22 February 2024
EMA/CHMP/82768/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 12 February 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

12 February 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.

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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 12 February 2024 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 12 February 2024 meeting will be adopted at the February 2024 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Francesca Luciani

2.1.1. Agenda and Minutes

- Minutes of the BWP December virtual meeting held on 04-06 December 2023
- Agenda of the BWP virtual meeting to be held on 12-14 February 2024

Action: For information

The CHMP noted the agenda and minutes.

2.1.2. Launch of Call for Nominations to Biological Quality ESEC

- Mandate and rules of procedure

Action: For information

The CHMP noted the launch of a call for nominations to Biological Quality ESEC.

2.2. Quality Working Party (QWP)

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

2.2.1. Agenda and Minutes

- Minutes of the face-to-face QWP meeting held on 4-5 December 2023
- Agenda of the QWP virtual meeting to be held on 12-13 February 2024

Action: For information

The CHMP noted the agenda and minutes.

2.2.2. CMDh request to QWP and MWP on in-vitro dissolution of modified release products in release media containing alcohol

Response to CMDh from the QWP and MWP about a clarification question related to the published Q&A about on the in-vitro dissolution of modified release products in release media containing alcohol. The proposed document is not intended to be published as an additional Q&A; it is intended to address the CMDh concerns. It has been drafted by a joint drafting group from MWP/QWP.

Action: For adoption

The CHMP adopted responses to the CMDh questions to QWP and MWP on in-vitro dissolution of modified release products in media containing alcohol.

2.2.3. Guideline on the pharmaceutical quality of inhalation and nasal products

Revision of the guideline describing the quality requirements for inhalation and nasal products. The main changes are the following: to increase clarity, inhalation and nasal products are separated in different parts. The guideline is updated according to published Q&A, medical device regulation and common practice. “Lifecycle management” is added as new section for inhalation respectively nasal products, including possible changes that might impact the quality, safety, or efficacy of the product. Specific information that needs to be included in the product information is extended, e.g. expression of strength.

Experts: Anna Hillgren, Peter Caspers

Action: For adoption

The CHMP adopted the guideline on the pharmaceutical quality of inhalation and nasal products.

2.2.4. CMDh question to QWP and NcWP on determining an Acceptable Intake (AI) if no Maximum Daily Dose (MDD) is mentioned in the SmPC

In February 2023, CMDh sent a question to QWP and NcWP via a letter from the CMDh chair to the chair of CHMP asking for a recommendation concerning the best way to determine a Maximum Daily Dose of a medicinal product when there is no information about it included in SmPC/PL. The request was discussed in the QWP nitrosamine OEG and also with the NcWP secretariat and it was concluded that it is not in the remit of QWP or NcWP to advise on the maximum daily dose. It is recommended that clinical experts in the member states be consulted if this information is not available in the SmPC. This position is formalised as a joint letter (reply) from the QWP and NcWP chairs to the CMDh chair and was adopted by both QWP and NcWP in January 2024.

Action: For adoption

The CHMP adopted the QWP and NCWP response to the CMDh question.

2.2.5. Launch of Call for Nominations to Chemical Quality ESEC

- Mandate and rules of procedure

Action: For information

The CHMP noted the launch of a call for nominations to Chemical Quality ESEC.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

No topics

3. Non-Clinical Domain

3.1. Non-Clinical Working Party (NcWP)

Chair: Susanne Brendler-Schwaab, Vice-Chair: Karen van Malderen

3.1.1. Agenda and Minutes

- Minutes of the virtual meeting held on 05-06 December 2023
- Draft agenda of the virtual meeting to be held on 13-14 February 2024

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. Nomination of New Approach Methodologies ESEC member

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

Nomination(s) received

Action: For endorsement

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

3.1.3. CMDh question to NcWP

Action: For adoption

The CHMP adopted the response from NcWP to the CMDh question.

3.1.4. CMDh question to NcWP

Action: For adoption

The CHMP endorsed the CMDh question to NcWP.

3.1.5. CMDh question to NcWP

Action: For adoption

The CHMP adopted the NcWP response to the CMDh question.

3.1.6. Environmental Risk Assessment (ERA) Guideline

The ERA guideline revision (1) is a major revision to the original guideline. The draft guideline has now been revised following implementation of changes following the public consultation in 2018 and legal and regulatory review. The main changes to the draft guideline following implementation of comments will be presented.

Expert: Éadaoin Griffin

Action: For adoption

The CHMP adopted the revision of the ERA Guideline. The updated document will be published on the EMA website.

3.1.7. CMDh question to NcWP on the duration of contraception following the use of a morphine-containing medicinal product

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 virtual meeting held on 22-23 November 2023
- Draft agenda of the virtual meeting held on 06-07 February 2024

Action: For information

The CHMP noted the agenda and minutes.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Christian B. Roes, Kristin Karlsson

4.1.1. Agenda and Minutes

- Agenda and minutes of the virtual MWP meeting held on 07 December 2023

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of Methodology ESEC experts

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

Nomination(s) received

Action: For endorsement

The CHMP endorsed the new member of the Methodology European Specialised Expert Community (ESEC).

4.1.3. Nomination of Methodology MSOEG experts

Nomination of EMA staff and new experts to enter the Methodology Modelling and Simulation Operational Expert Group (MSOEG).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the new member of the Methodology Modelling and Simulation Operational Expert Group (MSOEG).

4.1.4. Call for expression of interest for new MWP members

Following the opening of a call for nominations of 3 new members of the MWP launched on 15 January 2024 during the PROM meeting, the selection committee would like to extend the call for nominations until 31 March 2024.

The nominations will be chosen from those received up to this point, as well as any subsequent ones, and will be presented for approval at the PROM in April, following the selection committee's proposals.

MWP Chair: Christian B. Roes

Action: For adoption

The CHMP endorsed the extension of the call for expression of interest for new MWP members until 31 March 2024.

4.1.5. Concept paper on non-inferiority and equivalence comparisons

Following the GCG review, an update with only minor changes of the concept paper (that was presented to the PROM meeting in November 2023) was necessary. The updated concept paper is presented for adoption.

Action: For adoption

The CHMP adopted the concept paper on non-inferiority and equivalence comparisons for 3-months public consultation.

4.1.6. Draft product-specific guidelines for public consultation

- Trametinib film-coated tablets 0.5 and 2mg product-specific bioequivalence guidance (EMA/41624/2023)

Expert: Carolien Versantvoort

- Dabrafenib hard capsule 50 and 75 mg product-specific bioequivalence guidance (EMA/39771/2023)

Experts: Erika Fredriksson, Elin Lindhagen

- Nilotinib hard capsules 50, 150 and 200 mg product-specific bioequivalence guidance (EMA/518671/2023)

Expert: Carolien Versantvoort

Action: For adoption

The CHMP adopted the draft Dabrafenib hard capsule 50 and 75 mg and Trametinib film-coated tablets for 3-months product-specific guidelines for public consultation.

Nilotinib hard capsules 50, 150 and 200 mg product-specific bioequivalence guidance will be further discussed.

4.1.7. Revised overview of comments for liposomal amphotericin B product-specific guideline

A letter has been received from the MAH for the innovator liposomal amphotericin B product highlighting that specific comments submitted in the public consultation on the draft liposomal amphotericin B powder for dispersion for infusion 50 mg product-specific bioequivalence guidance (EMA/CHP/559889/2021) (ended 31 March 2022) were not included in the overview of comments (EMA/CHMP/275518/2022) published on 22 May 2023. The overview of comments has been updated to include these specific comments and a response addressing the points raised in the letter has been drafted.

Expert: Carolien Versantvoort

Action: For adoption

The CHMP adopted the revised overview of comments for liposomal amphotericin B product-specific guideline. The updated document will be published on the EMA website.

4.1.8. Decision Making in Multi-Arm Trials – Control of Error

MWP is looking to formulate guidance on the need for the control of errors in trials with multiple arms. This would apply, for example, to platform trial and master protocols but also to some bioequivalence trials with multiple test or reference formulations. Such a policy needs to be developed together with CHMP and volunteers are sought to join MWP members in drafting a position statement that will be brought back to CHMP for endorsement.

Action: For endorsement

The CHMP endorsed the proposal of formulating guidance regarding the control of errors in trials with multiple arms. CHMP members were invited to volunteer to join the drafting group.

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

- Agenda and Draft Table of Decisions of virtual CVSWP meeting held on 1 February 2024
- Table of Decisions of CVSWP meeting held on 10 November 2023

Action: For information

The CHMP noted the agenda and table of decisions.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre DemolisTemporary Drafting Group (tDG) composition for the concept paper on evaluation of therapeutic radiopharmaceuticals in oncology

Call for interest of RP experts for tDG for the concept paper on evaluation of therapeutic radiopharmaceuticals in oncology, included in the ONCWP Work Plan 2024.

Nomination(s) received

Expert: Serena Marchetti

Action: For endorsement

The CHMP endorsed the nominations of RP experts for the temporary DG for the concept paper on evaluation of therapeutic radiopharmaceuticals in oncology.

5.3.1. Cancer Medicines Forum points to consider on treatment optimisation in Oncology

In 2022, the European Medicines Agency (EMA) created the Cancer Medicines Forum (CMF). The CMF recommended developing regulatory tools to address treatment optimisation.

This draft Points to Consider document describes the current thinking on streamlining optimisation questions into the regulatory processes as maximising opportunities for stronger collaboration between different decision-makers, including regulators, payers, and academia.

Action: For discussion

The CHMP noted the topics for discussion on the Cancer Medicines Forum Points to Consider document on treatment optimisation in Oncology. CHMP members were invited to discuss within the NCAs and send comments until the next PROM meeting.

5.3.2. Agenda and Minutes

- Agenda of the virtual ONCWP meeting held on 17 January 2024
- Minutes of the hybrid ONCWP meeting held on 29 November 2023

Action: For information

The CHMP noted the agenda and minutes.

5.4. Rheumatology and Immunology Working Party (RIWP)

Chair: Caroline Auriche-Benichou, Vice-Chair: Karolina Törneke

5.4.1. Guideline on allergen products development in moderate to low-sized study populations

A concept paper was published in 2019 with 3-months consultation period to support the revision of the GL.

The main aim of the guideline is to address general guidance on the development of medicinal products for the diagnosis and immunotherapy of allergies, where only moderate to low-sized study populations are available in product development. In this document, guidance is provided on criteria and standards for patient selection, quality and non-clinical aspects, and possible indications concerning products for AIT and in vivo diagnosis of allergies. Recommendations are made on the clinical development, potential study designs and safety considerations for allergen products within the scope of the guideline. The guideline was adopted by RIWP.

Expert: Andreas Bonertz

Action: For adoption

The CHMP adopted the guideline on allergen products development in moderate to low-sized study populations.

5.4.2. Reflection Paper on Regulatory Requirements for the Development of Medicinal Products for Non-Alcoholic Steatohepatitis (NASH)

The reflection paper was discussed at the January PROM. Further updates are proposed based on the discussion.

Expert: Elmer Schabel

Action: For adoption

The CHMP discussed the reflection paper on regulatory requirements for the development of medicinal products for Non-Alcoholic Steatohepatitis (NASH). The rapporteur together with the drafting group will update the document for further discussion at the March PROM meeting.

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. Call for expression of interest for new VWP members

In the context of the new operational model of working parties established at the EMA Management Board in April 2021, it was agreed that the VWP composition would be a group of approximately 5 to 8 experts.

At the present time, the VWP includes 6 members, having lost two of the original 8 members appointed in 2022. The VWP proposes a call for nominations of 2 new members.

The following areas of expertise are requested:

- Non-clinical models for vaccines, specifically experience in assessing the non-clinical studies intended to support immunogenicity and efficacy
- Clinical studies with vaccines (safety, immunogenicity, and efficacy)
- Pharmacovigilance and monitoring of vaccines

In addition, the following expertise would be desirable:

- Member with experience of the PRAC Committee work
- Member with experience of the PDCO Committee work

Action: For endorsement

The CHMP endorsed the call for expression of interest for new VWP members.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Haemophilia ESEC Webinar on 1 March 2024

The webinar will present the general aspects of Haemophilia, the overview of the authorised medicines and the challenges encountered in clinical development, regulation, and clinical practice. In addition, study design and endpoints used in clinical trials will be discussed.

Action: For discussion

The CHMP noted the topics to be discussed on the Haemophilia ESEC Webinar and the CHMP representatives attending.

5.7.2. Joint Oncology and Haematology ESEC Webinar on HSCT (Hematopoietic Stem Cell Transplant) on 22 March 2024

The webinar will present the general aspects of HSCT, the overview of the authorised medicines and the challenges encountered in clinical development, regulation, and clinical practice. In addition, study design and endpoints used in clinical trials will be discussed.

Action: For discussion

The CHMP noted the topics to be discussed on the Joint Oncology and Haematology ESEC Webinar on HSCT and the CHMP representatives attending.

5.7.3. Nomination of Haematology ESEC experts

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

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new Haematology ESEC expert.

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)

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

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

6.1.1. Agenda and Minutes

- Summary report of the Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting with all eligible organisations held face-to-face on 14-15 November 2023
- Draft agenda of the Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting to be held face-to-face on 27-28 February 2024

Action: For information

The CHMP noted the agenda and summary report.

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. Step 2b ICH_E2D(R1) post-approval safety data: definitions and standards for management and reporting of individual case safety reports

The document is tabled for adoption and proposed to be subsequently released for a 4-months public consultation.

Action: For adoption

The CHMP adopted the ICH E2D(R1) harmonised guideline on post-approval safety data for a 4-months public consultation.

7.1.2. ICH Cell and Gene Therapy Discussion Group – appointment of expert

Following a call launched via CAT and BWP, CHMP is requested to appoint an expert covering quality aspects to the ICH Cell and Gene Therapy Discussion Group (CGTDG) which serves as a technical discussion forum for issues related to ICH harmonisation efforts in the field of CGT products.

CHMP: Bruno Sepodes

Action: For adoption

The CHMP adopted ICH's request to appoint an expert covering quality aspects to the ICH Cell and Gene Therapy Discussion Group (CGTDG).

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: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 05-08 February 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. Introduction of Annex to Letter of Intent

The pre-submission guidance has been updated in December 2023 to require companies to submit an Annex to Letter of Intent with additional information on the intended MAA or EU-M4All submissions. The Annexes will be distributed to the network within the rapporteur appointment process.

Action: For information

The CHMP noted the purpose of the introduction of the Annex to Letter of Intent.

9.2.3. Report from Group for Internal Rules on Extensions of Clock Stops

Report on outcomes and proposals to the CHMP. Comments to be sent by 29 February 2024.

Action: For discussion

The CHMP noted the report from the Group for Internal Rules on Extensions of Clock Stops. The CHMP was invited to send comments on the proposal until the 29 February. Further discussion and conclusions are expected on the next PROM meeting.

9.2.4. CHMP co-opted membership

The 3-year co-opted member mandate for Carla Torre comes to an end on 21/02/2024. The 3-year co-opted member mandate for Blanka Hirschlerova comes to an end on 18/03/2024.

Members were asked to submit nominations of experts in at least one of the following areas by 09 February 2024:

- Position 1: Quality (non-biologicals)

- Position 2: Pharmacoepidemiology; especially for methodological analysis and interpretation of data in particular study designs*. *The experience in pharmacoepidemiology should be applied to regulatory decision-making processes. The interpretation of data in particular study designs should include strengths and weaknesses (observational studies, RWD from different sources).

Nomination(s) received

The election for both positions is anticipated at the February 2024 plenary meeting.

Action: For information

The CHMP noted the nominations received for CHMP co-opted membership.

9.2.5. Mandate, objectives and rules of procedure for the Working Parties, Operational Expert Groups and Drafting Groups

Action: For adoption

The CHMP adopted the mandate, objectives, and rules of procedure for the Working Parties, Operational Expert Groups, and Drafting Groups.

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 of virtual meeting held on 05-08 February 2024
- Draft Table of Decisions of virtual meeting held on 05-08 February 2024

Action: For information

The CHMP noted the agenda and table of decisions.

10.1.3. Call for expression of interest for new SAWP members

Call for expression of interest for nomination of a SAWP member.

Required areas of expertise: pulmonology/immunology/internal medicine, oncology.

Applications should be sent by Thursday, 07 March 2024, EoB. The new SAWP member and his/her alternate starting date will immediately follow their nomination by the March CHMP PROM (11 March 2024).

Action: For information

The CHMP noted the call for expression of interest for new SAWP members.

10.1.4. ACT EU Priority Action 7

Priority Action 7 of ACT EU: strengthening the collaboration between SAWP and CTCG; Advice pilot.

Presentation: status update, outline of process principles, MS survey results, expected timeline.

Experts: Marianne Lunzer (CTCG Chair), Paolo Foggi (SAWP Chair)

Action: For information

The CHMP noted the updates on ACT EU Priority Action 7 and the collaboration between SAWP and CTCG.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting Date: 23 February 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting Date: 26 February 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting Date: 29 February 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.4. ITF meeting

Meeting Date: 11 March 2024

Action: For information

The CHMP endorsed the meeting.

10.2.5. ITF activities for the year 2023

Overview of the activities within the Innovation Task Force in 2023.

Action: For information

The presentation was postponed to the next PROM meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

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

12. Any Other Business

12.1. Rapporteurships

Update

Action: For information

The CHMP noted the update and the list of procedures with missing Rapporteurships.

12.2. EMA-HMA Lessons Learned from COVID-19 Pandemic

Joint report on the response to the Public Health Emergency. The report covers activities during the public health emergency phase of the pandemic, i.e., between 30 January 2020 and 5 May 2023. The ultimate goal of the lessons learned is to draw from the experiences of the emergency phase of the COVID-19 pandemic to strengthen the EMRN's crisis preparedness and its ability to respond rapidly if the EU were confronted with another pandemic or health crisis of this magnitude, as well as to improve other future activities.

Action: For information

The CHMP noted the report from EMA-HMA on the lessons learned from COVID-19 pandemic.

12.3. Health Threats and ETF Update

Action: For information

The CHMP noted the Health Threats and ETF updates.

12.4. Update on Real World Evidence – including DARWIN EU®

This is a quarterly update on Real World Evidence, including DARWIN EU®. EMA will present the progress of the onboarding of new data partners in DARWIN EU, as well as an update of ongoing and finalised RWD studies. CHMP PROM members will have an opportunity to raise any RWD study proposal for next year.

Action: For information

The CHMP noted the updates on Real-World Evidence, including DARWIN EU and the ongoing and completed RWD studies. The CHMP requested to have standing item on the

PROM agenda for 'Real-world evidence (including DARWIN EU) for regulatory decision making'. The discussions could serve as a trigger point for Rapporteurs to reflect on potential research questions as well as for updates.

12.5. New HMA-EMA Catalogues of real-world data sources and studies

The new HMA-EMA Catalogues of real-world data sources and studies are expected to go live in early 2024. The catalogues will describe real-world data sources and studies through a set of collected metadata to help pharmaceutical companies and researchers to identify and use such data when investigating the use, safety, and effectiveness of medicines. The catalogues aim to promote transparency and build trust in observational research and encourage the use of good practices.

- The catalogue of studies will cover studies performed on the data sources, enhancing and replacing the European Union electronic register of post-authorisation studies (EU PAS Register®)
- The catalogue of data sources will replace the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Resources Database

Action: For information

The CHMP noted the presentation on the new HMA-EMA Catalogues of real-world data sources and studies.

12.6. Concept paper on the development of a guideline on the non-clinical and clinical evaluation of antiviral medicinal products and monoclonal antibodies for the treatment and prevention of COVID-19

Disease due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) continues to be an important public health problem. During the declared public health emergency and thereafter, the EMA Emergency Task Force (ETF) has responded and continues to respond to many requests for scientific advice concerning the development of monoclonal antibodies and antiviral agents intended for the treatment and/or prevention of COVID-19. While the public health emergency has passed, the virus continues to evolve and to cause significant morbidity and variable mortality. There is a need for guidance built on experience thus far that addresses appropriate and feasible clinical study designs.

The CP will be released for one-month public consultation. The draft guidance is considered of utmost importance in view of the virus evolution, the cause of significant morbidity and the currently ongoing active clinical development in the field.

Action: For adoption

The CHMP adopted the concept paper on the development of a guideline on the non-clinical and clinical evaluation of antiviral medicinal products and monoclonal antibodies for the treatment and prevention of COVID-19 for one-month public consultation.

12.7. SharePoint – CHMP presentations

MSs could use this folder to share with EMA the final power point presentations for the plenary.

Action: For information

The topic was postponed to the CHMP March plenary.

13. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	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	
Lyubina Racheva Todorova	Member	Bulgaria	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	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No participation in final deliberations and voting on:	Concizumab - EMEA/H/C/005938 Insulin icodec - EMEA/H/C/005978 4.3.4. Ozempic - Semaglutide - EMEA/H/C/004174 /X/0043 4.3.5. Rybelsus - Semaglutide - EMEA/H/C/004953 /X/0038 4.3.6. Rybelsus - Semaglutide - EMEA/H/C/004953 /X/0039 4.3.7. Wegovy - Semaglutide - EMEA/H/C/005422 /X/0016
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in final deliberations and voting on:	9.1.1. Truvelog Mix 30 - insulin aspart - EMEA/H/C/005635
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	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	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 interests declared	
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Carolina Prieto Fernandez	Alternate	Spain	No interests declared	
Kristina Dunder	Member	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	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Kristin Karlsson	Expert	Sweden	No restrictions applicable to this meeting	
Caroline Auriche-Benichou	Expert	France	No interests declared	
Andreas Bonertz	Expert	Germany	No interests declared	
Elmer Schabel	Expert	Germany	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Carolien Versantvoort	Expert	Netherlands	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Eadaoin Griffin	Expert	Ireland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Gabriel Westman	Expert	Sweden	No interests declared	
Mette Tranholm	Expert	Sweden	No interests declared	
Leon van Aerts	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.