



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 February 2025  
EMA/82017/2025  
Human Medicines Division

## Committee for medicinal products for human use (CHMP) PROM<sup>1</sup> minutes for the meeting on 17 February 2025

Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

### 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

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions. See Annex of the current document for the list of participants and restrictions in relation to declarations of interests applicable to the items of this meeting. 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 were also considered.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared. Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

### 1.2. Adoption of agenda

The CHMP adopted the PROM agenda for the 17 February 2025 meeting.

### 1.3. Adoption of the minutes

CHMP PROM Minutes of 17 February 2025 meeting will be adopted at the February 2025 CHMP plenary.

## 2. Quality Domain

### 2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

#### 2.1.1. Agenda and minutes

- Draft Agenda of the BWP meeting to be held remotely on 17-19 February 2025
- Minutes of the BWP meeting held remotely on 2-4 December 2024

**Action:** For information

The CHMP noted the agenda and minutes.

### 2.1.2. Revision of the Q&A from BWP Learnings

---

Revision of the Q&A on Low Endotoxin Recovery and addition of 3 new Q&As from BWP learnings for publication.

**Action:** For adoption

The CHMP adopted the revision of the Q&A on Low Endotoxin Recovery and the addition of 3 new Q&As from BWP learnings, for publication on the EMA website.

### 2.1.3. Nomination of new Biologics Quality ESEC experts

---

Nomination of new experts to join the Biologics Quality European Specialised Expert Community (ESEC).

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of new experts to join the Biologics Quality European Specialised Expert Community (ESEC).

### 2.1.4. CHMP Revamp- D80 AR Quality templates

---

The revamped D80 AR Quality templates developed jointly by QWP and BWP in the context of the CHMP AR Revamp project are presented for CHMP adoption. Two documents have been drafted one for Biological products and one for Chemicals.

*Same as QWP item 2.2.5 below.*

**Action:** For adoption

The CHMP adopted the revamped D80 AR Quality templates developed jointly by QWP and BWP.

## 2.2. Quality Working Party (QWP)

Chair: Blanka Hirschlerova, Vice-Chairs: Marie-Hélène Sabinotto, Nicolas Lee

### 2.2.1. Agenda and minutes

---

- Draft Agenda of the QWP meeting to be held remotely on 17-18 February 2025
- Minutes of the QWP meeting held remotely on 2-3 December 2024

**Action:** For information

The CHMP noted the agenda and minutes.

### 2.2.2. Nomination of new Chemical Quality ESEC experts

---

Nomination of new experts to join the Chemical Quality European Specialised Expert Community (ESEC).

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of new experts to join the Chemical Quality European Specialised Expert Community (ESEC).

#### 2.2.3. Letter from QWP to QRD on Gravimetric compounding in hospital pharmacies

---

Gravimetric processing is compounding where the amount of liquid to be used or added in the preparation of medicinal products for administration is determined by weighing (instead of volumetric control). Advantages in the clinical setting are that weighing is more precise than volumetric dosing and that weighing can be automated (beneficial for aseptic processing and safer for the operator when processing hazardous products). Automation also reduces compounding errors.

In 2024, QWP sent a questionnaire to the European Association of Hospital Pharmacists (EAHP) and to the European Society of Oncology Pharmacy (ESOP) with the aim to get a better understanding of the extent to which gravimetric compounding is used across EU MSs, to get an understanding from where hospital pharmacies obtain information about the density of the liquids and if there is a need to provide this information, for example in the SmPC. The feedback received from the questionnaire was discussed by QWP.

QWP Chair Blanka Hirschlerova

**Action:** For adoption

The CHMP adopted the letter from QWP to QRD on Gravimetric compounding in hospital pharmacies.

#### 2.2.4. CHMP Revamp- D80 AR Quality templates

---

The revamped D80 AR Quality templates developed jointly by QWP and BWP in the context of the CHMP AR Revamp project are presented for CHMP adoption. Two documents have been drafted one for Biological products and one for Chemicals.

*Same as BWP item 2.1.5 above.*

**Action:** For adoption

The CHMP adopted the revamped D80 AR Quality templates developed jointly by QWP and BWP.

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

Chair: René Anour, Vice-Chair: Niklas Ekman

#### 2.3.1. Agenda and minutes

---

- Agenda and Minutes of the BMWP meeting held in-person on 18 – 19 November 2024

**Action:** For information

The CHMP noted the agenda and minutes.

### 2.3.2. Reflection paper on a tailored clinical approach in biosimilar development

---

Overview of the current status and further activities.

BMWP Chair: René Anour

**Action:** For discussion

The CHMP noted the status of the draft reflection paper on a tailored clinical approach in biosimilar development.

## 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

---

- Minutes of the NcWP meeting held remotely on 03 - 04 December 2024
- Draft agenda of the NcWP meeting to be held remotely on 18 - 19 February 2025

**Action:** For information

The CHMP noted the agenda and minutes.

#### 3.1.2. Nomination of New Approach Methodologies ESEC experts

---

Nomination of new experts to join the New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC).

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of new experts to join the New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC).

#### 3.1.3. Call for nominations for NcWP Chair and Vice-chair

---

The mandate of the NcWP Chair Susanne Brendler-Schwaab and Vice-chair Karen van Malderen will expire on 21 April 2025.

Nominations should be sent to the Agency by 16 April 2025. 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 April 2025 CHMP Plenary meeting.

**Action:** For endorsement

The CHMP endorsed the call for nominations for NcWP Chair and Vice-chair.

#### 3.1.4. Call for interest for one new NcWP member

---

Call for interest for nomination of a NcWP member's replacement.

Nominations should be sent to the Agency by 31 March 2025. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Nominations will take place at the April 2025 CHMP PROM meeting.

**Action:** For information

The CHMP noted the call for interest of a NcWP member's replacement.

#### 3.1.5. Call for interest for one new NcWP member - extended

---

The call for interest for nomination of a NcWP member's replacement was extended.

Nominations should be sent to the Agency by 31 March 2025. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Nominations will take place at the April 2025 CHMP PROM meeting.

**Action:** For information

The CHMP noted the extension of the call for interest of a NcWP member's replacement.

#### 3.1.6. CMDh question to NcWP

---

**Action:** For adoption

The CHMP adopted the CMDh question to NcWP.

#### 3.1.7. Webinar on the reflection paper on the qualification of non-mutagenic impurities

---

The [Reflection paper on the qualification of non-mutagenic impurities](#), which follows the earlier version published in 2018 with considerable updates, as adopted by the CHMP at its December 2024 PROM meeting, has been published by public consultation. Comments should be provided by 30 April 2025

Alongside the public consultation, EMA will organise an online [webinar](#) on 6 March 2025, starting 13:00 CET, intended for all interested stakeholders with expertise and/or interest in the safety qualification of impurities, explaining the main new elements in the updated reflection paper and addressing questions and requests for clarification received from stakeholders regarding the draft reflection paper.

If any of the CHMP members or their quality or non-clinical colleagues would like to participate and/or have any specific topics or questions related to the draft reflection paper discussed during the webinar, please register by 23 February 2025.

**Action:** For information

The CHMP noted the information given for the webinar on the reflection paper on the qualification of non-mutagenic impurities.



### 3.1.8. NcWP Drafting Group for the Reflection paper on the implementation of the mode of action driven oncology paediatric development plans

---

A new NcWP drafting group was launched, which includes members of the NcWP involved in PIP assessments and other experts from the network who expressed their interest in the topic. The group started preparatory discussions with the intention to include clinical paediatric oncology experts for interdisciplinary reflections.

The formation of this DG was foreseen in the NC workplan and the work is expected to be completed as an element of building preparedness for the implementation of the new Pharmaceutical Legislation.

**Action:** For information

The CHMP noted the information given on the NcWP drafting group for the reflection paper on the implementation of the mode of action driven oncology paediatric development plans.

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

Chair: Sonja Beken, Vice-Chair: Sarah Adler-Flindt

### 3.2.1. Agenda and Minutes

---

- Minutes of the 3Rs meeting held remotely on 20–21 November 2024
- Agenda of the 3Rs meeting held remotely on 4 - 5 February 2025

**Action:** For information

The CHMP noted the agenda and minutes.

## 4. Methodology Domain

### 4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

#### 4.1.1. Agenda and minutes

---

- Agenda and minutes of the MWP meeting held remotely on 17 October 2024

**Action:** For information

The CHMP noted the agenda and minutes.

#### 4.1.2. Nomination of new Methodology ESEC experts

---

Nomination of EMA staff and new experts to join the Methodology European Specialised Expert Community (ESEC).

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of new experts to join the Methodology European Specialised Expert Community (ESEC).

#### 4.1.3. Nomination of new Methodology BSOEG experts

---

Nomination of new experts to join the Methodology Biostatistics Operational Expert Group (BSOEG).

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of new experts to join the Methodology Biostatistics Operational Expert Group (BSOEG).

#### 4.1.4. Nomination of new Methodology MSOEG experts

---

Nomination of new experts to join the Methodology Modelling & Simulation Operational Expert Group (MSOEG).

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of new experts to join the Methodology Modelling & Simulation Operational Expert Group (MSOEG).

#### 4.1.5. Good Practice Guide for the use of the HMA-EMA Catalogues of real-world data sources and studies

---

The 'Good Practice Guide for the use of the HMA-EMA Catalogues of real-world data (RWD) sources and studies' is a deliverable of the Big Data Steering Group, which has been adopted by the MWP and GCG. This will be the second version of the guide, following a public consultation in 2022.

The HMA-EMA Catalogues of RWD sources and studies were launched in February 2024 and serve as a repository of metadata collected from RWD sources and studies.

The guide provides advice on how regulators, researchers, and other stakeholders can effectively use the HMA-EMA Catalogues of real-world data sources and studies to identify, evaluate, and select data sources for planned studies. It also explains how to review the metadata elements collected in the Catalogues to get an understanding of the quality of a data source, in line with the principles of the Data Quality Framework for EU medicines regulation. The guide is presented for adoption.

**Action:** For adoption

The CHMP adopted the Good Practice Guide for the use of the HMA-EMA Catalogues of real-world data sources and studies.

#### 4.1.6. Implementation strategy of ICH Guideline M13A on bioequivalence for immediate-release solid oral dosage forms

---

The ICH M13A Guideline is the first in a series (ICH M13A, M13B and M13C) describing the scientific and technical aspects of study design and data analysis to support bioequivalence

assessment for orally administered immediate-release solid oral dosage forms. ICH M13A came into effect in the EU on 25 January 2025 and the MWP has drafted an implementation strategy to enable practical application and the transition from the current EMA guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1). Endorsement is sought from CHMP.

**Action:** For endorsement

The CHMP endorsed the implementation strategy of ICH Guideline M13A on bioequivalence for immediate-release solid oral dosage forms.

#### 4.1.7. Product-Specific Guidelines

---

**Final guidelines after 3-month public consultation:**

- Tolvaptan tablets with the dose range 7.5, 15 and 30 mg and tolvaptan tablets with the dose range 15, 30, 45, 60 and 90 mg product-specific bioequivalence guidance (EMA/CHMP/254395/2024) and Overview of comments (EMA/339228/2024).

Expert: Marc Maliepaard

**Action:** For adoption

The CHMP adopted the product-specific bioequivalence guidance (EMA/CHMP/254395/2024) and overview of comments (EMA/339228/2024).

#### 4.1.8. Revision of the guidance on non-inferiority and equivalence comparisons in clinical trials

---

The MWP is revising the guidance on non-inferiority and equivalence comparisons in clinical trials in line with the concept paper published early 2024 [Non-inferiority and equivalence comparisons in clinical trials - Scientific guideline | European Medicines Agency \(EMA\)](#). The revised guideline will substitute the current two guidance documents on (i) [Choice of a non-inferiority margin - Scientific guideline | European Medicines Agency \(EMA\)](#) and (ii) [Switching between superiority and non-inferiority - Scientific guideline | European Medicines Agency \(EMA\)](#).

The drafting group has prepared a complete draft, and invites CHMP members to share comments by 4 April 2025, especially on the different objectives of non-inferiority and equivalence comparisons and their relevance for regulatory decision-making.

**Action:** For information

The CHMP noted the information provided on the revision of the guidance on non-inferiority and equivalence comparisons in clinical trials.

#### 4.1.9. MWP response to CMDh question

---

**Action:** For adoption

The CHMP adopted the MWP response to CMDh question.

#### 4.1.10. CMDh question to CNSWP and QWP/MWP

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**Action:** For adoption

The CHMP adopted the CMDh question to CNSWP and QWP/MWP.

## 5. Clinical Domain

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

Chair: Andre Elferink, Vice-Chair: Ewa Balkowiec Iskra

#### 5.1.1. Agenda and minutes

---

- Agenda and Minutes of the CNSWP meetings held remotely on 13 September 2024 and 13 December 2024

**Action:** For information

The CHMP noted the agenda and minutes.

#### 5.1.2. Nomination of new members to the CNSWP

---

Nomination of 2 new members to join the CNSWP.

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of Nicolas Beix (ANSM), Kristin Elf (Lakemedelsverket) to the CNSWP.

#### 5.1.3. Call for nominations for CNSWP Chair

---

The mandate of the CNSWP Chair Andre Elferink will expire on 21 April 2025.

Nominations should be sent to the Agency by 16 April 2025. 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 April 2025 CHMP Plenary meeting.

**Action:** For endorsement

The CHMP endorsed the call for nominations for CNSWP Chair.

#### 5.1.4. Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders

---

Following the public consultation, the third revision of the guideline on clinical investigation of medicinal products in the treatment of epileptic disorders is presented for CHMP adoption.

CNSWP Chair: André Elferink

**Action:** For adoption

The CHMP adopted the guideline on clinical investigation of medicinal products in the treatment of epileptic disorders.

## 5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

### 5.2.1. Call for nominations for CVSWP Chair and Vice-chair

---

The mandate of the CVSWP Chair Alar Irs will expire on 22 April 2025 and the mandate of the vice-chair Patrick Vrijlandt will expire on 19 May 2025. Nominations should be sent by 16 April 2025 for the CVSWP Chair and by 14 May 2025 for the CVSWP Vice-Chair. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Election of the CVSWP Chair will take place at the April 2025 CHMP Plenary meeting, while for the CVSWP Vice-Chair at the May 2025 CHMP Plenary meeting.

**Action:** For endorsement

The CHMP endorsed the call for nominations for CVSWP Chair and Vice-chair.

## 5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

### 5.3.1. Call for nominations for ONCWP Chair

---

The mandate of ONCWP Chair Pierre Demolis will expire on 21 April 2025.

Nominations should be sent to the Agency by 17 March 2025. 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 April 2025 CHMP Plenary meeting.

**Action:** For endorsement

The CHMP endorsed the call for nominations for ONCWP Chair.

### 5.3.2. ONCWP 3-year workplan 2025-2027

---

Adoption of the 3-year workplan of the Oncology Working Party.

**Action:** For adoption

The CHMP adopted the 3-year workplan of the ONCWP.

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

Chair: Caroline Auriche Benichou

### 5.4.1. Revision of the guideline on clinical investigation of medicinal products in patients with Acute Respiratory Distress Syndrome

---

This is the first revision of the guideline on clinical investigation of medicinal products in patients with ARDS issued in 2006. Updates of the diagnostic criteria for ARDS in 2012 and 2023 have implications for identifying patients both in clinical and research settings. The

key requirements are described in terms of study population, (co)primary and secondary efficacy endpoints. Specific issues, including biomarker and/or (sub)phenotype defined drug development and preparedness are addressed for a potential future pandemic due to a viral pathogen that causes ARDS. Furthermore, relevant published methodological guidance documents for decision making (e.g. estimand) were added.

The document will be published for 3-months public consultation after CHMP adoption.

CHMP: Janet Koenig

**Action:** For adoption

The CHMP adopted the revision of the guideline on clinical investigation of medicinal products in patients with Acute Respiratory Distress Syndrome.

## 5.5. Infectious Disease Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo, Vice-Chair: Maja Sommerfelt Gronvold

### 5.5.1. Call for nominations for IDWP Chair and Vice-Chair

---

The mandate of the IDWP Chair Maria Jesus Fernandez Cortizo and the Vice-Chair Maja Sommerfelt Grønvold will expire on 18 May 2025.

Nominations should be sent to the Agency by 17 March 2025. 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 April 2025 CHMP Plenary meeting.

**Action:** For endorsement

The CHMP endorsed the call for nominations for IDWP Chair and Vice-Chair.

### 5.5.2. Call for interest for two new IDWP members – extended

---

The call for interest for nomination of 2 new IDWP members, following the departure of 2 members, was extended.

Nominations should be sent to the Agency by 20 March 2025. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise, DoI, endorsement of the nomination by a Committee member or alternate.

Nominations will take place at the April 2025 CHMP PROM meeting.

**Action:** For information

The CHMP noted the extension of the call for interest of two new IDWP members.

### 5.5.3. IDWP 3-year workplan 2025-2027

---

Adoption of the 3-year workplan of the Infectious Disease Working Party.

IDWP Vice-Chair: Maja Sommerfelt Gronvold

**Action:** For adoption

The CHMP adopted the 3-year workplan of the IDWP.

## 5.6. Vaccines Working Party (VWP)

Chair: Mair Powell, Vice-Chair: Sol Ruiz

### 5.6.1. Addendum to the guideline on clinical evaluation of new vaccines

---

Adoption of the Addendum to the guideline on clinical evaluation of new vaccines (EMA/CHMP/VWP/164653/05 Rev. 1). This addendum provides guidance on clinical studies to be conducted in immunocompromised individuals before or after initial marketing authorization of vaccines in order to support recommendations for use in the Product Information. The Addendum has been released for public consultation, revised by the GCG and is presented for CHMP adoption.

**Action:** For adoption

The CHMP adopted the addendum to the guideline on clinical evaluation of new vaccines.

### 5.6.2. Call for nominations for VWP Chair

---

The mandate of the VWP Chair Mair Powell will expire on 21 April 2025.

Nominations should be sent to the Agency by 17 March 2025. 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 April 2025 CHMP Plenary meeting.

**Action:** For endorsement

The CHMP endorsed the call for nominations for VWP Chair.

## 5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

### 5.7.1. EMA workshop on challenges in drug development, regulation and clinical practice for immunoglobulins

---

Draft Agenda of the [EMA workshop on the on the challenges in drug development, regulation and clinical practice for immunoglobulins](#) to be held remotely on 5 March 2025. Participants can register by 3 March 2025 at the following [link](#).

**Action:** For information

The CHMP noted the information provided on the EMA workshop on challenges in drug development, regulation and clinical practice for immunoglobulins.

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

### **5.8.1. SAG mandate renewal and (re)nominations**

---

Update of the renewal of SAG mandate/call for nomination of experts for the 3 therapeutic SAGs (Neurology, Vaccines and Cardiovascular Issues).

**Action:** For discussion

The CHMP noted the update of the renewal of SAG mandate/call for nomination of experts for the 3 therapeutic SAGs (Neurology Vaccines and Cardiovascular Issues).

## **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)**

No topics

### **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**

---

PRAC Chair: Ulla Wandel Liminga

Summary of recommendations and advice of PRAC meeting held on 10-13 February 2025.

**Action:** For information



The CHMP noted the summary of recommendations and advice.

#### **8.2.2. Call for expression of interest on joint CHMP-CAT membership**

---

Call for expression of interest on the appointment of CHMP members to the Committee for Advanced Therapies (CAT).

**Action:** For discussion

The CHMP noted the call for expression of interest on joint CHMP-CAT membership.

### **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

The CHMP noted the proposed learnings.

##### **9.2.2. GIREX - Group for Internal Rules on Extensions of Clock Stops**

---

Update on requests for extensions of clock stops for ongoing procedures. See also point 11.

**Action:** For adoption

The CHMP discussed a request for extension of a clock stops for an ongoing procedure. See point 11.3.

### **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

The CHMP noted the appointment of CHMP peer review for SA.

##### **10.1.2. Agenda and Table of Decisions**

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- Agenda of the SAWP meeting held remotely on 10-13 February 2025

- Draft Table of Decisions of the SAWP meeting held as a hybrid meeting on 10-13 February 2025

**Action:** For information

The CHMP noted the agenda and table of decisions.

#### **10.1.3. Call for nominations for SAWP Vice-Chair**

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The mandate of the SAWP Vice-Chair Pierre Demolis will expire on 1 May 2025.

Nominations should be sent by 17 March 2025. 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 2025 CHMP plenary meeting.

**Action:** For endorsement

The CHMP endorsed the call for nominations for SAWP Vice-Chair.

#### **10.1.4. Call for interest for one new SAWP member and respective alternate**

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Call of interest for nomination of a SAWP member's replacement.

Required areas of expertise: Infectious diseases, Non-clinical, Ophthalmology, Pulmonology, Biosimilars, Neurology.

Nominations should be sent by 12 March 2025.

The new SAWP member and his/her alternate starting date will follow their endorsement by the CHMP at the March CHMP PROM meeting, for participation in the SAWP activities as of 7 – 10 April 2025.

**Action:** For information

The CHMP noted the call for interest for one new SAWP member and respective alternate.

### **10.2. Innovation Task Force**

#### **10.2.1. ITF meeting**

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Meeting date: 26 February 2025

**Action:** For endorsement

The CHMP endorsed the meeting.

#### **10.2.2. ITF meeting**

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Meeting date: 4 March 2025

**Action:** For endorsement

The CHMP endorsed the meeting.

## 11. Product related topics

### 11.1. Preview CHMP Plenary

CHMP: Bruno Sepodes

**Action:** For information

The CHMP Chair and members flagged some procedures on the agenda of the upcoming plenary.

### 11.2. Diflunisal - Orphan - EMEA/H/C/006248

AO Pharma AB; Treatment of ATTR amyloidosis

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in January 2025.

**Action:** For adoption

List of Outstanding Issues adopted on 30.01.2025. List of Questions adopted on 30.05.2024.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in January 2025.

## 12. Any Other Business

### 12.1. Rapporteurships

Update.

**Action:** For information

The CHMP noted the update.

### 12.2. ETF workplan

Updates to the ETF workplan 2023-2025.

**Action:** For information

The CHMP noted the updates to the ETF workplan 2023-2025.

### 13. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Bruno Sepodes	Chair	Portugal	No interests declared	
Daniela Philadelphia	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Member	Cyprus	No interests declared	
Katerina Savvidou	Alternate	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Boje Kvorning Pires Ehmsen	Alternate	Denmark	No interests declared	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member (Vice-Chair)	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuio	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Janet Koenig	Member	Germany	No interests declared	
Martin Mengel	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hjalte Kristinsson	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Martine Trauffer	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	3.3.7. EMA/H/C/006425 5.1.16. EMA/H/C/005159 /II/0021/G
John Joseph Borg	Member	Malta	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Peter Mol	Member	Netherlands	No interests declared	
Patrick Vrijlandt	Alternate	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Fatima Ventura	Member	Portugal	No restrictions applicable to this meeting	
Paulo Paixão	Alternate	Portugal	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Antonio Gomez-Outes	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Karen van Malderen	Expert	Belgium	No interests declared	
Christian (Kit) Roes	Expert	Netherlands	No participation in discussion, final deliberations and voting on:	2.2.2. & 5.3.1. EMEA/H/C/003820 /II/0154 4.1.3. EMEA/H/C/004536 /X/0037/G
Pierre Demolis	Expert	Iceland	No interests declared	
Maja Sommerfelt Gronvold	Expert	Norway	No interests declared	
René Anour	Expert	Austria	No interests declared	
Elina Asikanius	Expert	Finland	No restrictions applicable to this meeting	
Angelika Geroldinger	Expert	Austria	No interests declared	
Bergrún Tinna Magnúsdóttir	Expert	Iceland	No interests declared	
Katrien Oude Rengerink	Expert	Netherlands	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Marc Maliepaard	Expert	Netherlands	No interests declared	
Christoph Furtmann	Expert	Germany	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Susana Morales-Alcelay	Expert	Spain	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
André Elferink	Expert	Netherlands	No interests declared	
Ana Maria Imedio	Expert	Spain	No interests declared	
Juan Ignacio Bedoya Ponte	Expert	Spain	No restrictions applicable to this meeting	
Tina Engraff	Expert	Denmark	No interests declared	

Experts were evaluated against the agenda topics or activities they participated in.