27 January 2022
EMA/CHMP/25624/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 17 January 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

17 January 2022, 09:00–13:00, 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.

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1. Agenda and Minutes

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

1.2. Adoption of agenda

The CHMP adopted the PROM agenda for the 17 January 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 17 January 2022 meeting will be adopted at the January 2022 CHMP plenary.

2. Non therapeutic-area-specific working parties

2.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

No topics

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Nomination of new member

Nomination of new BWP member representing Finland (following the resignation of Jaana Vesterinen).

Action: For endorsement

CHMP endorsed the nomination of Niklas Ekman replacing Jaana Vesterinen as BWP member representing Finland.

2.2.2. Agenda and minutes

- Final minutes for BWP meeting held virtually on 3-5 November 2021
- Draft agenda for BWP meeting to be held virtually on 17-19 January 2022

Action: For information

CHMP noted the agenda and minutes.

2.2.3. Revision of the Guideline on the requirements for quality documentation concerning biological investigational medicinal products (IMPs) in clinical trials - EMA/CHMP/BWP/534898/2008

Request from European Commission related to Clinical Trial Regulation. QWP working in parallel on the guideline for chemical IMPs (see 2.3.2).

Updates are proposed to the classification of changes to IMPs which require substantial modification of the IMPD (guideline chapter 6).

Final guideline proposal to be published on 31 January 2022.

Action: For adoption

CHMP adopted the Guideline on the requirements for quality documentation concerning biological investigational medicinal products (IMPs) in clinical trials.

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Agenda

- Final agenda from the QWP Core Team meeting held by teleconference on 8 December 2021

Action: For information

CHMP noted the agenda.

2.3.2. Revision of the Guideline on requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products (IMPs) in clinical trials - EMA/CHMP/QWP/545525/2017

Request from European Commission related to Clinical Trial Regulation. BWP working in parallel on the guideline for biological IMPs (see 2.2.3).

Updates are proposed to the classification of changes to IMPs which require substantial modification of the IMPD (guideline chapter 9).

Final guideline proposal to be published on 31 January 2022.

Action: For adoption

CHMP adopted the Guideline on requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products (IMPs) in clinical trials.

2.3.3. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005, EMA/CPMP/QWP/2819/00, EMA/CVMP/814/00, Rev. 3)

Third revision of the Guideline on quality of herbal medicinal products/traditional herbal medicinal products which takes into account other new and revised guidelines, questions and answers and the Ph. Eur. revised general monograph "Herbal Drug Extracts" as well as experiences gained over the years with the application of the guideline.

Action: For adoption

CHMP adopted the Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005, EMA/CPMP/QWP/2819/00, EMA/CVMP/814/00, Rev. 3).

2.3.4. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005, EMA/CPMP/QWP/2820/00, EMA/CVMP/815/00, Rev. 3)

Third revision of the Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products which takes into account other new and revised guidance documents.

Action: For adoption

CHMP adopted the Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005, EMA/CPMP/QWP/2820/00, EMA/CVMP/815/00, Rev. 3).

2.4. Safety Working Party (SWP)

Chair: Susanne Brendler-Schwaab; vice-chair: Günter Waxenecker

2.4.1. Minutes

- Final minutes for SWP virtual meeting held on 8 November 2021

Action: For information

CHMP noted the minutes.

2.4.2. CMDh request on the AI for the nitrosamine N-nitroso-Mefanamic acid (NO-MFA)

CMDh question to SWP to determine the acceptable intake for nitrosamine N-nitroso-Mefanamic acid (NO-MFA) based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

CHMP adopted the CMDh request on the AI for the nitrosamine N-nitroso-Mefanamic acid (NO-MFA).

2.4.3. Corrigendum of the Ethanol report (EMA/CHMP/43486/2018)

Third party pointed out to EMA some calculation inconsistencies in the ethanol background report (EMA/CHMP/43486/2018) that was published in Nov 2019 by the Excipients DG. SWP has agreed on the correction.

Action: For adoption

CHMP adopted the Corrigendum of the Ethanol report (EMA/CHMP/43486/2018).

2.5. Biosimilar Medicinal Product Working Party (BMWP)

No topics

2.6. Biostatistics Working Party (BSWP)

No topics

2.7. Modelling and Simulation Working Party (MSWP)

No topics

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

2.9.1. PKWP Q&A on expectations for bootstrapping to calculate the 90% CI of f2 (EMA/410839/2021)

Following discussion at CHMP July 2021 PROM, PKWP has drafted a Q&A with the input of BSWP and QWP to clarify the conduct and reporting of f2 Confidence Interval bootstrapping for dissolution similarity.

Action: For adoption

CHMP adopted the PKWP Q&A on expectations for bootstrapping to calculate the 90% CI of f2.

3. Therapeutic-area-specific working parties and SAGs

3.1. Blood Products Working Party (BPWP)

No topics

3.2. Central Nervous System Working Party (CNSWP)

No topics

3.3. Cardiovascular Working Party (CVSWP)

No topics

3.4. Infectious Diseases Working Party (IDWP)

Chair: Maria Cortizo

3.4.1. Product Information of the HIV products

Follow-up from December 2021 discussion at PROM on the update of the Product Information of HIV products in what refers to the risk of transmission of HIV either due to sexual activity or breastfeeding.

Action: For adoption

CHMP adopted the proposed update on Product Information of HIV products recommending the removal of the disease information related to sexual transmission of HIV and take the opportunity to slightly update the wording on breast-feeding.

3.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

3.5.1. Agenda and Minutes

- Agenda of the ONCWP meeting held by Webex on 13 January 2022
- Minutes of the ONCWP meeting held by Webex on 02 December 2021

Action: For information

CHMP noted the agenda and minutes.

3.5.2. Launch call for nominations for Oncology Working Party

In the context of the new operational model of working parties that was agreed at the EMA Management Board in April 2021, this is a request to launch the call for nominations for Oncology Working Party.

Action: For information

CHMP noted the call for nominations for Oncology Working Party.

3.5.3. Revision of the Anticancer Guideline (EMA/593364/2020) – Appendix 3

Revision to the Appendix 3 of the Anticancer guideline. The Appendix 3 relates to section 4.8 of the SmPC for the Anticancer Medicinal products. The revised guideline is brought to the CHMP for adoption after 3-month external public consultation.

Action: For adoption

CHMP adopted the Appendix 3 of the Anticancer Guideline following a 3-month external public consultation.

3.6. Rheumatology/Immunology Working Party (RIWP)

No topics

3.7. Vaccines Working Party (VWP)

No topics

3.8. Scientific Advisory Groups (SAGs)

No topics

4. Drafting groups

4.1. Excipients Drafting Group

No topics

4.2. Gastroenterology Drafting Group (GDG)

No topics

4.3. Geriatric Expert Group (GEG)

No topics

4.4. Radiopharmaceuticals Drafting Group (RadDG)

No topics

4.5. Respiratory Drafting Group (RDG)

No topics

5. Harmonisation and consistency groups

5.1. International Council on Harmonisation (ICH)

5.1.1. ICH E14/S7B Q&As step 5 - Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential

The E14/S7B IWG Regulatory experts have completed step 3 sign-off of the Q&As and the Regulatory Members of the Assembly will be invited to adopt as final under Step 4 this document, which would subsequently be published on the ICH public website.

Action: For adoption

CHMP adopted the ICH E14/S7B Q&As - Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential to be published on the ICH public website.

5.2. Guideline Consistency Group (GCG)

No topics

5.3. Summary of product characteristics Advisory Group

No topics

6. Joint groups and collaboration with other Scientific committees

6.1. Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of medicinal products (J 3RsWG)

No topics

6.2. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

No topics

6.3. Collaboration with other Scientific committees

6.3.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 10-13 January 2022.

Action: For information

The CHMP noted the summary of recommendations and advice.

6.3.2. CMDh question to CHMP on the HMPC statement on the use of herbal medicinal products containing estragole

Following the adoption of the SWP response to HMPC in July 2021 PROM and subsequent HMPC public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005, Rev 1), CMDh seeks information on whether the recommendations set in the Public Statement are applicable to all medicinal products containing estragole either as excipient or as part of the active substance.

Action: For adoption

CHMP adopted the question to CHMP on the HMPC statement on the use of herbal medicinal products containing estragole and confirmed that recommendations included in the public statement are applicable to medicinal products containing the substance estragole either as excipient or as part of the active substance.

7. Regulatory / Organisational matters

7.1. Regulatory Issues / new legislation

No topics

7.2. CHMP organisation / templates

7.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

CHMP endorsed the proposed learnings.

7.2.2. CHMP Co-rapporteur critique

Experience of the implementation of Co-Rapporteur critique in initial marketing authorisation applications.

Action: For discussion

CHMP noted the experience on the implementation of the Co-Rapporteur critique in initial marketing authorisation applications.

7.2.3. New Working Parties Operating Model (WOM) - Call for nominations and 3 year workplans for workings parties in clinical, non-clinical and methodology domain

Progressing in the implementation of the WOM, the CHMP is presented with the draft call for nominations and 3 year workplans for workings parties in clinical, non-clinical and methodology domain

Clinical domain

- Central Nervous System Working Party (CNSWP)
- Cardiovascular Woking Party (CSSWP)
- Haematology Working Party (HAEMWP)
- Infectious Disease Working Party (IDWP)
- Rheumatology and Immunology Working Party (RIWP)
- Vaccines Working Party (VWP)

Non-Clinical domain:

- Non-Clinical Working Party (NCWP)
- Joint 3Rs Working Party (J3RsWP)

Methodology domain

- Methodology Working Party (MWP)

EMA: Silvy da Rocha

Action: For information

CHMP noted the draft call for nominations and 3-year workplans for workings parties in clinical, non-clinical and methodology domains. Call for nominations of the above-mentioned

WPs are planned to be launched in February after presentation at PROM. Members are encouraged to distribute further in their NCA for awareness.

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Appointment of CHMP peer review for SA

Action: For information

CHMP noted appointment of CHMP peer review for SA.

8.1.2. Qualification procedures in 2021 - Digital technologies

Overview of qualification procedures from Scientific Advice (SA) involving digital technologies received by the Agency in 2021. This activity was performed within the context of the CHMP Workplan 2021.

Action: For information

CHMP noted the overview of qualification procedures from Scientific Advice (SA) involving digital technologies received by the Agency in 2021. CHMP was informed that this topic will continue to be monitored as part of the CHMP Workplan 2022.

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 07 January 2022

Action: For information

CHMP endorsed the meeting.

8.2.2. ITF meeting

Meeting date: 31 January 2022

Action: For adoption

CHMP endorsed the meeting.

9. Product related topics

9.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

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

9.2. 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

CHMP noted the Covid-19 ongoing and upcoming procedures.

9.3. Ipique - bevacizumab - EMEA/H/C/005433

Rotterdam Biologics B.V.; indicated in adults for the treatment of neovascular macular degeneration associated with aging and diabetes.

Scope: Appointment of re-examination rapporteurs

Action: For adoption

Well-established use application (Article 10a of Directive No 2001/83/EC)

Opinion adopted on 11.11.2021. List of Outstanding Issues adopted on 20.05.2021. List of Questions adopted on 17.09.2020.

CHMP was updated with the status of this application. CHMP appointed re-examination Rapporteur and re-examination Co-Rapporteur.

9.4. Tepmetko - tepotinib - EMEA/H/C/005524

Merck Europe B.V.; treatment of advanced non-small cell lung cancer

Scope: Update on the status of this application.

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

Opinion adopted on 16.12.2021. List of Outstanding Issues adopted on 16.09.2021. List of Questions adopted on 25.03.2021.

CHMP was updated with the status of this application.

10. Any Other Business

10.1. 5-year review of PRIME experience

Presentation of the main findings and recommendations of the experience with the PRIME scheme since its launch in March 2016.

Action: For information

CHMP noted the 5-year review of PRIME experience and endorsed the main findings and recommendations. Introduction to the Lifecycle Regulatory Submissions Metadata Project

The purpose of the project is to deliver effective generation of evidence in support of benefit/risk decision making from data-driven interrogation of scientific information within regulatory submissions.

Action: For information

CHMP noted the Introduction to the Lifecycle Regulatory Submissions Metadata Project looking at the investigation of information in the MAA dossier or regulatory documents, be it structured or unstructured. CHMP will be consulted again once concrete proposals are available to ensure they are fit for purpose for CHMP members and assessors.

11. 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	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Thalia Marie Estrup Blicher	Alternate	Denmark	No restrictions applicable to this meeting	
Ondřej Slanař	Member	Czechia	No restrictions applicable to this meeting	
Tomas Radimersky	Alternate	Czechia	No interests declared	
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	
Alexandre Moreau	Member	France	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	
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Armando Genazzani	Member	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No participation in final deliberations and voting on	COVID-19 vaccines
Silvijus Abramavicius	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffler	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
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	
Bruno Sepodes	Member (Vice-Chair)	Portugal	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	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Blanca Garcia-Ochoa	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	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	
Deirdre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Luca Santi	Expert - via WebEx*	Italy	No restrictions applicable to this meeting	
Martina Perini	Expert - via WebEx*	Italy	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
Paula Contreras Alarcón	Expert - via WebEx*	Spain	No involvement with respect to medicinal products from the relevant company, i.e. no part in discussions, final deliberations and voting as appropriate as regards medicinal products from the relevant company	Rinvoq - upadacitinib - EMEA/H/C/004760/X/0012/G
Maria Victoria Tudanca Pacios	Expert - via WebEx*	Spain	No restrictions applicable to this meeting	
Alfredo García-Arieta	Expert - via WebEx*	Spain	No interests declared	
Carolien Versantvoort	Expert - via WebEx*	Netherlands	No interests declared	
Anja Schiel	Expert - via WebEx*	Norway	No interests declared	
Maria Jesus Fernández Cortizo	Expert - via WebEx*	Spain	No interests declared	
Trine Jensen	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Sigrid Klaar	Expert - via WebEx*	Sweden	No restrictions applicable to this meeting	
Maria Grazia Evandri	Expert - via WebEx*	Italy	No interests declared	
Jaqueline Wiesner	Expert - via WebEx*	Germany	No interests declared	
Dominique Masset	Expert - via WebEx*	France	No interests declared	
Nora Cascante Estepa	Expert - via WebEx*	Germany	No interests declared	
Roland Froetschl	Expert - via WebEx*	Germany	No interests declared	
Sabine Mayrhofer	Expert - via WebEx*	Germany	No interests declared	
Meeting run with the help of EMA staff				