



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 June 2025  
EMA/398900/2025  
Human Medicines Division

## Committee for medicinal products for human use (CHMP) PROM<sup>1</sup> Minutes for the meeting on 10 June 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 10 June 2025 meeting.

### 1.3. Adoption of the minutes

CHMP PROM Minutes of the 10 June 2025 meeting will be adopted at the June 2025 CHMP plenary.

## 2. Quality Domain

### 2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

#### 2.1.1. Revision of the Biological medicinal products Questions and Answers (Q&As)

Revision of the Q&As on Media Composition and Low Endotoxin Recovery for publication.

**Action:** For adoption

The CHMP adopted the revised Biological medicinal products Q&As.

#### 2.1.2. Agenda and minutes

- Draft Agenda of the BWP meeting to be held remotely on 10-12 June 2025

- Minutes of the BWP meeting held remotely on 14-16 April 2025

**Action:** For information

The CHMP noted the agenda and minutes.

### 2.1.3. [Nomination of new Biologics Quality ESEC experts](#)

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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. [Draft BWP 3-year Work Plan 2026-2028](#)

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Initial draft BWP work plan 2026-2028 for interested parties' consultation.

**Action:** For information

The CHMP noted the draft BWP work plan 2026-2028.

### 2.1.5. [Revision of the BWP-PMF Guideline on epidemiological data on blood transmissible infections](#)

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Revision of chapter 9 of the Guideline on epidemiological data on blood transmissible infections. The document will be published for 2-month public consultation after CHMP adoption.

**Action:** For adoption

The CHMP adopted the revised chapter 9 of the Guideline on epidemiological data on blood transmissible infections.

## 2.2. [Quality Working Party \(QWP\)](#)

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

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

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- Draft Agenda of the QWP meeting to be held remotely on 11-12 June 2025
- Minutes of the QWP meeting held remotely on 14-15 April 2025

**Action:** For information

The CHMP noted the agenda and minutes.

### 2.2.2. [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).

### 2.2.3. Draft QWP 3-year Work Plan 2026-2028

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Initial draft QWP work plan 2026-2028 for interested parties' consultation.

**Action:** For information

The CHMP noted the draft QWP work plan 2026-2028.

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

Chair: René Anour, Vice-Chair: Niklas Ekman

### 2.3.1. Agenda and minutes

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- Agenda and Minutes of the BMWP meeting held remotely on 28 April 2025

**Action:** For information

The CHMP noted the agenda and minutes.

### 2.3.2. Multi-Stakeholder Workshop on Tailored Clinical Approach for Biosimilars

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BMWP will hold a hybrid workshop on 22 September 2025 as part of the consultation process following the CHMP's adoption of the [draft Reflection Paper](#). The event will bring together stakeholders from the EU and non-EU regulatory network, international partners, patient and healthcare professional organisations, and industry. Participants will be required to register by Monday, 15 September 2025.

Related information: [Register to attend \(MS Teams\)](#)

**Action:** For information

The CHMP noted the information on the Multi-Stakeholder Workshop on Tailored Clinical Approach for Biosimilars.

## 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 Non-clinical and New Approach Methodologies ESEC experts

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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. Reflection paper on lessons learned from the COVID-19 pandemic: Scientific considerations on non-clinical aspects

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This reflection paper covers SARS-CoV-2 vaccines and medicinal products intended to prevent or treat COVID-19 and its complications. It focuses on the experiences gained during the pandemic and the resulting non-clinical scientific considerations for pivotal, non-clinical data used to support clinical development and marketing authorisation. The document will be published for 3-month public consultation after CHMP adoption.

Expert: Susanne Brendler-Schwaab

**Action:** For adoption

The CHMP adopted the reflection paper on lessons learned from the COVID-19 pandemic: Scientific considerations on non-clinical aspects.

### 3.1.3. Agenda and minutes

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- Minutes of the NcWP meeting held remotely on 15 - 16 April 2025
- Draft agenda of the NcWP meeting to be held remotely on 10 - 11 June 2025

**Action:** For information

The CHMP noted the agenda and minutes.

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

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**Action:** For adoption

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

### 3.1.5. 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. NcWP/OEG-Nitrosamines response to CMDh question

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**Action:** For adoption

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

## 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

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- Minutes of the Stakeholder meeting held as a hybrid meeting on 2 April 2025.
- Minutes of the 3RsWP meeting held as a hybrid meeting on 3 April 2025.
- Agenda of the 3RsWP meeting held remotely on 20 - 21 May 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

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- Agenda and minutes of the MWP meeting held remotely on 30 April 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. Product-Specific Guidelines

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**Final guidelines after public consultation:**

- Aprepitant, hard capsules, 80mg, 125mg, 80+125mg and powder for oral suspension 125mg product-specific bioequivalence guidance (EMA/13174/2025).
- Paclitaxel (nanoparticle albumin-bound) powder for suspension for infusion, 5mg/ml product-specific bioequivalence guidance (EMA/418520/2024).
- Azacitidine powder for suspension for injection 25 mg/ml product-specific bioequivalence guidance (EMA/CHMP/172895/2023) and Overview of comments (EMA/264768/2024).

**Revised guidelines in line with ICH M13A for publication:**

- Cholic acid capsules 50 mg and 250 mg product-specific bioequivalence guidance (EMA/CHMP/800759/2017 Rev. 1\*).

- Colchicine tablet 0.5 mg and 1 mg product-specific bioequivalence guidance (EMA/CHMP/35552/2019 Rev. 1\*).
- Emtricitabine/rilpivirine/tenofovir disoproxil film-coated tablets 200 mg/25 mg/245 mg product-specific bioequivalence guidance (EMA/CHMP/805532/2016 Rev. 1\* ).
- Emtricitabine/Tenofovir Disoproxil film-coated tablets 200mg/245 mg product-specific bioequivalence guidance (EMA/CHMP/675839/2014 Rev. 1\*).
- Entecavir film-coated tablets 0.5 and 1 mg, oral solution 0.05mg/ml product-specific bioequivalence guidance (EMA/CHMP/160445/2016 Rev. 1\*).
- Fingolimod capsules 0.25 and 0.5 mg product-specific bioequivalence guidance (EMA/CHMP/154812/2016 Rev.2\*).
- Pirfenidone film-coated tablets 267, 537 and 801 mg, and hard capsules 267 mg product-specific bioequivalence guidance (EMA/CHMP/901584/2022 Rev. 1\*).
- Rilpivirine film-coated tablets 25 mg product-specific bioequivalence guidance (EMA/CHMP/356878/2017 Rev. 1\*).
- Rivaroxaban film-coated tablets 2.5, 10, 15 and 20mg product-specific bioequivalence guidance (EMA/CHMP/160650/2016 Rev. 1\*).
- Sitagliptin film-coated tablets 25, 50 and 100 mg product-specific bioequivalence guidance (EMA/CHMP/158934/2016 Rev.1\*).
- Tacrolimus granules for oral suspension 0.2 and 1 mg product-specific bioequivalence guidance (EMA/CHMP/159744/2016 Rev.1\*).
- Ticagrelor film-coated tablets 90mg product-specific bioequivalence guidance (EMA/CHMP/177281/2016 Rev.1\*).
- Vortioxetine hydrobromide immediate release tablets 5 mg, 10 mg, 15 mg, and 20 mg; vortioxetine lactate oral drops solution 20 mg/ml product-specific bioequivalence guidance (EMA/CHMP/474974/2016 Rev.1\*).
- Zonisamide hard capsules 25, 50 and 100 mg, orodispersible tablets 25, 50, 100 and 300 mg product-specific bioequivalence guidance (EMA/CHMP/159882/2016 Rev.1\*).

Expert: Carolien Versantvoort

**Action:** For adoption

The CHMP adopted the Product-Specific Guidelines.

#### 4.1.4. [MWP response to CMDh](#)

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Expert: Michiel van den Heuvel

**Action:** For adoption

The CHMP adopted the MWP response to CMDh.

## 5. Clinical Domain

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

No topics

### 5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

#### 5.2.1. Agenda and Table of Decisions

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- Agenda of the CVSWP meeting held remotely on 23 May 2025
- Draft Table of Decisions of the CVSWP meeting held remotely on 23 May 2025

**Action:** For information

The CHMP noted the agenda and table of decisions.

### 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 4 June 2025
- Minutes of the ONCWP meeting held remotely on 14 May 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. Guideline on allergen products development for immunotherapy and allergy diagnosis in moderate to low-sized study populations

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Following the public consultation, the new guideline on allergen products development for immunotherapy and allergy diagnosis in moderate to low-sized study populations is presented for CHMP adoption.

Expert: Andreas Bonertz

**Action:** For adoption

The CHMP adopted the guideline on allergen products development for immunotherapy and allergy diagnosis in moderate to low-sized study populations.

#### 5.4.2. Concept paper on the new reflection paper on the clinical investigation of medicinal products for the treatment of Systemic Sclerosis

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There is currently no scientific guidance from the EMA on the clinical investigation of medicinal products for the treatment of Systemic sclerosis (SSc). This is needed to guide development and support marketing authorisation applications for this condition. Therefore, the RIWP recommends drafting a new reflection paper on the clinical investigation of medicinal products for the treatment of SSc.

Expert: Anna Vikerfors

**Action:** For adoption

The CHMP adopted the concept paper on the new reflection paper on the clinical investigation of medicinal products for the treatment of Systemic Sclerosis.

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

No topics

### 5.6. Vaccines Working Party (VWP)

No topics

### 5.7. Haematology Working Party (HaemWP)

No topics

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

## 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. Report from ICH MC in Madrid

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Following the recent ICH meeting, an update is provided to CHMP on progress of relevant guideline discussions and decisions taken.

CHMP: Bruno Sepodes

**Action:** For information

The CHMP noted the report from ICH MC in Madrid.

### 7.1.2. ICH M4Q(R2) Draft Guideline on the common technical document for the registration of pharmaceuticals for human use: quality – Step 2b

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The ICH M4Q Expert Working Group has completed a draft guideline that establishes the location and structure of quality information for registration applications of all medicinal products for human use. It supports various submission types, including those referring to or consisting of master files, and applies to both initial marketing authorisation and post-approval submissions. This guideline is structured to be flexible to accommodate all types of medicinal products and their components. The document is presented for adoption for a 4-month public consultation.

**Action:** For adoption

The CHMP adopted the ICH M4Q(R2) Draft Guideline on the common technical document for the registration of pharmaceuticals for human use: quality – Step 2b for a 4-month public consultation.

### 7.1.3. Nomination of experts for ICH working groups – New ICH guideline on framework for determining utility of comparative efficacy studies in biosimilar development programs

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Following the ICH adoption of a new topic for harmonisation, which aims to establish a framework for determining utility of comparative efficacy studies in biosimilar development programs, nominations are proposed to serve as the two experts in the new guideline drafting group to be formed.

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed the nomination of experts for ICH working groups.

### 7.1.4. ICH Cell & Gene Therapy discussion group (CGTDG) – upcoming consultation on draft recommendations on future ATMP-related guidelines

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The ICH CGTDG was tasked to assess the scientific and regulatory landscape related to existing ATMP guidance and provide recommendations for potential ICH ATMP-related guidance across the clinical, nonclinical and quality domain. An update is provided to the CHMP.

CHMP: Jan Muller-Berghaus

**Action:** For information

The CHMP noted the information on the ICH CGTDG upcoming consultation on draft recommendations on future ATMP-related guidelines.

## 7.2. Guideline Consistency Group (GCG)

Chair: Kristina Dunder

### 7.2.1. Nomination of the GCG Chair

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Nomination of the new Guideline Consistency Group Chair.

Nomination(s) received

**Action:** For endorsement

The CHMP endorsed Elita Poplavska as GCG Chair.

### 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 PRAC meeting held on 02-05 June 2025.

PRAC Chair: Ulla Wändel Liminga

**Action:** For information

The CHMP noted the summary of recommendations and advice.

## 9. Regulatory/Organisational matters

### 9.1. Regulatory Issues/new legislation

No topics

### 9.2. CHMP organisation/templates

#### 9.2.1. Pilot face-to-face (F2F) oral explanations

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Proposal for a 1-year pilot to allow F2F oral explanations for in-person CHMP plenary meetings.

**Action:** For discussion

The CHMP agreed with the proposal for a 1-year pilot to allow F2F oral explanations for in-person CHMP plenary meetings.

## 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 of the SAWP meeting held remotely on 02-05 June 2025
- Draft Table of Decisions of the SAWP meeting held remotely on 02-05 June 2025

**Action:** For information

The CHMP noted the agenda and table of decisions.

### 10.2. Innovation Task Force

#### 10.2.1. ITF meeting

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Meeting date: 11 June 2025

**Action:** For endorsement

The CHMP endorsed the meeting.

#### 10.2.2. ITF meeting

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Meeting date: 20 June 2025

**Action:** For endorsement

The CHMP endorsed the meeting.

#### 10.2.3. ITF meeting

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Meeting date: 30 June 2025

**Action:** For endorsement

The CHMP endorsed the meeting.

### 10.3. Real-world evidence (including DARWIN EU) for regulatory decision making

Regular touchpoint to explore emerging research questions at the time of pre-submission meetings and provide updates on the development of DARWIN EU, upcoming trainings and workshops and report on study requests received as well as planned/completed RWD studies. CHMP members will have an opportunity to raise RWD study proposals.

**Action:** For information

The CHMP noted the updates on Real-world evidence

## 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. [Winlevi - Clascoterone - EMEA/H/C/006138](#)

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Cassiopea S.p.A.; indicated for the topical treatment of acne vulgaris in adults and adolescents

Scope: Re-examination timetable

**Action:** For adoption

Opinion adopted 25.04.2025. List of Outstanding Issues adopted on 27.03.2025, 12.12.2024, 17.10.2024. List of Questions adopted on 22.02.2024.

The CHMP adopted the re-examination timetable.

## 12. Any Other Business

### 12.1. Rapporteurships

Update.

**Action:** For information

The CHMP noted the update.

### 12.2. European Shortages Monitoring Platform overview for NCAs

The European Medicines Agency (EMA) has launched the European Shortages Monitoring Platform (ESMP) to gather information about medicine availability, supply and demand in order to prevent, detect, and manage human medicine shortages in the European Union (EU) and European Economic Area (EEA).

**Action:** For information

The CHMP noted the information on the European Shortages Monitoring Platform overview for NCAs.

### 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 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 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	
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	
Outi Mäki-Ikola	Member (Vice-Chair)	Finland	No interests declared	
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	
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	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Hjalti 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 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
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	
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	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Anna Vikerfors	Expert	Sweden	No interests declared	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Nicolas Lee	Expert	Ireland	No participation in discussion, final deliberations and voting on:	10.2.1. ITF meeting; 5.1.12. Revolade - Eltrombopag - EMEA/H/C/001110 /II/007
Susanne Brendler-Schwaab	Expert	Germany	No restrictions applicable to this meeting	
Caroline Auriche Benichou	Expert	Iceland	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
Andreas Bonertz	Expert	Germany	No interests declared	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Christoph Furtmann	Expert	Germany	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Michiel van den Heuvel	Expert	Netherlands	No interests declared	
Carolien Versantvoort	Expert	Netherlands	No interests declared	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Juan Ignacio Bedoya Ponte	Expert	Spain	No restrictions applicable to this meeting	
Enrique Blanco Cortina	Expert	Spain	No restrictions applicable to this meeting	
Priscilla Schoondermark	Expert	Netherlands	No interests declared	
Johanna de Groot	Expert	Netherlands	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.