



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 February 2021  
EMA/CHMP/96864/2021 Rev.1  
Human Medicines Division

## Committee for medicinal products for human use (CHMP) PROM<sup>1</sup> minutes 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).

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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.



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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

The CHMP adopted 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

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Process to collect and record CHMP learnings.

CHMP: Outi Mäki-Ikola

**Action:** For discussion

CHMP endorsed learnings.

#### 2.2.2. CHMP Co-opted membership

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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

The CHMP noted the nominations received by the deadline. The election of the co-opted member will take place during the February CHMP plenary.

## 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(s) and minutes

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- 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

CHMP noted the Agenda and Minutes

#### 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

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Revised statement and Overview of comments.

**Action:** For adoption

The CHMP noted and adopted the position statement on quality and safety assessment for the Plasma Master File (PMF) certification with regards to donor deferral criteria for risk behaviour with no further comments. Given differing risk level and risk mitigation measures in countries from which the plasma for fractionation originates, differing donor deferral criteria and periods of deferral for at risk donors can be justified.

#### 4.1.3. EMA response to third party (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

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EMA response.

**Action:** For endorsement

CHMP endorsed the response letter to third party dated 15<sup>th</sup> of September 2020 in relation to the supply of plasma derived medicinal products (PDMP) to EU citizens where detailed proposals for changes to the EU donor acceptance criteria with regards to plasma for fractionation are provided.

#### 4.1.4. Change to BWP composition

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Nomination of Sofie Termont as a new member for Belgium.

**Action:** For endorsement

CHMP endorsed the appointment of Sofie Termont as new BWP member for Belgium.

## 4.2. Safety Working Party (SWP)

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

### 4.2.1. Minutes

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

**Action:** For information

CHMP noted the minutes.

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

Chair: Elena Wolff-Holz

### 4.3.1. Call for nominations for BMWP Vice-Chair

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The mandate of the BMWP Vice-Chair Niklas Ekman ended on 14 September 2020.

**Action:** For information

CHMP noted the call for nominations for BMWP Vice-Chair. Nominations should be sent to the Agency to the BMWP Secretariat by **26 February 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.

## 4.4. Biostatistics Working Party (BSWP)

Chair: Kit Roes

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

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The mandate of the BMWP Vice-Chair Jörg Zinserling ended on 24 January 2021.

**Action:** For information

CHMP noted the 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.

## 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

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

**Action:** For endorsement

CHMP endorsed the organisation of a BPWP meeting in March.

**Action:** For discussion

#### 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

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- 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

CHMP noted Agenda and minutes.

#### 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

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

**Action:** For information

CHMP noted the minutes.

### 7.1.2. Call for nominations for a QWP Core Team member

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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 Core Team member are eligible for the position. Elections will take place at the March QWP Plenary meeting.



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

**Action:** For information

CHMP noted call for nominations for a QWP Core Team member.

## **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**

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- 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**

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

**Action:** For information

CHMP noted the Summary of recommendations and advice.

## **8. Product development support**

### **8.1. Scientific Advice Working Party (SAWP)**

Chair: Anja Schiel

#### **8.1.1. Appointment of CHMP peer review for Scientific Advice**

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**Action:** For information

CHMP noted the appointment of CHMP per review for Scientific Advice

## 8.2. Innovation Task Force

### 8.2.1. ITF meeting

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Meeting date: 4<sup>th</sup> February 2021.

**Action:** For information

CHMP endorsed the meeting.

### 8.2.2. ITF meeting

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Meeting date: 24<sup>th</sup> February 2021.

**Action:** For adoption

CHMP endorsed the meeting.

## 9. Any Other Business

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

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PRIME 5-year analysis: criteria for adoption

**Action:** For adoption

CHMP was updated with PRIME 5-year analysis criteria.

### 9.1.2. Patient Engagement at CHMP; new pilot

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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

CHMP was presented with the new pilot.

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

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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

CHMP noted developments 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.

### 9.1.4. Preview CHMP Plenary

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CHMP: Harald Enzmann

**Action:** For information

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

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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

CHMP was updated on the status of this application.

## 10. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on the PROM agenda and draft CHMP plenary Agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Daniela Philadelphy	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Ilko Getov	Member	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Emilia Mavrokordatou	Alternate	Cyprus	No restrictions applicable to this meeting	COVID-19 vaccines
Ondřej Slanař	Member	Czechia	No restrictions applicable to this meeting	
Tomas Radimersky	Alternate	Czechia	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Konstantinos Markopoulos	Member	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	

Armando Genazzani	Member	Italy	No interests declared	
Simona Stankeviciute	Alternate	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Paula Boudewina van Hennik	Alternate	Netherlands	No interests declared	
Bjorg Bolstad	Member	Norway	No restrictions applicable to this meeting	
Ingrid Wang	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	COVID-19 vaccines
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Francisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No restrictions applicable to this meeting	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Christian Gartner	Co-opted member	Austria	No restrictions applicable to this meeting	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Conception Gimenez Rebollo	Expert - via Adobe*	Spain	No restrictions applicable to this meeting	
Deirdre Mannion	Expert - via Adobe*	Denmark	No restrictions applicable to this meeting	
Elita Poplavska	Expert - via Adobe*	Latvia	No interests declared	
Jacqueline Kerr	Expert - via Adobe*	Germany	No interests declared	
Maria Victoria Tudanca Pacios	Expert - via Adobe*	Spain	No restrictions applicable to this meeting	
Mette Tranholm	Expert - via Adobe*	Denmark	No interests declared	

Milena Peraita Ezcurra	Expert - via Adobe*	Spain	No interests declared	
Nora Cascante Estepa	Expert - via Adobe*	Germany	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with the help of EMA staff				

\*Experts were evaluated against the product(s) they have been invited to talk about