02 October 2024
EMA/CHMP/330703/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

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

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 July 2024, 09:00–16:00, virtual meeting

Disclaimers

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

Note on access to documents

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[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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PROM meeting to be held on 15 July 2024. 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 are also considered. See July 2024 PROM minutes.

1.2. Adoption of agenda

The CHMP adopted the PROM agenda for 15 July 2024 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of 15 July 2024 meeting will be adopted at the August 2024 CHMP written procedure.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chair: Sean Barry

2.1.1. Nomination of new Biological Quality ESEC experts

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

Nomination(s) received

Action: For endorsement

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

2.1.2. Agenda and Minutes

- Minutes of the BWP meeting held remotely on 21-23 May 2024
- Agenda of the BWP meeting to be held remotely on 15-17 July 2024

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. Agenda and Minutes

- Minutes of the QWP meeting held remotely on 23-24 May 2024
- Agenda of the QWP meeting to be held remotely on 15-16 July 2024

Action: For information

The CHMP noted the agenda and minutes.

2.2.2. Nomination of new Chemical Quality ESEC experts

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

Nomination(s) received

Action: For endorsement

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

2.2.3. Draft guideline on development and manufacture of oligonucleotides

This guideline addresses specific aspects regarding the manufacturing process, characterisation, specifications and analytical control for synthetic oligonucleotides not covered by other guidelines; it mirrors the draft guideline on synthetic peptides, and similarly contains requirements related to conjugation, to medicinal product development, to generics development, and to clinical trial applications (human products only). In addition to this, it contains guidance on active substance in solution and N of 1/personalised medicines. The draft guideline is part of the QWP workplan, it was authored taking into account stakeholders' comments on the Concept Paper, as well as the discussion on active substance in solution from an ITF meeting. The draft guideline is to be released for 6-month public consultation.

Action: For adoption

The CHMP adopted the draft guideline on development and manufacture of oligonucleotides for 6-month public consultation.

2.2.4. Q&A regarding co-processed excipients used in solid oral dosage forms (H&V)

This Q&A outlines the quality requirements for co-processed excipients (CoPE). CoPE have been under QWP discussion since 2015 when the first draft Ph. Eur. monograph on co-processed excipients was published. CoPEs are manufacture by processing two or more excipients without the formation of covalent bonds; they have specific physico-chemical characteristics for which they are used in the manufacture of finished medicinal products. The use of CoPEs in pharmaceutical formulations is considered to have a higher degree of uncertainty than using individual excipients due to several factors: e.g. complexity of composition, quality control, formulation development and stability issues due to combination of different materials. The Q&As aims to harmonise and clarify dossier requirements for CoPEs using a risk-based approach. It defines three risk categories, the risk criteria for a risk assessment that applicants need to perform and quality dossier requirements according to the risk ranking, that MAH/applicants need to provide as part of

new MAA or variations. The Q&A has been adopted by IWG/QWP on 01 July 2024, planned for adoption by CHMP PROM on 15 July 2024, CVMP adoption 16 July 2024, and for public H&V consultation in August/September 2024.

Action: For adoption

The CHMP adopted the Q&A regarding co-processed excipients used in solid oral dosage forms (H&V) for public consultation in August/September 2024.

2.2.5. Revision of the guideline on chemistry of active substances (H)

As recommended in the Sartans Lessons Learnt Exercise (LLE), this guideline was revised with the objective of preventing N-nitrosamines from being present in medicines and to provide clarifications, where necessary, to help both companies and regulators to better prevent and/or assess the potential presence of N-nitrosamines impurities. Taking into account the recommendations from the LLE and the comments received from the public consultation on the concept paper, the guideline text was revised in a QWP drafting group. The main sections that were amended are:

- chapter 4.2.2 (Description of Manufacturing Process and Process Controls 3.2.S.2.2): clarifying requirements related to the schematic representation of the manufacturing process, the sequential procedural narrative and recovery.
- chapter 4.2.3 (Control of Materials 3.2.S.2.3): clarifying requirements in the introduction and related to active substance starting materials. In addition, there is now a clear separation between starting materials of animal or human origin and starting materials of plant origin. A new sub-section was introduced related to semi-synthetic drug substances. Requirements related to solvents, reagents and other materials were also clarified.
- chapter 4.2.6 (Manufacturing Process Development 3.2.S.2.6)
  chapter 4.3.2 (Impurities 3.2.S.3.2)
  chapter 4.4.5 (Justification of Specification 3.2.S.4.5)
  chapter 4.7.1 (Stability)

On recovery of solvents, GMDP IWG was consulted. Where references are made to biological materials, BWP was consulted in a targeted consultation and where references are made to herbal substances, the QWP member who is also a member of the HMPC, was consulted.

The revised guideline text was adopted by the QWP following the May QWP meeting and is now tabled for adoption for this PROM to then be released for public consultation (6 months).

Action: For adoption

The CHMP adopted the guideline on chemistry of active substances (H) for 6 months public consultation.

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 3 June 2024

Action: For information

The CHMP noted the agenda and minutes.

2.3.2. Work Plan for 2025 – 2027

The 2025-27 BMWP work plan has been agreed upon by BMWP members and is being presented at the July PROM as a draft proposal. The formal adoption and publication of the 3-year BMWP work plan will take place later in the year (Q4), simultaneously with all other quality-domain WPs' work plans.

Action: For adoption

The CHMP adopted the draft BMWP work plan for 2025-2027 for stakeholders consultation before the Final BMWP work plan is adopted by the CHMP. The CHMP members were invited to send comments.

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

3.1.2. Agenda and Minutes

- Minutes of the meeting held remotely on 21-22 May 2024
- Draft agenda of the meeting to be held remotely on 16-17 July 2024

Action: For information

The CHMP noted the agenda and minutes.

3.1.3. Non-clinical domain Workplan 2025-2027

NcWP and 3RsWP members have agreed on a draft work plan for 2025-2027 which highlights the strategic, tactical and operational activities for the next three years. The workplan for 2025-2027 will now be shared with both internal and external stakeholders for consultation to ensure alignment and gather valuable feedback from all parties involved.

Action: For adoption

The CHMP adopted the draft NcWP and 3RsWP work plan for 2025-2027 for stakeholders consultation before the Final NcWP work plan is adopted by the CHMP. The CHMP members were invited to send comments.

3.1.4. CMDh questions to NcWP

Action: For adoption

The CHMP adopted the CMDh questions to NcWP .

3.1.5. CMDh question to NCWP on the Contraindication of propofol-containing products in patients with history of egg, soy and peanut allergy

In the April 2024 CMDh meeting, the CMDh discussed if medicines containing propofol, which contain purified soybean oil and egg lecithin as excipients, should have a contraindication in patients with history of egg, soy, or peanut allergy. The CMDh agreed to consult the NcWP on the risk of allergic reactions with the use of propofol containing medicines and if the Guideline on Excipients in the labelling and package leaflet of medicines for human use should be revised. The NcWP discussed their views at the NcWP Meeting on 19 June and the final response was adopted by written procedure on 05 June 2024.

Action: For adoption

The CHMP adopted the CMDh question to NcWP CMDh question to NCWP on the Contraindication of propofol-containing products in patients with history of egg, soy and peanut allergy.

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

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

3.2.1. Minutes

Draft minutes of the 3RsWP stakeholder meeting held on 20 and 21 March 2024.

- Stakeholder minutes
- Core 3RsWP minutes

Action: For information

The CHMP noted the minutes.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chair: Kit Roes, Vice-Chair: Kristin Karlsson

4.1.1. Agenda and Minutes

- Agenda and minutes of the virtual MWP meeting held on 30 May 2024

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of Methodology ESEC experts

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

Nomination(s) received

Action: For endorsement

The CHMP endorsed the new experts to enter the Methodology European Specialised Expert Community (ESEC).

4.1.3. MWP Work Plan

MWP 3-year work plan 2025-2027.

Experts: Kit Roes (Chair) and Kristin Karlsson (Vice-Chair)

Action: For adoption

The CHMP adopted the Draft MWP 3-year work plan for 2025-2027 for stakeholders consultation before the Final MWP work plan is adopted by the CHMP. The CHMP members were invited to send comments.

4.1.4. Product-Specific Guidelines

Draft product-specific bioequivalence guideline for adoption for 3-month public consultation:

- Tolvaptan tablets 7.5, 15 and 30 mg and tolvaptan tablets 15, 30, 45, 60 and 90 mg product-specific bioequivalence guidance (EMA/CHMP/254395/2024)

Final product-specific bioequivalence guideline for adoption:

- Paliperidone palmitate depot suspension for injection (every 3 months) 175, 263, 350 and 525 mg product-specific bioequivalence guidance (EMA/CHMP/890768/2024)

Action: For adoption

The CHMP adopted the draft tolvaptan tablets product-specific bioequivalence guideline for 3-month public consultation and the final paliperidone palmitate depot suspension for injection product-specific bioequivalence guideline.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

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

5.1.1. CNS Working Party Draft Work Plan 2025 - 2027

CNS WP 3-year Draft work plan 2025-2027 is proposed for adoption. It is planned to release the Draft Work Plan for stakeholders consultation before the Final CNS WP work plan is proposed for adoption by the CHMP.

CHMP: Ewa Balkowiec Iskra

Expert: Andre Elferink (Chair)

Action: For adoption

The CHMP adopted the CNS Working Party draft work plan for 2025 – 2027 for stakeholders consultation before the Final CNS WP work plan is adopted by the CHMP. The CHMP members were invited to send comments.

5.1.2. Guideline on clinical development of medicinal products for the treatment and prevention of bipolar disorder rev

With the transition of DSM-IV into DSM- 5, bipolar and related disorders have been separated from depressive disorders, and BD II is no longer considered a milder form of BD I. Other changes in the DSM, such as addition of new specifiers, have subsequent implications for identifying patients both in clinical and research settings. The guideline is updated accordingly. The guideline will be released for a 3-month public consultation.

Expert: Taina Mattila

Action: For adoption

The CHMP adopted the guideline on clinical development of medicinal products for the treatment and prevention of bipolar disorder for 3-month public consultation.

5.1.3. Agenda and Minutes

- CNS WP meetings Agendas and Minutes from Q1 and Q2 2024

Action: For information

The CHMP noted the agenda and minutes.

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Cardiovascular Working Party Draft Work Plan 2025 - 2027

CVS WP 3-year Draft work plan 2025-2027 is proposed for adoption. It is planned to release the Draft Work Plan for stakeholders consultation before the Final CVS WP work plan is proposed for adoption by the CHMP.

CHMP: Alar Irs

Action: For adoption

The CHMP adopted the Cardiovascular Working Party draft work plan for 2025 – 2027 for stakeholders consultation before the Final CVS WP work plan is adopted by the CHMP. The CHMP members were invited to send comments.

5.2.2. Concept paper on the need for a Reflection Paper on assessment of cardiovascular safety of oncology medicinal products

The purpose of the reflection paper considered in the concept paper is to provide recommendations for the planning, collection of data and evaluation of cardiovascular safety of oncology medicinal products taking into account specific issues that apply to the oncology setting with respect to type of medicinal products applied, patients and trials designs. This is in line with CVS WP Work plan - Priorities for 2024. The Concept Paper will be released for a 3-month public consultation.

CHMP: Antonio Gómez Outes

Action: For adoption

The CHMP adopted the concept paper on the need for a Reflection Paper on assessment of cardiovascular safety of oncology medicinal products for 3-month public consultation.

5.2.3. Stakeholders consultation regarding the revision of the Paediatric Addendum to the guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension (EMA/CHMP/213972/2010)

This Stakeholders consultation is organised in order to have a Stakeholder's perspectives on new developments for treatment of paediatric pulmonary arterial hypertension (PAH) before initiating the drafting of a revised Paediatric Addendum to the guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension (EMA/CHMP/213972/2010) in line with the Cardiovascular Working Party (CVS WP) Work Plan for 2024.

The draft briefing document that contains the LoQ and the draft Agenda are tabled.

Expert: Clemens Mittmann

Action: For adoption

The CHMP adopted the Stakeholders consultation regarding the revision of the Paediatric Addendum to the guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension (EMA/CHMP/213972/2010).

The CHMP noted the draft stakeholders meeting draft agenda and the LoQ to be addressed.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis, Vice-Chair: Olli Tenhunen

5.3.1. Agenda and Minutes

- Agenda of the meeting of 18 June 24 and minutes of the meeting of 15 May 24

Action: For information

The CHMP noted the agenda and minutes.

5.3.2. CHMP points to considered on treatment optimisation – Reflection Paper

CHMP to consider whether to develop a reflection paper on treatment optimisation.

Action: For discussion

The CHMP agreed to draft a reflection paper on treatment optimisation. CHMP members were invited to join the drafting group. .

5.3.3. Oncology ESEC webinar on Breast Cancer

- Agenda of the planned webinar of 27 September 2024

Action: For discussion

The CHMP noted the agenda of the Oncology ESEC webinar on Breast Cancer.

5.4. Rheumatology and Immunology Working Party (RIWP)

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

5.4.1. Concept paper for the development of a guideline on the demonstration of therapeutic equivalence for nasal products

Prepared by RIWP with the aim to detail the data requirements for demonstrating therapeutic equivalence between nasal products containing the same active moiety(ies), as these are currently insufficiently covered in existing guidelines. The guideline will be released for a 3-month public consultation.

Action: For adoption

The CHMP adopted the Concept paper for the development of a guideline on the demonstration of therapeutic equivalence for nasal products for 3-month public consultation.

5.5. Infectious Disease Working Party (IDWP)

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

5.5.1. IDWP Work Plan

Draft IDWP 3-year work plan 2025-2027.

Experts: Maria Jesus Fernandez Cortizo (Chair) and Maja Sommerfelt Grønvold (Vice-Chair)

Action: For adoption

The CHMP adopted the draft IDWP 3-year work plan for 2025-2027 for stakeholder consultation.

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. Addendum to the Guideline on clinical development of vaccines to address clinical trials in immunocompromised individuals

Immunocompromised subjects are generally excluded from clinical trials conducted before the first licensure of new vaccines, and therefore there is a need to generate appropriate clinical evidence to identify appropriate dose regimens for these subjects. This Addendum to the Guideline on clinical evaluation of vaccines EMEA/CHMP/VWP/164653/05 Rev. 1 provides guidance on such clinical studies to support recommendations for use in the Product Information.

Action: For adoption

The CHMP adopted the Addendum to the Guideline on clinical development of vaccines to address clinical trials in immunocompromised individuals.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Nomination of new Haematology experts

Nomination of new expert to join the Haematology European Specialised Expert Community

Nominations received

Action: For endorsement

The CHMP endorsed the nomination of new experts to join the Haematology European Specialised Expert Community.

5.7.2. Nomination of new Vice-Chair to the HAEMWP

The candidates for the Vice-Chair position of the HAMEWP 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 by 31 July 2024. The election will take place in the CHMP September 2024 Plenary meeting.

Action: For endorsement

The CHMP endorsed the nomination of new Vice-Chair to the HAEMWP.

5.7.3. Workshop on challenges in drug development, regulation and clinical practice in hemoglobinopathies

The workshop took place on 1 July 2024. The presentations and video recording have been published on the following link: EMA workshop on the challenges in drug development, regulation and clinical practice in hemoglobinopathies | European Medicines Agency (europa.eu).

Presentation and report of the workshop and next steps.

CHMP: Daniela Philadelphy

Action: For discussion

The CHMP noted the presentation of the Workshop on challenges in drug development, regulation and clinical practice in hemoglobinopathies

5.7.4. Agenda

- Final agenda for HAEMWP meeting to be held virtually on 09 and 11 July 2024

Action: For information

The CHMP noted the agenda.

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)

No topics

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. Report from ICH MC in Fukuoka

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

CHMP: Bruno Sepodes

Action: For information

The CHMP noted the agenda and minutes of the ICH Management Committee and Assembly.

7.1.2. ICH Reflection Paper on RWE Terminology

Following the presentation to CHMP of the updated draft ICH reflection paper entitled: "Pursuing Opportunities for Harmonisation in Using Real-World Data to Generate Real-World Evidence, with a focus on Effectiveness of Medicines" in April 2024, the reflection paper was adopted without further revision by ICH Assembly in Fukuoka. CHMP is requested to adopt the final reflection paper ahead of EMA publication.

CHMP: Bruno Sepodes

Action: For adoption

The CHMP adopted the ICH Reflection Paper on RWE Terminology.

7.1.3. ICH E11A Adoption of ICH E11A on Paediatric Extrapolation – Step 5

The ICH E11A guideline provides recommendations for the use of paediatric extrapolation to support the development and authorisation of paediatric medicines. Following the finalisation of the guideline by the expert working group, CHMP adoption of Step 5 requested. The guideline will be implemented 6 months after adoption.

Action: For adoption

The CHMP adopted the ICH E11A guideline.

7.1.4. ICH M13A Adoption of Guideline and Q&As on Bioequivalence for Immediate-Release Solid Oral Dosage Forms – Step 5

Following the finalisation of the first of three M13 guidelines by the expert working group, CHMP adoption of ICH M13A Step 5 is requested. The guideline will be implemented 6 months after adoption.

Action: For adoption

The CHMP adopted the ICH M13A Guideline and Q&As on Bioequivalence for Immediate-Release Solid Oral Dosage Forms – Step 5. A mapping exercise of the topics included in the ICH M13 guidelines against the current European guidelines is required to ensure consistency. The CHMP noted that MWP give high priority to this exercise as part of the topics included in the MWP work plan.

7.1.5. Nomination of non-clinical experts for ICH working groups – ICH Q3E and ICH M7

Non-clinical Working party has put forward experts to participate in the following two working groups:

1. A new sub-group under the ICH M7(R3) Maintenance group to develop an "Addendum to ICH M7 on Risk Assessment and Control of Nitrosamine Impurities".
2. The existing Q3E Guideline on Assessment and Control of Extractables and Leachables.

Action: For endorsement

The CHMP endorsed the nomination of non-clinical experts for ICH working groups – ICH Q3E and ICH M7.

7.1.6. Nomination of replacement quality expert for ICH Q1/Q5C

Following a call through QWP to identify a replacement for the outgoing network expert in ICH Q1/Q5C, CHMP was updated on the process to identify an expert to join the ICH working group drafting this guidance document.

Action: For information

The CHMP noted the call.

7.1.7. ICH E20 Guideline on Adaptive Clinical Trials

ICH E20 is a new guideline on the design, conduct, analysis, and interpretation of adaptive clinical trials, which aims to provide a transparent and harmonised set of principles for the design, conduct, analysis, and interpretation of adaptive clinical trials. This update is to explain the potential impact of E20 current text on regulatory assessment and decision-making. It will also give a heads-up to CHMP who are expected to comment during the constituency review planned in August and September, ahead of the completion of a draft guideline later in 2024 for public consultation.

Expert (SAWP): Armin Koch

Action: For information

The CHMP noted the ICH E20 Guideline on Adaptive Clinical Trials. The guideline will be circulated to CHMP in August/September for CHMP comments.

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 July 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. Consultation procedure for medical devices that are systematically absorbed

Call for expression of interest to participate in the Development of a guideline in support of the consultation procedure for medical devices that are systematically absorbed.

Action: For endorsement

The CHMP endorsed the Call for expression of interest to participate in the Development of a guideline in support of the consultation procedure for medical devices that are systematically absorbed.

9.2. CHMP organisation/templates

9.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP endorsed the proposed learnings.

9.2.2. Mandate of CHMP Chairperson and Vice-Chairperson – call for nominations

The mandate of the CHMP Chair, Harald Enzmann, will expire on 20 September 2024 and that of the CHMP Vice-Chair, Bruno Sepodes on 14 October 2024. The elections of a new CHMP Chair will take place at the September 2024 meeting and that of the new Vice-Chair at the October 2024 meeting. Expressions of interest for the position of CHMP Chair should be sent to the Agency, to the CHMP secretariat by **11 September 2024**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Action: For information

The CHMP noted the information on the mandate of the CHMP Chairperson and Vice-Chairperson positions and the call for nominations for the position of CHMP Chair.

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 July 2024 meeting held by Webex
- Table of Decisions from 08–11 July 2024 meeting held by Webex

Action: For information

The CHMP noted the agenda and table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 19 July 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 22 July 2024

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 9 September 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 update on the development of DARWIN EU, upcoming trainings and workshops and report on study requests received as well as planned/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.

11.2. Request for clock stop extension – filgrastim (EMEA/H/C/006400)

The applicant requested an extension to the clock stop to respond to the List of Questions.

Action: For discussion

The CHMP did not agree with the request by the applicant for an extension to the clock stop to respond to the list of questions. The CHMP made reference to the revised clock-stop rules and to the stricter approach to be applied.

12. Any Other Business

12.1. Rapporteurships

Update. **Action:** For information

The CHMP noted the update.

12.1.1. Syfovre - Pegcetacoplan - EMEA/H/C/005954

Apellis Europe B.V.; Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Scope: Re-examination rapporteurs appointment

The CHMP adopted a Re-examination Rapporteur and a Re-examination Co-Rapporteur.

12.2. Health Threats and ETF Update

Action: For information

The CHMP noted the Health Threats and ETF updates.

12.3. EMA response to DRIVE study deferral 2024

The MAHs for flu vaccines in the DRIVE consortium requested a deferral to submit vaccine effectiveness studies in 2024 due to insufficient sample sizes. The EMA and the Emergency Task Force agreed to this deferral as a pragmatic solution for this season, a decision endorsed by the CMDh for nationally authorised influenza vaccines.

Action: For information

The CHMP noted the agreement to the deferral.

12.4. Update to CxMPs on IRIS for Regulatory Procedure

Update on further procedures to be implemented in IRIS by the end of 2024 (PSURs, PAMs, Line extensions, Renewals, Annual Reassessments, PASS, Referrals). The aim is to have all post authorisation procedures in IRIS live on 1 January 2025 to meet the new fee regulation implementation deadline. This also applies to the procedures managed by EMA with NAPs, MRPs, DCPs.

Action: For information

In the interest of time the presentation was cancelled and a demo recording was made available in MMD together with the slides for CHMP members consultation and information.

12.5. Revision 3 of the GVP Module XVI and its new Addendum II

Revision 3 of the GVP Module XVI and its new Addendum II, contains guidance on risk minimisation measures (Module) and methods for the effectiveness evaluation of the measures (Addendum).

The comments from the public consultation were very supportive, and therefore in the revision, all original intents to enhance and clarify the guidance from the perspective of practical experience have been maintained.

Action: For information

The CHMP noted the revision 3 of the GVP Module XVI and its new Addendum II.

12.6. Direct healthcare professionals communications (DHPCs) - preparation, review and publication of DHPCs and communication plans

A process for the review of DHPCs by EMA and CHMP has been in place for several years. The process has recently been amended to highlight that EMA medical writers' review is done in parallel with the review performed by CHMP Rapporteurs. The process has also been updated to reflect the publication of DHPCs on the EMA website.

Action: For information

The CHMP noted the process of the direct healthcare professionals communications (DHPCs) the preparation, the review and the publication of DHPCs and communication plans.

12.7. Proposal for medicine shortage communications (MSCs) – template and governance

Following recent cases highlighting the unsuitability of the DHPC template for communicating about medicine shortages unrelated to quality, safety, or efficacy, a new template for medicine shortage communication (MSCs) and related governance is proposed.

Action: For information

The CHMP was in agreement with the streamlined proposal to improve shortages communication to HCP, including the template and governance for medicine shortage communications (MSCs). The templates will be presented in the MSSG in September for

endorsement and will be operational afterwards.

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

The nitrosamines guidance is updated based on evolving scientific understanding of the risks in light of the recently introduced policies for setting limits: Updates to Q&As 8, 9, 10, 14 and 15 to clarify the expectations for risk assessments, confirmatory testing and dossier requirements for products where nitrosamine impurities can be controlled according to ICH Q3A/B limits. Update to Q&A 10 to update Ames test acceptability section. Update to Q&A 16 to clarify the responsibilities of MAHs and API manufacturers when reference is made to ASMFs and CEPs. Editorial correction of Q&A 4.

Action: For adoption

The CHMP adopted the editorial correction of Q&A for MAHs/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products. The Q&A will be published on the EMA website.

12.9. Multi-stakeholder hybrid workshop on Pharmacogenomics

The EC, the HMA and the EMA are organising a multi-stakeholder hybrid workshop on pharmacogenomics on 24 September at EMA in Amsterdam.

The objectives of the event are to:

- Identify priority areas for additional regulatory action to promote the clinical implementation of pharmacogenomics.
- Discuss how medicines regulators can facilitate the uptake of genomics by national healthcare systems.
- Discuss how to leverage genomic data linked to real-world data sources with examples of current studies using such data.
- Discuss how to increase the regulatory impact of EU-funded projects in personalised medicine.

The outcome of the workshop will inform a roadmap towards the clinical implementation of pharmacogenomics in Europe.

Action: For information

The CHMP noted the information of the Multi-stakeholder hybrid workshop on Pharmacogenomics.

12.10. EMA guidance documents on the use of medicinal products for treatment in case of exposure to Biological or Chemical agents used as weapons of terrorism, crime, or warfare

These guidance documents explain the various types of agents that could be used maliciously and the medicines that can be used to prevent or treat their effects. Both guidance documents have been updated and will be published mid-July on the EMA webpage Biological and chemical threats | European Medicines Agency (europa.eu).

Action: For information

The CHMP noted the EMA guidance documents on the use of medicinal products for treatment in case of exposure to Biological or Chemical agents used as weapons of terrorism, crime, or warfare.

12.11. Joint HMA/EMA multi-stakeholder workshop on submission predictability

This multi-stakeholder workshop on 25 September 2024, 9.00-13.30 (CEST) will gather representatives from national competent authorities, the European Medicines Agency, and industry stakeholders.

The workshop aims to raise awareness and foster mutual understanding of how changing submission dates for initial centralised Marketing Authorisation Applications (MAAs) affect EMA and network resources, workload, and expertise planning. Additionally, it will provide a platform for industry stakeholders to share best practices for submissions and discuss strategies to enhance the predictability of MAAs submissions and overall network resource management.

The objectives of the workshop are as follows:

- To showcase data and trends on submissions predictability – problem statement
- To share best practices approach for submission of initial marketing authorisation applications
- To create awareness of the impact from a resource perspective when changing submission dates
- To strengthen cooperation and communication amongst stakeholders
- To discuss strategies to improve submission predictability

Deadline for registering is 16 September 2024.

Action: For information

The CHMP noted the information on the multi-stakeholder workshop.

12.12. Clinical Domain Governance Meeting

The clinical governance meetings are established to coordinate efforts, avoid duplication of work and identify areas where the clinical working parties can support each other. The second clinical domain meeting mainly focuses on the budget the planning of the upcoming workplans/external consultation and the collaboration with the Methodology working party.

Action: For information

The CHMP noted the information on the clinical governance meetings.

The CHMP noted the need for consistency across the WPs not only on the scientific content but procedural issues as well.

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	
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	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Emilia Mavrokordatou	Alternate	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. Rybelsus - Semaglutide - EMEA/H/C/004953/X/0039 5.1.20. Wegovy - Semaglutide - EMEA/H/C/005422/II/0017 9.1.2. Wegovy - Semaglutide - EMEA/H/C/005422/II/0019
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	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	4.2.1. Cerdelga - Eliglustat - Orphan - EMEA/H/C/003724/X/0036/G 5.1.5. Dupixent - Dupilumab - EMEA/H/C/004390/II/0081 5.1.7. Kevzara - Sarilumab - EMEA/H/C/004254/II/0044 5.1.16. SARCLISA - Isatuximab - EMEA/H/C/004977/II/0030
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	
Simona Badoi	Member	Romania	No interests declared	
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	Member	Spain	No interests declared	
Antonio Gomez-Outes	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Taina Mattila	Expert	Netherlands	No interests declared	
Maria Jesus Fernández Cortizo	Expert	Spain	No interests declared	
Clemens Mittmann	Expert	Germany	No interests declared	
Armin Koch	Expert	Germany	no part in discussions, final deliberations and voting as appropriate as regards the medicinal product or a rival product:	3.1.11. Vevizye - Ciclosporin - EMEA/H/C/006250

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Paula Contreras Alarcón	Expert	Spain	No restrictions applicable to this meeting	
Ana Maria IMEDIO	Expert	Spain	No interests declared	
Maja Sommerfelt Grønvold	Expert	Norway	No interests declared	

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