



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 April 2023  
EMA/CHMP/153279/2023 Rev.1  
Human Medicines Division

## Committee for medicinal products for human use (CHMP) PROM<sup>1</sup> agenda for the meeting on 17 April 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

17 April 2023, 09:00–16:00, virtual meeting

### 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 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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PROM meeting to be held on 17 April 2023. As the PROM is a preparatory meeting for the CHMP plenary session, restrictions and declarations of interests applicable to the items in the draft agenda of the upcoming CHMP plenary session are also considered. See April 2023 PROM minutes.

### 1.2. Adoption of agenda

CHMP PROM agenda for 17 April 2023 meeting

### 1.3. Adoption of the minutes

CHMP PROM Minutes of 17 April meeting will be adopted at the April 2023 CHMP plenary.

## 2. Quality Domain

### 2.1. Biologics Working Party (BWP)

Chair: Sean Barry

#### 2.1.1. 3-year workplan and call for nominations of new members

Call for nominations and 3-year workplan for the BWP.

Progressing the implementation of the WOM for the Quality domain, the CHMP is presented with the call for nominations including member and chair selection timelines and draft 3-year workplan for BWP.

**Action:** For adoption

#### 2.1.2. Call for nomination for the BWP Vice-Chair

Following the election of Sean Barry as the new BWP Chair last month, the position of Vice-Chair is now vacant. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Nominations should be sent to the Agency by 12 April 2023.

The election will take place at the April 2023 CHMP plenary meeting.

**Action:** For information

#### 2.1.3. Draft agenda and Minutes

- Final minutes of the BWP meeting held F2F on 13-15 February 2023
- Draft agenda of the BWP meeting to be held F2F on 17-19 April 2023

**Action:** for information

#### 2.1.4. Nomination of new member for the BWP

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Nomination of new Irish member, Niamh Curran replacing Sean Barry.

**Action:** for endorsement

## 2.2. Quality Working Party (QWP)

Chair: Blanka Hirschlerova, Vice-Chairs: Marie-Hélène Sabinotto, Laivi Saaremäel

#### 2.2.1. 3-year workplan and call for nominations of new members

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Call for nominations and 3-year workplan for the QWP.

Progressing the implementation of the WOM for the Quality Domain, the CHMP is presented with the call for nominations including member and chair selection timelines and draft 3-year workplan for QWP.

**Action:** For adoption

#### 2.2.2. Nomination of new member for the QWP

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Nomination of new Austrian member, Gernot Hirn replacing Susanne Stotter (H+V) for the QWP (interim measure pending reorganisation of the QWP).

**Action:** For endorsement

#### 2.2.3. Agenda and minutes

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- Final agenda and minutes for QWP-CT meeting held virtually on 22 March 2023

**Action:** For information

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

Chair: Vacant, Vice-Chair: Niklas Ekman

#### 2.3.1. 3-year workplan and call for nominations of new members

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Call for nominations and 3-year workplan for the BMWP.

Progressing the implementation of the WOM for the Quality Domain, the CHMP is presented with the call for nominations including member and chair selection timelines and draft 3-year workplan for BMWP.

**Action:** For adoption

## 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)

Chair: Susanne Brendler-Schwaab, Vice-Chair: Karen van Malderen

#### 3.1.1. Agenda and minutes

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- Draft minutes for the NcWP meeting held virtually on 21-22 March 2023
- Draft agenda for the NcWP meeting to be held virtually on 18-19 April 2023
- Final agenda for the NS OEG f2f meeting of 28-29 March 2023

**Action:** For information

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

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The CMDh requests that the NcWP determines the acceptable intake for:

- N-nitroso-2-isopropyl-5,5 dimethyl thiazolidine-4 carboxylic acid (NIPDMTC)
- N-nitroso-desmethyl-terbinafine (NDT), N-nitroso-terbinafine impurity A (NTA) and N-nitroso-terbinafine degradant (NTD)
- N-nitroso-tamsulosin
- 2-(4-nitrosopiperazine-1-yl)-pyrimidine and N-nitroso-piperazine
- N-nitroso-clonidine
- N-nitroso-enalapril
- N-nitroso-cilazapril
- N-nitroso-ketamine

based on lifetime daily exposure including information on the points of departure and methodology used.

**Action:** For adoption

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

No topics

## 4. Methodology Domain

### 4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

#### 4.1.1. [Concept Paper on Platform trials](#)

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The concept paper on platform trials was published on the EMA website in November 2022 and the public consultation period ended 31 January 2023: [Platform trials - Scientific guideline | European Medicines Agency \(europa.eu\)](#)

Comments from 12 organisations were received. The reply to stakeholders addressing their comments will be published, outlining the comments which will be addressed and others that will likely not be addressed in the reflection paper.

**Action:** For information

#### 4.1.2. [Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation](#)

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The reflection paper on single-arm trials was presented at CHMP PROM in December 2022 with a written consultation of CHMP and SAWP members until January 2023. The paper was submitted for review to the Guideline Consistency Group (GCG) in January 2023 and a revised version was agreed to by the GCG on 12 April 2023. Following its adoption by the CHMP, the reflection paper is planned to be released for public consultation with a consultation period of approximately 5 months.

The presentation will cover the final scope of the reflection paper, changes implemented following comments from CHMP and SAWP members or the GCG, and an outline of the planned communication activities.

MWP Chair: Kit Roes

**Action:** For adoption

#### 4.1.3. [Nomination of Methodology ESEC experts](#)

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Nomination by MWP of the experts to enter the Methodology European Specialised Expert Community (ESEC).

Nomination(s) received

**Action:** For endorsement

#### 4.1.4. [Nomination of Modelling & Simulation Operational Expert Group \(MSOEG\)](#)

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Nomination by MWP of the experts to enter the Modelling and Simulation Operational Expert Group (MSOEG).

Nomination(s) received

**Action:** For endorsement

#### 4.1.5. [Nomination of Biostatistics Operational Expert Group \(BSOEG\)](#)

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Nomination by MWP of the experts to Biostatistics Operational Expert Group (BSOEG).

Nomination(s) received

**Action:** For endorsement

#### 4.1.6. [Question and Answers on in vitro profile comparison for bioequivalence inference](#)

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CHMP at July 2022 PROM requested a Q&A from MWP addressing the statistical handling of the f<sub>2</sub> value in dissolution comparison including recommending where a 90% confidence interval applies and, also considering there are currently several places where this is addressed in guidance. The resulting Q&A has also received input from QWP.

MWP Expert: Alfredo Garcia-Arieta

**Action:** For endorsement

### 4.2. **Pharmacokinetics Working Party (PKWP)**

Chair: Carolien Versantvoort

#### 4.2.1. [Product-specific guidelines](#)

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##### **Final versions of revised product-specific guidelines**

The revision of the following 3 guidelines concerned defining what is meant by 'comparable' T<sub>max</sub> as an additional main pharmacokinetic variable. The public consultation period ended 31 July 2022:

- Ibuprofen oral use immediate release formulations 200 – 800 mg product-specific bioequivalence guidance (EMA/CHMP/356876/2017 Rev.1) and Overview of comments
- Paracetamol oral use immediate release formulations product-specific bioequivalence guidance (EMA/CHMP/356877/2017 Rev.1) and Overview of comments
- Tadalafil film-coated tablets 2.5 mg, 5 mg, 10 mg, and 20 mg product-specific bioequivalence guidance (EMA/CHMP/315234/2014 Rev.2) and Overview of comments

PKWP expert: Alfredo Garcia-Arieta

**Action:** For adoption

#### 4.2.2. [PKWP response to CMDh questions on ibuprofen product-specific guidance](#)

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Request from CMDh relating to ongoing DCPs for ibuprofen oro-dispersible tablets received in July 2022 coinciding with the public consultation on revision 1 of the ibuprofen product-specific guidance (see topic 4.2.1). Request considered by PKWP along with comments received in the consultation.

PKWP expert: Alfredo Garcia-Arieta

**Action:** For adoption

## 5. **Clinical Domain**

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

No topics

## 5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

### 5.2.1. Nomination of new members for the CVS ESEC

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Nomination of new members for the CVS ESEC.

Nomination(s) received

**Action:** For endorsement

### 5.2.2. CVS WP Work Plan – priorities 2023

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Updated 3-years rolling work plan with priorities for 2023.

CVSWP Chair: Alar Irs

**Action:** For adoption

## 5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

### 5.3.1. Cancer Medicines Forum

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Presentation on the 1-year review of the Cancer Medicines Forum.

ONCWP Chair: Pierre Demolis

**Action:** For discussion

### 5.3.2. Nomination of oncology ESEC experts

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Nomination by Oncology WP of experts to enter the Oncology European Specialised Expert Community (ESEC).

Nomination(s) received

**Action:** For endorsement

### 5.3.3. Agenda and minutes

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- Agenda for the ONCWP meeting held virtually on 23 March 2023
- Minutes of the ONCWP meeting be held virtually on 15 February 2023

**Action:** For information

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

Chair: Caroline Auriche-Benichou

### 5.4.1. Drafting group on ARDS

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Concept paper on Acute Respiratory Distress syndrome (ARDS).

Rapporteur: Janet Koenig

**Action:** For adoption

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

No topics

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

Chair: Mair Powel

### **5.6.1. VWP 3-year workplan - priorities for 2023**

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3-year workplan for the VWP, priorities for 2023.

**Action:** For adoption

## **5.7. Haematology Working Party (HaemWP)**

Chair: Daniela Philadelphy

### **5.7.1. Nomination of haematology ESEC experts**

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Nomination by Haematology WP of experts to enter the Haematology European Specialised Expert Community (ESEC).

Nomination(s) received

**Action:** For endorsement

### **5.7.2. Minutes**

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- Final minutes of the Blood cluster TC held on 10 March 2023

**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. Nomination for EMA/EC expert to the ICH M11 (Clinical Electronic Structured 21 Harmonised Protocol Template) expert working group

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This new harmonised Guideline on Clinical electronic Structured Harmonised Protocol (CeSHarP) will introduce the clinical protocol template and the technical specification to ensure that protocols are prepared in a consistent fashion and provided in a harmonised data exchange format acceptable to the regulatory authorities. A new expert to represent CHMP/EMA/EC in the M11 working group was sought from the Clinical Trial Coordination Group (CTCG). An expert nomination is now brought to CHMP for endorsement.

Nomination(s) received

**Action:** For endorsement

### 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 11-14 April 2023.

**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

## 10. Product development support

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

Chair: Paolo Foggi, Vice-Chair: Pierre Demolis

#### 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 11-13 April 2023 meeting held by Webex
- Draft Table of Decisions from 11-13 April 2023 meeting held by Webex

**Action:** For information

### 10.2. Innovation Task Force

#### 10.2.1. ITF meeting

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Meeting date: 5 May 2023

**Action:** For adoption

## 11. Product related topics

### 11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

**Action:** For information

### 11.2. Ieniolisib - Orphan - EMEA/H/C/005927

Pharming Technologies B.V.; Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)

Applicant's timetable extension request.

**Action:** For adoption

List of Questions adopted on 24.01.2023.

## 12. Any Other Business

### 12.1. Rapporteurships

Update.

**Action:** For information

### 12.2. Update on COVID-19

**Action:** For information

### 12.3. Joint EMA-HMA statement on the interchangeability of biosimilars

The HMA Biosimilar Working Group has agreed an update of the interchangeability statement and Q&A document.

**Action:** For endorsement

### 12.4. GCP Inspections

The EMA Inspections Office will give a short presentation on triggers for routine and for-cause GCP inspections and the need for early communication between Rapporteurs and their inspectors to ensure capacity for CAP inspections.

**Action:** For information

### 12.5. Joint EU GCP Inspectors-clinical Assessors virtual workshop 26 June

Presentation on the scope of the Joint EU GCP Inspectors-clinical Assessors virtual workshop organised by the subgroup of GCP inspectors and Assessors working on *Embedding the outcome of GCP inspections into the B/R assessment and modernisation of the inspection process*. The presentation will also include a brief update on the deliverables of this subgroup.

**Action:** For information

### 12.6. PRIME implementation of 5-year review recommendations – 2023 Pilot features and guidance updates

Presentation of key aspects of the newly launched PRIME features arising from implementation of the recommendations of the first 5 years' experience with the scheme (see also PRIME 5-year report), as adopted by CHMP in September 2022.

Presentation of the approach to overhauled PRIME guidance documents

**Action:** For endorsement