25 January 2024
EMA/CHMP/51462/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

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

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 January 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 15 January 2024 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 15 January 2024 meeting will be adopted at the January 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 November virtual meeting held on 30-31 October 2023
- Agenda of the BWP virtual meeting to be held on 15-17 January 2024

Action: For information

The CHMP noted the agenda and minutes.

2.1.2. BWP Work Plan

BWP 3-year work plan 2024-2026.

Action: For adoption

The CHMP adopted the BWP Work Plan 2024-2026.

2.2. Quality Working Party (QWP)

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

2.2.1. Q&A on assessment of quality of finished products containing known active substances

This Q&A document is intended for assessors/applicants; it addresses in a general way the strategy for the assessment of the quality of medicinal products containing existing/known active substances. The Q&A reflects how a harmonised approach of the evaluation of medicinal products containing existing/known active substances should be handled within the European pharmaceutical legislative framework, taking into account both the legal requirements and the protection of European patients and animals to facilitate availability of high-quality medicinal products across the EU. This Q&A will replace "QWP Recommendation on the Assessment of the quality of medicinal products containing existing/known active substances" at the EMA website.

Action: For adoption

The CHMP adopted the Q&A on assessment of quality of finished products containing known active substances. The Q&A will be discussed by CVMP in its January meeting. The document will be published in the EMA website once adopted.

[Post-meeting note: The CVMP adopted the Q&A document. The Q&A will be published accordingly]

2.2.2. Q&A on how to use a CEP in the context of a Marketing Authorisation Application (MAA) or a Marketing Authorisation Variation (MAV)

The CEP procedure is widely used in EU for submission of pharmacopoeial active substance manufacturer data. Based on experience gained by NCAs and the extensive use of CEPs in MAA/MAV, it has become apparent that some aspects of MAH/applicant responsibilities need to be elucidated.

This document aims to clarify existing guidance as a compilation of required data to be submitted in a MAA or in certain MAVs when a CEP is referred to in the MA dossier. It is also applicable when an excipient covered by a CEP is used as an active substance (AS).

Expert: Maryam Mehmandoust

Action: For adoption

The CHMP adopted the Q&A on how to use a CEP in the context of a Marketing Authorisation Application (MAA) or a Marketing Authorisation Variation (MAV). The Q&A will be discussed by CVMP in its January meeting. The document will be published in the EMA website once adopted.

[Post-meeting note: The CVMP adopted the Q&A document. The Q&A is published accordingly]

2.2.3. Agenda and Minutes

- Minutes of the QWP meeting held remotely on 30-31 October 2023
- Agenda of the QWP virtual meeting to be held on 15-16 January 2024
- Minutes of Joint Meeting of GMP/GDP Inspectors Working Group (GMDP IWG) and Quality Working Party (QWP) held remotely on 27 September 2023

Action: For information

The CHMP noted the agenda and minutes.

2.2.4. QWP Work Plan

QWP 3-year work plan 2024-2026.

Action: For adoption

The CHMP adopted the QWP Work Plan 2024-2026.

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 face-to-face meeting held on 23-24 November 2023

Action: For information

The CHMP noted the agenda and minutes.

2.3.2. Concept Paper for the development of a Reflection Paper on a tailored clinical approach in biosimilar development

Concept paper on tailored clinical approach in biosimilar development. Currently under GCG consultation, comments expected until 15 January; in case no major revision required, possible formal adoption at the January CHMP plenary.

Action: For adoption

The CHMP discussed the concept paper for the development of a reflection paper on a tailored clinical approach in biosimilar development. CHMP members were invited to send comments, if any, before the CHMP adoption in the January plenary.

[Post-meeting note: The concept paper was adopted at the CHMP January plenary.]

2.3.3. BMWP Work Plan

BMWP 3-year work plan 2024-2026.

Action: For adoption

The CHMP adopted the BMWP Work Plan 2024-2026.

2.4. Quality Innovation Group (QIG)

Chair: Marcel Hoefnagel

2.4.1. QIG Work Plan

QIG 3-year work plan 2024-2026.

Action: For adoption

The CHMP adopted the QIG Work Plan 2024-2026.

2.5. Formulation Expert Group (FEG)

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 26 and 31 October 2023
- Draft agenda of the virtual meeting to be held on the 09 and 17 January 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 member of the New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC).

3.1.3. NcWP Work Plan

The work plan priorities for 2024 for the NC domain. The priorities were agreed by the NcWP and 3RsWP and endorsed by the Non-Clinical Domain Governance.

Action: For adoption

The CHMP adopted the NcWP Work Plan 2024.

3.1.4. CMDh question to NcWP

CMDh question to NcWP regarding – 2-(4-nitrosopiperazin-1-yl) ethanol detected in medicinal products containing opipramol.

Action: For adoption

The CHMP endorsed the CMDh question to NcWP.

3.1.5. Q&A for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products

Update of Q&A 3 and Q&A 10 to include guidance on non-mutagenic nitrosamine impurities (NMI) handling. Update to Q&A 9 to clarify sensitivity requirements for analytical methods. Update to Q&A 10 to include Ames test acceptability timelines.

Action: For adoption

The CHMP adopted the Q&A for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on 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. Overview of the current regulatory testing requirements for medicinal products for human and veterinary use and opportunities for implementation of the 3Rs

Revision of reflection papers:

These reflection papers (RPs) were originally published in 2018 and are being revised, in accordance with the NC domain work plan, 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 these RPs 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. Initial revised drafts of the reflection papers have been drafted by subgroups within the 3RsWP, but review and input are required from the relevant working parties to ensure that (1) all available 3Rs opportunities have been identified and (2) their usefulness in a regulatory context has been correctly interpreted. CHMP endorsement is sought to engage with relevant CHMP WPs to provide input on the revision of these RPs. The WP consultation period is envisaged for approximately 3 months, after which a public consultation is expected.

Action: For endorsement

The CHMP endorsed the proposed plan to revise the relevant reflection papers on regulatory testing requirements for medicinal products for human and veterinary use and opportunities for implementation of the 3Rs.

3.2.2. Batch Release Testing OEG - Final composition

The Batch Release Testing Operational Experts Group (BRT OEG) is mandated to review protocols related to the quality control and batch release testing of human and (mainly) veterinary medicinal products authorised via the centralised procedure between 1996 and 2013, with a view to promote and implement 3Rs-compliant testing methods within these processes as far as possible.

A call for nominations for experts to this OEG was launched at the PROM meeting in June 2023 and nominations closed on 30 November 2023. In total, nine nominations were received. The required expertise was discussed by members of the 3RsWP, and the composition of the group was agreed.

Action: For endorsement

The CHMP endorsed the Batch Release Testing Operational Experts Group (BRT OEG).

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Christian B. Roes, Kristin Karlsson

4.1.1. Agenda and Minutes

- Final agenda and minutes for MWP meeting held virtually on 16 November 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 nomination of the new experts and EMA staff members of the Methodology European Specialised Expert Community (ESEC).

4.1.3. Nomination of Methodology BSOEG experts

Nomination of EMA staff and new experts to enter the Methodology Biostatistics Operational Expert Group (BSOEG).

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of the new experts of the Methodology Biostatistics Operational Expert Group (BSOEG).

4.1.4. MWP Work Plan

Adoption of revised MWP work plan for 2024 after public consultation and MWP Stakeholder Interaction Meeting.

Action: For adoption

The CHMP adopted the MWP Work Plan 2024.

4.1.5. Call for expression of interest for new MWP members

Methodology Working Party recently revised the rolling 3-year work plan, identifying areas of work to be initiated in 2024. Additionally, the development of the next iteration of the work plan for 2025-2027 will begin in early 2024 to ensure that the proposed programme of work is delivering the needs of the committees.

Since the workplan was first generated, it is clear that some areas of expertise are required more often than others, especially in terms of operational product support. Additional areas within the EMRN have been highlighted as requiring guidance, and this is reflected in the draft work plan. For example, the recently published Big Data Sterring Group Multi-Annual AI work plan 2023-2028 foresees a deliverable to "develop AI Guidance in Medicines Lifecycle, with MWP, including domain-specific guidance, e.g. Pharmacovigilance".

When MWP was first founded, it was envisaged there would be 25-30 members, and it currently stands at 21. Now that the ways of working have been embedded, there is a much clearer view of the specific expertise required, but also the amount of it needed to deliver the work plan.

Given this, MWP proposes to open a call for nominations for 3 new members.

The following areas of expertise are requested:

- Expertise in diagnostic tests, including but not limited to radiopharmaceuticals or genomic-based biomarkers
- Biostatistics, with a particular interest in indirect comparisons and external control of clinical trials.
- Artificial Intelligence, with a particular interest in pharmacovigilance

MWP Chair: Christian B. Roes

Action: For adoption

The CHMP adopted the call for expression of interest for new MWP members.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

No topics

5.2. Cardiovascular Working Party (CVSWP)

No topics

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis

5.3.1. Nomination of Oncology ESEC experts

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

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of new Oncology ESEC experts.

5.3.2. Oncology ESEC Webinar on Multiple Myeloma

Presentation on the draft agenda of the Oncology ESEC webinar on Multiple Myeloma which is planned on 9 February 2024.

The next Oncology ESEC webinar is planned in February 2024. A CHMP representative is sought for this webinar.

Action: For discussion

The CHMP noted the proposal of an Oncology ESEC Webinar on Multiple Myeloma planned to be held on 9 February 2024. A CHMP representative was sought for this webinar.

5.3.3. Second Joint FDA/EMA Conversations on Cancer - World Cancer Day (1 February 2024)

Action: For discussion

The CHMP noted the discussion on the Second Joint FDA/EMA Conversations on Cancer, which is going to be held on 1 February 2024, on the World Cancer Day.

5.4. Rheumatology and Immunology Working Party (RIWP)

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

5.4.1. Acute Respiratory Distress Syndrome (ARDS) Workshop

Report from multi-stakeholder workshop on Acute Respiratory Distress Syndrome (ARDS) held on 21 November 2023.

CHMP: Janet Koenig

Action: For information

The CHMP noted the report from the multi-stakeholder workshop on Acute Respiratory Distress Syndrome (ARDS) held on 21 November 2023.

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

The reflection paper aims to provide a high-level description of the requirements for drug development in the field. For NASH, the regulatory experience with the licensing of new medicinal products is limited. Therefore, this paper aims at a preliminary definition of development strategies, which, in the case of successful marketing authorisation applications occurring in the future, will have to be refined, and may finally be superseded by a full guidance document.

Expert: Elmer Schabel

Action: For discussion

The CHMP continued the discussions on the outstanding issues from the previous month. The rapporteur will propose an updated version of the reflection paper on regulatory requirements for the development of medicinal products for Non-Alcoholic Steatohepatitis (NASH). In case different views have to be reflected and no agreement can be reached prior to the meeting, the rapporteur will propose two alternative versions of the document. Further discussion is expected in the next PROM/CHMP plenary.

5.4.3. RIWP Work Plan

RIWP 3-year work plan 2024-2026

Expert: Caroline Auriche-Benichou

Action: For adoption

The CHMP adopted the RIWP Work Plan 2024-2026.

5.4.4. RIWP nomination for two temporary drafting groups

- Systemic sclerosis
- Psoriasis Arthritis

Action: For endorsement

The CHMP endorsed the nomination of two RIWP temporary drafting groups.

5.5. Infectious Disease Working Party (IDWP)

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

5.5.1. Concept Paper on the Revision of the Guideline on the Clinical Evaluation of Medicinal Products intended for the Treatment of Hepatitis B

In recent years there have been several applications for scientific advice on new products and treatment strategies aimed at achieving functional cure, including finite and combination treatment regimens. Furthermore, there has been development of new antiviral and immunomodulatory treatment options with mechanisms of action different to those of nucleos(t)ide analogues (NUCs) or peg-interferon alfa-2a (PEG-IFN). Therefore, a revision of

the guideline is proposed to reflect these new developments and the implications for clinical development programmes.

Action: For adoption

The CHMP adopted the concept paper on the revision of the Guideline on the Clinical Evaluation of Medicinal Products intended for the Treatment of Hepatitis B.

5.6. Vaccines Working Party (VWP)

No topics

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. 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 could not endorse the nomination of new Haematology ESEC experts because of the Conflicts of interest of the 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)

No topics

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. Revision of ICH Q6A/B on Quality Specifications - appointment of experts

Following a call launched via QWP and BWP, CHMP is requested to appoint two experts to the ICH Expert Working Group, which will revise the existing Q6A and Q6B guidelines on the setting and justification of quality specifications for chemical substances and biological products.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the appointment of the new experts of the ICH Expert Working Group.

7.1.2. ICH QS1B Implementation Working Group - appointment of experts

Following a call launched via NCWP, CHMP is requested to appoint two experts to the ICH S1(B) Implementation Working Group to monitor the implementation of the revised ICH S1B(R1) guidance on the weight of evidence (WoE) approach for carcinogenicity assessments.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the appointment of the new experts of the ICH S1(B) Implementation Working Group.

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 January 2024.

Action: For information

The CHMP noted the summary of recommendations and advice.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

9.1.1. Implementation of Regulation (EU) 2023/1182 (Windsor Framework) on CAPs for human use

Brexit - Guidance on the implementation of Regulation (EU) 2023/1182 with regards to CAPs for human use.

Action: For information

The CHMP noted the Brexit Guidance on the implementation of Regulation (EU) 2023/1182 (Windsor Framework) on CAPs for human use.

The Protocol on IE/UK(NI) Windsor Framework is part of the Withdrawal Agreement which establishes the terms of the UK's withdrawal from the EU. Based on the Windsor Framework, EU pharmaceutical law applies to and in the UK in respect of NI only as of 1 January 2021 and to the extent provided for in the Windsor Framework. A Political agreement between the EU and the UK to amend the Protocol in order to address some of the challenges concerning NI following the UK's withdrawal is included in the EU Regulation (EU) 2023/1182 of 14 June 2023 that sets new terms for the relationships with NI for medicinal products for human use.

Further information on the implications can be found on the published Q&A.

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 topic was postponed to the January CHMP Plenary Meeting.

9.2.2. Joint CHMP-CAT membership

Nomination of joint members to CAT. According to the ATMP Regulation, CAT membership includes five members or co-opted members of the CHMP from five Member States, with alternates either proposed by their respective Member State or, in the case of co-opted members of the CHMP, identified by the latter on the advice of the corresponding co-opted member. The Lithuanian Agency expressed interest to step into the joint CHMP-CAT membership.

Action: For endorsement

The CHMP endorsed the nominations for the joint Lithuanian CHMP-CAT membership.

9.2.4. 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 topic was postponed to the February PROM Meeting.

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

Action: For information

The CHMP noted the agenda and table of decisions.

10.1.3. Scientific Advice Working Party call for interest for nomination of replacement of SAWP member

Call for interest for nomination of a replacement SAWP member.

Required areas of expertise:

- Real-world evidence
- Pharmacoepidemiology
- Biosimilars
- Haematology

Action: For endorsement

The CHMP endorsed the nomination of the new SAWP member

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 22 January 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 31 January 2024

Action: For adoption

The CHMP endorsed the 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. Health Threats and ETF Update

Action: For information

The CHMP noted the Health Threats and ETF updates.

12.3. 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 topic was postponed to the February PROM Meeting. The CHMP was informed of the upcoming Multistakeholder workshop on Patient Registries on 12-13 February 2024.

12.4. New EMA-HMA catalogues of data sources and non-interventional studies

The new EMA-HMA catalogues of data sources and non-interventional 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 topic was postponed to the February PROM Meeting.

12.5. ETF Work Plan

Emergency Task Force 3-year work plan was revised to amend the priorities for 2024.

Action: For information

The CHMP noted the ETF Work Plan 2024-2026.

12.6. Scientific Explorer (ScEx) Demo

Scientific Explorer (ScEx) is an AI enabled tool for EU regulators that facilitates easy, focused, and precise searches within regulatory procedure documents. It supports scientific decision-making by providing access to relevant scientific information. The first version of the tool focuses on Scientific Advice letters documents and is going to be launched in March 2024.

Action: For information

The CHMP noted the Scientific Explorer (ScEx) Demo, a AI tool that facilitates easy, focused, and precise searches within regulatory procedure documents. The CHMP welcomed the tool that will be launch in March 2024.

12.7. Update on IRIS platform for core Regulatory Procedures

The presentation aims to update the committee on Variations, Article 61.3 and MA Transfers roll out to IRIS platform and next steps.

Action: For information

The CHMP noted the presentation on IRIS developmental updates, in particular Variations, Art. 61(3) and MA Transfers into IRIS.

12.8. CHMP co-opted membership

The 3-year co-opted member mandate for Carla Torre comes to an end on 21.02.2024. Her area of expertise is Pharmaco-Epidemiology; especially for methodology (bias, effect modifications etc.) and interpretation of data, in particular study designs (observational studies, RWD etc.), strengths and weaknesses.

The 3-year co-opted member mandate for Blanka Hirschlerova comes to an end on 18.03.2024. Her area of expertise is Quality (non-biologicals) and pharmacokinetics.

The nomination procedure foresees that the CHMP should decide on their areas of expertise in order to proceed with the nominations.

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

Action: For endorsement

The CHMP members were invited to send comments on the areas of expertise for the new co-opted members' mandates prior to the CHMP plenary endorsement.

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	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Alternate	Cyprus	No restrictions applicable to this meeting	
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 final deliberations and voting on:	5.1.16. Wegovy - Semaglutide - EMEA/H/C/005422/II/0017
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	
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:	5.1.5. Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0005 5.1.7. Dupixent - Dupilumab - EMEA/H/C/004390/II/0079
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	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	
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	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Susanne Høpner Rasmussen	Expert	Denmark	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Maryam Mehmandoust	Expert	France	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Karen van Malderen	Expert	Belgium	No interests declared	
Elmer Schabel	Expert	Germany	No interests declared	
Caroline Auriche-Benichou	Expert	France	No interests declared	
Maja Sommerfelt Gronvold	Expert	Norway	No interests declared	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Meeting run with support from relevant EMA staff.				

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