



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 October 2022
EMA/CHMP/795987/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 3 October 2022

Vice-Chair: Bruno Sepodes, deputising for the Chair Harald Enzmann

3 October 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 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 3 October 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 3 October 2022 meeting will be adopted at the October CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz, Sean Barry

2.1.1. Agenda and minutes

- Draft agenda for BWP meeting to be held F2F on 3-5 October 2022
- Final minutes for BWP meeting held virtually on 11-13 July 2022

Action: For information

The CHMP noted the agenda and the minutes.

2.1.2. Nomination of new alternate

Nomination of new BWP alternate, replacing Monta Emerson, representing Latvia.

Action: For endorsement

The CHMP endorsed the nomination of the new BWP alternate Ineta Popena (LV) to replace Monta Emerson representing Latvia.

2.1.3. Nomination of new member

Nomination of new BWP member, replacing Marcos Timon, representing Spain.

Action: For endorsement

The CHMP endorsed the nomination of the new BWP member Pablo de Felipe (ES) to replace Marcos Timon representing Spain.

2.2. Quality Working Party (QWP)

Chairs: Blanka Hirschlerova

2.2.1. Agenda and minutes

- Final minutes for QWP-CT meeting held virtually on 7 September 2022
- Final minutes for QWP meeting held virtually in June 2022

Action: For information

The CHMP noted the minutes.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

No topics

2.4. Quality Innovation Group (QIG)

No topics

2.5. Formulation Expert Group (FEG)

No topics

3. Non-Clinical Domain

3.1. Non-Clinical Working Party (NCWP)

Chairs: Susanne Brendler-Schwaab, Karen van Malderen

3.1.1. Agenda and minutes

- Draft minutes for NcWP meeting held virtually on 1 & 7 September 2022
- Draft agenda for NcWP meeting to be held face-to-face on 4-5 October 2022, including annual stakeholders meeting
- Draft agenda for EMA/FDA non-clinical oncology cluster teleconference to be held virtually on 18 October 2022

Action: For information

The CHMP noted the agenda and the minutes.

3.1.2. CMDh questions to NcWP on new nitrosamines

CMDh requests that the NcWP determines the acceptable intake for the following nitrosamines based on lifetime daily exposure including information on the points of departure and methodology used.

- N-nitroso-vortioxetine
- N-nitroso-mirabegron
- N-nitroso-bupropion

Action: For adoption

The CHMP adopted the CMDh request that the NcWP determines the acceptable intake for the above nitrosamines based on lifetime daily exposure including information on the points of departure and methodology used. It was clarified that the request for N-nitrosobupropion was already endorsed in the previous PROM meeting.

3.1.3. [Questions and Answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5\(3\) of Regulation \(EC\) No 726/2004 referral on nitrosamine impurities in human medicinal products \(EMA/409815/2020\)](#)

Additional update of Questions and Answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products.

Action: For adoption

The CHMP adopted the updated CMDh Q&A.

3.2. **3Rs Replacement, Reduction and Refinement Working Party (3RsWP)**

No topics

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. [Agenda and minutes](#)

- Final agenda and minutes for MWP meetings held virtually on 8 September 2022

Action: For information

The CHMP noted the agenda and the minutes.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

Chair: Andre Elferink

5.1.1. [Nomination of member to CNSWP](#)

Nomination of a new member to CNSWP.

Action: For endorsement

The CHMP endorsed the nomination of Ewa Balkowiec Iskra (PL) as new member to the CNSWP representing Poland.

5.1.2. Call for nomination for CNSWP vice chair

Following nomination of one additional member to CNSWP, a call for nomination for the position of vice chair of the CNSWP is launched. Nominations should be sent to the Agency **by 20 October 2022**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Elections will take place in November PROM (31 October).

Action: For endorsement

The CHMP endorsed to launch the call for nomination for a CNSWP vice chair.

5.2. Cardiovascular Working Party (CVSWP)

No topics

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis

5.3.1. Nomination of Oncology ESEC experts

- Nomination by ONCWP of the experts to enter the Oncology European Specialised Expert Community (ESEC)

Action: For endorsement

The CHMP endorsed the nomination of ONCWP experts to enter the Oncology European Specialised Expert Community (ESEC).

5.3.2. Update on Oncology ESEC activities

- Composition of the drafting group reviewing the anti-cancer guideline (EMA/CHMP/205/95 Rev.6):

Action: For endorsement

CHMP endorsed the composition of the drafting group reviewing the anti-cancer guideline (EMA/CHMP/205/95 Rev.6).

- EUNTC Webinar – Challenges in drug development, regulation and clinical practice in Follicular lymphoma (Friday 7 October, 13.30-15 pm)

Action: For information

CHMP noted the EUNTC Webinar – Challenges in drug development, regulation and clinical practice in Follicular lymphoma (Friday 7 October, 13.30-15 pm).

- Call for interest to have a CHMP representative for the 2nd EU NTC webinar on Diffuse Large B-Cell Lymphoma (DLBCL)

Action: For discussion

CHMP endorsed Aaron Sosa, Paula van Hennik and Alexandre Moreau as CHMP representatives for the 2nd EU NTC webinar on Diffuse Large B-Cell Lymphoma (DLBCL).

- Survey on how to improve quality of submission dossiers

Action: For information

CHMP noted the proposed survey on how to improve the quality of dossier.

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

No topics

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Agenda and minutes

- Agenda of the HAEMWP to be held virtually on 9 September 2022
- Minutes of the HAEMWP held virtually on 9 September 2022

Action: For information

The CHMP noted the agenda and the minutes.

5.8. Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEG)

No topics

6. Patients, Healthcare Professionals and Consumers

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

No topics

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. ICH M11 - Clinical electronic structured harmonised protocol

Following the completion of the Step 1 ICH M11 EWG Technical Document, Template and Technical Specification, the agreed draft versions are brought to CHMP for adoption (document available in MMD) before a 3-4 month public consultation.

Action: For adoption

The CHMP adopted the draft versions of the ICH M11 "Clinical electronic structured harmonised protocol" technical document, template and technical specification for public consultation.

7.2. Guideline Consistency Group (GCG)

No topics

7.3. Summary of product characteristics Advisory Group

No topics

8. Joint groups and collaboration with other Scientific committees

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

No topics

8.2. Collaboration with other Scientific committees

8.2.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 26-29 September 2022.

Action: For information

The CHMP noted the summary of recommendations and advice.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP endorsed the proposed learnings.

9.2.2. Proposal for a CHMP-CAT project on the usefulness of preference elicitation as an add-on to expert advice

This proposal is to run a short project to understand if formal elicitation, alongside the traditional meeting summaries, can be useful to provide expert opinions to scientific committees for instance, in the context of Scientific Advisory Group. The project will focus on perceived usefulness by CHMP-CAT associated members/assessors and experts in receiving and providing expert advice.

CHMP: Hans Hillege

Action: For discussion

The CHMP noted the proposal for a CHMP-CAT project on the usefulness of preference elicitation as an add-on to expert advice. Members are encouraged to join the group as volunteers.

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

10.1.1. Appointment of CHMP peer review for SA

Action: For information

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

10.1.2. Agenda and Table of Decisions

- Agenda from 26-29 September 2022 meeting held by Webex
- Draft Table of Decisions from 26-29 September 2022 meeting held by Webex

Action: For information

The CHMP noted the agenda and the table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 10 October 2022

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 17 October 2022

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 19 or 21 October 2022 (TBC)

Action: For adoption

The CHMP endorsed the meeting.

10.2.4. ITF meeting

Meeting date: October 2022 (TBC)

Action: For adoption

The CHMP endorsed the meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

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

11.2. 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 COVID-19 ongoing and upcoming procedures.

11.3. vadadustat - EMEA/H/C/005131

Treatment of anaemia

Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in September 2022.

Action: For adoption

List of Outstanding issues adopted on 15.09.2022. List of Questions adopted on 24.03.2022.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in September 2022.

11.4. Janus kinase (JAK) inhibitors: abrocitinib - CIBINQO (CAP); baricitinib - OLUMIANT (CAP); filgotinib - JYSELECA (CAP); tofacitinib - XELJANZ (CAP); upadacitinib - RINVOQ (CAP) – EMEA/H/A-20/1517

Applicant(s): AbbVie Deutschland GmbH & Co. KG (Rinvoq), Eli Lilly Nederland B.V. (Olumiant), Galapagos N.V. (Jyseleca), Pfizer Europe MA EEIG (Cibinqo, Xeljanz)

Scope: Review of the benefit-risk balance following notification by the European Commission (EC) of a referral under Article 20 of Regulation (EC) No 726/2004, based on pharmacovigilance data

Action: For information

The CHMP noted the status of this procedure.

11.5. mavacamten - EMEA/H/C/005457

Treatment of hypertrophic cardiomyopathy

Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in July 2022.

Action: For adoption

List of Outstanding issues adopted on 21.07.2022. List of Questions adopted on 27.01.2022.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in July 2022.

12. Any Other Business

12.1. Rapporteurships

Update

Action: For information

The CHMP noted the update.

12.2. Regulatory & scientific conference on RNA based medicines

This conference aims to facilitate the dialogue between industry/academia and regulators, to discuss scientific and regulatory opportunities and challenges to promote the development of RNA-based innovative medicines.

Action: For information

This topic was not covered and was postponed.

13. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Andrea Laslop	Member	Austria	No interests declared	
Daniela Philadelphia	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	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	
Thalia Marie Estrup Blicher	Member	Denmark	No restrictions applicable to this meeting	
Aaron Sosa Mejia	Alternate	Denmark	No participation in final deliberations and voting on:	Main Agenda - Refixia - nonacog beta pegol - EMEA/H/C/004178/X/0027/G
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No restrictions applicable to this meeting	
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, deputising for the Chair)	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
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on:	COVID-19 vaccines
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	
Line Praest Lauridsen	Expert	Denmark	No restrictions applicable to this meeting	
Luca Santi	Expert	Italy	No restrictions applicable to this meeting	
Marina Perini	Expert	Italy	No restrictions applicable to this meeting	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert	Spain	No restrictions applicable to this meeting	
Mas Parra Paloma	Expert	Spain	No restrictions applicable to this meeting	
Andre Elferink	Expert	Netherlands	No interests declared	
Elena Wolff-Holz	Expert	Germany	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Vincent Gazin	Expert	France	No interests declared	
Meeting run with the help of EMA staff				

Experts were evaluated against the agenda topics or activities they participated in.