



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ agenda for the meeting on 13 June 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

13 June 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

CHMP PROM agenda for 13 June 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 13 June 2022 meeting will be adopted at the June 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, Sean Barry

2.2.1. Agenda and minutes

- Draft agenda of BWP meeting to be held virtually on 13-15 June 2022
- Final minutes of BWP meeting held virtually on 11-13 April 2022

Action: For information

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Agenda and minutes

- Final Agenda and minutes for QWP-CT meeting held by teleconference on 11 May 2022

Action: For information

2.3.2. Removal or replacement of Titanium Dioxide Q&A

Proposal for adoption of EMA's Quality Working Party (QWP) Questions and Answers to provide technical and procedural guidance to replace/remove titanium dioxide (TiO₂) in medicines.

Action: For adoption

2.4. Non-clinical Working Party (NcWP)

Chairs: Susanne Brendler-Schwaab, Karen van Malderen

2.4.1. Minutes

- Draft minutes for NcWP meeting held virtually on 10-11 May 2022

Action: For information

2.4.2. Launch of the Nitrosamines Safety Operational Experts Group (NS OEG)

The SWP nitrosamines expert group has been converted into the Nitrosamines Safety Operational Expert group (NS OEG). The NcWP is seeking endorsement of the group and the experts.

Action: For endorsement

2.4.3. NcWP position on new nitrosamine nitrosoduloxetine

NcWP position on the acceptable intake (AI) for nitrosoduloxetine based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

2.4.4. CMDh question to NcWP on new nitrosamines N-nitrosoparoxetine

CMDh question to the NcWP to determine the acceptable intake for N-nitrosoparoxetine based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

2.5. Biosimilar Medicinal Product Working Party (BMWP)

No topics

2.6. Methodology Working Party (MWP)

Chairs: Christian Roes, Kristin Karlsson

2.6.1. Agenda and minutes

- Final Agenda & minutes for QWP-CT meeting held by teleconference on 10 and 24 May 2022

Action: For information

2.6.2. Nominations for additional expertise for Methodology Working Party

CHMP is presented with nominations for additional expertise for MWP.

The recent call for nominations included a general call for expertise in Real World Evidence. Nominations were received in the area of Artificial Intelligence, the Information Technology

side of Data Science, and several other applicants indicated they had such expertise. However:

- No candidates appear to have specific expertise in pharmacoepidemiology;
- Some candidates did not give sufficient granularity in their answers to be able to ascertain whether they had the required expertise.

Following reopening of call of nominations of experts are proposed.

Action: For endorsement

2.7. Pharmacogenomics Working Party (PGWP)

No topics

2.8. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

2.8.1. Product-specific guidelines

The public consultation on the following product-specific guidelines finished on 31 March 2022. No comments were received, and it is therefore proposed that the published drafts will also be the final versions.

Final product-specific guidelines for publication:

- Enzalutamide soft capsule 40 mg and film-coated tablet 40 & 80 mg product-specific bioequivalence guidance (EMA/CHMP/371467/2021)
- Ibrutinib hard capsules 140 mg and film-coated tablet 140, 280, 420 & 560 mg product-specific bioequivalence guidance (EMA/CHMP/371445/2021)
- Olaparib film-coated tablet 100 & 150 mg product specific bioequivalence guidance (EMA/CHMP/371470/2021)
- Ursodeoxycholic acid capsule 250 mg, film-coated tablet 150, 300, 450, 500 & 600 mg and suspension 50 mg/ml (250 mg/5 ml) product-specific bioequivalence guidance (EMA/CHMP/559890/2021)

Action: For adoption

3. Therapeutic-area-specific working parties and SAGs

3.1. Haematology Working Party (HaemWP)

Chair(s): Vacant

3.1.1. Minutes

- Final minutes for the Blood cluster meeting held by teleconference on 18 March 2022

Action: For information

3.1.2. Election of HAEMWP chair

- Election of HAEMP chair following the implementation of the new Working Parties Operating Model (WOM).

Action: For adoption

3.1.3. Agenda of the annual meeting with PPTA and IPFA

- Agenda of the annual meeting with PPTA and IPFA held on 7 June 2022

Action: For information

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)

Chairs: Pierre Demolis, Sigrid Klaar

3.5.1. Agenda and minutes

- Final Agenda for ONCWP meeting held by teleconference on 20 May 2022
- Final minutes for ONCWP meeting held by teleconference on 22 April 2022

Action: For information

3.5.2. Nomination of Oncology ESEC experts

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

Action: For endorsement

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

4.6. Diabetes Drafting Group

No topics

5. Harmonisation and consistency groups

5.1. International Council on Harmonisation (ICH)

5.1.1. Call for expression of interest to the upcoming ICH M15

A call for expression of interest for appointment of two experts to represent CHMP/EMA/EC in the newly formed ICH M15 working group, working on a new guideline on General Principles of Model-Informed Drug Development, was launched via the Methodology WP with deadline on 25 May. The two expert nominations are now brought for CHMP endorsement.

Action: For adoption

5.1.2. Call for expression of interest to the upcoming revision of the ICH Q1 series/ICHQ5C

A call for expression of interest for appointment of two experts to represent CHMP/EMA/EC in the newly formed ICH Q1/Q5C working group, working on a new guideline on revision of the stability guideline series, was launched via the Quality and Biologics WPs with deadline on 27th May. The two expert nominations are now brought for CHMP endorsement.

Action: For adoption

5.2. Guideline Consistency Group (GCG)

Chair: TBC

5.2.1. Nomination of new members of GCG

Nominations received of new GCG members.

Action: For endorsement

5.2.2. Call for expression of interest for a Chair of the GCG

Following the end of mandate of Arantxa Sancho as Chair of GCG on 25 July 2021, a call for expression of interest for appointment for a Chair of the GCG is launched. The Chair should be appointed from the current members. Nominations should be sent to the Agency by **4 July 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

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 7-10 June 2022.

Action: For information

7. Regulatory/Organisational matters

7.1. Regulatory Issues/new legislation

7.1.1. Procedural guidance for variation for variant update to COVID-19 vaccines - Revision

Revision of the procedural guidance for variation for variant update to COVID-19 vaccines, regarding naming of variant strain qualifiers for COVID-19 vaccines based on NRG proposal.

Action: For adoption

7.1.2. Finalisation of the Companion Diagnostics (CDx) consultation procedure

Further to public consultation on the draft version published in December 2021, the EMA guidance on the CDx consultation has been updated and is now final. The CHMP/CAT AR CDx template as well as the application forms for both initial and follow-up procedures have also been updated.

Action: For adoption

7.2. CHMP organisation/templates

7.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

7.2.2. Call for nominations for CHMP co-opted members

- At the May 2022 CHMP PROM meeting the Committee agreed that a co-opted member should be appointed in the following area of expertise: **Medical Statistics**. Nominations should be sent to the Agency. 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 at the June CHMP Plenary meeting.

- At the May 2022 CHMP PROM meeting the Committee agreed that a co-opted member should be appointed in the following area of expertise: **Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies)**. Nominations should be sent to the Agency. 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 at the July CHMP Plenary meeting.

Action: For information

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

8.1.1. Agenda and Table of Decisions

- Agenda from 07-10 June 2022 meeting held by Webex
- Draft Table of Decisions from 07-10 June 2022 meeting held by Webex

Action: For information

8.1.2. Appointment of CHMP peer review for SA

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 20 June 2022

Action: For adoption

8.2.2. ITF meeting

Meeting date: 21 June 2022

Action: For adoption

9. Product related topics

9.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

9.2. 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

10. Any Other Business

10.1. Rapporteurships

List of rapporteurships.

Action: For information

10.2. A workshop of the ESC Cardiovascular Round Table; “Real World Evidence”

Draft Agenda and List of participants from the EMA working parties.

Action: For adoption

10.3. EMA study on the impact of RWE in applicants’ submissions

Presentation highlighting the study results and reflections.

Action: For information

10.4. EMA funded registry-based study on Spinal muscular atrophy

Presentation highlighting the study objectives and timelines.

Action: For information