



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

29 September 2022  
EMA/CHMP/770426/2022 Rev.2  
Human Medicines Division

## Committee for medicinal products for human use (CHMP) PROM<sup>1</sup> agenda for the meeting on 3 October 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

3 October 2022, 09:00–16:00, 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.



## 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>Quality Domain</b>	<b>4</b>
2.1.	Biologics Working Party (BWP) .....	4
2.2.	Quality Working Party (QWP) .....	4
2.3.	Biosimilar Medicinal Product Working Party (BMWP) .....	5
2.4.	Quality Innovation Group (QIG) .....	5
2.5.	Formulation Expert Group (FEG).....	5
<b>3.</b>	<b>Non-Clinical Domain</b>	<b>5</b>
3.1.	Non-Clinical Working Party (NCWP) .....	5
3.2.	3Rs Replacement, Reduction and Refinement Working Party (3RsWP) .....	6
<b>4.</b>	<b>Methodology Domain</b>	<b>6</b>
4.1.	Methodology Working Party (MWP).....	6
<b>5.</b>	<b>Clinical Domain</b>	<b>6</b>
5.1.	Central Nervous System Working Party (CNSWP) .....	6
5.2.	Cardiovascular Working Party (CVSWP) .....	6
5.3.	Oncology Working Party (ONCWP) .....	6
5.4.	Rheumatology and Immunology Working Party (RIWP).....	7
5.5.	Infectious Disease Working Party (IDWP).....	7
5.6.	Vaccines Working Party (VWP).....	7
5.7.	Haematology Working Party (HaemWP) .....	7
5.8.	Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEG).....	7
<b>6.</b>	<b>Patients, Healthcare Professionals and Consumers</b>	<b>7</b>
6.1.	Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP) .....	7
<b>7.</b>	<b>Harmonisation and consistency groups</b>	<b>8</b>
7.1.	International Council on Harmonisation (ICH) .....	8
7.2.	Guideline Consistency Group (GCG).....	8
7.3.	Summary of product characteristics Advisory Group .....	8
<b>8.</b>	<b>Joint groups and collaboration with other Scientific committees</b>	<b>8</b>
8.1.	Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG) .....	8

8.2.	Collaboration with other Scientific committees .....	8
<b>9.</b>	<b>Regulatory/Organisational matters</b>	<b>8</b>
9.1.	Regulatory Issues/new legislation .....	8
9.2.	CHMP organisation/templates .....	8
<b>10.</b>	<b>Product development support</b>	<b>9</b>
10.1.	Scientific Advice Working Party (SAWP).....	9
10.2.	Innovation Task Force .....	9
<b>11.</b>	<b>Product related topics</b>	<b>10</b>
11.1.	Preview CHMP Plenary.....	10
11.2.	COVID-19 ongoing and upcoming procedures .....	10
11.3.	vadadustat - EMEA/H/C/005131 .....	10
11.4.	Janus kinase (JAK) inhibitors: abrocitinib - CIBINQO (CAP); baricitinib - OLUMIANT (CAP); filgotinib - JYSELECA (CAP); tofacitinib - XELJANZ (CAP); upadacitinib - RINVOQ (CAP) – EMEA/H/A-20/1517.....	10
11.5.	mavacamten - EMEA/H/C/005457 .....	10
<b>12.</b>	<b>Any Other Business</b>	<b>11</b>
12.1.	Rapporteurships .....	11
12.2.	Regulatory & scientific conference on RNA based medicines .....	11

## 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 3 October 2022 meeting.

### 1.3. Adoption of the minutes

CHMP PROM Minutes of 3 October 2022 meeting will be adopted at the October CHMP plenary.

## 2. Quality Domain

### 2.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz, Sean Barry

#### 2.1.1. Agenda and minutes

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- Draft agenda for BWP meeting to be held F2F on 3-5 October 2022
- Final minutes for BWP meeting held virtually on 11-13 July 2022

**Action:** For information

#### 2.1.2. Nomination of new alternate

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Nomination of new BWP alternate, replacing Monta Emersone, representing Latvia.

**Action:** For endorsement

#### 2.1.3. Nomination of new member

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Nomination of new BWP member, replacing Marcos Timon, representing Spain.

**Action:** For endorsement

### 2.2. Quality Working Party (QWP)

Chairs: Blanka Hirschlerova

#### 2.2.1. Agenda and minutes

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- Final minutes for QWP-CT meeting held virtually on 7 September 2022
- Final minutes for QWP meeting held virtually in June 2022

**Action:** For information

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

No topics

## 2.4. Quality Innovation Group (QIG)

No topics

## 2.5. Formulation Expert Group (FEG)

No topics

# 3. Non-Clinical Domain

## 3.1. Non-Clinical Working Party (NCWP)

Chairs: Susanne Brendler-Schwaab, Karen van Malderen

### 3.1.1. Agenda and minutes

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- Draft minutes for NcWP meeting held virtually on 1 & 7 September 2022
- Draft agenda for NcWP meeting to be held face-to-face on 4-5 October 2022, including annual stakeholders meeting
- Draft agenda for EMA/FDA non-clinical oncology cluster teleconference to be held virtually on 18 October 2022

**Action:** For information

### 3.1.2. CMDh questions to NcWP on new nitrosamines

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CMDh requests that the NcWP determines the acceptable intake for the following nitrosamines based on lifetime daily exposure including information on the points of departure and methodology used.

- N-nitroso-vortioxetine
- N-nitroso-mirabegron
- N-nitroso-bupropion

**Action:** For adoption

### 3.1.3. Questions and Answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products (EMA/409815/2020)

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Additional update of Questions and Answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products.

**Action:** For adoption

### 3.2. 3Rs Replacement, Reduction and Refinement Working Party (3RsWP)

No topics

## 4. Methodology Domain

### 4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

#### 4.1.1. Agenda and minutes

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- Final agenda and minutes for MWP meetings held virtually on 8 September 2022

**Action:** For information

## 5. Clinical Domain

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

Chair: Andre Elferink

#### 5.1.1. Nomination of member to CNSWP

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Nomination of a new member to CNSWP.

**Action:** For endorsement

#### 5.1.2. Call for nomination for CNSWP vice chair

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Following nomination of one additional member to CNSWP, a call for nomination for the position of vice chair of the CNSWP is launched. Nominations should be sent to the Agency **by 20 October 2022**. 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 in November PROM (31 October).

**Action:** For endorsement

### 5.2. Cardiovascular Working Party (CVSWP)

No topics

### 5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis

#### 5.3.1. Nomination of Oncology ESEC experts

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- Nomination by ONCWP of the experts to enter the Oncology European Specialised Expert Community (ESEC)

**Action:** For endorsement

### 5.3.2. Update on Oncology ESEC activities

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- Composition of the drafting group reviewing the anti-cancer guideline (EMA/CHMP/205/95 Rev.6):

**Action:** For endorsement

- EUNTC Webinar – Challenges in drug development, regulation and clinical practice in Follicular lymphoma (Friday 7 October, 13.30-15 pm)

**Action:** For information

- Call for interest to have a CHMP representative for the 2nd EU NTC webinar on Diffuse Large B-Cell Lymphoma (DLBCL)

**Action:** For discussion

### 5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

### 5.5. Infectious Disease Working Party (IDWP)

No topics

### 5.6. Vaccines Working Party (VWP)

No topics

### 5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

#### 5.7.1. Agenda and minutes

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- Agenda of the HAEMWP to be held virtually on 9 September 2022
- Minutes of the HAEMWP held virtually on 9 September 2022

**Action:** For information

### 5.8. Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEG)

No topics

## 6. Patients, Healthcare Professionals and Consumers

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

No topics

## 7. Harmonisation and consistency groups

### 7.1. International Council on Harmonisation (ICH)

#### 7.1.1. ICH M11 - Clinical electronic structured harmonised protocol

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Following the completion of the Step 1 ICH M11 EWG Technical Document, Template and Technical Specification, the agreed draft versions are brought to CHMP for adoption (document available in MMD) before a 3-4 month public consultation.

**Action:** For adoption

### 7.2. Guideline Consistency Group (GCG)

No topics

### 7.3. Summary of product characteristics Advisory Group

No topics

## 8. Joint groups and collaboration with other Scientific committees

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

No topics

### 8.2. Collaboration with other Scientific committees

#### 8.2.1. PRAC report to CHMP

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Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 26-29 September 2022.

**Action:** For information

## 9. Regulatory/Organisational matters

### 9.1. Regulatory Issues/new legislation

No topics

### 9.2. CHMP organisation/templates

#### 9.2.1. CHMP learnings

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Collection, discussion and recording of CHMP learnings.



CHMP: Outi Mäki-Ikola

**Action:** For discussion

### 9.2.2. Proposal for a CHMP-CAT project on the usefulness of preference elicitation as an add-on to expert advice

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This proposal is to run a short project to understand if formal elicitation, alongside the traditional meeting summaries, can be useful to provide expert opinions to scientific committees for instance, in the context of Scientific Advisory Group. The project will focus on perceived usefulness by CHMP-CAT associated members/assessors and experts in receiving and providing expert advice.

CHMP: Hans Hillege

**Action:** For discussion

## 10. Product development support

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

Chair: Paolo Foggi

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

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**Action:** For information

#### 10.1.2. Agenda and Table of Decisions

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- Agenda from 26-29 September 2022 meeting held by Webex
- Draft Table of Decisions from 26-29 September 2022 meeting held by Webex

**Action:** For information

### 10.2. Innovation Task Force

#### 10.2.1. ITF meeting

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Meeting date: 10 October 2022

**Action:** For adoption

#### 10.2.2. ITF meeting

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Meeting date: 17 October 2022

**Action:** For adoption

#### 10.2.3. ITF meeting

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Meeting date: 19 or 21 October 2022 (TBC)

**Action:** For adoption

#### 10.2.4. ITF meeting

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Meeting date: October 2022 (TBC)

**Action:** For adoption

## 11. Product related topics

### 11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

**Action:** For information

### 11.2. 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

### 11.3. vadadustat - EMEA/H/C/005131

Treatment of anaemia

Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in September 2022.

**Action:** For adoption

List of Outstanding issues adopted on 15.09.2022. List of Questions adopted on 24.03.2022.

### 11.4. Janus kinase (JAK) inhibitors: abrocitinib - CIBINQO (CAP); baricitinib - OLUMIANT (CAP); filgotinib - JYSELECA (CAP); tofacitinib - XELJANZ (CAP); upadacitinib - RINVOQ (CAP) – EMEA/H/A-20/1517

Applicant(s): AbbVie Deutschland GmbH & Co. KG (Rinvoq), Eli Lilly Nederland B.V. (Olumiant), Galapagos N.V. (Jyseleca), Pfizer Europe MA EEIG (Cibinqo, Xeljanz)

Scope: Review of the benefit-risk balance following notification by the European Commission (EC) of a referral under Article 20 of Regulation (EC) No 726/2004, based on pharmacovigilance data

**Action:** For information

### 11.5. mavacamten - EMEA/H/C/005457

Treatment of hypertrophic cardiomyopathy

Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in July 2022.

**Action:** For adoption

## 12. Any Other Business

### 12.1. Rapporteurships

Update

**Action:** For information

### 12.2. Regulatory & scientific conference on RNA based medicines

This conference aims to facilitate the dialogue between industry/academia and regulators, to discuss scientific and regulatory opportunities and challenges to promote the development of RNA-based innovative medicines.

**Action:** For information