



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 July 2025  
EMA/CHMP/230038/2025  
Human Medicines Division

## Committee for medicinal products for human use (CHMP) PROM<sup>1</sup> Minutes for the meeting on 14 July 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 14 July 2025 meeting.

### 1.3. Adoption of the minutes

CHMP PROM Minutes of the 14 July 2025 meeting will be adopted at the July 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

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- Draft Agenda of the BWP meeting to be held remotely on 14-16 July 2025
- Minutes of the BWP meeting held remotely on 12-14 May 2025

**Action:** For information

The CHMP noted the agenda and minutes.

### 2.1.2. 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).

### 2.1.3. CHMP AR Revamp - D80-210 Overview template - Quality part

---

The quality part of the D80-210 Overview template was developed jointly by QWP and BWP in the context of the CHMP AR Revamp project. The document has been now finalised and endorsed by QWP and BWP and is presented for adoption.

**Action:** For adoption

The CHMP adopted the revamped quality part of the D80-210 Overview template.

## 2.2. Quality Working Party (QWP)

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

### 2.2.1. Revision of the Guideline on the pharmaceutical quality of inhalation and nasal medicinal products (EMA/CHMP/20607/2024)

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The revised guideline is presented for CHMP adoption following the 6 months public consultation.

Experts: Peter Casper, Anna Hillgren

**Action:** For adoption

The CHMP adopted the revised Guideline on the pharmaceutical quality of inhalation and nasal medicinal products (EMA/CHMP/20607/2024).

### 2.2.2. CHMP AR Revamp - D80-210 Overview template - Quality part

---

The quality part of the D80-210 Overview template was developed jointly by QWP and BWP in the context of the CHMP AR Revamp project. The document has been now finalised and endorsed by QWP and BWP and is presented for adoption.

**Action:** For adoption

The CHMP adopted the revamped quality part of the D80-210 Overview template.

### 2.2.3. Agenda and minutes

---

- Draft Agenda of the QWP meeting to be held remotely on 14-15 July 2025
- Minutes of the QWP meeting held remotely on 12-13 May 2025

**Action:** For information

The CHMP noted the agenda and minutes.

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

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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).

#### 2.2.5. Nomination of two new members to the QWP

---

Following two calls for nominations launched in May 2025 for two new QWP members, the Quality Domain governance has recommended two new QWP members to be endorsed by CHMP. The recommendations are made based on expertise and geographical spread.

Nomination(s) received

CHMP: Blanka Hirschlerova

**Action:** For endorsement

The CHMP endorsed the nomination of Cynthia Huettner (DE) and Luka Kosec (SI) as new QWP members.

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

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. Nomination of new Non-clinical and New Approach Methodologies ESEC experts

---

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

#### 3.1.2. Agenda and Minutes

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- Minutes of the NcWP meeting held remotely on 13 - 14 May 2025.

- Draft agenda of the NcWP meeting to be held remotely on 15 - 16 July 2025.

**Action:** For information

The CHMP noted the agenda and minutes.

### 3.1.3. [CMDh question to NcWP/NS-OEG](#)

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**Action:** For adoption

The CHMP adopted the CMDh question to NcWP/NS-OEG.

### 3.1.4. [NcWP/NS-OEG response to CMDh question](#)

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**Action:** For adoption

The CHMP adopted the NcWP/NS-OEG response to CMDh question.

### 3.1.5. [NcWP/NS-OEG response to CMDh question](#)

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**Action:** For adoption

The CHMP adopted the NcWP/NS-OEG response to CMDh question.

### 3.1.6. [CMDh question to CHMP](#)

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**Action:** For adoption

The CHMP adopted the CMDh question to CHMP.

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

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

### 3.2.1. [3RsWP Stakeholder Meeting Minutes](#)

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- Minutes of the 3RsWP stakeholder meeting held on 2 April 2025

**Action:** For information

The CHMP noted the minutes.

## 4. **Methodology Domain**

### 4.1. **Methodology Working Party (MWP)**

Chairs: Kit Roes, Kristin Karlsson

#### 4.1.1. [Agenda and minutes](#)

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- Agenda and Minutes of the MWP meetings held remotely on 15, 28 May and 12 June 2025

**Action:** For information

The CHMP noted the agenda and minutes.

#### 4.1.2. [Nomination of new Methodology ESEC experts](#)

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Nomination of 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 member to the MWP](#)

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Proposed nomination of a new member to the Methodology Working Party.

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of Tobias Fellingner (AGES) as a new MWP member.

#### 4.1.4. [Draft concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making](#)

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MWP has drafted a concept paper outlining the high-level content for a reflection paper on the use of external controls. Comments have been collected, and the document is presented to the CHMP before a 3-month public consultation which shall also foster points for discussion at a dedicated workshop on 3 November.

**Action:** For adoption

The CHMP adopted the draft concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making for a 3-month public consultation.

#### 4.1.5. [Product-Specific Guidelines](#)

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##### **Draft guidelines for public consultation:**

- Eltrombopag film-coated tablets 12.5 mg, 25 mg, 50 mg, 75 mg and powder for oral suspension 25 mg product-specific bioequivalence guidance (EMA/226445/2025).

Expert: Jutta Dedorath

- Melatonin prolonged release-tablets 2 mg product-specific bioequivalence guidance (EMA/226444/2025).

Expert: Erika Fredriksson

**Action:** For adoption

The CHMP adopted the Product-Specific Guidelines for 3-months public consultation.

## 5. Clinical Domain

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

Chair: Ewa Balkowiec Iskra

#### 5.1.1. Concept paper on the need for revision of the Guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease

---

Presentation of the concept paper for adoption for a 6-month public consultation.

Expert: Marion Haberkamp

**Action:** For adoption

The CHMP adopted the Concept paper on the need for revision of the guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease for a 6-month public consultation.

### 5.2. Cardiovascular Working Party (CVSWP)

No topics

### 5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

#### 5.3.1. Agenda and minutes

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- Agenda of the ONCWP meeting held remotely on 2 July 2025
- Minutes of the ONCWP meeting held remotely on 4 June 2025

**Action:** For information

The CHMP noted the agenda and minutes.

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

Chair: Caroline Auriche Benichou

#### 5.4.1. Revision of the Guideline on the requirements for demonstrating therapeutic equivalence between orally inhaled products (OIP) for asthma and chronic obstructive pulmonary disease (COPD)

---

This is the second revision of the Guideline formerly known as "Guideline on the requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of asthma and chronic obstructive pulmonary disease (COPD) in adults and for use in the treatment of asthma in children and adolescents". It addresses the requirements for demonstration of therapeutic equivalence (TE) between orally inhaled products containing the same active moiety(ies).

The document is presented for CHMP adoption following the 6-month public consultation.

Expert: Karolina Törneke

**Action:** For adoption

The CHMP adopted the revised Guideline on the requirements for demonstrating therapeutic equivalence between orally inhaled products (OIP) for asthma and chronic obstructive pulmonary disease (COPD).

#### 5.4.2. [Call for interest for one new RIWP member](#)

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Call for interest for nomination of a new RIWP member.

Nominations should be sent to the Agency by 05 September 2025. Candidates/related CHMP member are kindly asked to submit a brief recommendation from the CHMP member/alternate supporting the nomination, a detailed CV to support the expertise required, a confirmation from the expert confirming his/her availability to participate to the meetings, as well as to take rapporteurship/s for tasks relevant to his/her expertise, if applicable and an up-to-date declaration of interest that confirms that the expert can be part of the Working Party.

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

**Action:** For information

The CHMP noted the call for interest for nomination of a new RIWP member.

#### 5.4.3. [Agenda and minutes](#)

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- Agenda and Minutes of the RIWP meeting held remotely on 24-25 July 2025

**Action:** For information

The CHMP noted the agenda and minutes.

### 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 and minutes of the HaemWP meeting held remotely on 24 June 2025
- Agenda of the Blood cluster meeting held remotely on 27 June 2025
- Agenda of the ad hoc non-malignant haematology meeting held remotely on 27 June 2025

**Action:** For information

The CHMP noted the agendas.

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

### 5.8.1. Appointment of the newly elected SAG Cardiovascular, Diabetes and Obesity Chair and vice-chair

---

At its February 2025 plenary meeting, the CHMP adopted the list of newly appointed members of the SAG on Cardiovascular, Diabetes and Obesity. Following this appointment (in line with the procedure outlined in the SAG mandate), a call for expression of interest for the positions of Chair and vice-Chair was sent to the newly appointed SAG members.

In response, the SAG Secretariat received two applications. The SAG Secretariat subsequently organised the elections and both the Chair and vice-Chair were elected by the group.

The next step in the process is the appointment of the Chairperson and vice-Chairperson by the CHMP.

**Action:** For endorsement

The CHMP appointed Prof Jan Staessen as the Chairperson and Prof Igor Tauveron as the vice-Chairperson of the SAG Cardiovascular, Diabetes and Obesity.

## 6. Patients, Healthcare Professionals and Consumers

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

PCWP: Co-chair: Juan Garcia Burgos (EMA)

HCPWP: Co-chair: Juan Garcia Burgos (EMA)

#### 6.1.1. Call for nomination of representatives to the PCWP and HCPWP

---

Call for nomination of a representative (and alternate) for each working party for the mandate June 2025 to May 2028.

**Action:** For information

The CHMP noted the call for nomination of a representative (and alternate) for PCWP and HCPWP.

## 7. Harmonisation and consistency groups

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

#### 7.1.1. ICH E22 EWG - General Considerations for Patient Preference Studies – update on the technical document

---

CHMP was invited to provide comments on the Draft Technical Document at its March 2025 PROM meeting. An update on the progress of the E22 Expert Working Group will be provided.

**Action:** For information

The CHMP noted the update on the technical document for ICH E22 EWG - General Considerations for Patient Preference Studies.

#### 7.1.2. ICH Q3E draft Guideline on Extractables and leachables - Step 2b

---

The ICH Q3E Expert Working Group has completed a draft guideline covering the assessment and control of extractables and leachables (E&L). The document is presented for adoption for a 4-month public consultation.

**Action:** For discussion

The CHMP noted the update of the ICH Q3E draft Guideline on Extractables and leachables - Step 2b.

#### 7.1.3. ICH E20 adaptive designs for clinical trials – nomination of regulatory Chair

---

Following the adoption of the draft ICH E20 guideline on adaptive designs for clinical trials, EMA seeks to nominate a new Regulatory Chair to the E20 expert working group.

**Action:** For endorsement

The CHMP endorsed the nomination of a regulatory Chair to the ICH E20 expert working group.

#### 7.1.4. ICH Expert Working Group for ICH M16 EWG: Structured Quality Product Submissions - Appointment of Experts

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Following the publication of the draft M4Q guideline, a new working group will launch harmonise international standards for structured data in the quality part of the CTD. A call launched via QWP and BWP to appoint quality expert, which is presented for CHMP endorsement.

A call has been launched through CHMP, as well as HMA and the Network Data Steering Group (NDSG) to appoint data standards expert for this ICH Expert Working Group, with a deadline of 31 August 2025.

**Action:** For endorsement

The CHMP endorsed the nomination of a quality expert to the ICH Expert Working Group for ICH M16 EWG: Structured Quality Product Submissions.

#### 7.1.5. ICH Expert Working Group for ICH E23 EWG: Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making with a Focus on Effectiveness of Medicines – Appointment of Experts

---

Following a call launched via CHMP to appoint an expert for a new ICH Expert Working Group to draft the ICH E23 guideline on “Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making with a Focus on Effectiveness of Medicines”

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of an expert to the ICH Expert Working Group to draft the ICH E23 guideline on “Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making with a Focus on Effectiveness of Medicines”.

#### 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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Summary of recommendations and advice of the PRAC meeting held on 07-10 July 2025.

PRAC Chair: Ulla Wändel Liminga

**Action:** For information

The CHMP noted the summary of recommendations and advice.

### 8.3. Collaboration with Inspections

## 9. Regulatory/Organisational matters

### 9.1. Regulatory Issues/new legislation

#### 9.1.1. GVP Module XVI Addendum I – Risk minimisation measures for medicinal products with embryo-fetal risks

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Guideline on good pharmacovigilance practices (GVP) Module XVI Addendum I – Risk minimisation measures for medicinal products with embryo-fetal risks for CHMP consultation following public consultation and PRAC adoption.

**Action:** For adoption

The CHMP adopted the GVP Module XVI Addendum I – Risk minimisation measures for medicinal products with embryo-fetal risks.

### 9.2. CHMP organisation/templates

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

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

**Action:** For adoption

The CHMP discussed requests for extensions of clock-stops for ongoing procedures. See point 11.

## 10. Product development support

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

Chair: Paolo Foggi, Vice-Chairs: Pierre Demolis, Ewa Balkowiec Iskra

#### 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 & draft Table of Decisions of the SAWP meeting held remotely on 07-10 July 2025

**Action:** For information

The CHMP noted the agenda and draft table of decisions.

## 10.2. Innovation Task Force

### 10.2.1. ITF meeting

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Meeting date: 18 July 2025

**Action:** For endorsement

The CHMP endorsed the meeting.

### 10.2.2. ITF meeting

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Meeting date: 25 July 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.

#### 11.1.1. Tolebrutinib - EMEA/H/C/006386

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treatment of non-relapsing secondary progressive multiple sclerosis (nrSPMS) in adults

Scope Request by the Applicant for a change of timetable to respond to the list of questions adopted in June 2025

List of Questions adopted on 19.06.2025.

**Action:** For information

The CHMP noted the request by the applicant for a change of timetable to respond to the list of questions adopted in June 2025.

#### 11.1.2. Dupixent – Dupilumab - EMA/VR/0000248778

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Sanofi Winthrop Industrie

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola

Scope: Request by the applicant for an extension to the clock-stop to respond to the request for supplementary information adopted in May 2025.

Extension of indication to include treatment of adults with bullous pemphigoid (BP) for DUPIXENT, based on final results from study R668-BP-1902 (LIBERTY-BP ADEPT); this is a phase 2/3, multicentre, randomized, double blind, placebo-controlled, parallel group study to assess the efficacy and safety of dupilumab in adult patients with bullous pemphigoid;

As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 12.0 of the RMP has also been submitted.

Request for supplementary information adopted on 22.05.2025.

**Action:** For adoption

The CHMP agreed with the request by the applicant for an extension to the clock-stop to respond to the request for supplementary information adopted in May 2025.

### 11.1.3. Eflornithine - Orphan - EMEA/H/C/006067

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Norgine B.V.; treatment of high-risk neuroblastoma responsive to prior multiagent, multimodality therapy

Scope: Request by the applicant for an extension to the clock stop to respond to the list of questions adopted in April 2025

**Action:** For adoption

List of Questions adopted on 25.04.2025.

The CHMP did not agree to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in April 2025.

## 12. Any Other Business

### 12.1. Rapporteurships

Update.

**Action:** For information

The CHMP noted the update.

### 12.2. Nitrosamines Multidisciplinary Expert Group (NMEG)

Nomination of a new Chair and new members to the NMEG.

Chair nomination(s) received

New members nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of Paweł Pawłowski (PL) as a new NMEG member and Priscilla Schoondermark (NL) as a new NMEG Chair.

### 12.3. Companion diagnostic expert group update

Formalisation of the Companion diagnostics expert group under Clinical Domain.

CHMP: Patrick Vrijlandt

Expert: Jorg Engelbergs

**Action:** For endorsement

The CHMP endorsed the formalisation of the Companion diagnostics expert group under Clinical Domain together with its Mandate.

#### **12.4. Post-workshop recommendations on pharmacogenomics**

Last year, EMA convened a public workshop co-organised by the European Commission and the Heads of Medicines Agencies that brought together patient and healthcare professional representatives, the pharmaceutical industry, medicines regulators, academia, and representatives of healthcare systems to discuss these issues and identify opportunities to catalyse the use of pharmacogenomics in medicines development and healthcare. The [eleven key recommendations](#) arising from the discussions are for better regulation, facilitating the uptake of pharmacogenomics by healthcare systems, gaining insights by linking genomics and real-world data, and increasing the impact of research funding.

**Action:** For information

The CHMP noted the recommendations provided following the workshop on pharmacogenomics.

### 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 restrictions applicable to this meeting	
Daniela Philadelphy	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 restrictions applicable to this meeting	
Gergana Lazarova	Alternate	Bulgaria	No restrictions applicable to this meeting	
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	
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 Lähteenvuo	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No restrictions applicable to this meeting	
Janet Koenig	Member	Germany	No interests declared	
Martin Mengel	Alternate	Germany	No interests declared	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No restrictions applicable to this meeting	
Vilma Petrikaite	Member	Lithuania	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martine Trauffer	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No interests declared	
Peter Mol	Member	Netherlands	No restrictions applicable to this meeting	
Patrick Vrijlandt	Alternate	Netherlands	No restrictions applicable to this meeting	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No restrictions applicable to this meeting	
Ewa Balkowiec Iskra	Member	Poland	No restrictions applicable to this meeting	
Fatima Ventura	Member	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No restrictions applicable to this meeting	
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Carolina Prieto Fernandez	Member	Spain	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	
Bruno Delafont	Co-opted member	France	No interests declared	
Carla Torre	Co-opted member	Portugal	No restrictions applicable to this meeting	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Susanna Uiterwaal	Expert	Netherlands	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Nicolas Lee	Expert	Ireland	No participation in discussion, final deliberations and voting on:	3.3.11. Remibrutinib - EMEA/H/C/006313 ; 4.3.7. Scemblix - Asciminib - EMA/X/000025668 8; 5.1.19. Scemblix - Asciminib -

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				EMA/VR/0000265010
Peter Caspers	Expert	Netherlands	No interests declared	
Christian B. (Kit) Roes	Expert	Netherlands	No participation in discussion, final deliberations and voting on:	2.1.2. Pridopidine - Orphan - EMEA/H/C/006261
Karolina Törneke	Expert	Sweden	No interests declared	
Joerg Engelbergs	Expert	Germany	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Juan Ignacio Bedoya Ponte	Expert	Spain	No restrictions applicable to this meeting	
Jutta Dedorath	Expert	Germany	No interests declared	
A representative from the European Commission attended the meeting.				
Meeting run with support from relevant EMA staff.				

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