EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 September 2024
EMA/CHMP/280125/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 17 June 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

17 June 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 17 June 2024 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 17 June 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 15-17 April 2024
- Agenda of the BWP meeting to be held remotely on 17-19 June 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. Nomination of new Chemical Quality ESEC experts

Nomination of new experts to join the Chemical Quality European Specialised Expert Community (ESEC). Includes the requested general update on the set-up of the ESECs in the quality domain.

Nomination(s) received

Action: For endorsement

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

2.2.2. Agenda and Minutes

- Minutes of the QWP meeting held remotely on 15-16 April 2024
- Agenda of the QWP meeting to be held remotely on 17-18 June 2024

Action: For information

The CHMP noted the agenda and minutes.

2.2.3. Revision of the Quality of Medicines Q&A: Part 1 – Impurities Calculation of Thresholds for Impurities

Revision of the Q&A published on the EMA website under the Quality of Medicines Questions and Answers: Part 1. The revision concerns the calculation of thresholds for impurities' question and specifically the mono-component product text. Text is added outlining that the same pharmaceutical form should be considered.

Action: For adoption

The CHMP adopted the revision of the Quality of Medicines Q&A: Part 1 – Impurities Calculation of Thresholds for Impurities.

2.2.4. QWP response to the CMDh question to QWP regarding orphan similarity assessment

The CMDh agreed to seek the opinion of the QWP on the similarity assessment of the principal molecular structural features (PMSFs) of two substances The CMDh discussed the

orphan similarity assessment in the framework of a recently finalised decentralised procedure

The QWP discussed the topic and its position reflected in the response document is tabled for adoption and transmission to CMDh.

Action: For adoption

The CHMP adopted the QWP response to the CMDh question to QWP regarding orphan similarity assessment.

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 25 April 2024

Action: For information

The CHMP noted the agenda and minutes.

2.4. Quality Innovation Group (QIG)

Chair: Marcel Hoefnagel

2.4.1. Agenda and Minutes

- Agenda and minutes of the QIG meeting held remotely on 8 April 2024

Action: For information

The CHMP noted the agenda and minutes.

3. Non-Clinical Domain

3.1. Non-Clinical Working Party (NcWP)

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

3.1.1. Agenda and Minutes

- Minutes of the meeting held remotely on 21-22 May 2024
- Draft agenda of the meeting to be held remotely on 18-19 June 2024

Action: For information

The CHMP noted the agenda and minutes.

3.1.2. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to the NcWP.

3.1.3. CMDh question to NcWP

Action: For adoption

The CHMP adopted the CMDh question to the NcWP.

3.1.4. Question from CMDh to the NcWP regarding 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.

Action: For adoption

The CHMP adopted the CMDh question to the NcWP.

3.1.5. Request from PDCO to NcWP

Action: For adoption

The CHMP adopted the request from PDCO to the NcWP.

3.1.6. ERA ESEC mandate and call for nominations

The objective of the ERA ESEC is to provide a platform of bidirectional information sharing and communication on the topics that are of relevance to the community and to support the delivery of the ERAWP work plan. The ESEC provides the opportunity for experts to establish links with other experts across the community, to the different Working Parties, Committees, and across multinational assessment teams. Furthermore, the ERA ESEC aims to function as a multidisciplinary and interagency collaborative network to support the implementation of the "One Health" approach in the area of environmental risk assessment, with the goal to proactively share information between experts across domains and to help identify and address the multiple environmental challenges facing the EU in the areas of human, animal, plant, and ecosystem health related to the use of medicines. Following the endorsement at PROM experts for ERA ESEC can be nominated.

Action: For adoption

The CHMP adopted the ERA ESEC mandate and call for nominations.

3.1.7. Nomination of New Approach Methodologies ESEC experts

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

Nomination(s) received

Action: For endorsement

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

3.1.8. Response from NcWP to the CMDh on the duration of contraception following the use of a morphine-containing medicinal product

In November-December 2023, the CMDh was made aware of a national variation to include recommendations in the product information of a morphine-containing medicinal product on the duration of contraception following treatment (according to the published SWP/NcWP recommendation on the duration of contraception following the end of treatment with a genotoxic compound, EMA/CHMP/SWP/74077/2020 rev. 1*). The CMDh asked the NcWP to advise about the genotoxic potential of morphine and the recommended duration of contraception following the end of treatment with morphine on male and female patients.

Action: For adoption

The CHMP adopted the response from NcWP to the CMDh.

3.1.9. Call for nomination for new NcWP member

Following the departure of Fernando Mendez Hermida at the end of June 2024, the NcWP is launching a call for nomination of a new member. The deadline for nominations is 15 September 2024.

Action: For information

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

3.1.10. Nomination of new member for the NcWP

Following the departure of Günter Waxenecker at the end of April 2024, the NcWP is nominating a new member.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of a new NcWP member.

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

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

3.2.1. Request for meeting outside EMA premises and/or for CxMP/EMA external representation

Sonja Beken has been invited to attend the EUROoCs 2024 Annual Meeting taking place in Milan from 03-05 July, in order to provide the view of the EMA 3Rs Working Party (during keynote and roundtable discussion) on advancing regulatory acceptance of microphysiological systems (MPS) including Organ-on-Chip Models within the EU.

The EUROoCs (European Organ-on-Chip Society) Annual Meeting 2024 will bring together global delegates active in the field of organs-on-chip (OoC) and microphysiological systems (MPS). Considering the work plan of the 3RsWP with a strong focus on (regulatory acceptance of) 3Rs testing approaches and New Approach Methods (NAMS), including MPS and OoC (cfr. ongoing revision of the EMA Guideline on regulatory acceptance of 3Rs testing approaches) and on stakeholder interaction in line with the EMA Regulatory Science Strategy, involvement in the EUROoCs 2024 is considered strategically important. This meeting might prove an excellent forum for attracting interest towards ITF and/or SAWP qualification procedures of novel 3R testing approaches in this field.

Sonja's in-person attendance at this meeting is considered in line with the EMA Regulatory Science strategy 2025 and 3RsWP 3-year work plan which has been endorsed by CHMP.

Action: For endorsement

The CHMP endorsed the participation of Sonja Beken as a 3RsWP expert in the EUROoCs 2024 Annual Meeting, which is taking place in Milan from 3 to 5 July 2024.

3.2.2. Call for nomination of CHMP/CVMP Joint 3Rs Working Party (3RsWP) members

At its meeting of 27 May 2024, EMA's Human Division Leadership group agreed to the recruitment of two additional members for the 3RsWP. The working party has consisted of six members since its inception in 2022. At that time, it was difficult to predict the working party's workload and since then, 3Rs activities have gained significant momentum. As a result, the 3RsWP work plan is ambitious, reflecting the demands from external stakeholders, including the European Commission. The current 3-year work plan (2022–2024) is published on the EMA 3RsWP webpage (as part of the Non-clinical domain work plan), and the 3-year work plan for 2025–2027 is currently under development.

The two additional members of the 3RsWP will be experts' representatives of the human or veterinary areas and may also be members of the Non-Clinical Working Party (NCWP), Safety Working Party-Veterinary (SWP-V), Immunologicals Working Party-Veterinary (IWP), Biologics Working Party (BWP) and Efficacy Working Party-Veterinary (EWP-V), though this is not a requirement. In accordance with EMA's working party model, members will be chosen on the basis of the best and available expertise needed for the working parties to deliver on the tasks allocated by the Committees and on the priorities highlighted in the 3-year work plan. Therefore, members should have specific expertise as per the tabled document (section 4).

The document also outlines the procedure and timetable for submission of nominations by CHMP (and CVMP) members.

Action: For endorsement

The CHMP endorsed the launch of a call for nomination of two new CHMP/CVMP Joint 3Rs Working Party (3RsWP) members.

3.2.3. Agenda and Minutes

- Agenda and minutes from the Batch Release Testing (BRT) OEG meeting held remotely on 3 April 2024

Action: For information

The CHMP noted the agenda and minutes.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Christian B. Roes, Kristin Karlsson

4.1.1. Agenda and Minutes

- Agenda and minutes of the MWP meeting held remotely on 8 May 2024

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Nomination of new Methodology ESEC experts

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

Nomination(s) received

Action: For endorsement

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

4.1.3. Nomination of new Methodology Biostatistics OEG experts

Nomination of new experts to join the Methodology Biostatistics Operational Expert Group (Biostatistics OEG).

Nomination(s) received

MWP Chair: Christian B. Roes

Action: For endorsement

The CHMP endorsed the nomination of the new member of the Methodology Biostatistics Operational Expert Group (Biostatistics OEG).

4.1.4. Nomination of new members to the MWP

Following the call for nominations of three new members of the MWP launched on 15 April 2024 during the PROM meeting, the selection committee would like to propose the following candidate to be endorsed by the CHMP as new member of the MWP.

Nomination(s) received

MWP Chair: Christian B. Roes

Action: For endorsement

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

4.1.5. MWP input into Section 5.1 of the SmPC Guidance

Due to the range of views expressed by different NCAs in relation to the consultation on the content of Section 5.1 of the SmPC, MWP would like to provide consolidated feedback to CHMP.

MWP Chair: Christian B. Roes

Action: For endorsement

The CHMP agreed that the MWP will review the input provided during the consultation on the content of Section 5.1. of the SmPC Guidance. The CHMP will discuss the guidance following the MWP review.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

No topics

5.2. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs, Vice-Chair: Patrick Vrijlandt

5.2.1. Agenda and Minutes

- Draft minutes of the CVSWP meeting held remotely on 6 June 2024
- Final agenda of the CVSWP meeting held remotely on 6 June 2024

Action: For information

The CHMP noted the agenda and minutes.

5.2.2. Draft Paediatric addendum to the guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension (EMA/CHMP/213972/2010)

The CP explaining the need to revise PA on PAH was released for public consultation in 2023. In order to prepare the Draft of the revised Paediatric Addendum, the CHMP agreed on the need for the SAG CV. The List of Questions for SAG CV was adopted during PROM in March 2024. Given that it was not feasible to convene the SAG CV, it is proposed to cancel the call for a SAG.

It is proposed to proceed with the Stakeholders Consultation meeting. The Draft List of Stakeholders as agreed by the CVSWP meeting of 6 June 2024 is tabled.

CHMP: Patrick Vrijlandt

Expert: Clemens Mittmann

Action: For adoption

The CHMP adopted the request on the cancellation of the call for a SAG CV and to proceed instead with a Stakeholders Consultation meeting. The CHMP adopted the list of stakeholders to be consulted.

5.2.3. Nomination of experts for Temporary Drafting Group (tDG) on 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)

Following the call for expression of interest of experts for the Temporary Drafting Group (tDG) the Revision of the "Paediatric Addendum on to the guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension (EMA/CHMP/213972/2010)" included in the CVSWP Work Plan 2024, the following nominations have been received.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the nomination of experts for the Temporary Drafting Group (tDG) on 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).

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis

5.3.1. Cancer Medicines Forum

Discussion on next steps.

Video and presentations of the workshop have been published: Cancer Medicines Forum workshop: April 2024 | European Medicines Agency (europa.eu).

Action: For discussion

The CHMP noted the report on the Cancer Medicines Forum workshop which was held on 5 April 2024.

5.4. Rheumatology and Immunology Working Party (RIWP)

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

5.4.1. Concept Paper on the need for revision of the guideline on clinical investigation of medicinal products for the treatment of psoriatic arthritis

The current Guideline (GL) on clinical investigation of medicinal products for the treatment of psoriatic arthritis (PsA) came into effect in 2007. Since then, several medicinal products have been approved in the EU for the treatment of PsA and consecutively there are also substantial updates in general treatment approaches and treatment goals for this condition. Therefore, a revision of the GL is proposed to reflect these new developments and the implications for clinical development programmes.

Expert: Anna Vikerfors

Action: For adoption

The CHMP adopted the concept paper on the need for revision of the guideline on clinical investigation of medicinal products for the treatment of psoriatic arthritis.

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. Election of new Chair to the VWP

The candidates for the Chair position of the VWP are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise. Nominations should be sent to the VWP secretariat by 19 July 2024. The election will take place at the July 2024 CHMP Plenary Meeting.

Action: For information

The CHMP noted the call for nomination of a new chair to the VWP.

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphy

5.7.1. Revised guideline on the clinical investigation of recombinant and human plasma-derived factor IX products (EMA/CHMP/BPWP/144552/2009 rev. 2) and Guideline on core SmPC for human plasma derived and recombinant coagulation factor IX products (EMA/CHMP/BPWP/518142/2023 rev. 3)

Following the public consultation held in 2019, and after the BCP, the HAEMWP has now finalised the revision of the FIX guideline and core SmPC.

CHMP: Daniela Philadelphy

Expert: Karri Penttila

Action: For adoption

The CHMP adopted the revised guideline on the clinical investigation of recombinant and human plasma-derived factor IX products (EMA/CHMP/BPWP/144552/2009 rev. 2) and Guideline on core SmPC for human plasma derived and recombinant coagulation factor IX products (EMA/CHMP/BPWP/518142/2023 rev. 3).

5.7.2. Workshop on haemoglobinopathies

- Agenda of the workshop to be held remotely on 1 July 2024, 14:00-18:00

Action: For discussion

The CHMP noted the agenda.

5.7.3. Agenda and Minutes

- Draft agenda of the Blood Cluster TC to be held on 28 June 2024

Action: For information

The CHMP noted the agenda.

5.8. Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEG)

5.8.1. Request to extend the mandate of existing therapeutic SAGs

SAG Oncology and Neurology mandates expire in July 2024; SAGs Vaccines, Infections Diseases, and Cardiology in September 2024.

Proposal to ask the CHMP to consider extending the mandate of the established SAGs by six months for the following reasons:

- To guarantee there are SAGs in place for the planned meetings in early September
- To allow discussions within the EMA task force on SAGs to mature with possible proposals to create new therapeutic SAGs
- To allow the revisions on the policy on handling of competing interests to be finalised

Action: For discussion

The CHMP adopted the request on the extension of the mandate of existing therapeutic SAGs by six months.

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. ICH E6(R3) update

Update on the progress of the rewrite of ICH E6 (R3) (global guideline on good clinical practice (GCP) applying to the conduct of clinical trials). This is a brief update and opportunity to circulate an advanced draft of the guideline, prior to formal adoption the CHMP will need to provide in September. A finalised version will be forwarded in due course.

Action: For information

The CHMP noted the update on the progress of the rewrite of ICH E6 (R3) (global guideline on good clinical practice (GCP) applying to the conduct of clinical trials).

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 10-13 June 2024

Action: For information

The CHMP noted the summary of recommendations and advice.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP endorsed the proposed learnings.

9.2.2. Joint Resolution on the principles of conduct within EMA Scientific Committees, Working Parties and CMDx

Action: For information

The CHMP noted the joint resolution on the principles of conduct within EMA Scientific Committees Working Parties and CMDh/CMDv.

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 the 10-13 June 2024 meeting held by Webex
- Table of Decisions from the 10-13 June 2024 meeting held by Webex
- Time schedule and outcomes from the 10-13 June 2024 meeting held by Webex

Action: For information

The CHMP noted the agenda, table of decisions, and time schedule and outcomes.

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

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

Required areas of expertise:

- Ophthalmology
- Pulmonology
- Internal Medicine
- Biosimilars
- Neurology

Applications should be sent to the SAWP Secretariat

Action: For information

The CHMP noted the extension of a call for nomination of new SAWP members.

10.1.4. SAWP mandate revision

Minor revision of SAWP mandate to optimize the composition.

If you have any comments, please send them to the SAWP Secretariat by Friday, 21 June 2024, EoB. If there are no comments received, the document will be considered adopted at the 24-27 June 2024 CHMP Plenary Meeting.

Action: For adoption

The CHMP adopted the revision of the SAWP mandate.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 20 June 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.

10.3.1. Pre-submission meetings as opportunity for RWD study support

Action: For discussion

The CHMP noted the requests received.

10.3.2. Update on selected new DARWIN EU studies

Action: For discussion

The CHMP noted the updates on Real-World Evidence, including DARWIN EU, upcoming events and the ongoing and completed RWD studies.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

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

12. Any Other Business

12.1. Rapporteurships

Update.

Action: For information

The CHMP noted the update and the list of procedures.

12.2. Health Threats and ETF Update

Action: For information

The CHMP noted the Health Threats and ETF updates.

12.3. Concept paper for the revision of the COVID-19 vaccines guidance documents

ETF has drafted a concept paper for the revision of the COVID-19 vaccines guidance documents.

Action: For adoption

The CHMP adopted the concept paper for the revision of the COVID-19 vaccines guidance documents.

12.4. Joint HTAb-EMA methodological workshop series: understanding key evidence challenges, managing remaining uncertainties and exploring potential solutions

Information about the planning of a joint workshop led by HTA bodies on the management of uncertainties in planning, guided by a (regulatory and HTAs) joint ambition to enable the generation of evidence that might answer different questions for benefit/risk and relative effectiveness assessment whilst managing some residual uncertainties.

Action: For information

The CHMP noted the information on the planning of a joint workshop led by HTA bodies on the management of uncertainties in planning (understanding key evidence challenges, managing remaining uncertainties and exploring potential solutions).

12.5. GMP Inspections in MAAs

The presentation will provide information concerning the checks performed at validation stage concerning GMP inspections, what constitute validation blocking issues and what are triggers for pre-approval inspections and how these are conducted, as well as how EMA is looking to improve GMP preparedness for applications.

Action: For information

The CHMP noted the information concerning GMP inspections in MAAs.

12.6. Request from Taiwan for a speaker for the APEC Workshop

A speaker is requested for the "2024 APEC Good Registration Management Regulatory Science Center of Excellence Workshop" scheduled for 3-5 September 2024.

Action: For endorsement

The CHMP endorsed the request of a speaker for the "2024 APEC Good Registration Management Regulatory Science Center of Excellence Workshop", scheduled for 3-5 September 2024.

13. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
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	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Alternate	Cyprus	No interests declared	
Tomas Radimersky	Member	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:	5.1.2. Esperoct - Turoctocog alfa pegol - EMEA/H/C/004883/II/0023 5.1.14. Wegovy - Semaglutide - EMEA/H/C/005422/II/0017
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
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	
Janet Koenig	Alternate	Germany	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
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	
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Anna Vikerfors	Expert	Sweden	No interests declared	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Charlotte Hejl	Expert	Denmark	No restrictions applicable to this meeting	
Christoph Furtmann	Expert	Germany	No interests declared	
Marianne Schmidt	Expert	Denmark	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Karen Van Malderen	Expert	Belgium	No interests declared	
Christian B. Roes	Expert	Netherlands	No participation in discussion, final deliberations and voting on:	
Clemens Mittmann	Expert	Germany	No interests declared	
Violette Dirix	Expert	Belgium	No interests declared	
Edwige Haelterman	Expert	Belgium	No interests declared	
Meeting run with support from relevant EMA staff.				

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