exceptions where a full co-rapporteur AR is needed for IMA for non-Covid related application to be raised by interested members at the time of eligibility, rapporteur appointment or pre-submission meeting for discussion in PROM meetings. CHMP also agreed on the approach for participation of Co-rapporteur in extension of indication and line extensions to be decided by Rapporteur/Co-Rapporteur at the time of validation.

In addition, CHMP members were reminded on the list of products where no biddings have been received for May Rapporteur Appointment and were encouraged to bid. CHMP members expressed concerns on past and recent cases of initial submissions where the submitted dossier was not mature enough for MA or not of a minimum quality leading to a sub-optimal use of assessment resources.

6.5.2. External CHMP Engagement and Communication

Progress on initiative external CHMP Engagement and Communication, currently included as part of CHMP workplan 2021. Introduction to CHMP's regular information on selected procedures (CRISP).

CHMP: Harald Enzmann

Action: For information

CHMP noted progress on initiative External CHMP Engagement and Communication currently present in WP 2021.

7. Product development support

7.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

7.1.1. Appointment of CHMP peer review for SA

Action: For information

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

7.2. Innovation Task Force

7.2.1. ITF meeting

Meeting date: 27 May 2021

Action: For adoption

CHMP endorsed the meeting.

7.2.2. ITF meeting

Meeting date: 28 May 2021

Action: For adoption

CHMP endorsed the meeting.

8. Product related topics

8.1.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

8.1.2. 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 currently COVID-19 ongoing and upcoming procedures.

8.1.3. Vaxzevria – COVID-19 Vaccine (ChAdOx1-S [recombinant]) - EMEA/H/005675

AstraZeneca AB; active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older

Rapporteur: Sol Ruiz, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-

Michel Dogné

Scope: Post-authorisation activities

Action: For information

CHMP was updated on the status of post-authorisation activities for this medicinal product.

8.1.4. Doxorubicin Hydrochloride - EMEA/H/005330

treatment of breast cancer, treatment of ovarian cancer, treatment of multiple myeloma, treatment of AIDS related Kaposi's sarcoma.

Scope: Update on the status of this application

Action: For information

CHMP was updated with the status of this procedure.

8.1.5. Doxorubicin - EMEA/H/005320

treatment of breast cancer, ovarian cancer, progressive multiple myeloma and AIDS-related Kaposi's sarcoma

Scope: Update on the status of this application

Action: For information

CHMP was updated with the status of this procedure.

9. Any Other Business

No topics

10. 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 | |
| Ilko Getov | Member | Bulgaria | No interests declared | |
| Margareta Bego | Member | Croatia | 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 | |
| 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 | |
| Konstantinos Markopoulos | Member | Greece | No interests declared | |
| Agnes Gyurasics | Alternate | Hungary | 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 for which restrictions apply |
|-------------------------------|---------------------|-----------------------------|---|---|
| Peter Kiely | Alternate | Ireland | 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 | |
| Bjorg Bolstad | Member | Norway | No restrictions applicable to this meeting | |
| 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 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 | |

| Name | Role | Member State or affiliation | Outcome restriction following evaluation of e-DoI | Topics on Agenda for which restrictions apply |
|-------------------------------|---------------------|-----------------------------|---|---|
| Christian Gartner | Co-opted member | Austria | No restrictions applicable to this meeting | |
| 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 | |
| Jan Willem van der Laan | Expert - via Webex* | Netherlands | No interests declared | |
| Carolien Versantvoort | Expert - via Webex* | Netherlands | No interests declared | |
| Anja Schiel | Expert - via Webex* | Norway | No interests declared | |
| Irene Bachmann | Expert - via Webex* | Germany | No interests declared | |
| Maria Victoria Tudanca Pacios | Expert - via Webex* | Spain | No restrictions applicable to this meeting | |
| Conception Gimenez Rebollo | Expert - via Webex* | Spain | no participation in final deliberations and voting on | Ozempic - semaglutide - EMEA/H/C/004174/X/0021 WS1941 Edistride - dapagliflozin - EMEA/H/C/004161/WS1941/0043 Forxiga - dapagliflozin - EMEA/H/C/002322/WS1941/0062 Jardiance - empagliflozin - EMEA/H/C/002677/II/0055 |
| Theis Moeslund Jensen | Expert - via Webex* | Denmark | No restrictions applicable to this meeting | |
| Deirdre Mannion | Expert - via Webex* | Denmark | No restrictions applicable to this meeting | |
| Agustin Portela | Expert - via Webex* | Spain | No interests declared | |
| Nora Cascante | Expert - via Webex* | Germany | No interests declared | |
| Sabine Mayhofer | Expert - via Webex* | Germany | No interests declared | |

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