14 December 2023
EMA/CHMP/573158/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft PROM[1] Minutes for the meeting on 04 December 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

04 December 2023, 09:00–16:00, virtual meeting

Disclaimers

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

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

Note on access to documents

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

[1] The CHMP PROM is a meeting to discuss CHMP organisational matters and other topics in preparation for the CHMP Plenary meeting. It is a virtual meeting, which usually takes place on Monday before the CHMP Plenary meeting. CHMP members, working party chairs and national experts together with EMA staff are participating in this forum. Depending on the nature of the issue and availability of documents and experts some PROM topics can be discussed at the CHMP Plenary.

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

1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions. See Annex of the current document for the list of participants and restrictions in relation to declarations of interests applicable to the items of this meeting. As the PROM is a preparatory meeting for the CHMP plenary session, restrictions and declarations of interests applicable to the items in the draft agenda of the upcoming CHMP plenary session were also considered.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared. Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

The CHMP adopted the PROM agenda for the 04 December 2023 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 04 December 2023 meeting will be adopted at the December 2023 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Francesca Luciani

2.1.1. Joint EMA-FDA Q&As on PRIME/Breakthrough

Following the EMA-FDA Stakeholder workshop on support to quality development in early access approaches, such as PRIME and Breakthrough Therapies held at EMA on 26 November 2018, which led to the development of the 'EMA Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME and certain marketing authorisation applications targeting an unmet medical need' (which was widely used during the pandemic), EU and FDA colleagues have continued the dialogue on the four areas identified that would benefit from further discussion between both regions: control

strategy, innovative process validation approaches, stability data, and launching from the clinical manufacturing site or with investigational medicinal product batches.

This Q&A document has been developed to capture and share with our stakeholders the outcome from those discussions. The document has been presented and discussed at relevant time points with BWP, QWP and GDMP-IWG, and has been adopted by these groups.

Action: For adoption

The CHMP adopted the Joint EMA-FDA Q&A document on Quality and GMP aspects of PRIME/Breakthrough therapy applications.

2.1.2. Concept paper on the establishment of a guideline on the development and manufacture of bacteriophage medicinal products

This concept paper proposes to establish a scientific guideline for the pharmaceutical development and manufacture of bacteriophage medicinal products intended for the therapeutic treatment or prophylaxis of one or more specific bacterial infection(s) or infectious disease(s) in humans. Although an EMA guideline for such products exists for veterinary medicinal products, there is currently no appropriate regulatory guidance for medicinal products for human use in the EU.

Bacteriophages are a promising alternative to antibiotics for the treatment of infections that do not respond to conventional treatment options. There is an increasing interest in the use of bacteriophages for the treatment of infections both from the healthcare providers and pharmaceutical industry.

The intention behind the proposed guideline is to solve this issue by clarifying the quality requirements and thus minimising the regulatory and scientific gap to innovators addressing the problem of antimicrobial resistance.

Expert: Helerin Eiche

Action: For adoption

The CHMP adopted the concept paper on the establishment of a guideline on the development and manufacture of bacteriophage medicinal products. The concept paper will be released for 3-month public consultation.

2.1.3. Agenda and Minutes

- Draft agenda of the BWP meeting to be held virtually on 4-6 December 2023
- Minutes of the BWP meeting held virtually on 2-4 October 2023

Action: For information

The CHMP noted the agenda and minutes.

2.2. Quality Working Party (QWP)

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

2.2.1. QWP Interim Analysis on TiO2

QWP interim feedback to the EU Commission request to evaluate the feasibility of alternatives to replace titanium dioxide (TiO2) in medicinal products and its possible impact on medicines' availability.

Action: For adoption

The CHMP adopted the QWP Interim Analysis on TiO2.

2.2.2. Agenda and Minutes

- Draft Agenda of the QWP meeting to be held on 4-5 December 2023
- Minutes of the QWP meeting held remotely on 5-6 of October 2023

Action: For information

The CHMP noted the agenda and minutes.

2.2.3. Joint EMA-FDA Q&As on PRIME/Breakthrough

Please refer to 2.1.1. under BWP.

2.2.4. Q&A on Note for Guidance on Maximum shelf-life for sterile products for human use after first opening or following reconstitution

QWP proposes a Q&A on the Note for Guidance on Maximum shelf-life for sterile products for human use after first opening or following reconstitution (CPMP/QWP159/96 corr). The NfG describes expectations for Product Information relating to parenteral products which have an in-use period after reconstitution or dilution for administration. There has been confusion (amongst industry and regulators) on the application of physicochemical stability versus microbiological stability in-use shelf-life requirements. The QWP determined that the NfG itself did not need updating, however, the Q&A would be an important additional document to clarify implementation.

The Q&A elaborates additional flexibility for storage periods beyond 24 hours, however, requiring specific assurance on microbiological stability. This flexibility has been requested by stakeholders, e.g. European Association of Hospital Pharmacists, to enable staging of procedures and avoid wastage. The Q&A consists of six specific points to observe depending on the product type and a flow chart detailing the various reconstitution/dilution scenarios and resultant shelf-life/storage expectations. The Q&A has been adopted by both QWP and BWP.

Action: For adoption

The CHMP adopted the Q&A document on the Note for Guidance on maximum shelf-life for sterile products for human use after first opening or following reconstitution (CPMP/QWP159/96 corr.).

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: René Anour, Vice-Chair: Niklas Ekman

2.3.1. Agenda and Minutes

- Agenda of the BMWP face-to-face meeting held on 23-24 November 2023
- Minutes of the BMWP meeting held remotely on 20 October 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

Draft concept paper on tailored clinical approach in biosimilar development.

BMWP Chair: René Anour

Action: For discussion

The CHMP adopted the concept paper for the development of a Reflection Paper on a tailored clinical approach in biosimilar development to be released for 3-month public consultation.

Post-meeting note: the GCG review of the CP will start at the end of December 2023 with an outcome in January 2024.

2.4. Quality Innovation Group (QIG)

No topics

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. Nomination of new NcWP member

Following the departure of Javier Cristobal at the end of October 2023, the NcWP is launching a call for nomination of a new member.

Action: For information

The CHMP noted the launch of a call for nomination of a new NcWP member. Nominations should be sent to the Agency by 2 February 2024. Candidates are kindly asked to submit a

brief CV in support of their candidature together with a cover letter highlighting their expertise. The appointment will take place at the March 2024 CHMP PROM Meeting.

3.1.2. Nomination of New Approach Methodologies ESEC members

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

Nomination(s) received

Action: For endorsement

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

3.1.3. CMDh questions to NcWP

Questions received from CMDh to NcWP:

- N-nitroso-betahistine detected in products containing betahistine
- N-nitroso-iminodibenzyl detected in imipramine-containing medicinal product
- N-nitroso-N-desmethyl-citalopram (NDCIT) detected in citalopram-containing medicinal product
- Mutagenic impurity G in alprozalam

Action: For adoption

The CHMP adopted the CMDh questions to NcWP.

3.1.4. Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'

The excipients drafting group (ExcpDG) finalised the report on polysorbates following the public consultation. It was endorsed by the NcWP and the EC Notice to Applicants group.

Expert: Dominique Masset

Action: For adoption

The CHMP adopted the proposed Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'.

3.1.5. Agenda

- Draft Agenda of the virtual NcWP meeting of 5-6 December 2023

Action: For information

The CHMP noted the agenda.

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 3RsWP meeting held on 19 September 2023
- Agenda of the hybrid meeting held on 22 and 23 November 2023

Action: For information

The CHMP noted the agenda and minutes.

3.2.2. Proposal for 3RsWP Chair to attend an external meeting

Proposal to have Sonja Beken, the Chair of the 3RsWP, attend, representing CHMP/EMA, in the workshop on the EC roadmap for phasing out animal testing in chemical safety assessments. This workshop has been organised as part of the Commission's response to the European Citizens' Initiative (ECI) 'Save Cruelty-free Cosmetics - Commit to a Europe without Animal Testing' and will be held in Brussels on 11 and 12 December. She is invited to present the activities of the 3Rs Working Party and implementation of 3Rs in the pharmaceutical sector. Stakeholders from other EU regulatory agencies, NGOs, industry associations and research institutes will be present, and discussion will focus on ways to accelerate the validation and acceptance of non-animal methods across sectors. Therefore, the workshop is considered highly relevant to the EMA Regulatory Science strategy 2025 and the 3RsWP work plan.

Action: For endorsement

The CHMP endorsed the proposal for the 3RsWP Chair to attend an external meeting.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Christian B. Roes, Kristin Karlsson

4.1.1. Agenda and Minutes

- Agenda and minutes from MWP meeting held virtually on 19 and 20 October 2023

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of Methodology ESEC experts

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

4.1.3. Nomination of Methodology BSOEG experts

Nomination by MWP of new experts to enter the Methodology Biostatistics Operational Expert Group (BSOEG).

Nomination(s) received

Action: For endorsement

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

4.1.4. Reflection paper on investigation of pharmacokinetics in the obese population

A GCG request for PKWP guidance on pharmacokinetics in obese patients was adopted by the CHMP in 2015. A draft reflection paper went for 6-month public consultation in 2018. The comments received have now been addressed by MWP in a final version.

Expert: Alessia Proietti

Action: For adoption

The CHMP adopted the reflection paper on the investigation of pharmacokinetics in the obese population.

4.1.5. MWP response to CMDh question on referral

CMDh requested advice from MWP on the requirements for bridging to the literature for gastro-resistant products in the context of an ongoing referral procedure.

Expert: Alfredo Garcia-Arieta

Action: For adoption

The CHMP endorsed the MWP response to CMDh's question.

4.1.6. MWP response to CMDh question on bioequivalence requirements for lenalidomide

Issues have arisen in procedures at CMDh on dissolution and bioequivalence study conditions for lenalidomide.

Expert: Marcel Maliepaard

Action: For adoption

The CHMP endorsed the MWP response to CMDh's question.

4.1.7. Draft product-specific guidelines for public consultation

- Azacitidine powder for suspension for injection 25 mg/ml product-specific bioequivalence guidance (EMA/172895/2023)

Expert: Alfredo García-Arieta

- Paliperidone palmitate depot suspension for injection (every 3 months) 175, 263, 350 and 525 mg product-specific bioequivalence guidance (EMA/890768/2022)

Experts: Erika Fredriksson, Elin Lindhagen

Action: For adoption

The CHMP adopted the draft product-specific guidelines to be released for 3-month public consultation.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

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

5.1.1. CNSWP Work Plan 2024

The CNSWP adopted the work plan for 2024 and is presenting it to CHMP for adoption.

Expert: André Elferink

Action: For adoption

The CHMP adopted the CNSWP Work Plan for 2024.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Agenda and Minutes

- Final Agenda of the CVS WP face-to face meeting held on 10 November 2023
- Draft Minutes of the CVS WP face-to face meeting held on 10 November 2023

Action: For information

The CHMP noted the agenda and minutes.

5.2.2. CVSWP Work Plan 2024

The updated CVSWP Work Plan with priorities for 2024 was adopted by the CVSWP during its meeting on 10 November 2023. It is now proposed for CHMP adoption.

Action: For adoption

The CHMP adopted the CVSWP Work Plan for 2024.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-chair: Olli Tenhunen

5.3.1. Agenda and Minutes

- Agenda of the ONCWP meeting held virtually on 18 October 2023
- Minutes of the ONCWP meeting held virtually on 20 September 2023

- Agenda of the ONCWP meeting held virtually on 29 November 2023
- Minutes of the ONCWP meeting held virtually on 18 October 2023

Action: For information

The CHMP noted the agenda and minutes.

5.3.2. ONCWP Work Plan 2024

The ONCWP adopted the work plan for 2024 and is presenting it to CHMP for adoption.

Action: For adoption

The CHMP adopted the ONCWP Work Plan for 2024.

5.3.3. ONCWP Membership

The ONCWP is seeking an additional member with specific expertise in haematology (malignant).

The expert nomination should be sent by 3 January 2024 and shall be accompanied by a brief recommendation from the CHMP member/alternate supporting the nomination and detailed CV to support the expertise required.

Action: For information

The CHMP noted the launch of a call for nomination of a new ONCWP member.

5.3.4. Nomination of Oncology ESEC experts

Nomination by Oncology WP 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.

5.3.5. Planning of Oncology ESEC webinars for 2024

Based on the initial MAA forecast for 2024, the Oncology Working Party is proposing a list of Oncology ESEC webinars to be held in 2024.

Action: For discussion

The CHMP noted the ONCWP proposal on a list of Oncology ESEC webinars to be held in 2024.

5.4. Rheumatology and Immunology Working Party (RIWP)

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

5.4.1. Reflection paper on regulatory requirements for the development of medicinal products for Acute Kidney Injury (AKI)

The RP aims to provide high level summary of to-date experience about the prevention and treatment of AKI, based on regulatory experience in conjunction with currently available scientific knowledge.

Expert: Frank Holtkamp

Action: For adoption

The CHMP adopted the reflection paper on regulatory requirements for the development of medicinal products for Acute Kidney Injury (AKI). The document will be published on the EMA website.

5.4.2. Reflection paper on regulatory requirements for the development of medicinal products for non-alcoholic steatohepatitis (NASH)

The RP 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 adoption

The CHMP discussed the reflection paper on regulatory requirements for the development of medicinal products for non-alcoholic steatohepatitis (NASH). The CHMP raised comments that will be further discussed on the next January PROM meeting.

5.4.3. Reflection paper on regulatory requirements for the development of medicinal products for primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC)

The RP aims to provide a high-level description of the requirements for drug development in the field. For both disease entities, the regulatory experience with licensing of new medicinal products is limited. Therefore, this paper aims at a preliminary definition of development strategies. Additional regulatory decision making is anticipated and will be helpful to replace this reflection paper with a potential full guidance document in the future.

Expert: Sif Ormarsdóttir

Action: For adoption

The CHMP adopted the reflection paper on regulatory requirements for the development of medicinal products for primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC).

5.5. Infectious Disease Working Party (IDWP)

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

5.5.1. IDWP Work Plan 2024

The IDWP adopted the work plan for 2024 and is presenting it to CHMP for adoption.

IDWP Vice-Chair: Maja Sommerfelt Gronvold

Action: For adoption

The CHMP adopted the IDWP Work Plan for 2024.

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. VWP Work Plan 2024

The Vaccine Working Party work plan was revised to amend the priorities for 2024.

VWP Chair: Mair Powell

Action: For adoption

The CHMP adopted the VWP Work Plan for 2024.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Agenda and Minutes

- Agenda of the HaemWP meeting held on 16-17 November 2023
- Minutes of the HaemWP meeting held on 16-17 November 2023
- Agenda of the Blood Cluster meeting held on 17 November 2023
- Minutes of the Blood Cluster meeting held on 17 November 2023

Action: For information

The CHMP noted the agenda and minutes.

5.7.2. HaemWP Work Plan 2024

The HaemWP adopted the work plan for 2024 and is presenting it to CHMP for adoption.

CHMP: Daniela Philadelphy

Action: For adoption

The CHMP adopted the HaemWP Work Plan for 2024.

5.7.3. HaemWP workshop on hemoglobulopathy 2024

The HaemWP is proposing to hold a workshop on hemoglobulopathy (sickle cell and beta-thalassemia) to be held in June 2024.

CHMP: Daniela Philadelphy

Action: For endorsement

The CHMP endorsed the HaemWP proposal to hold a workshop on hemoglobulopathy (sickle cell and beta-thalassemia) in June 2024.

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. Report from ICH meeting in Prague

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

Action: For information

The CHMP noted the report from the ICH meeting in Prague, including upcoming ICH expert nominations to be channelled via the WP domains in the coming weeks/months.

7.1.2. Nomination of Rapporteurs for new areas of ICH harmonisation

Following the endorsement by ICH of the two following guideline projects, EMA was asked to put forward Rapporteurs to ICH:

- Non-clinical Safety Studies for Oligonucleotide-based Therapeutics (ICH S13).

Nomination proposed

- General Principles for Patient preference studies (ICH E22).

Nomination proposed

Action: For adoption

The CHMP endorsed the nominations of the proposed rapporteurs.

7.1.3. Step 5 ICH Q5A (R2) Viral Safety Evaluation of Biotechnology Products Derived from Cell lines of Human or Animal Origin

Following conclusion of the drafting activities, this guideline is tabled for CHMP adoption.

Action: For adoption

The CHMP adopted the guideline, which will be published with an implementation date of 6-month after publication on the EMA website.

7.1.4. Step 5 ICH Q2(R2) Validation of Analytical Procedures and ICH Q14 Analytical Procedure Development

Following conclusion of the drafting activities, this guideline is tabled for CHMP adoption.

Action: For adoption

The CHMP adopted the guidelines, which will be published with an implementation date of 6-month after publication on the EMA website.

7.2. Guideline Consistency Group (GCG)

No topics

7.3. Summary of product characteristics Advisory Group

7.3.1. Nominations of PRAC and QRD representatives

Following recent departure of their current SmPC AG representative, PRAC and QRD have nominated new representatives.

Nomination(s) received

Action: For endorsement

The topic was postponed to the December CHMP Plenary Meeting.

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 27-30 November 2023.

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. Guideline on the acceptability of names for human medicinal products processed through the centralised procedure (EMA/CHMP/287710/2014 – Rev. 7)

Updated version of the NRG guideline (revision 7). The final version is brought to the CHMP for adoption following a 3-month public consultation.

Action: For adoption

The CHMP adopted the NRG guideline on the acceptability of names for human medicinal products processed through the centralised procedure (EMA/CHMP/287710/2014 – Rev. 7).

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 learnings were postponed to the next January PROM meeting.

9.2.2. CHMP co-opted memberships

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 whether new co-opted members should be appointed and if so, on the required specific complementary scientific expertise (there could be more than one area). Afterwards, calls for nominations will be launched.

Action: For endorsement

The CHMP agreed to appoint new co-opted members. The areas of expertise will be discussed at the January 2024 CHMP PROM Meeting.

9.2.3. Joint CHMP-CAT membership

Nomination by CHMP 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 mandates for the current joint CHMP-CAT memberships will expire on 17.12.2023.

Action: For information

The topic was postponed to the December CHMP Plenary Meeting.

9.2.4. Revision of the CHMP Rules of Procedure, to reflect changes to the OPEN framework

The need for revision of the CHMP rules of procedure was identified further to the changes introduced to the OPEN scheme (which is currently reflected as a pilot project for COVID-19 products only in the annex to the CHMP rules of procedure). Considering that EMA extended the scope of OPEN in June 2023 to cover medicines beyond COVID-19, this should be reflected in the CHMP rules of procedure.

Action: For adoption

The CHMP adopted the revision of the CHMP Rules of Procedure to reflect the changes introduced to the OPEN scheme.

9.2.6. CHMP Work Plan 2024

CHMP: Harald Enzmann

Action: For discussion/adoption

The topic was postponed to the December CHMP Plenary 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 27-30 November 2023 meeting held as a hybrid meeting
- Draft Table of Decisions from 27-30 November 2023 meeting held as a hybrid meeting

Action: For information

The CHMP noted the agenda and table of decisions.

10.1.3. Call for interest for nomination of a replacement SAWP member

Call for interest for nomination of a replacement SAWP member following departure of Nanna Borup Johansen.

Required areas of expertise: endocrinology/diabetes/metabolism, real-world evidence/pharmacoepidemiology.

Applications should be sent by **Thursday, 4 January 2024, EoB.** The new SAWP member and his/her alternate starting date will immediately follow their nomination by the CHMP PROM (15 January 2024).

Action: For information

The topic was postponed to the December CHMP Plenary Meeting.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 07 December 2023

Action: For adoption

The discussion on this topic was cancelled.

10.2.2. ITF meeting

Meeting date: 18 December 2023

Action: For adoption

The discussion on this topic was cancelled.

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.

12.2. 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 members will have an opportunity to raise any RWD study proposal for next year.

Action: For information

The topic was postponed to the next January PROM meeting.

12.3. Health Threats and ETF Update

Action: For information

The CHMP noted the Health Threats and ETF updates.

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 next January PROM meeting.

12.5. ETF Work Plan 2024

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

Action: For information

The topic was postponed to the next January PROM meeting.

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	
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	
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:	concizumab - EMEA/H/C/005938
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
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 interests declared	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Finbarr Leacy	Alternate	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:	Fexinidazole Winthrop - fexinidazole - EMEA/H/W/002320 /II/0016
John Joseph Borg	Member	Malta	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Peter Mol	Member	Netherlands	No interests declared	
Patrick Vrijlandt	Alternate	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on:	COVID-19 vaccines
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
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 participation in final deliberations and voting on:	TAGRISSO - osimertinib - EMEA/H/C/004124 /II/0053 Sipavibart - H0006291 Tremelimumab AstraZeneca - tremelimumab - EMEA/H/C/004650 /II/0002
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Anne Hasle Buur	Expert	Denmark	No interests declared	
Alessia Proietti	Expert	Italy	No interests declared	
Marcel Maliepaard	Expert	Netherlands	No interests declared	
Alfredo García-Arieta	Expert	Spain	No interests declared	
Helerin Eiche	Expert	Estonia	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Karen van Malderen	Expert	Belgium	No interests declared	
Dominique Masset	Expert	France	No interests declared	
André Elferink	Expert	Netherlands	No interests declared	
Pierre Demolis	Expert	France	No interests declared	
Frank Holtkamp	Expert	Netherlands	No interests declared	
Sif Ormarsdóttir	Expert	Iceland	No participation in final deliberations and voting on:	aztreonam/ avibactam - EMEA/H/C/006113
Mair Powell	Expert	Ireland	No interests declared	
Maja Sommerfelt Gronvold	Expert	Norway	No interests declared	
Tina Soon Engraff	Expert	Denmark	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Isabelle Puff	Expert	France	No interests declared	
René Anour	Expert	Austria	No interests declared	
Meeting run with support from relevant EMA staff.				

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