17 January 2025
EMA/CHMP/558008/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] Minutes for the meeting on 02 December 2024

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

02 December 2024, 09:00–16:00, virtual meeting

Disclaimers

Some of the information contained in this document is considered commercially confidential or sensitive and therefore not disclosed.

Of note, agendas and minutes are working documents primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

[1] 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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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 02 December 2024 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 02 December 2024 meeting will be adopted at the December 2024 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry

2.1.1. Agenda and minutes

- Agenda for the BWP meeting to be held virtually on 2-4 December 2024
- Minutes for the BWP meeting held virtually on 7-9 October 2024

Action: For information

The CHMP noted the agenda and minutes.

2.1.2. Nomination of new Biological Quality ESEC experts

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

Nomination(s) received.

Action: For endorsement

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

2.1.3. BWP 3-year workplan 2025-2027

Adoption of the 3-year workplan of the BWP as adopted by BWP in November 2024.

Action: For adoption

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

2.1.4. Call for nomination of BWP Vaccine Quality Operational Expert Group (BV-OEG)

Call for nomination of experts on the creation of a specialised BWP Vaccine Quality Operational Expert Group (BV-OEG) to assist the BWP in handling of vaccine quality-related issues including influenza-related issues (therefore taking over and disbanding the current Ad hoc Influenza Working group for annual strain recommendations).

Action: For endorsement

The CHMP endorsed the nomination of BWP Vaccine Quality Operational Expert Group (BV-OEG).

2.2. Quality Working Party (QWP)

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

2.2.1. Agenda and minutes

- Agenda for the QWP meeting to be held virtually on 2-3 December 2024
- Minutes for the QWP meeting held virtually on 7-8 October 2024

Action: For information

The CHMP noted the agenda and minutes.

2.2.2. Nomination of new Chemical Quality ESEC experts

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

Nomination(s) received.

Action: For endorsement

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

2.2.3. QWP 3-year workplan 2025-2027

Adoption of the 3-year workplan of the QWP as adopted by QWP in November 2024.

Action: For adoption

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

2.2.4. Q&A on "Granules in Capsules for Opening"

Adoption of a short Q&A for the EMA website to support adoption of a new standard term by the European Pharmacopoiea Commission.

Action: For adoption

The CHMP adopted the Q&A for the EMA website to support adoption of a new standard term by the European Pharmacopoiea Commission.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: René Anour, Vice-Chair: Niklas Ekman

2.3.1. Agenda and Minutes

- Agenda and Minutes for the BMWP meeting held virtually on 21 October 2024

Action: For information

The CHMP noted the agenda and minutes.

2.3.2. BMWP 3-year workplan 2025-2027

Adoption of the 3-year workplan of the BMWP as adopted by BMWP in November 2024.

Action: For adoption

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

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 for the NcWP meeting held face-to-face on 8-9 October 2024
- Draft agenda for the NcWP meeting to be held virtually on 3-4 December 2024

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Nomination of New Approach Methodologies ESEC experts

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

Nomination(s) received.

Action: For endorsement

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

3.1.3. Non-clinical domain 3-year Workplan 2025-2027

Adoption of the 3-year workplan of the non-clinical domain including the NcWP and 3RsWP after the external stakeholders' consultation.

Action: For adoption

The CHMP adopted the 3-year workplan of the non-clinical domain including the NcWP and 3RsWP.

3.1.4. Nomination of new members to the NcWP

Nomination of 2 new members following the departure of Mikael Andersson and Fabienne Gaugaz at the end of October 2024.

Nomination(s) received.

Action: For endorsement

The CHMP endorsed the nomination of Eugenio Aiello (AIFA) and Camilla Svensson (NOMA) to the NcWP.

3.1.5. Information for the package leaflet regarding dextrans used as excipients in MPs for human use

Following public consultation from November 2018 to May 2019 the NcWP Excipients tDG has revised the proposed information for the package leaflet regarding dextrans used as excipients, meant to be integrated to the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. The document was endorsed by the "Notice to Applicants" group.

Expert: Dominique Masset

Action: For adoption

The CHMP adopted the information for the package leaflet regarding dextrans used as excipients, meant to be integrated to the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'.

3.1.6. NcWP Reflection Paper on qualification of non-mutagenic impurities - Revision

The NcWP tDG has completed a draft reflection paper that addresses the qualification of non-mutagenic impurities (NMI), meaning the acceptability of certain levels of NMI from a safety perspective. It does not consider the acceptability of impurity levels from a quality perspective. It provides alternative strategies to qualify novel impurities or to qualify higher levels of impurities that were previously qualified at a lower level. It considers that the level of concern for impurities may vary depending on many factors, which determine how much data is needed, ranging from none to compound-specific experimental data. It replaces a previous draft version (Reflection paper on the qualification of non-genotoxic impurities. EMA/CHMP/SWP/545588/2017) after substantial comments were received indicating that industry seeks guidance on qualification of non-mutagenic impurities (NMI) in early development. The previous version of the RP also did not address qualification of an NMI during clinical development. The document has been reviewed by the NcWP and GCG and is presented for adoption for a 3-month public consultation.

Expert: Leon van Aerts

Action: For adoption

The CHMP adopted the revised NcWP Reflection Paper on qualification of non-mutagenic impurities for a 3-month public consultation.

3.1.7. CMDh question to NcWP/NS-OEG

Action: For adoption

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

3.1.8. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.9. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

3.1.10. NcWP/NS-OEG response to CMDh question

Action: For adoption

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

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

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

3.2.1. Agenda and minutes

- Minutes for the 3RsWP meeting held face-to-face on 24-25 September 2024.
- Agenda for the 3RsWP meeting held virtually on 20-21 November 2024.

Action: For information

The CHMP noted the agenda and minutes.

3.2.2. Nomination of new members to the 3RsWP

Nomination of 2 new members following the call for nomination which closed on 18 October, to assist in the delivery of the 3RsWP workplan.

Nomination(s) received.

Action: For endorsement

The CHMP endorsed the nomination of Karen Ekkelund Petersen (DKMA) and Peter van Meer (MEB) for the 3RsWP.

3.2.3. Reflection paper on the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs

This reflection papers (RP) was originally published in 2018 was revised in accordance with the NC domain work plan 2023-2025, to ensure the most up-to-date and state-of-the-art 3Rs opportunities are included. This follows a significant increase in research and development in the field of new approach methodologies (NAMs) in recent years, as well as a number of pharmacopoeial updates, etc. relevant to 3Rs.

The structure of the RP follows a tabular format for each of the relevant CHMP and CVMP working parties and for the CAT, providing for each an overview of regulatory requirements and both formally implemented and newly identified 3Rs opportunities. An initial revised draft was prepared by the 3RsWP and was subsequently updated following consultation with all of the relevant working parties/committees. The RP has been reviewed by all comments addressed and is presented toCHMP for endorsement for for public consultation. For information, a parallel RP relating to veterinary medicinal products has also been revised and is expected to be released for public consultation concurrently.

Action: For endorsement

The CHMP endorsed the Reflection paper on the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs to be released for public consultation

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Agenda and minutes

- Agenda and minutes for the MWP meeting held face-to-face on 19-20 September 2024

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of new Methodology ESEC experts

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

Nomination(s) received.

Action: For endorsement

The CHMP endorsed the nomination of Aynur Sert (DKMA), Camilla Ærtebjerg Bæk (DKMA), Stephanie Wittrup Berg (DKMA), Emma Louise Nautrup Ravn Stadsbjerg (DKMA), Kay-Martin Hanschmann (PEI), Ana Chilaika (MPA), Katarina Ekholm Selling (MPA), Catharina Apelthun (MPA), Catrin Wessman (MPA) to join the Methodology European Specialised Expert Community (ESEC).

4.1.3. Call for interest for nomination of the Methodology Working Party Chair and vice-Chair

Nominations should be sent to the Agency by 21 March 2025. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Elections are planned at the March 2025 CHMP Plenary meeting.

Action: For information

The CHMP noted the call for interest for nomination of the MWP Chair and vice-Chair.

4.1.4. Implementation strategy of ICH Guideline M12 on drug interaction studies (Guideline)

An implementation notice has been developed to outline the implementation steps for the ICH M12 guideline in the EU.

Unlike the existing EMA Guideline on the investigation of drug interactions (CPMP/EWP/560/95/Rev. 1 Corr. 2**), ICH M12 does not address a number of topics, including, but not limited to food effect, contraceptives, enterohepatic binding (full list can be found in Table 1 of the document).

After 30 November 2024, the existing EMA Guideline on drug interaction studies pertaining to these specific topics will continue to apply until it will be replaced by new EMA guidance. Endorsement is sought from CHMP.

Action: For endorsement

The CHMP endorsed the Implementation strategy of ICH Guideline M12 on drug interaction studies (Guideline).

4.1.5. MWP 3-year workplan 2025-2027

Adoption of the 3-year workplan of the MWP.

Action: For adoption

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

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

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

5.1.1. CNSWP 3-year workplan 2025-2027

Adoption of the 3-year workplan of the CNSWP and the priorities 2025.

Action: For adoption

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

5.1.2. Call for interest for a new CNSWP member

Call for interest for new CNSWP member.

Action: For information

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

5.1.3. Call for interest for CNSWP drafting groups members

Call for interest for members of new drafting groups for guideline for ALS, myasthenia gravis, retinopathies, Parkinson's Disease and Alzheimer's disease.

Action: For information

The CHMP noted the call for interest for members of new drafting groups for guideline for ALS, myasthenia gravis, retinopathies, Parkinson's Disease and Alzheimer's disease.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. CVSWP 3-year workplan 2025-2027

Adoption of the 3-year workplan CVSWP and the priorities 2025.

Action: For adoption

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

5.2.2. Agenda

- Agenda for the CVSWP meeting held virtually on 28 November 2024.

Action: For information

The CHMP noted the agenda.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Nomination of new Oncology ESEC members to the Oncology Working party

Nomination of new Oncology European Specialised Expert Community (ESEC) members.

Nomination(s) received.

Action: For endorsement

The CHMP endorsed the nomination of Elina Rantala (FIMEA), Schadel Dina (PEI), Dario Trapani (AIFA) as Oncology European Specialised Expert Community (ESEC) members to the Oncology Working party.

5.3.2. Nomination of Oncology ESEC members to the drafting group working on the revision 7 of the anti-cancer guideline (EMA/CHMP/205/95 Rev.7)

Nominations of Oncology European Specialised Expert Community (ESEC) members.

Nomination(s) received.

Action: For endorsement

The CHMP endorsed the nomination Oncology European Specialised Expert Community (ESEC) members to the drafting group working on the revision 7 of the anti-cancer guideline.

5.3.3. Conversation on cervical cancer – speaker needed

Speaker for the next Conversation on cervical cancer.

Action: For discussion

The CHMP endorsed the speaker for the conversation on cervical cancer.

5.3.4. Cancer Medicines Pathfinder

General update and proposal for pilot with industry focus group.

Action: For information

The CHMP noted the update and the proposal for pilot with industry focus group on the Cancer Medicines Pathfinder.

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. Call for nominations for VWP Vice-Chair

Nominations should be sent to the Agency by 20 January 2025. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Elections will take place at the January 2025 CHMP Plenary meeting.

Action: For information

The CHMP noted the call for nominations for VWP Vice-Chair.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Nomination of new ESEC members to the Haematology Working party

Nomination of new Haematology European Specialised Expert Community (ESEC) members.

Nomination(s) received.

Action: For endorsement

The CHMP endorsed the nomination of Irene Saugar (AEMPS) and Chamorro Somoza Díaz-Sarmiento (AEMPS) as ESEC members to the HaemWP.

5.7.2. Minutes

- Final minutes for the Blood cluster meeting held virtually on 18 October 2024
- Final minutes for the non-malignant haematology meeting held virtually on 18 October 2024
- Final minutes for the Haematology working party meeting held face-to-face on 24-25 October 2024

Action: For information

The CHMP noted the minutes.

5.7.3. Guideline on the clinical requirements for non-replacement therapy in haemophilia (EMA/CHMP/BPWP/518080/2024)

The guideline on the clinical requirements for non-replacement therapy in haemophilia (EMA/CHMP/BPWP/518080/2024) has been adopted by HAEMWP and is presented for CHMP adoption.

CHMP: Daniela Philadelphy

Action: For adoption

The CHMP adopted the guideline on the clinical requirements for non-replacement therapy in haemophilia (EMA/CHMP/BPWP/518080/2024).

5.7.4. Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg) (EMA/CHMP/BPWP/496692/2023 rev 2)

The Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg) (EMA/CHMP/BPWP/496692/2023 rev 2) has been adopted by HAEMWP and is presented for CHMP adoption.

Expert: Claudia Gramiccioni

Action: For adoption

The CHMP adopted the Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg) (EMA/CHMP/BPWP/496692/2023 rev 2).

5.7.5. Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration (SCIg/IMIg) (EMA/CHMP/BPWP/143744/2011 rev.2)

The Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration (SCIg/IMIg) (EMA/CHMP/BPWP/143744/2011 rev.2) has been adopted by HAEMWP and is presented for CHMP adoption.

Expert: Claudia Gramiccioni

Action: For adoption

The CHMP adopted the Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration (SCIg/IMIg) (EMA/CHMP/BPWP/143744/2011 rev.2).

5.7.6. HaemWP 3-year workplan 2025-2027

Adoption of the 3-year workplan of the HaemWP.

CHMP: Daniela Philadelphy

Action: For adoption

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

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

5.8.1. Update on the renewal of SAG mandate

Update of the renewal of SAG mandate/call for nomination of experts for the 5 therapeutic SAGs (Neurology, Oncology, Vaccines, Infectious Diseases and Cardiovascular Issues).

Action: For information

The CHMP noted the update of the renewal of SAG mandate/call for nomination of experts for the 5 therapeutic SAGs (Neurology, Oncology, Vaccines, Infectious Diseases and Cardiovascular Issues).

6. Patients, Healthcare Professionals and Consumers

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

No topics

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. Training on estimands (ICH E9(R1))

A webinar Introduction to the Estimand Framework and Application to Specific Indications is organised.

Action: For information

The CHMP noted the webinar Introduction to the Estimand Framework and Application to Specific Indications.

7.1.2. Report from ICH MC in Montreal

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 Montreal.

7.1.3. ICH E6 (R3) Guideline on Guideline for good clinical practice - Principles and Annex 1 – Step 5

Following the finalisation of the guideline by the expert working group, CHMP adoption of Step 5 is requested. The guideline will be implemented 6 months after adoption.

Action: For adoption

The CHMP adopted the ICH E6 (R3) Guideline on Guideline for good clinical practice - Principles and Annex 1 – Step 5.

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

Chair: Ulla Wändel Liminga

Summary of recommendations and advice of PRAC meeting held on 25-28 November 2024

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. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP endorsed the proposed learnings.

9.2.2. Creation of a focus group on revamp of pre-submission interactions

Information to CHMP on the launch of this initiative that will kick-off in Q1-2025.

Action: For information

The CHMP noted the information on the creation of a focus group on revamp of pre-submission interactions.

9.2.3. CHMP Work Plan 2025

CHMP: Bruno Sepodes

Action: For adoption

The CHMP adopted the CHMP Work Plan for 2025.

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi, Vice-Chair: Pierre Demolis

10.1.1. Appointment of CHMP peer review for SA

Action: For information

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

10.1.2. Agenda and Table of Decisions

- Agenda for the SAWP meeting held virtually on 25-28 November 2024
- Table of Decisions for the SAWP meeting held virtually on 25-28 November 2024

Action: For information

The CHMP noted the agenda and table of decisions.

10.1.3. Nomination of SAWP members

A call for expression of interest for nomination of a SAWP member's replacement was launched following the departure of Andrea Laslop and to complete the SAWP composition.

Nominations received.

The new SAWP members and their alternates' starting date will immediately follow their nomination by the CHMP PROM (2 December 2024).

Action: For endorsement

The CHMP endorsed the nominations of Martin Walter, Linda Trauffler (AT), Elsa Grangier, Céline Jumeau (FR) as SAWP members/alternates.

10.1.4. Call for nominations for SAWP Chair

The mandate of SAWP Chair Paolo Foggi will expire on 13 March 2025. Nominations should be sent to the Agency by 31 January 2025. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Elections will take place at the February 2025 CHMP plenary meeting.

Action: For endorsement

The CHMP endorsed the call for nominations for SAWP Chair.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 16 December 2024

Action: For endorsement

The CHMP endorsed the meeting.

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

Monthly 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 discussion

The CHMP noted the updates on Real-world evidence (including DARWIN EU) for regulatory decision making.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Bruno Sepodes

Action: For information

The CHMP Chair flagged some procedures on the agenda for the upcoming plenary.

11.2. Cinainu – liquid ethanolic extract of *Allium cepa* (onion) fresh bulb and *Citrus limon* (lemon) fresh fruit/dry aqueous extract of *Paullinia cupana* (guarana) seed/dry hydroethanolic extract of *Theobroma cacao* (cocoa) seed - EMEA/H/C/004155/0000

Legacy Healthcare (France) S.A.S.; treatment of alopecia areata in children and adolescents

Scope: Update on the procedure

Action: For discussion.

The CHMP noted the status of this procedure.

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update.

12.2. Referrals rapporteurships

Update on rapporteurships for referrals.

Action: For adoption

The CHMP adopted the rapporteurships for referrals.

12.3. GCP inspection programme 2025-2026

Action: For adoption

The CHMP adopted the GCP inspection programme 2025-2026.

12.4. Rapporteur's team assessment - workload over end-of-year period

Action: For discussion

The CHMP agreed with the proposal on the timelines to handle the workload over end-of-year period.

12.5. Procedure contact point details template

Information on a separate procedure-contact-details-template for the various procedures.

Action: For information

The CHMP noted the procedure-contact-details-template and its use.

13. List of participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Bruno Sepodes	Chair	Portugal	No interests declared	
Daniela 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	
Gergana Lazarova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Boje Kvorning Pires Ehmsen	Alternate	Denmark	No interests declared	
Edward Laane	Alternate	Estonia	No interests declared	
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 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	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No restrictions applicable to this meeting	
John Joseph Borg	Member	Malta	No interests declared	
Peter Mol	Member	Netherlands	No interests declared	
Patrick Vrijlandt	Alternate	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Fatima Ventura	Member	Portugal	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Antonio Gomez-Outes	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Anne Halse Buur	Expert	Denmark	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Claudia Gramiccioni	Expert	Italy	No interests declared	
Ana Maria Imedio	Expert	Spain	No interests declared	
Leon van Aerts	Expert	Netherlands	No interests declared	
Dominique Masset	Expert	France	No interests declared	
Elsa Grangier	Expert	France	No interests declared	
Celine Jumeau	Expert	France	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christophe Furtmann	Expert	Germany	No interests declared	
Carmen Purdel	Expert	Romania	No interests declared	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	

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