



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 February 2021
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Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ agenda for the meeting on 15 February 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 February 2021, 09:30–12:30, 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 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. Please note that the PROM meeting is not taking place every month.



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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 15 February 2021 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of February 2021 meeting will be adopted at the February 2021 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

No topics

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

Process to collect and record CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

2.2.2. CHMP Co-opted membership

Update on call for nomination of CHMP co-opted member in light of the end of the mandate of Blanka Hirschlerova as co-opted member on 18 March 2021.

Action: For discussion

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

No topics

3.2. Guideline Consistency Group (GCG)

No topics

3.3. Summary of product characteristics Advisory Group

No topics

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz/Nanna Aaby Kruse

4.1.1. Agenda and minutes

- Draft agenda for the BWP meeting to be held via Adobe Connect on 15-17 February 2021
- Draft minutes for the BWP meeting held via Adobe Connect on 30 November–2 December 2020

Action: For information

4.1.2. CHMP position statement on quality and safety assessment for the Plasma Master File (PMF) certification with regards to donor deferral criteria for risk behaviour

Revised statement and Overview of comments.

Action: For adoption

4.1.3. EMA response to PPTA-IPFA: Proposals for revision of donor deferral criteria in the context of the COVID-19 situation in order to maintain access to plasma-derived medicinal products for patients in EU

EMA response.

Action: For endorsement

4.1.4. Change to BWP composition

Nomination of a new member for Belgium.

Action: For endorsement

4.2. Safety Working Party (SWP)

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

4.2.1. Minutes

- Final minutes for SWP meeting held by teleconference on 9 November 2020

Action: For information

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

4.3.1. Call for nominations for BMWP Vice-Chair

Nominations should be sent to the EMA BMWP Secretariat by **26 February 2021**. Elections will take place at the March CHMP Plenary meeting.

Action: For information

4.4. Biostatistics Working Party (BSWP)

Chair: Kit Roes

4.4.1. Call for nominations for BSWP Vice-Chair

Nominations should be sent to the Agency to the BSWP Secretariat by **12 March 2021**. 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 March CHMP Plenary meeting.

Action: For information

4.5. Modelling and Simulation Working Party (MSWP)

No topics

4.6. Pharmacogenomics Working Party (PGWP)

No topics

4.7. Pharmacokinetics Working Party (PKWP)

No topics

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

5.1.1. Organisation of a BPWP TC in March 2021

The BPWP would like to seek agreement from CHMP to organise a TC in March.

Action: For endorsement

5.2. Central Nervous System Working Party (CNSWP)

No topics

5.3. Cardiovascular Working Party (CVSWP)

No topics

5.4. Infectious Diseases Working Party (IDWP)

No topics

5.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

5.5.1. Agenda and minutes

- Draft agenda for the ONCWP meeting held via Adobe Connect on 11 February 2021
- Draft minutes for the ONCWP meeting held via Adobe Connect on 13 January 2021

Action: For information

5.6. Rheumatology/Immunology Working Party (RIWP)

No topics

5.7. Vaccines Working Party (VWP)

No topics

5.8. Scientific Advisory Groups (SAGs)

No topics

6. Drafting groups

6.1. Excipients Drafting Group

No topics

6.2. Gastroenterology Drafting Group (GDG)

No topics

6.3. Geriatric Expert Group (GEG)

No topics

6.4. Radiopharmaceuticals Drafting Group (RadDG)

No topics

6.5. Respiratory Drafting Group (RDG)

No topics

7. Joint groups and collaboration with other committees

7.1. Quality Working Party (QWP)

Chairs: Blanka Hirschlerova/Laivi Saaremäel

7.1.1. QWP Core Team

- Minutes from January QWP CT meeting held 20 January 2021.

Action: For information

7.1.2. Call for nominations for a QWP Core Team member

QWP Members and Alternates who wish to apply for this position are requested to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Only Member States which do not have a QWP CT member are eligible for the position. Elections will take place at the March QWP Plenary meeting.

Nominations should be sent **by 22nd February 2021 EOB.**

Action: For information

7.2. 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)

7.2.1. Agenda

- Draft Agenda from the PCWP/HCPWP Joint meeting on 2-3 March 2021

Action: For information

7.3. 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

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

No topics

7.5. Collaboration with other committees

7.5.1. PRAC report to CHMP

Summary of recommendations and advice of PRAC meeting held on 8-11 February 2021.

Action: For information

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

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 4 February 2021

Action: For information

8.2.2. ITF meeting

Meeting date: 24 February 2021

Action: For adoption

9. Any Other Business

9.1.1. PRIME 5-year analysis criteria: for CHMP comments and final adoption

PRIME 5-year analysis: criteria for adoption.

Action: For discussion

9.1.2. Patient Engagement at CHMP; new pilot

Presentation on new pilot project to establish contact with relevant patient organisations at start of MAA's for orphan medicines. Enables patients to share aspects such as quality of life, treatment options and unmet medical needs, so CHMP can be well-aware of all aspects from the beginning. This activity is in line with CHMP workplan.

Action: For information

9.1.3. Update on the CONSIGN project (Covid-19 infectiOn aNd medicineS in pregnancy)

Update on the CONSIGN project (Covid-19 infectiOn aNd medicineS in pregnancy) including interim results of COVI-PREG and INOSS studies, and on international collaboration activities.

Action: For discussion

9.1.4. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

9.1.5. satralizumab - Orphan - EMEA/H/C/004788

Roche Registration GmbH; treatment of adult and adolescent patients from 12 years of age with neuromyelitis optica spectrum disorders (NMOSD)

Scope: Update on the status of this application

Action: For Discussion