06 December 2021
EMA/CHMP/678431/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 06 December 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

06 December 2021, 11:00–17:30, 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.

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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 06 December 2021 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 06 December 2021 meeting will be adopted at the December 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 and minutes

- Meeting summary of the PCWP-HCPWP joint meeting held by teleconference on 21-22 September 2021.
- Draft agenda of the annual PCWP-HCPWP joint meeting with all Eligible organisations held by teleconference on 24 November 2021.

Action: For information

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by teleconference on 4-6 October 2021.
- Draft agenda for BWP meeting to be held by teleconference on 6-8 December 2021.

Action: For information

2.2.2. Nomination of new alternate to the BWP

Nomination of new BWP alternate replacing Sean Barry representing Ireland.

Action: For endorsement

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Minutes

- Final minutes for QWP meeting held by teleconference on 22-23 September 2021.
- Final minutes for the Joint QWP-IWG meeting held by teleconference on 22 September 2021.

Action: For information

2.4. Safety Working Party (SWP)

Chairs: Susanne Brendler-Schwaab

2.4.1. Minutes

- Final minutes for SWP virtual meeting held on 4-5 October 2021

Action: For information

2.4.2. Update on call for nominations for SWP chair

Susanne Brendler-Schwaab (DE) left her position as SWP vice-chair to undertake the SWP chair position following election at the October 2021 CHMP meeting. The election of the SWP vice-chair is planned for December 2021 plenary meeting.

Nominations received

Action: For information

2.4.3. Nomination of new member to the SWP

Nomination of new SWP member replacing Sortvik Nilssen representing Norway.

Action: For endorsement

2.4.4. Nomination of new member to the SWP

Following the election of Susanne Brendler-Schwaab as SWP chair, the German membership became vacant. Nomination of a new German SWP representing Germany.

Action: For endorsement

2.5. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

2.5.1. Agenda and minutes

- Final minutes for BMWP meeting held by Webex on 22 September 2021.
- Agenda for BMWP meeting held by Webex on 17 November 2021.

Action: For information

2.6. Biostatistics Working Party (BSWP)

No topics

2.7. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

2.7.1. Agenda and Minutes

- Agenda of the MSWP meeting held by Webex on 24 November 2021.
- Final minutes for MSWP meeting held by Webex on 24 November 2021.

Action: For information

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

2.9.1. Product-specific guidelines

Draft product-specific guidelines for public consultation.

- Ursodeoxycholic acid product-specific bioequivalence guidance (EMA/CHMP/559890/2021)
- Liposomal amphotericin B product-specific bioequivalence guidance (EMA/CHMP/559889/2021)

Action: For adoption

2.9.2. PKWP response to CMDh question on ibuprofen oral lyophilisate versus film coated tablets and oral suspension

Response from PKWP to request from CMDh for PKWP input relating to the ibuprofen product-specific guideline (EMA/CHMP/356876/2017) and requirements for T_{max}.

Action: For adoption

2.9.3. PKWP response to CMDh question on bioequivalence waiver for oily parenteral (i.m.) solutions

PKWP response to CMDh request for PKWP input on bioequivalence waiver for an oily parenteral (i.m.) solution to clarify if viscosity, and/or what other in vitro comparative, data are needed to demonstrate comparable physicochemical characteristics of oily solutions, sufficient to support a biowaiver.

Action: For adoption

2.9.4. Request for CHMP/EMA external representation

Request from PKWP Chair Carolien Versantvoort to represent CHMP/EMA at the Marbach Castle International Drug-Drug Interaction (DDI) Workshop 29–31 May 2021 regarding the EMA DDI Guideline and ICH M12.

Action: For endorsement

3. Therapeutic-area-specific working parties and SAGs

3.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

3.1.1. Minutes

- Final minutes of the Blood cluster held by teleconference on 29 October 2021.

Action: For information

3.1.2. Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) (EMA/CHMP/BPWP/94033/2007 rev. 4)

Update of the guideline in order to provide recommendation to use immunoglobulins for the treatment of measles pre and post-exposure prophylaxis for susceptible persons in whom active immunisation is contraindicated or not advised.

Action: For adoption

3.1.3. Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg) (EMA/CHMP/BPWP/94038/2007 Rev. 6)

Update of the guideline in order to provide recommendation to use immunoglobulins for the treatment of measles pre and post-exposure prophylaxis for susceptible persons in whom active immunisation is contraindicated or not advised.

Action: For adoption

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)

Chair: Maria Cortizo

3.4.1. Product Information of the HIV products

Update of the Product Information of the HIV products in what refers to the risk of transmission of HIV either due to sexual activity or breastfeeding.

Action: For adoption

3.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

3.5.1. Agenda and minutes

- Agenda of the ONCWP meeting held by Webex on 19 November 2021.
- Minutes of the ONCWP meeting held by Webex on 15 October 2021.

Action: For information

3.5.2. Therapeutic indication of the SmPC of Multiple Myeloma products

Guidance on the wording of the therapeutic indication under section 4.1 of the SmPC of Multiple Myeloma products.

Action: For adoption

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. ICH report from November 2021 Virtual meeting (Vancouver, Canada)

Presentation and written report with information on the topics discussed during the last ICH Assembly meeting held virtually on 17-18 November 2021.

Action: For adoption

5.1.2. ICH Q9(R1) – Quality Risk Management

Step2b - ICH Q9(R1) to be adopted for a public consultation until 15 March 2022.

Action: For adoption

5.1.3. ICH new topic proposal

ICH new topic proposal to be adopted for submission to ICH.

Action: For adoption

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 29 November–2 December 2021.

Action: For information

7. Regulatory / Organisational matters

7.1. Regulatory Issues / new legislation

7.1.1. Update on the Companion Diagnostics (CDx) consultation procedure

EMA guidance on CDx consultation and CHMP/CAT AR CDx template have been reviewed at the November meeting. Comments received are taken into account. Public consultation is planned in January 2022.

Action: For adoption

7.1.2. Guideline on the acceptability of names for human medicinal products processed through the centralised procedure, Revision 7 (EMA/CHMP/287710/2014)

Updated version of the NRG guideline. The draft guideline is brought to the CHMP for adoption prior to a 3-month external consultation.

Action: For adoption

7.1.3. Revision of the Pharmaceutical legislation

Follow up on new Pharmaceutical Strategy.

Action: For information

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. CHMP Work Plan 2022

Discussion on draft CHMP Work Plan 2022. CHMP members are invited to send comments by 10 December 2021.

Action: For discussion

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Update on call for nominations for Scientific Advice Chair

The mandate of Scientific Advice Working Party Chair Anja Schiel will expire on 28 February 2022.

Nomination(s) received

Action: For information

8.1.2. Qualification procedures in 2021 - Digital technologies

Overview of qualification procedures from Scientific Advice (SA) involving digital technologies received by the Agency in 2021. This activity is being performed within the context of the CHMP Workplan 2021.

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 10 December 2021

Action: For adoption

8.2.2. ITF meeting

Meeting date: 15 December 2021

Action: For adoption

9. Product related topics

9.1.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

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

10. Any Other Business

10.1.1. Introduction to the Lifecycle Regulatory Submissions Metadata Project

The purpose of the project is to deliver effective generation of evidence in support of benefit/risk decision making from data-driven interrogation of scientific information within regulatory submissions.

Action: For information

10.1.2. Management of shortages of CAPs

Description of the processes for handling shortages of CAPs, including the review of DHPCs and (Co)-Rapporteurs involvement as well as the EU SPOC Network (single points of contact in NCAs for shortages).

Action: For information

10.1.3. Nitrosamines Multidisciplinary Expert Group (NMEG) on metformin

Follow-up to 1 December 2020 meeting on metformin and considerations for any potential subsequent NMEG.

Action: For information

10.1.4. Initial experience on OPEN Pilot

The OPEN Pilot started in December 2020 to allow experts from 5 non-EU regulatory Authorities (Autralia TGA, Health Canada, Japan MHLW/PMDA, Switzerland, Swissmedic and WHO) to attend and contribute the EMA's CHMP and WTF meetings.

EMA would like to share with the Committee the first reflections on initial experience and plans to better define with CHMP how the pilot could be moving forward.

Action: For information