15 March 2021
EMA/CHMP/128280/2021 Rev.2
Human Medicines Division

# Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 15 March 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 March 2021, 09:30–14:30, virtual meeting / room 08-A

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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 15 March 2021 meeting

## 1.3. Adoption of the minutes

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

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

**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

- Agenda of BWP meeting to be held by Adobe Connect on 15-17 March 2021
- Minutes of BWP meeting held by Adobe Connect on 18-20 January 2021

**Action:** For information

## 4.2. Safety Working Party (SWP)

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

### 4.2.1. Agenda and minutes

- Draft agenda for SWP meeting in replacement of face-to-face to be held by Adobe Connect on 17-18 March 2021
- Final minutes for SWP meeting held by teleconference on 25 January 2021

**Action:** For information

### 4.2.2. CMDh request to Safety Working Party (SWP) on acceptable intake for new nitrosamine (N-nitrosodiethanolamine (NDELA))

CMDh requests to SWP on determination of acceptable intake for new nitrosamine. During ORGAM meeting in November 2020, the CHMP and CMDh adopted a generic question to the SWP which can be triggered when a "new nitrosamine" is identified without the need for adoption by CHMP.

**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

The first mandate of the Vice Chair Niklas Ekman expired in September 2020. The election is scheduled at the March CHMP Plenary meeting. Candidates were asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

**Action**: For information

## 4.4. Biostatistics Working Party (BSWP)

Chair: Kit Roes

### 4.4.1. Call for nominations for BSWP Vice-Chair

The first mandate of the Vice-Chair Jörg Zinserling expired in January 2021. The election is scheduled at the March CHMP Plenary meeting. Candidates were asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

**Action**: For information

### 4.4.2. Change to BSWP Composition

Philippe Zamia (FR) to step down as additional assessor. Proposal for nomination of an additional assessor was introduced.

**Action**: For endorsement

## 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. Agendas

- Agenda of BPWP meeting held by teleconference on 11 March 2021
- Agenda for Blood cluster meeting to be held by teleconference on 19 March 2021

**Action:** For information

## 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

- Agenda of ONCWP meeting held by teleconference on 11 March 2021
- Minutes of ONCWP meeting held by teleconference on 11 February 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)

# 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)

Chair: Blanka Hirschlerova//Laivi Saaremäel

### 7.1.1. Minutes

- Minutes from QWP Core Team meeting held by Adobe Connect on 17 February 2021
- Minutes for QWP plenary meeting held by Adobe Connect on 14-16 December 2020

**Action:** For information

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

No topics

## 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)

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. Committee for Advanced Therapies (CAT)

Chair: Martina Schüssler-Lenz

- Guideline on quality, non-clinical and clinical requirements for medicinal products containing genetically modified cells – Revision 1 (EMA/CAT/GTWP/671639/2008 Rev.1)

The Guideline was adopted by CAT in October 2020 and by CHMP during the November 2020 ORGAM meeting. In December 2020, comments were received from the ONCWP that necessitated an update of the Annex I (Clinical considerations for CAR-T cells). The updated Annex I to the guideline was adopted by CAT in January 2021.

**Action**: For adoption

### 7.5.2. Pharmacovigilance Risk Assessment Committee (PRAC)

Chair: Sabine Straus

PRAC report to CHMP. Summary of recommendations and advice of PRAC meeting held on 08-11 March 2021.

**Action:** For information

# 8. Product development support

## 8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

### 8.1.1. Outcome of the pilot of tailored biosimilar scientific advice

The outcome of the pilot of tailored scientific advice for biosimilars, which invited biosimilar developers to present extensive Quality and in vitro Non-Clinical data towards a tailored further development, is presented to the CHMP for information and for endorsement of the proposal to integrate such tailored scientific advice in regular SAWP operations. Towards this end, a minor update of the SAWP mandate is also presented for adoption.

**Action:** For adoption

### 8.1.2. Appointment of CHMP peer review for Scientific Advice

**Action:** For information

## 8.2. Innovation Task Force

### 8.2.1. ITF meeting

Meeting date: 19th March 2021

**Action:** For adoption

### 8.2.2. ITF meeting

Meeting date: 22 March 2021

**Action:** For adoption

### 8.2.3. ITF meeting

Meeting date: 29 March 2021

**Action:** For adoption

# 9. Any Other Business

### 9.1.1. EMA draft pregnancy strategy

Since July 2020 EMA has started the international collaboration on building an infrastructure for drug safety in pregnancy studies (building on the work initiated for COVID & pregnancy), held a stakeholders workshop and published the report from this (available at https://www.ema.europa.eu/en/documents/report/report-workshop-benefit-risk-medicines-used-during-pregnancy-breastfeeding_en.pdf)

The presentation will give an update on what is done to further develop and implement the strategy and to obtain feedback on CHMP needs in this space.

**Action:** For discussion

### 9.1.2. WebEx rollout plan for CHMP

Update to the CHMP on Webex rollout strategy.

**Action:** For discussion

### 9.1.3. Revised PROM Agenda template

Adaptation of the PROM agenda template following transition from ORGAM meeting.

**Action:** For information

### 9.1.4. Type II variations discussed at CHMP plenary

Type II variations discussed at the CHMP plenary: following topic presented in 2019 at CHMP ORGAM meetings (May and November), a proposal is presented to CHMP for endorsement on the type of variations discussed by default in the CHMP plenary.

**Action**: For endorsement

### 9.1.5. In vitro diagnostic regulation implementation for CDx–update on discussions with Notified Bodies and legacy IVDs

The IVDR will become fully effective as of 26 May 2022 and notified bodies need to seek a scientific opinion on the "suitability" of the device (CDx) in relation to the medicinal product concerned from a medicine authority/EMA. Proposal to ask interested CHMP members and/or assessors to join informal discussions with NBs to understand each other's requirements.

**Action:** For information

### 9.1.6. Call for interest for nomination of CHMP members to join temporary ad-hoc group on Lifecycle Regulatory Submissions Raw Data

Call for interest for nomination of CHMP members to join temporary ad-hoc group on raw data.

EMA's Lifecycle Regulatory Submissions Raw Data project is focusing on utilising raw data to generate evidence for better and more efficient regulatory decision making.

This project is part of the Data Analytics Programme also known as the Agency's vehicle for evolving to data-driven medicines regulation and constitutes one of the priority recommendations of the EMA-HMA Big Data Taskforce.

Interested members should contact directly by 22 March 2021.

**Action:** For information

### 9.1.7. New COVID application tracker

To improve oversight of ongoing and upcoming COVID-19 applications, EMA is introducing a tracking table. The table will be updated on a regular basis and brief updates will be provided at each PROM meeting.

**Action:** For information

### 9.1.8. Preview CHMP Plenary

CHMP: Harald Enzmann

**Action:** For information

### 9.1.9. 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