



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

07 May 2021  
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Human Medicines Division

## Committee for medicinal products for human use (CHMP) PROM<sup>1</sup> agenda for the meeting on 10 May 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

10 May 2021, 09:00–16:00<sup>2</sup>, 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).

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<sup>1</sup> 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.

<sup>2</sup> Note that the meeting may finish earlier depending on the length of the discussions.



## Table of contents

<b>1.</b>	<b>Agenda and Minutes</b>	<b>4</b>
1.1.	Welcome and declarations of interest of members, alternates and experts .....	4
1.2.	Adoption of agenda.....	4
1.3.	Adoption of the minutes .....	4
<b>2.</b>	<b>Non therapeutic-area-specific working parties</b>	<b>4</b>
2.1.	Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP) .....	4
2.2.	Biologics Working Party (BWP) .....	4
2.3.	Quality Working Party (QWP) .....	4
2.4.	Safety Working Party (SWP).....	5
2.5.	Biosimilar Medicinal Product Working Party (BMWP) .....	5
2.6.	Biostatistics Working Party (BSWP) .....	5
2.7.	Modelling and Simulation Working Party (MSWP) .....	5
2.8.	Pharmacogenomics Working Party (PGWP).....	5
2.9.	Pharmacokinetics Working Party (PKWP).....	5
<b>3.</b>	<b>Therapeutic-area-specific working parties and SAGs</b>	<b>6</b>
3.1.	Blood Products Working Party (BPWP).....	6
3.2.	Central Nervous System Working Party (CNSWP) .....	6
3.3.	Cardiovascular Working Party (CVSWP) .....	6
3.4.	Infectious Diseases Working Party (IDWP) .....	7
3.5.	Oncology Working Party (ONCWP) .....	7
3.6.	Rheumatology/Immunology Working Party (RIWP) .....	7
3.7.	Vaccines Working Party (VWP).....	7
3.8.	Scientific Advisory Groups (SAGs) .....	7
<b>4.</b>	<b>Drafting groups</b>	<b>7</b>
4.1.	Excipients Drafting Group .....	7
4.2.	Gastroenterology Drafting Group (GDG) .....	7
4.3.	Geriatric Expert Group (GEG).....	7
4.4.	Radiopharmaceuticals Drafting Group (RadDG).....	7
4.5.	Respiratory Drafting Group (RDG) .....	8
<b>5.</b>	<b>Harmonisation and consistency groups</b>	<b>8</b>
5.1.	International Council on Harmonisation (ICH) .....	8
5.2.	Guideline Consistency Group (GCG).....	8
5.3.	Summary of product characteristics Advisory Group .....	8

<b>6.</b>	<b>Joint groups and collaboration with other Scientific committees</b>	<b>8</b>
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) .....	8
6.2.	Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG) .....	8
6.3.	Collaboration with other Scientific committees .....	8
6.4.	Regulatory Issues / new legislation .....	9
6.5.	CHMP organisation / templates .....	9
<b>7.</b>	<b>Product development support</b>	<b>9</b>
7.1.	Scientific Advice Working Party (SAWP).....	9
7.2.	Innovation Task Force .....	9
<b>8.</b>	<b>Product related topics</b>	<b>10</b>
<b>9.</b>	<b>Any Other Business</b>	<b>10</b>

## **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 the 10 May 2021 meeting.

### **1.3. Adoption of the minutes**

CHMP PROM Minutes of May 2021 meeting will be adopted at the May 2021 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/Nanna Aaby Kruse

#### **2.2.1. Agenda and minutes**

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- Final minutes for BWP meeting held by Adobe Connect on 15-17 March 2021
- Draft agenda for BWP meeting to be held by WebEx on 10-12 May 2021

**Action:** For information

#### **2.2.2. Nomination of new alternate to the BWP**

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Nomination of new BWP alternate representing Estonia.

**Action:** For endorsement

### **2.3. Quality Working Party (QWP)**

Chair: Blanka Hirschlerova

#### **2.3.1. Minutes**

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- Final minutes from QWP Core Team meeting held by teleconference on 14 April 2021

**Action:** For information

### 2.3.2. Update on EFSA assessment on TiO<sub>2</sub>: Final opinion published

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EFSA opinion on TiO<sub>2</sub> has been finalised and published on the 6<sup>th</sup> of May. A short summary on the main conclusions of the final EFSA opinion will be presented together with the next steps in agreement with DG SANTE.

**Action:** For information

### 2.3.3. CMDh question to QWP on Ph. Eur. Product Monographs

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CMDh question to QWP seeking clarification on the compliance with Ph. Eur. Product Monographs on Finished Products containing chemically defined active substances.

**Action:** For adoption

## 2.4. Safety Working Party (SWP)

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

### 2.4.1. Agendas and minutes

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- Final minutes for SWP meeting held virtually in replacement for face-to-face on 17-18 March 2021
- Draft agenda for ad-hoc SWP meeting with EFSA on TiO<sub>2</sub> to be held by teleconference on 10 May 2021
- Draft agenda for SWP Nitrosamines Interested Party Meeting to be held by teleconference on 31 May 2021

**Action:** For information

## 2.5. Biosimilar Medicinal Product Working Party (BMWP)

No topics

## 2.6. Biostatistics Working Party (BSWP)

No topics

## 2.7. Modelling and Simulation Working Party (MSWP)

No topics

## 2.8. Pharmacogenomics Working Party (PGWP)

No topics

## 2.9. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

### 2.9.1. Product-specific guidelines

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#### **Final product-specific guidelines**

- Deferasirox product-specific bioequivalence guidance (EMA/CHMP/472383/2020) and Overview of comments

**Action:** For adoption

#### **Proposed new product-specific guidelines**

- CMDh request to CHMP (PKWP) for new ad-hoc product specific bioequivalence guidelines for ibrutinib, olaparib, enzalutamide, liposomal amphotericin B, ursodeoxycholic acid and lanreotide.

**Action:** For adoption

### 2.9.2. Questions from Committees, other Working Parties

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- CMDh question to CHMP (PKWP) related to Tapentadol prolonged release capsules

**Action:** For adoption

## 3. Therapeutic-area-specific working parties and SAGs

### 3.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

#### 3.1.1. Adverse reactions to COVID-19 vaccination and the safety of substances of human origin

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ECDC draft recommendations for EMA input.

**Action:** For discussion

#### 3.1.2. Minutes

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- Final minutes of the Blood cluster TC on 19 March 2021

**Action:** For information

### 3.2. Central Nervous System Working Party (CNSWP)

No topics

### 3.3. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs

#### 3.3.1. Cancelled - Call for nominations for CVS WP chair and CVS WP vice-chair

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The call for nomination is cancelled in light of the ongoing EMA Working Party restructuring.

**Action:** For information

### **3.4. Infectious Diseases Working Party (IDWP)**

No topics

### **3.5. Oncology Working Party (ONCWP)**

Chairs: Sinan B. Sarac/Paolo Foggi

#### **3.5.1. Agenda and minutes**

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- Final minutes for ONCWP meeting held by Adobe Connect on 11 March 2021
- Final agenda for ONCWP meeting held by Adobe Connect on 06 May 2021

**Action:** For information

### **3.6. Rheumatology/Immunology Working Party (RIWP)**

No topics

### **3.7. Vaccines Working Party (VWP)**

No topics

### **3.8. Scientific Advisory Groups (SAGs)**

#### **3.8.1. Participants to the SAG**

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Update to CHMP on the exclusion criteria and restrictions applicable to participants to this SAG.

**Action:** For discussion

## **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. Adoption of Guidelines

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- ICH Q3C(R8) Step 5 - Residual solvents

This updated document contains PDE levels for three solvents: 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol. Implementation foreseen 6 months after publication.

**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

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Summary of recommendations and advice of PRAC meeting held on 03-06 May 2021.

**Action:** For information



## 6.4. Regulatory Issues / new legislation

### 6.4.1. Procedural guidance for variation for variant update to covid-19 vaccines

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Update to CHMP on draft procedural guidance for variation for variant update to covid-19 vaccines. CHMP members are invited send comments by 24 May 2021.

**Action:** For information

## 6.5. CHMP organisation / templates

### 6.5.1. CHMP learnings

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Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

**Action:** For discussion

### 6.5.1. Resourcing of Covid-19 applications: Follow up from April CHMP meeting

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Update to the CHMP on the progress and next steps on resourcing of Covid-19 applications following discussion at April CHMP meeting.

**Action:** For discussion

### 6.5.2. External CHMP Engagement and Communication

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Progress on initiative external CHMP Engagement and Communication, currently included as part of CHMP workplan 2021. Introduction to CHMP's regular information on selected procedures (CRISP).

CHMP: Harald Enzmann

**Action:** For information

## 7. Product development support

### 7.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

#### 7.1.1. Appointment of CHMP peer review for SA

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**Action:** For information

### 7.2. Innovation Task Force

#### 7.2.1. ITF meeting

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Meeting date: 27 May 2021

**Action:** For adoption

### 7.2.2. ITF meeting

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Meeting date: 28 May 2021

**Action:** For adoption

## 8. Product related topics

### 8.1.1. Preview CHMP Plenary

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CHMP: Harald Enzmann

**Action:** For information

### 8.1.2. COVID-19 ongoing and upcoming procedures

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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

### 8.1.3. Vaxzevria – COVID-19 Vaccine (ChAdOx1-S [recombinant]) - EMEA/H/005675

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AstraZeneca AB; active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older

Scope: Post-authorisation activities

**Action:** For information

### 8.1.4. Doxorubicin Hydrochloride - EMEA/H/005330

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treatment of breast cancer, treatment of ovarian cancer, treatment of multiple myeloma, treatment of AIDS related Kaposi's sarcoma.

Scope: Update on the status of this application

**Action:** For information

### 8.1.5. Doxorubicin - EMEA/H/005320

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treatment of breast cancer, ovarian cancer, progressive multiple myeloma and AIDS-related Kaposi's sarcoma

Scope: Update on the status of this application

**Action:** For information

## 9. Any Other Business

No topics