15 April 2024
EMA/CHMP/254908/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 15 April 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 April 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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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 15 April 2024 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 15 April 2024 meeting will be adopted at the April 2024 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry Agenda and Minutes

2.1.1. Agenda and Minutes

- Minutes of the BWP meeting held remotely on 12-14 February 2024
- Agenda of the BWP meeting to be held in person on 15-17 April 2024

Action: For information

The CHMP noted the agenda and minutes.

2.1.2. Nomination of new BWP member

Following the call for nominations launched in March 2024 for a new BWP member, the Quality Domain governance has recommended the new BWP member to be endorsed by CHMP.

Nomination(s) received

Quality Domain governance recommendation

Action: For endorsement

The CHMP endorsed the nomination of the new member of the BWP.

2.1.3. Revision of the CHMP Position Statement on Creutzfeldt-Jakob disease and plasma derived and urine-derived medicinal products

Revision of the Position Statement on Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products for CHMP adoption following a public consultation and comments from external stakeholders and review and comments from BWP, HAEMWP, ECDC, and EC.

Expert: Johannes Blümel

Action: For adoption

The topic was postponed to the May 2024 PROM Meeting.

2.1.4. Concept Paper on the Revision of the Guideline on Epidemiological Data on Blood Transmissible Infections – EMA/CHMP/BWP/548524/2008 Rev.1

The guideline on epidemiological data on blood transmissible infections (EMA/CHMP/BWP/548524/2008 Rev. 1) outlines the scientific data requirements for epidemiological data on blood transmissible infections to be included in applications for Plasma Master File (PMF) certification or annual recertification submitted to the EMA.

In view of the experience gathered during the review of the alert limits information in recent PMF annual updates (AU) and the requests from the plasma fractionation industry for further guidance, the need to expand the information for PMF holders on the approach and the statistical method for the appropriate calculation of alert limits was identified.

The revision of the guideline is scheduled to start in 2024 as part of the 3-year BWP work plan. Public consultation is planned for 2 months. It is anticipated that a draft revised guideline will be released for external consultation during 2024.

Expert: Maria Chamorro Somoza Díaz-Sarmiento

Action: For adoption

The CHMP adopted the concept paper on the revision of the Guideline on Epidemiological Data on Blood Transmissible Infections – EMA/CHMP/BWP/548524/2008 Rev.1 for 2 month public consultation.

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 QWP meeting held remotely on 12-13 February 2024
- Agenda of the QWP meeting to be held remotely on 15-16 April 2024

Action: For information

The CHMP noted the agenda and minutes.

2.2.2. Addendum to EMA/CHMP/CVMP/QWP/17760/2009 Rev. 3: Defining the Scope of an NIRS Procedure

- Revised addendum for adoption and publication
- Stakeholder comments and responses for adoption and publication

QWP Vice-Chair: Nicholas Lee

Action: For adoption

The CHMP adopted the Addendum to EMA/CHMP/CVMP/QWP/17760/2009 Rev. 3: Defining the Scope of an NIRS Procedure and the stakeholder comments responses

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: René Anour, Vice-Chair: Niklas Ekman

2.3.1. Agenda and Minutes

- Agenda and minutes of the BMWP meeting held remotely on 26 February 2024

Action: For information

The CHMP noted the agenda and minutes.

2.4. Quality Innovation Group (QIG)

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 meeting held remotely on 13-14 February 2024
- Draft agenda of the meeting to be held in person on 16-17 April 2024
- EMA/FDA Oncology Cluster minutes of the meeting held remotely on 6 February 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 the new members of the New Approach Methodologies European Specialised Expert Community (ESEC).

3.1.3. Nomination of new members to the Temporary ICHS1B OEG

The ICH guideline S1B(R1) Operational Experts Group (OEG) evaluates waiver requests for rodent carcinogenicity testing. The group reviews industry's scientific assessment of the human carcinogenicity potential of pharmaceuticals.

Nomination(s) received

Action: For endorsed

The CHMP endorsed the nomination of the new members of the Temporary ICHS1B OEG.

3.1.4. Call for expression of interest for nomination of new NcWP member

Following the departure of Günter Waxeneckerat at the end of April 2024, the NcWP is launching a call for nomination of a new member. Expression of interest should be sent by 31 May 2024.

Action: For information

The CHMP noted the launch of a call for expression of interest for the nomination of new members to the NcWP.

3.1.5. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to the NcWP.

3.1.6. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to the NcWP.

3.1.7. Nitrosamines appendix – Update

Appendix 3 to the Q&A for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral has been updated with a checklist for the Enhanced Ames Test conditions. The purpose of the checklist is to ensure that the information required for assessors to determine if the study has been performed in accordance with the EAT conditions is present. The table in the checklist may

be used to summarise the conditions used and the overall result of the study, but the full study report should always be submitted (link).

Action: For adoption

The CHMP adopted the update on the nitrosamines appendix (Appendix 3 to the Q&A for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral).

3.1.8. Q&A Nitrosamine impurities in human medicinal products – Revision

Question 10 of the Q&A document has been updated. The update relates to the "removal of the text that specified the date (31 January 2024) until when non-EAT compliant reports could be submitted for evaluation".

Action: For adoption

The CHMP adopted the revision of the Question 10 of the Q&A Nitrosamine impurities in human medicinal products.

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 meeting held remotely on 06-07 February 2024
- Agenda of the meeting held in person on 21 March 2024
- Agenda of the annual stakeholders meeting held remotely on 20 March 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 MWP meeting held remotely on 25 January, 9 February, and 29 February 2024

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of Methodology ESEC experts

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

Nomination(s) received

Action: For endorsement

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

4.1.3. Nomination of new members to the MWP

Following the call for nominations of three new members of the MWP launched on 15 January 2024 during the PROM meeting, the selection committee proposed candidates to be endorsed by the CHMP as new members of the MWP.

Nomination(s) received

MWP Chair: Christian B. Roes

Action: For endorsement

The CHMP endorsed the nomination of the new members of the MWP.

4.1.4. ACT EU Multistakeholder Workshop on Methodology Guidance – Key Learnings

Presentation of the key learnings from the ACT EU methodology workshop, focusing on guidance needs and agreements of the network participants for a closer collaboration in guidance development (CTCG, MWP, HTA).

Action: For information

The CHMP noted the key learnings from the ACT EU Multistakeholder Workshop on Methodology Guidance. The report of the ACT EU workshop is available here.

4.1.5. Reflection paper on the use of real-world data to generate real-world evidence in non-interventional studies

Presentation of main comments received from EMA committees and working parties and main changes made in the revised RP. For adoption for a 3-month public consultation.

Expert: Olaf Klungel

Action: For adoption

The CHMP adopted the reflection paper on the Use of real-world data in non-interventional studies to generate real-world evidence for a 3-month public consultation.

4.1.6. Final Implementation Strategy for ICH Guideline M10 on Bioanalytical Method Validation (EMA/449486/2023) and Overview of Comments

A strategy has been developed to address specific considerations relating to the timing of studies and the validation of bioanalytical methods to enable the practical implementation in the European Union of ICH M10 – Guideline on Bioanalytical Methods Validation

(EMA/CHMP/ICH/172948/2019). A two-month public consultation ended on 31 January 2024. The strategy has been updated to account for the comments received, which are for publication in an Overview.

Expert: Jan Welink

Action: For adoption

The CHMP adopted the Final Implementation Strategy for ICH Guideline M10 on Bioanalytical Method Validation.

4.1.7. CMDh request and MWP response on bioequivalence requirements for generic applications containing tolvaptan

In January 2024, CMDh requested MWP's input on specific bioequivalence requirements for tolvaptan. The MWP has drafted a response.

Expert: Marcel Maliepaard

Action: For adoption

The CHMP adopted the MWP response on the CMDh's request on specific bioequivalence requirements for generic applications containing tolvaptan. The MWP will develop a PSBG on tolvaptan.

4.1.8. Call for expression of interest for nomination of new MWP members

After the resignation of an MWP member, a new call for nomination of an expert in clinical pharmacology is proposed. In addition, the previous call for expertise in biostatistics remains open for nominations.

The following areas of expertise are requested:

- Clinical Pharmacology, with particular interest in bioequivalence, biowaivers and PK.
- Biostatistics, with a particular interest in indirect comparisons and external control of clinical trials.

MWP Chair: Christian B. Roes

Action: For endorsement

The CHMP endorsed the call for expression of interest for the nomination of new members to the MWP.

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. Nomination of new Cardiovascular ESEC expert

Nomination of new expert to join the Cardiovascular European Specialised Expert Community (ESEC).

Nomination(s) received

Action: For endorsement

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

5.2.2. Nomination of experts for Temporary Drafting Group (tDG) on the Revision of the Paediatric Addendum on Weight Control in Children (EMEA/CHMP/EWP/517497/2007)

Following the call for expression of interest of experts for the Temporary Drafting Group (tDG) on the Revision of the Paediatric Addendum on Weight Control in Children (EMEA/CHMP/EWP/517497/2007), included in the CVSWP Work Plan 2024, the following nominations have been received.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of experts to the Temporary Drafting Group (tDG) on the Revision of the Paediatric Addendum on Weight Control in Children.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis

5.3.1. Nomination of Oncology ESEC experts

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

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new members of the Oncology European Specialised Expert Community (ESEC).

5.3.2. Cancer Medicines Forum meeting

- Agenda and minutes of the Cancer Medicines Forum meeting held remotely on 26 February 2024

Action: For information

The CHMP noted the agenda and minutes.

5.3.3. Cardiovascular Safety of Oncology Medicinal Products

- Guideline and scientific paper to be drafted

Action: For information

The CHMP noted the composition of the new drafting group on Cardiovascular Safety of Oncology Medicinal Products.

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo, Vice-Chair: Maja Sommerfelt Gronvold

5.5.1. Nomination of new member to the IDWP

Nomination of new member to join the IDWP, following the departure of Lourdes Rodriguez.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new member of the IDWP.

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. Nomination of new members to the VWP

Nomination of new members to join the VWP.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new members of the VWP.

5.6.2. Election of new Chair to the VWP

The candidates for the Chair position of the VWP are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Nominations should be sent to the VWP secretariat by 21 May 2024. The election will take place at the May 2024 CHMP Plenary Meeting.

Action: For endorsement

The CHMP endorsed the launch of elections for a new Chair to the VWP.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Minutes

- Minutes of the Blood Cluster meeting held remotely on 8 March 2024

Action: For information

The CHMP noted the minutes.

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. Call for expression of interest for new CHMP volunteers to support EMA stakeholder activities

A group of CHMP members (Fátima Ventura, Carla Torre, and Edward Laane) are involved in the selection of products for *i)* early dialogue methodology and *ii)* identification of CHMP oral explanations where patients and healthcare professionals can be invited to engage. After departure of Maria Concepcion Prieto Yerro, EMA is looking for a CHMP member to join to support these activities and be a CHMP representative on the Patients and Consumers Working Party (PCWP). A call for interest will be launched for a CHMP member to volunteer.

Action: For information

The CHMP noted the call for expression of interest for new CHMP volunteers to support EMA stakeholder activities (PCWP).

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. ICH minor revision of Q3C (R9) Impurities Guideline for Residual Solvents

Revision 9 of the Guideline for Residual Solvents was implemented through a "minor revision" ICH procedure and concerned specific considerations for solvent volatility for analytical methods. Following conclusion of the work, the guideline is presented for CHMP adoption.

Action: For adoption

The CHMP adopted the ICH minor revision of Q3C (R9) Impurities Guideline for Residual Solvents.

7.1.2. ICH M14 Draft Guideline on General Principles on Planning and Designing Pharmacoepidemiological Studies that Utilize RWD for Safety Assessment of a Medicine

The ICH M14 Expert Working Group has completed a draft guideline covering the general principles on planning, designing, and analysing observational (non-interventional) pharmacoepidemiological studies that utilize fit-for-purpose data for safety assessment of medicines. The document is presented for adoption for a 3-month public consultation.

Action: For adoption

The CHMP adopted the ICH M14 Draft Guideline on General Principles on Planning and Designing Pharmacoepidemiological Studies that Utilize RWD for Safety Assessment of a Medicine for a 3-month public consultation.

7.1.3. Call for expression of interest – new ICH Expert Working Group

Following endorsement by ICH of a proposal for a new nonclinical guideline on "Nonclinical safety studies for Oligonucleotide-based Therapeutics", a call has been launched through CHMP and NcWP to appoint experts for a new ICH Expert Working Group to draft the ICH guideline. Nominations can be sent by 8 May 2024.

Action: For endorsed

The CHMP endorsed the call for expression of interest for a new ICH Expert Working Group to draft the ICH guideline.

7.1.4. Update on ICH Reflection Paper on RWE Terminology

Update on the ICH reflection paper: "International Harmonisation of Real-World Evidence Terminology and Convergence of General Principles Regarding Planning and Reporting of Studies Using Real-World Data, with a Focus on Effectiveness of Medicines".

Comments received during the public consultation on the ICH RP.

The tentative plan is to submit the updated RP to ICH for adoption in June 2024.

Link to the current published version:
ICH_ReflectionPaper_Harmonisation_RWE_Terminology_Endorsed-For Consultation_2023_0613.pdf.

CHMP: Bruno Sepodes

Action: For discussion

The CHMP noted the update on the status of the ICH Reflection Paper newly entitled "Pursuing Opportunities for Harmonization in Using Real-World Data to Generate Real-World Evidence, with a focus on Effectiveness of Medicines" following the public consultation.

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 08-11 April 2024

Action: For information

The CHMP noted the summary of recommendations and advice.

8.2.2. Concept paper on the revision of the Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling

This concept paper, prepared by a CHMP/PRAC multistakeholders drafting group, presents the high-level topics to update the 'CHMP Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling', triggered by PRAC and CHMP work plans for 2023-2024, on the development/update of population specific guidance in terms of risk assessment of medicinal products on human reproduction and lactation. With the objective to strengthen systematic generation of information on the benefits and risks of medicines in pregnancy and breastfeeding, the update will consider developments in the non-clinical field and post-authorisation data, among others, ensuring alignment with other relevant guidelines. Adoption of the concept paper for endorsement for public consultation.

CHMP: Jan Müller-Berghaus, PRAC: Ulla Wändel Liminga

Action: For adoption

The CHMP adopted the concept paper on the revision of the Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling for publication for public consultation

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.

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 from 08-11 April 2024 meeting held by Webex
- Draft Table of Decisions from 08-11 April 2024 meeting held by Webex

Action: For information

The CHMP noted the agenda and table of decisions.

10.1.3. Nomination of new members to the SAWP

Nomination of new members to join the SAWP, following resignation of Sheila Killalea and Larissa Higgins.

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

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new members to the SAWP.

10.1.4. Call for expression of interest for nomination of SAWP members

Extension of call for expression of interest for nomination of a SAWP member's replacement, following planned departure of Kerstin Wickström.

Required areas of expertise:

- Ophthalmology

- Pulmonology
- Internal Medicine
- Biosimilars
- Neurology

Applications should be sent to the SAWP Secretariat.

Action: For information

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

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 18 April 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 24 April 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 29 April 2024

Action: For adoption

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, upcoming events and the ongoing and completed RWD studies.

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.

12.2. Health Threats and ETF Update

Action: For information

The CHMP noted the Health Threats and ETF updates.

12.3. Paediatric procedures on IRIS

Paediatric procedures governed by the Paediatric Regulation with the aim to ensure that medicines for use in children are of high quality, ethically researched and authorised appropriately, will be onboarded on IRIS. This presentation aims to inform the CHMP about the progress and training activities on paediatric procedures that will be onboarded in IRIS on 4 June 2024.

Action: For information

The CHMP noted the updates on the progress and training activities on paediatric procedures that will be onboarded in IRIS on 4 June 2024.

12.4. BWP reports on IRIS

Following the reorganisation of the Quality Domain in May 2023, the QWP and BWP Secretariat have been working on a transition to a new flexible and collaborative way of working, taking into consideration the specificities of the Quality Domain and product-related work involved. This presentation is aimed to inform the Committee about the new processes starting in April 2024.

Action: For information

The CHMP noted the new procedure for the BWP reports.

12.5. Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) Multistakeholder Workshop on Patient Registries

Feedback on the workshop on patient registries held on 12-13 February 2024. Presentation of the key recommendations and next steps.

Link: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) Multistakeholder workshop on Patient Registries | European Medicines Agency (europa.eu).

CHMP: Peter Mol, Bruno Sepodes, Carla Torre

Action: For information

The CHMP noted the feedback on the Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) Multistakeholder Workshop on Patient Registries, held on 12-13 February 2024. The report is planned to be published in June 2024.

12.6. Update on the AMA project and attendance of the Evaluation of Medicinal Products Technical Committee (EMP TC) to CHMP

Provide an update on the Agency's support to AMA and the draft agenda for the visit of the EMP TC at EMA on June 24-27.

Action: For information

The CHMP noted the update on the AMA project and attendance of the Evaluation of Medicinal Products Technical Committee (EMP TC) to CHMP. The EMTC visit is a learning opportunity for EMP TC members of the functioning of the CHMP and EU Network.

12.7. Joint virtual GCP inspectors-assessors meeting

Actions from the 2023 joint workshop will be presented as well as the upcoming joint GCP inspectors-assessors virtual meeting to be held on 6 June 2024.

Action: For information

The CHMP noted the actions from the 2023 joint workshop and the upcoming joint GCP inspectors-assessors virtual meeting to be held on 6 June 2024.

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	
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 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	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No participation in discussion, final deliberations and voting on:	4.1.3. Ozempic - Semaglutide - EMEA/H/C/004174/X/0043 4.1.5. Rybelsus - Semaglutide - EMEA/H/C/004953/X/0038 4.1.6. Wegovy - Semaglutide - EMEA/H/C/005422/X/0016 5.1.22. Wegovy - Semaglutide - EMEA/H/C/005422/II/0017
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Jean-Michel Race	Alternate	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 participation in discussion, final	2.1.3. Omecamtiv mecarbil - EMEA/H/C/006112

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			deliberations and voting on:	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
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	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	4.3.1. Cerdelga - Eliglustat - Orphan - EMEA/H/C/003724/X/0036/G 4.3.3. Kevzara - Sarilumab - EMEA/H/C/004254/X/0043/G 5.1.4. Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0005
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	
Carolina Prieto Fernandez	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	
Susan Uiterwaal	Expert	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Meera Varma	Expert	Denmark	No restrictions applicable to this meeting	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Marcel Maliepaard	Expert	Netherlands	No interests declared	
Maria Jesús Fernández Cortizo	Expert	Spain	No interests declared	
Maria Chamorro Somoza Díaz-Sarmiento	Expert	Spain	No interests declared	
Paula Contreras Alarcón	Expert	Spain	No participation in discussion, final deliberations and voting on:	4.2.3. Skyrizi - Risankizumab - EMEA/H/C/004759/X/0043/G
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.