05 December 2022
EMA/CHMP/923033/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 5 December 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

5 December 2022, 09:00–16:15, virtual meeting/room 08-A

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

1. Agenda and Minutes

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

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

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

1.2. Adoption of agenda

The CHMP adopted the PROM agenda for 5 December 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 5 December 2022 meeting will be adopted at the December 2022 CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz, Sean Barry

2.1.1. Call for nomination for the BWP Chair

BWP Chair Sol Ruiz's last term will expire in February 2023. A call of nomination for a new BWP Chair is being launched. Nominations should be sent to the Agency. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

The election will take place at the February 2023 CHMP plenary meeting.

Action: For information

CHMP noted the call for nomination for a BWP chair and upcoming election.

2.1.2. Agenda and minutes

- Agenda for the BWP meeting to be held by Webex on 5-7 December 2022
- Minutes of the BWP meeting held F2F on 3-5 October 2022

Action: For information

CHMP noted the agenda and minutes.

2.2. Quality Working Party (QWP)

Chairs: Blanka Hirschlerova, Marie-Hélène Sabinotto, Laivi Saaremäe

2.2.1. Call for nomination for the QWP Chair

QWP Chair Blanka Hirschlerova's first term will expire in February 2023. A new call of nomination for a QWP chair is being launched. Nominations should be sent to the Agency. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

The election will take place at the January 2023 CHMP plenary meeting.

Action: For information

CHMP noted the call for nomination for a QWP chair and upcoming election.

2.2.2. Minutes

- Final minutes of QWP meeting held F2F in September 2022
- Final minutes of joint GMDP IWG – QWP meeting held F2F in September 2022

Action: For information

CHMP noted the minutes.

2.2.3. QWP Core Team Agenda

- Final agenda and minutes for QWP-CT meeting held by teleconference on 3 November 2022

Action: For information

CHMP noted the agenda and minutes.

2.2.4. QWP workplan

The workplan has been agreed by the QWP and is presented to the CHMP for adoption.

Action: For adoption

CHMP adopted the QWP workplan.

2.2.5. CMDh letter regarding mobile tank containers for medicinal gases

Response to the CMDh letter regarding mobile tank containers for medicinal gases agreed by QWP and IWG.

Action: For adoption

CHMP adopted the response to CMDh regarding mobile tank containers for medicinal gases.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz, Niklas Ekman

2.3.1. Agenda and minutes

- Agenda of the BMWP meeting held by Webex on 23 November 2022

Action: For information

CHMP noted the agenda.

2.3.2. A data driven approach to support tailored clinical programmes for biosimilar monoclonal antibodies

Presentation of research on biosimilars accepted for publication by Clinical Pharmacology and Therapeutics (expected for publication in January 2023).

BMWP: Elena Wolff-Holz, Niklas Ekman

Action: For information

CHMP noted the information regarding research on biosimilars approvals.

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)

Chairs: Susanne Brendler-Schwaab, Karen van Malderen

3.1.1. Agenda and minutes

- Draft minutes for the NcWP meeting held virtually on 3-4 November 2022
- Draft agenda for the NcWP meeting to be held virtually on 6-7 December 2022

Action: For information

CHMP noted the agenda and minutes.

3.1.2. CMDh questions to NcWP on new nitrosamines

CMDh requests that the NcWP determines the acceptable intake for the following nitrosamines based on lifetime daily exposure including information on the points of departure and methodology used.

- 2-Nitroso-octahydrocyclopenta(c)pyrrole
- "Nitroso impurity C" [N-(2,6-dimethylphenyl)-2-(4-nitrosopiperazin-1-yl)acetamide]

Action: For adoption

CHMP endorsed the CMDh questions to NcWP on new nitrosamines.

3.1.3. Questions and answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products

Following the CHMP adoption of NcWP positions on new nitrosamines in November, the question 10 of the Q&A document has been updated to include the limits for:

- N-nitroso-fluoxetine
- N-nitrosoparoxetine
- N-nitroso-diphenylamine NDPh
- N-nitroso-mefenamic acid
- N-nitroso-pyrrolidine NPYR
- N-nitroso-diethanolamine NDELA

Action: For adoption

CHMP adopted the updated questions and answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products.

3.1.4. NcWP response to third party on the SWP response to CMDh on genotoxicity and contraception

In February 2020, based on a request from CMDh, the Safety working party (SWP) published advice on the duration of contraception in male and female patients after cessation of treatment with a genotoxic drug in the context both of clinical trial applications as well as marketing authorisation applications (EMA/CHMP/SWP/74077/2020). In July 2022, the CMDh and EMA have received questions from a third-party which NcWP addressed.

NcWP Chair: Susanne Brendler-Schwaab

Action: For adoption

CHMP adopted the NcWP response to third party on the SWP response to CMDh on genotoxicity and contraception.

3.1.5. NcWP response to CMDh question on potentially mutagenic impurity chloromethyl isopropyl carbonate (CMIC) in tenofovir disoproxyl-containing medicinal products

At the July 2022 CMDh meeting, the CMDh discussed the potentially mutagenic impurity chloromethyl isopropyl carbonate (CMIC) in tenofovir disoproxyl-containing medicinal products. The CMDh agreed to request an assessment by the Non-clinical Working Party to determine the mutagenic risk of CMIC, based on the existing data.

NcWP member: Louise Bang-Lauritsen

Action: For adoption

CHMP adopted the NcWP response to the CMDh question on potentially mutagenic impurity chloromethyl isopropyl carbonate (CMIC) in tenofovir disoproxyl-containing medicinal products.

3.1.6. New nomination in the Excipients Drafting Group

Nomination of experts for the drafting group for the revision of the Annex to guideline on 'Excipients in the labelling and package leaflet of medicines for human use' (EMA/CHMP/302620/2017).

Action: For endorsement

CHMP endorsed the nomination of experts for the Excipient Drafting Group for the revision of the guidance stated above.

3.1.7. CMDh request to NcWP/ExcpDG on benzyl alcohol

Request to include a threshold dose above zero for orally applied medicinal products in the Annex to the Guideline on Excipients in the labelling and package leaflet of medicinal products for human use in order to remove unnecessary labelling requirements for medicinal products containing traces of benzyl alcohol only.

NcWP Chair: Susanne Brendler-Schwaab

Action: For adoption

CHMP endorsed the CMDh request to NcWP/ExcpDG on benzyl alcohol.

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

No topics

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Agenda and minutes

- Final Agenda & minutes for MWP meetings held by teleconference on 17 November 2022

Action: For information

CHMP noted the agenda and minutes.

4.1.2. MWP 3-year workplan

The 3 years workplan including priorities was endorsed by the MWP on 17 November 2022.

Action: For adoption

CHMP adopted the MWP 3-year workplan. CHMP highlighted the need for inclusion of methodology related activities on companion diagnostics as part of the work of the MWP.

4.1.3. Call for nominations for Methodology European Specialised Expert Community (ESEC)

Following the re-organisation of the EMA Working Parties and the set-up of the new Methodology Domain and Methodology Working Party (MWP), MWP is launching an open call for Methodology European Specialised Expert Community (ESEC).

Committee members are invited to nominate experts in the area of e.g. statistics, clinical trial methodology, modelling & simulation, physiological based pharmacokinetic (PBPK) modelling and simulation, pharmacokinetics, pharmacogenomics, epidemiology, Real World Evidence, or artificial intelligence that are part of the European Regulatory Network (e.g. assessors working for a NCA, members of the different WPs or members from academia in institutions/universities with relevant expertise for the Methodology ESEC).

Nominations (along with a brief summary their expertise) should be sent to the Agency.

Action: For information

CHMP noted the call for nominations for Methodology European Specialised Expert Community (ESEC).

4.1.4. Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation

Presentation about the scope and content of the reflection paper on single-arm trials from the CHMP work plan which is also part of the 3-year work plan from the MWP. The objective is to have the reflection paper adopted by CHMP in Q1 2023 and published for public consultation.

Presenter: Kit Roes (MWP chair)

Action: For information

CHMP noted the progress on the drafting of the reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation and next steps for public consultation. CHMP members' comments are welcome until 2 January 2023.

4.2. Biostatistics Operational Expert Group (BOEG)

No topics

4.3. Modelling and Simulation Operational Expert Group (MSOEG)

No topics

4.4. Real World Data Operational Expert Group (RWDOEG)

No topics

4.5. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

4.5.1. Product-specific guidelines

Final product-specific guidelines

- Lanreotide acetate, prolonged-release solution for injection in pre-filled syringe 60, 90 and 120 mg product-specific bioequivalence guidance (EMA/559891/2021) and Overview of comments
- Liposomal amphotericin B powder for dispersion for infusion 50 mg product-specific bioequivalence guidance (EMA/596406/2022) and Overview of comments

Both guidelines have been finalised following 3-month public consultation and consideration of the comments received.

Action: For adoption

The CHMP adopted the above specified product-specific guidelines.

4.5.2. PKWP Q&A 3.12 on whether viscosity and/or other in vitro comparative data are needed to demonstrate comparable physicochemical characteristics of oily solutions, sufficient to support a biowaiver

CMDh sent a query for PKWP input that was agreed by the CHMP in July 2021 relating to a procedure in which a general issue was raised on Appendix II of the 'Guideline on the investigation of bioequivalence' (CPMP/EWP/QWP/1401/98 Rev. 1/ Corr **) relating to oily parenteral solutions. The PKWP response was adopted at the CHMP December 2021 PROM with support for a Q&A on the topic. The resulting Q&A (which CMDh also supported) has now been finalised for publication with QWP input to the wording of the original PKWP response (viscosity as a quality attribute).

Action: For adoption

CHMP adopted the Q&A 3.12 on whether viscosity and/or other in vitro comparative data are needed to demonstrate comparable physicochemical characteristics of oily solutions, sufficient to support a biowaiver.

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

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

5.1.1. CNSWP 3-year work plan

CNSWP adopted the final work plan during 2 December meeting.

Action: For adoption

CHMP adopted the CNSWP 3-year workplan.

5.1.2. CNSWP drafting group membership

CHMP is asked to confirm the appointment of membership of drafting groups for migraine, depression, epilepsy and bipolar disorder guidelines.

Action: For endorsement

CHMP endorsed the appointment of membership of drafting groups for migraine, depression, epilepsy and bipolar disorder guidelines.

5.1.3. Agenda and minutes

- Agenda of the CNS WP meeting held by Teams on 9 September 2022
- Minutes of the CNS WP meeting held by Teams on 9 September 2022
- Agenda of the CNS WP meeting held by Teams on 2 Dec 2022

Action: For information

CHMP noted the agenda and minutes.

5.2. Cardiovascular Working Party (CVSWP)

Chairs: Alar Irs, Patrick Vrijlandt

5.2.1. ESEC – Cardiovascular Diseases mandate adoption

Preparations for the ESEC-Cardiovascular Diseases, the CVSWP adopted its mandate.

Action: For adoption

CHMP adopted the mandate of ESEC – Cardiovascular Diseases.

5.2.2. ESEC – Cardiovascular Diseases members' appointment

CHMP is asked to confirm the automatic appointment of members of the CVSWP and SAG CV issues as ESEC members.

Action: For endorsement

CHMP confirmed that WP and standing SAG members have automatic access to ESEC membership.

5.2.3. Agenda and minutes

- Agenda of the CVSWP face-to-face meeting held on 11 November 2022
- Minutes of the CVS WP face-to-face meeting held on 11 November 2022

Action: For information

CHMP noted the agenda and minutes.

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 by Webex on 25 November 2022
- Minutes of the ONCWP meeting held by Webex on 19 October 2022

Action: For information

CHMP noted the agenda and minutes.

5.3.2. Nomination of Oncology ESEC experts

Nomination by ONCWP of an expert to enter the Oncology European Specialised Expert Community (ESEC).

Action: For endorsement

CHMP endorsed the nomination of an expert to join Oncology ESEC.

5.3.3. Oncology ESEC activities

The CHMP to be updated on the Oncology ESEC activities.

Action: For information

CHMP noted the upcoming Oncology ESEC activities.

5.3.4. ONCWP 3-year workplan

The workplan has been edited to reflect changes in chairs positions. In addition, an annex is included listing an update on the work done in 2022.

Action: For adoption

CHMP adopted the ONCWP 3-year workplan.

5.4. Rheumatology and Immunology Working Party (RIWP)

Vice-Chair: Caroline Auriche

5.4.1. RIWP 3-year Workplan

The 3-year workplan was endorsed by the RIWP on 7 November 2022.

Vice-Chair: Caroline Auriche

Action: For adoption

The CHMP noted the RIWP 3-year workplan. The final version of the RIWP workplan will be adopted during the December 2022 CHMP plenary meeting.

5.4.2. Nomination of a new member to the RIWP

Nomination of a new RIWP members. The call for nomination of a new RIWP member was launched at November PROM with a deadline for nominations by 25 November 2022.

Action: For endorsement

The CHMP endorsed the nomination of Karin Janssen as RIWP member. The nomination of Hrefna Gudmundsdottir was also endorsed provided a further seat at RIWP can be made available considering the substantial workplan.

5.4.3. Call for nominations for the RIWP Chair

Candidates 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 Agency. Proposed candidates must be already members of the RIWP.

Elections will take place at the January 2023 CHMP Plenary meeting.

Action: For information

CHMP noted the call for nomination for a RIWP chair and upcoming election.

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

Chair: Mair Powell

5.6.1. VWP 3-year workplan

The 3-year VWP workplan was endorsed by the VWP on 28 September 2022.

Action: For adoption

CHMP adopted the 3-year VWP workplan.

5.7. Haematology Working Party (HaemWP)

No topics

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. ICH report to CHMP

Summary of the ICH bi-annual meeting in Incheon, South Korea (12-16 November 2023).

Action: For information

The CHMP noted the ICH report for the ICH meeting held in Incheon, the presentation and supported the ongoing ICH activities.

7.1.2. ICH E21 – Inclusion of pregnant women in CTs – appointment of experts

Following a call launched via CTCG, CHMP is requested to appoint an expert to the ICH working group drafting this new guidance document.

Action: For adoption

The CHMP endorsed the nomination of Giorgia Berardi as deputy topic lead for the development of the new guideline on the inclusion of pregnant and breastfeeding individuals in clinical trials.

7.1.3. ICH Q13 – Continuous Manufacturing – Step 4 guideline

Following ICH adoption of this guideline, CHMP is requested to adopt the ICH document.

Action: For adoption

The CHMP adopted the final version of ICH Q13 – Continuous Manufacturing – Step 4 guideline. This guideline will be implemented in the EU 6 months after publication on the EMA website.

7.1.4. ICH M11 Clinical electronic Structured Harmonised Protocol (CeSHarP) – Step 2b – ongoing public consultation

This new harmonised Guideline on Clinical electronic Structured Harmonised Protocol (CeSHarP) is to introduce the clinical protocol template and the technical specification to ensure that protocols are prepared in a consistent fashion and provided in a harmonised data exchange format acceptable to the regulatory authorities. The public consultation is open until 26 February 2023. Members are invited to participate as volunteers, interested member can express their interest by **9 December 2022**.

Action: For information

The CHMP noted the ongoing consultation for ICH M11 Clinical electronic Structured Harmonised Protocol (CeSHarP). Members were encouraged to participate as volunteers.

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)

8.1.1. Update on Q&A guidance on Active Substance Master File (ASMF) (CMDh/CMDv/280/2012, Rev.12)

Update on Q&A guidance on Active Substance Master File (ASMF) (CMDh/CMDv/280/2012, Rev.12) with additional information. Questions 22, 23 and 25 have been updated and questions 26 and 27 have been added as new questions.

Action: For information

CHMP noted update on Q&A guidance on Active Substance Master File (ASMF) (CMDh/CMDv/280/2012, Rev.12).

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 28 November - 01 December 2022.

Action: For information

The CHMP noted the summary of recommendations and advice.

8.2.2. Revision of CHMP Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling (EMEA/CHMP/203927/2005)

Joint collaboration PRAC-CHMP for revision of the CHMP Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling. This activity is part of the CHMP Workplan 2023.

Action: For information

CHMP noted proposal for revision of the above specified guidance.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

9.2. CHMP organisation/templates

9.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

This topic was not covered and has been postponed for the next PROM meeting.

9.2.2. Practical working instructions for Multinational assessment Teams (MNATs)

5-year update of guidance

CHMP: Outi Mäki-Ikola

Action: For discussion

This topic was not covered and has been postponed for the next PROM meeting.

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi, Vice-Chair: Sylvie Louet

10.1.1. Appointment of CHMP peer review for SA

Action: For information

CHMP noted the appointment of CHMP peer review for Scientific Advice.

10.1.2. Agenda and Table of Decisions

- Agenda from 28 November- 01 December 2022 meeting held by Webex
- Draft Table of Decisions from 28 November - 01 December 2022 meeting held by Webex

Action: For information

The CHMP noted the agenda and the table of decisions.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 15 December 2022

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 21 December 2022

Action: For adoption

The CHMP endorsed the meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

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

11.2. COVID-19 ongoing and upcoming procedures

List of currently ongoing and upcoming (imminently, i.e. expected within the next 2 months) applications for COVID-19 vaccines and therapeutics.

Action: For information

The CHMP noted the COVID-19 ongoing and upcoming procedures.

12. Any Other Business

12.1. Rapporteurships

Update

Action: For information

CHMP noted the update.

12.2. Diabetes Drafting Group - Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus - (CPMP/EWP/1080/00)

Update on the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus (CPMP/EWP/1080/00) further to the comments received at the public consultation.

CHMP: Kristina Dunder

Expert: Peter Mol

Action: For adoption

The CHMP discussed the update on the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus (CPMP/EWP/1080/00). The topic will be re-discussed during the January 2023 PROM meeting.

12.3. Regulatory & Scientific conference on RNA based medicines

This conference on 2 February 2023 aims to facilitate the dialogue between industry/academia and regulators, to discuss scientific and regulatory opportunities and challenges to promote the development of RNA based innovative medicines.

Action: For information

The CHMP noted the upcoming Regulatory & Scientific conference on RNA based medicines.

12.4. Update on IRIS for core regulatory procedures

Update on how core regulatory procedures will be further implemented in IRIS and highlight open opportunities for NCA experts to contribute to ongoing work.

Action: For information

The EMA updated the CHMP how core regulatory procedures will be further implemented in IRIS and highlighted open opportunities for NCA experts to contribute to ongoing work.

The CHMP noted the update on the implementation of IRIS.

12.5. EMA labelling review process improvement

Streamlining proposals for improvement of EMA labelling review process.

Action: For information

The CHMP noted the changes in the EMA labelling review process.

12.6. Q&A "Is the monitoring of bioequivalence clinical trials mandatory?"

Q&A "Is the monitoring of bioequivalence clinical trials mandatory?" published on EMA corporate website – Q&A: Good clinical practice (GCP) | European Medicines Agency (europa.eu) please refer to B.16. A further clarification document: *Assessment of the adequacy of monitoring information in bioequivalence clinical trials* drafted.

CHMP: Jayne Crowe

Action: For information

This topic was not covered and has been postponed for the next PROM meeting.

13. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Daniela Philadelphy	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Margareta Bego	Member	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Emilia Mavrokordatou	Alternate	Cyprus	No participation in final deliberations and voting on:	COVID-19 vaccines
Ondřej Slanař	Member	Czechia	No restrictions applicable to this meeting	
Tomas Radimersky	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:	8.1.1. concizumab - H0005938
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	
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	
Konstantina Alexopoulou	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Paula Boudewina van Hennik	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	
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on:	COVID-19 vaccines
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Francisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No interests declared	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Blanca Garcia-Ochoa	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Christian Gartner	Co-opted member	Austria	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Christian B (Kit) Roes	Expert	Netherlands	No restrictions applicable to this meeting	
Caroline Auriche-Benichou	Expert	France	No interests declared	
Nienke Rodenhuis	Expert	Netherlands	No interests declared	
Martina Perini	Expert	Italy	No restrictions applicable to this meeting	
Luca Santi	Expert	Italy	No restrictions applicable to this meeting	
Louise Frederikke Swaffield Bang-Lauritsen	Expert	Denmark	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Kristin Karlsson	Expert	Sweden	No restrictions applicable to this meeting	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Elena Wolff-Holz	Expert	Germany	No interests declared	
Mas Parra Paloma	Expert	Spain	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Vincent Gazin	Expert	France	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Irene Bachmann	Expert	Germany	No interests declared	
Christina Thygesen Eltorp	Expert	Denmark	No interests declared	
Meera Varma	Expert	Denmark	No restrictions applicable to this meeting	
Carolien Versantvoort	Expert	Netherlands	No interests declared	
Niklas Ekman	Expert	Finland	No interests declared	
Ramla Hamada	Expert	France	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Anne Isabel Roth	Expert	Germany	No interests declared	
Susanne Winterscheid	Expert	Germany	No interests declared	
Kora Doorduyn - van der Stoep	Expert	Netherlands	No restrictions applicable to this meeting	
Meeting run with support from relevant EMA staff.				

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