



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 June 2026  
EMA/CHMP/137794/2026  
Human Medicines Division

## Committee for medicinal products for human use (CHMP) PROM<sup>1</sup> Minutes for the meeting on 15 June 2026

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**

The Chairperson opened the meeting by welcoming all participants. The meeting was held remotely.

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 meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants 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. Restrictions applicable to this meeting are captured in the list of participants included in the minutes. 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.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members, alternates (where applicable) and experts in line with the relevant provisions of the [Rules of Procedure](#). All decisions taken at this meeting were made in the presence of a quorum of members. All opinions, recommendations, decisions and advice were agreed by consensus, unless otherwise specified. The members of the EEA-EFTA States agreed with the recommendation of the CHMP, unless otherwise specified.

### **1.2. Adoption of agenda**

The CHMP adopted the PROM agenda of the 15 June 2026 meeting.

### **1.3. Adoption of the minutes**

CHMP PROM Minutes of the 15 June 2026 meeting will be adopted at the June 2026 CHMP plenary.

## **2. Quality Domain**

### **2.1. Biologics Working Party (BWP)**

Chair: Sean Barry, Vice-Chair: Andreea Barbu

#### **2.1.1. Call for nominations for BWP Chair**

---

The mandate of the BWP Chair Sean Barry will expire on 19 July 2026.

Nominations should be sent to the Agency by 15 July 2026. Candidates are kindly asked to submit a brief CV in support of their candidature together with a letter of motivation

highlighting their expertise. Elections will take place at the July 2026 CHMP Plenary meeting.

**Action:** For endorsement

The CHMP endorsed the call for nominations for BWP Chair.

#### 2.1.2. Minutes

---

- Minutes of the BWP meeting held remotely on 13-15 April 2026

**Action:** For information

The CHMP noted the minutes.

#### 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).

### 2.2. Quality Working Party (QWP)

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

#### 2.2.1. Call for nominations for QWP Chair

---

The mandate of the QWP Chair Blanka Hirschlerova will expire on 3 August 2026.

Nominations should be sent to the Agency by 15 July 2026. 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 July 2026 CHMP Plenary meeting.

**Action:** For endorsement

The CHMP endorsed the call for nominations for QWP Chair.

#### 2.2.2. Minutes

---

- Minutes of the QWP meeting held remotely on 13-14 April 2026

**Action:** For information

The CHMP noted the minutes.

### 2.2.3. 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).

### 2.2.4. Call for interest for a new QWP member

---

Call for interest for nomination of a new QWP member, following a resignation.

Nominations should be sent to the Agency by 3 July 2026.

Nominations will take place at the July 2026 CHMP PROM meeting.

**Action:** For information

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

### 2.2.5. Nomination of a new member to the QWP

---

Nomination of a new QWP member following a call for interest in May 2026.

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of Tommaso Eliseo as a new QWP member.

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

Chair: René Anour, Vice-Chair: Niklas Ekman

### 2.3.1. Call for nominations for BMWP Chair

---

The mandate of the BMWP Chair Rene Anour will expire on 19 July 2026.

Nominations should be sent to the Agency by 15 July 2026. 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 July 2026 CHMP Plenary meeting.

**Action:** For endorsement

The CHMP endorsed the call for nominations for BMWP Chair.

### 2.3.2. Agenda and minutes

---

Agenda and minutes of the BMWP meeting held remotely on 30 March 2026

**Action:** For information

The CHMP noted the agenda and minutes.

## 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 14-15 April 2026
- Draft agenda of the NcWP meeting to be held remotely on 16-17 June 2026

**Action:** For information

The CHMP noted the agenda and minutes.

#### 3.1.2. Nomination of two NcWP members' temporary replacements

---

Nomination of temporary replacements of two NcWP members following a call for interest in May 2026.

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of Anya Staal and Višnja Drinovac Vlah as temporary replacements of two NcWP members.

#### 3.1.3. CMDh question to NcWP/NSOEG

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**Action:** For adoption

The CHMP adopted the CMDh question to NcWP/NSOEG.

#### 3.1.4. NcWP/NS-OEG response to CMDh question

---

**Action:** For adoption

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

#### 3.1.5. CMDh question to NcWP

---

**Action:** For adoption

The CHMP adopted the CMDh question to NcWP.

### 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 3RsWP hybrid meeting held on 01 April 2026
- Agenda of the 3RsWP meeting held remotely on 02-03 June 2026

**Action:** For information

The CHMP noted the agenda and minutes.

### 3.2.2. Expansion of 3RsWP membership

---

With the agreement of the H Division extended leadership group and the non-clinical domain governance, the 3RsWP is expanding its membership by one, to a total of nine members. This is in line with the size of all other small working parties and reflects the increasing workload of the group. A call for nominations will be launched at CVMP only (July meeting), as the additional expertise sought at this time is in the veterinary area.

**Action:** For endorsement

The CHMP endorsed the expansion of the 3RsWP membership.

### 3.2.3. New Approach Methodologies (NAMs) Operational Expert Group (OEG)

---

As part of the European Medicines Agency's ongoing activities to support the regulatory integration of New Approach Methodologies (NAMs), and in line with the requirements of the new pharmaceutical legislation, the Agency is establishing an operational expert group (OEG) on NAMs. The NAMs OEG mandate is to support the scientific and regulatory evaluation of NAMs and contribute to the development of regulatory knowledge, consistency and expertise across the EU network. As an initial activity, the OEG will support the implementation of the Voluntary Data Submission (VDS) framework, including the review and discussion of voluntarily submitted NAM data.

**Action:** For endorsement

The CHMP endorsed the New Approach Methodologies (NAMs) Operational Expert Group (OEG).

### 3.2.4. Call for interest for new NAMs OEG experts

---

Call for interest for nomination of new NAMs OEG experts, following the endorsement of the new NAMs OEG.

Nominations should be sent to the Agency by 30 July 2026.

Nominations will take place at the September 2026 CHMP PROM meeting.

**Action:** For information

The CHMP noted the call for interest for nomination of new NAMs OEG experts.

## 4. Methodology Domain

### 4.1. Methodology Working Party (MWP)

Chair: Kit Roes, Vice-Chair: Kristin Karlsson

#### 4.1.1. Agenda and minutes

---

- Agenda and minutes of the MWP meetings held remotely on 29 April 2026 and 13 May 2026

**Action:** For information

The CHMP noted the agenda and minutes.

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

---

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 Methodology BSOEG expert

---

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

Nomination(s) received

**Action:** For endorsement

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

#### 4.1.4. Guideline on drug-drug interactions in the gastrointestinal tract

---

On 30 November 2024, ICH M12 Guideline on drug interaction studies (EMA/CHMP/ICH/652460/2022) formally superseded EMA Guideline on the investigation of drug interactions Revision 1 (CPMP/EWP/560/95/Rev. 1 Corr. 2\*\*) which had been in effect since 01 January 2013. The main focus of ICH M12 is on pharmacokinetic drug interactions mediated by metabolic enzymes and drug transporters, however, it does not address a number of topics to the same extent that the previous EMA guideline did, with one of these topics being interactions in the upper gastro-intestinal tract.

This document, therefore, describes the investigation of absorption-related interactions with a medicinal product by extrinsic factors in the gastrointestinal tract. It includes advice on study design, presentation of study results and translation of these results to treatment recommendations in the labelling of the medicinal product. The document is presented for CHMP adoption for a 3-month public consultation.

Expert: Carolien Versantvoort

**Action:** For adoption

The CHMP adopted the guideline on drug-drug interactions in the gastrointestinal tract for a 3-month public consultation.

#### 4.1.5. Q&A on drug-drug interaction studies with oral contraceptives

---

On 30 November 2024, ICH M12 Guideline on drug interaction studies (EMA/CHMP/ICH/652460/2022) formally superseded EMA Guideline on the investigation of drug interactions Revision 1 (CPMP/EWP/560/95/Rev. 1 Corr. 2\*\*) which had been in effect since 01 January 2013. The main focus of ICH M12 is on pharmacokinetic drug interactions mediated by metabolic enzymes and drug transporters, however it does not address drug-drug interaction studies with oral contraceptives, hence this Q&A which is presented for CHMP adoption before publication.

Expert: Carolien Versantvoort

**Action:** For adoption

The CHMP adopted the Q&A on drug-drug interaction studies with oral contraceptives.

## 5. Clinical Domain

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

Chair: Ewa Balkowiec Iskra, Vice-Chair: Marion Haberkamp

#### 5.1.1. Call for interest for a new CNSWP member

---

Call for interest for nomination of a new CNSWP member, following a resignation. The working party is seeking a member with expertise in the field of ophthalmology.

Nominations should be sent to the Agency by 30 June 2026.

Nominations will take place at the July 2026 CHMP PROM meeting.

**Action:** For information

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

#### 5.1.2. Guideline on clinical investigation of medicinal products in the treatment of migraine

---

The revision of the guideline on clinical investigation of medicinal products in the treatment of migraine is presented for CHMP adoption for a 4-month public consultation.

Expert: Darius Matusevicius

**Action:** For adoption

The CHMP adopted the guideline on clinical investigation of medicinal products in the treatment of migraine for a 4-month public consultation.

## 5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

### 5.2.1. Addendum to the guideline on the clinical evaluation of medicinal products for weight management in the treatment of children and adolescents

---

This is the first revision of the Guideline on clinical evaluation of medicinal products used in weight control - Addendum on weight control in children (EMA/CHMP/EWP/517497/2007), that came into effect in 2008.

Changes to the addendum are introduced with the aim to align it, where appropriate, with the guideline for adults and to reflect recent developments in this rapidly evolving field with respect to approval of new medicinal products for the treatment of childhood and adolescent overweight and obesity as well as clinical practice guidelines.

The Concept Paper was released for public consultation until February 2025. The draft PA was elaborated in coordination with PDCO, GCG consultation has been performed. The document is presented for CHMP adoption for a 6-month public consultation.

**Action:** For adoption

The CHMP adopted the addendum to the guideline on the clinical evaluation of medicinal products for weight management in the treatment of children and adolescents for a 4-month public consultation.

### 5.2.2. Nomination of a new member to the CVSWP

---

Nomination of a new CVSWP member following a call for interest in April 2026.

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of Louise Bagge as new CVSWP member.

### 5.2.3. Agenda and Minutes

---

- Agenda and Minutes of the CVSWP meeting held remotely on 28 May 2026

**Action:** For information

The CHMP noted the agenda and minutes.

## 5.3. Oncology Working Party (ONCWP)

No topics

## 5.4. Immune and Inflammatory Diseases Working Party (IIWP)

No topics

## 5.5. Infectious Disease Working Party (IDWP)

Chair: Maja Sommerfelt Gronvold, Vice-Chair: Anders Lignell

#### 5.5.1. Draft concept paper to update the Guideline on the clinical evaluation of antifungal agents

---

The concept paper proposes an update of the guideline on the clinical evaluation of antifungal agents intended for the treatment and prophylaxis of invasive fungal disease (IFD) (CHMP/EWP/1343/01) that was originally adopted by CHMP in May 2003 and revised in 2009 (CHMP/EWP/1343/01 Rev. 1). The document is presented for CHMP adoption for a 3-month public consultation.

Expert: Maria Jesus Fernandez Cortizo

**Action:** For adoption

The CHMP adopted the draft concept paper to update the Guideline on the clinical evaluation of antifungal agents for a 3-month public consultation.

### 5.6. Vaccines Working Party (VWP)

Chair: Sol Ruiz, Vice-Chair: Eleonora G. Wijnans

#### 5.6.1. Nomination of a new member to the VWP

---

Nomination of a new VWP member following a call for interest in January 2026.

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of Juliane Meissner as new VWP member.

### 5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphia, Vice-chair: Viktoriia Starokozhko

#### 5.7.1. Agendas

---

- Draft agenda of the Blood cluster meeting to be held remotely on 12 June 2026
- Draft agenda of the non-malignant haematology cluster meeting to be held remotely on 12 June 2026

**Action:** For information

The CHMP noted the agendas.

#### 5.7.2. Nomination of two new members to the HAEMWP

---

Nomination of two new HAEMWP members following a call for interest in April 2026 and the departure of a member.

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of Claudia Reichmann and Walter Johannes Beiersdorff as new HAEMWP members.

### 5.7.3. Nomination of new Haematology ESEC experts

---

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

Nomination(s) received

**Action:** For endorsement

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

## 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 E6(R3) Guideline for good clinical practice Annex 2

---

Following the EU public consultation on ICH E6 annex 2 from November 2024 to February 2025, the document has been finalised and was endorsed by ICH (step 4) at its recent bi-annual meeting. The document is presented for CHMP adoption and will be implemented 6 months after publication on the EMA website.

**Action:** For adoption

The CHMP adopted the ICH E6(R3) Guideline for good clinical practice Annex 2 with an implementation in January 2027.

### 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 Wändel Liminga

Summary of recommendations and advice of the PRAC meeting held on 08-11 June 2026.

**Action:** For information

The CHMP noted the summary of recommendations and advice of the PRAC meeting held on 08-11 June 2026.

#### 8.2.2. Call for interest for new Novel Therapies ESEC experts

---

Call for interest for nomination of new experts to join the Novel Therapies (NTs) European Specialised Expert Community (ESEC).

Nominations should be sent to the Agency. As this is an open call, no fixed submission deadline applies. Nominations will be assessed on a rolling basis. Nominations received during a given period will be considered for endorsement at the next available CHMP PROM meeting.

**Action:** For information

The CHMP noted the call for interest for nomination of new experts to join the Novel Therapies (NTs) European Specialised Expert Community (ESEC).

## 9. Regulatory/Organisational matters

### 9.1. Regulatory Issues/new legislation

No topics

### 9.2. CHMP organisation/templates

No topics

## 10. Product development support

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

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

#### 10.1.1. Agenda and Outcomes

---

SAWP Agenda and Outcomes, SAWP presentation for CHMP and List of procedures for discussion at CHMP.

**Action:** For information

The CHMP noted the agenda and the outcomes table.

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

---

List of procedures for discussion at CHMP

**Action:** For information

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

#### 10.1.3. SAWP report

---

Report from the SAWP meeting held on 08-11 June 2026. Table of conclusions

SAWP Chair: Paolo Foggi

**Action:** For information

Information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.

The CHMP noted the report from the SAWP meeting and the table of conclusions.

#### 10.1.4. Qualification of Novel Methodologies (QoNM) for medicinal product development – revised procedural guidance to applicants

---

The QoNM procedural guidance to applicants has been revised in line with the action plan for future-proofing QoNM after input from 3RSWP, MWP and SAWP providing updated procedural guidance and scoping considerations, as well as introducing new procedural elements, e.g. early-interaction support with scoping meetings and introduction of high-level information publication of Qualification advice, and is presented for CHMP adoption before publication.

**Action:** For adoption

The CHMP adopted the qualification of Novel Methodologies (QoNM) for medicinal product development – revised procedural guidance to applicants.

#### 10.1.5. Call for interest for a new SAWP member and respective alternate

---

Call for interest for nomination of a new SAWP member and alternate, following the departure of a member and respective alternate.

Required areas of expertise:

- Cardiovascular medicine
- Rheumatology/Immunology

Nominations should be sent to the Agency by 30 June 2026.

Nominations will take place at the July 2026 CHMP PROM meeting. The new SAWP member and his/her alternate starting date will follow their endorsement by the CHMP, for participation in the SAWP activities as of 31 August 2026.

**Action:** For information

The CHMP noted the call for interest for nomination of a new SAWP member and respective alternate.

## 10.2. Innovation Task Force

### 10.2.1. ITF meeting

---

Meeting date: 17 June 2026

**Action:** For endorsement

The CHMP endorsed the meeting.

### 10.2.2. ITF meeting

---

Meeting date: 1 July 2026

**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. IMFINZI - Durvalumab - EMA/VR/0000289524

AstraZeneca AB

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Carolina Prieto Fernandez, PRAC  
Rapporteur: David Olsen

Scope: Update on the procedure

Extension of indication for IMFINZI in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adults with BCG-naïve, high-risk non-muscle-invasive bladder cancer (NMIBC), based on results from the POTOMAC study. POTOMAC is a phase 3, randomized multi-centre, open-label, global study to determine the efficacy and safety of durvalumab + BCG (induction + maintenance) combination therapy vs BCG (induction + maintenance) alone, and durvalumab + BCG (induction only) combination therapy vs BCG (induction + maintenance) alone for the treatment of patients with high-risk NMIBC. 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 with the SmPC. In addition, the Applicant took the opportunity to implement editorial changes to SmPC sections 4.2 and 5.1. Version 15 (Succession 1) of the RMP has also been submitted.

**Action:** For discussion

The Committee discussed the issues identified in this application.

### **11.3. REZOLSTA - Darunavir / Cobicistat - EMA/X/0000268372**

Janssen Cilag International

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli

Scope: Update on the procedure

Extension application to introduce a new pharmaceutical form associated with new strength (600 mg darunavir/90 mg cobicistat dispersible tablet). The new presentation is indicated to include treatment for paediatric patients aged  $\geq 3$  years and older weighing at least 15 kg and less than 25 kg. The extension application is grouped with a type II clinical variation (C.I.4) to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 in order to add efficacy and PK data in children based on final results from study GS-US-215-0128; this is a Phase 2/3, Multicentre, Open-label, Multicohort Study Evaluating Pharmacokinetics (PK), Safety, and Efficacy of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 Infected, Virologically Suppressed Paediatric Participants. The Package Leaflet and Labelling are updated in accordance. Version 7.2 of the RMP has also been submitted.

**Action:** For discussion

The Committee discussed the issues identified in this application.

The CHMP agreed that an oral explanation was not needed at this time.

### **11.4. SYMTUZA - Darunavir / Cobicistat / Emtricitabine / Tenofovir alafenamide - EMA/X/0000248421**

Janssen Cilag International

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Update on the procedure

Extension application to add a new strength of 675 mg/150 mg/ 20mg/ 10 mg film-coated tablets grouped with an Extension of indication (C.I.6) to include treatment of human immunodeficiency virus type 1 (HIV 1) infection in paediatric patients (aged 6 years and older with body weight at least 25 kg) for SYMTUZA, based on the 24-week interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicentre, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1, 6.3, 6.4, 6.5 and 8 of the SmPC are updated. The Annex II, Labelling and Package Leaflet are updated accordingly. Version 9.1 of the RMP has also been submitted. Furthermore, the MAH took the opportunity to bring the PI in

line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet.

**Action:** For discussion

The Committee discussed the issues identified in this application.

The CHMP agreed that an oral explanation was not needed at this time.

## **12. Any Other Business**

### **12.1. Rapporteurships**

Update.

**Action:** For information

The CHMP noted the update.

### **12.2. Joint HTAb-EMA regulatory collaboration on evidence needs - proposal of follow up workshop**

Taking the [published](#) joint perspectives on understanding evidence challenges as a basis, proposal of a follow up workshop focused on the use of innovative clinical trial designs, specifically adaptive, multi-arm platform trials and other 'master protocol' designs, for evidence generation in drug development, across products life cycles.

**Action:** For information

The CHMP noted the call for expression of interest for the joint HTAb-EMA regulatory collaboration on evidence needs - proposal of follow up workshop.

### **12.3. Call for expression of interest for remunerated external experts**

Details on the call can be found on this [link](#) and the applications can be accessed directly through [this EC link](#) or through the list of Ongoing Tenders on the [Procurement page](#) of EMA website.

This call targets regulators and experts in various expertise areas related to development and evaluation of medicines. This call will provide a framework to remunerate experts supporting EMA activities.

Successful applicants will be included in a dedicated pool of external experts. The inclusion in the pool will not guarantee any assignment of tasks but when such expertise is needed, the expert can be chosen by EMA and approached for the respective remunerated task. Tasks under remuneration fall under EMA remit including, but not limited to, mentoring, development of training, providing ad-hoc input or advice on a scientific or regulatory matter.

**Action:** For information

The CHMP noted the call for expression of interest for remunerated external experts.

### 13. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 15 June 2026 CHMP PROM meeting, which was held remotely.

| Name                        | Role                | Member State or affiliation | Outcome restriction following evaluation of DoI                    | Topics for which restrictions apply                                                                                                                |
|-----------------------------|---------------------|-----------------------------|--------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| Bruno Sepodes               | Chair               | Portugal                    | No restrictions applicable to this meeting                         |                                                                                                                                                    |
| 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                                              |                                                                                                                                                    |
| Gergana Lazarova            | Alternate           | Bulgaria                    | No restrictions applicable to this meeting                         |                                                                                                                                                    |
| Selma Arapovic Dzakula      | Member              | Croatia                     | No interests declared                                              |                                                                                                                                                    |
| Hrvoje Rimac                | Alternate           | Croatia                     | No participation in discussion, final deliberations and voting on: | 4.1.2. EMA/X/000026837 2;<br>4.1.4. EMA/X/000024842 1;<br>5.1.22. EMA/VR/00003162 05;<br>5.1.23. EMA/VR/00003222 79;<br>5.1.24. EMA/VR/00003362 74 |
| 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                                              |                                                                                                                                                    |
| Outi Mäki-Ikola             | Member (Vice-Chair) | Finland                     | No interests declared                                              |                                                                                                                                                    |
| Johanna Lähteenvuori        | Alternate           | Finland                     | No interests declared                                              |                                                                                                                                                    |
| Alexandre Moreau            | Member              | France                      | No interests declared                                              |                                                                                                                                                    |
| Nicolas Beix                | 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                                              |                                                                                                                                                    |

| Name                                 | Role            | Member State or affiliation | Outcome restriction following evaluation of DoI | Topics for which restrictions apply |
|--------------------------------------|-----------------|-----------------------------|-------------------------------------------------|-------------------------------------|
| Finbarr Leacy                        | Member          | Ireland                     | No interests declared                           |                                     |
| Ruth Kieran                          | Alternate       | 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      |                                     |
| Larisa Gorobets                      | Alternate       | Lithuania                   | 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      |                                     |
| Paulo Paixão                         | Alternate       | 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      |                                     |
| 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                           |                                     |
| Christian B. (Kit) Roes              | Co-opted member | Netherlands                 | No restrictions applicable to this meeting      |                                     |
| Carla Torre                          | Co-opted member | Portugal                    | No restrictions applicable to this meeting      |                                     |
| Jan Mueller-Berghaus                 | Co-opted member | Germany                     | No interests declared                           |                                     |
| Blanka Hirschlerova                  | Co-opted member | Czechia                     | No interests declared                           |                                     |
| Marie Louise Schougaard Christiansen | Expert          | Denmark                     | No interests declared                           |                                     |

| Name                                                                | Role   | Member State or affiliation | Outcome restriction following evaluation of DoI | Topics for which restrictions apply |
|---------------------------------------------------------------------|--------|-----------------------------|-------------------------------------------------|-------------------------------------|
| Moritz Sander                                                       | Expert | Denmark                     | No restrictions applicable to this meeting      |                                     |
| Macarena Gajardo Álvarez                                            | Expert | Spain                       | No interests declared                           |                                     |
| Ana Moreno Oliver                                                   | Expert | Spain                       | No interests declared                           |                                     |
| Sabine Mayrhofer                                                    | Expert | Germany                     | No interests declared                           |                                     |
| Ana Rita Lemos                                                      | Expert | Portugal                    | No restrictions applicable to this meeting      |                                     |
| Susan Uiterwaal                                                     | Expert | Netherlands                 | No interests declared                           |                                     |
| Tina Soon Engraff                                                   | Expert | Denmark                     | No interests declared                           |                                     |
| Johanna de Groot                                                    | Expert | Netherlands                 | No interests declared                           |                                     |
| Mette Linnert Jensen                                                | Expert | Denmark                     | No interests declared                           |                                     |
| Carolien Versantvoort                                               | Expert | Netherlands                 | No interests declared                           |                                     |
| Darius Matusevicius                                                 | Expert | Sweden                      | No interests declared                           |                                     |
| Maria Jesus Fernandez Cortizo                                       | Expert | Spain                       | No interests declared                           |                                     |
| Paolo Foggi                                                         | Expert | Italy                       | No interests declared                           |                                     |
| Kristina Bech Jensen                                                | Expert | Denmark                     | No interests declared                           |                                     |
| Joerg Zinserling                                                    | Expert | Germany                     | No restrictions applicable to this meeting      |                                     |
| Silvijus Abramavicius                                               | Expert | Lithuania                   | No restrictions applicable to this meeting      |                                     |
| Karoline Buhre                                                      | Expert | Germany                     | No interests declared                           |                                     |
| Mario Miguel Coelho da Silva Rosa                                   | Expert | Portugal                    | No restrictions applicable to this meeting      |                                     |
| Elisabeth Wischnitzki                                               | Expert | Austria                     | No interests declared                           |                                     |
| Gabriele Schlosser-Weber                                            | Expert | Germany                     | No interests declared                           |                                     |
| A representative from the European Commission attended the meeting. |        |                             |                                                 |                                     |
| Meeting run with support from relevant EMA staff.                   |        |                             |                                                 |                                     |

Experts' declared interests were evaluated against the topics or activities they participated in.