12 April 2021
EMA/CHMP/210409/2021 Rev.0
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 12 April 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

12 April 2021, 09:00–14:30, 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 Organisationa 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 PROM Agenda for 12 April 2021 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of April 2021 meeting will be adopted at the April 2021 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)

Chairs: Sol Ruiz/Nanna Aaby Kruse

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by Adobe Connect on 15-17 February 2021
- Draft agenda for BWP meeting to be held by Adobe Connect on 12-14 April 2021

Action: For information

CHMP noted the Agenda and Minutes.

2.3. Quality Working Party (QWP)

Chairs: Blanka Hirschlerova/Laivi Saaremäel

2.3.1. Minutes

- Final minutes from QWP Core Team meeting held by teleconference on 17 March 2021

Action: For information

CHMP noted the Minutes.

2.3.1. CMDh question to QWP on applicability of Q5 to intermediate manufacturers

CMDh question to QWP on possibility to expand the applicability of Q5 of the CMDh Q&A on QP declaration (CMDh/340/2015/Rev.6, July 2020) to also include intermediate manufacturers was adopted at November 2020 ORGAM meeting. The CMDh at its March 2021 plenary meeting agreed to withdraw this question.

Action: For information

CHMP noted withdrawal of CMDh question to QWP on applicability of Q5 to intermediate manufacturers.

2.4. Safety Working Party (SWP)

Chairs: Jan Willem Van der Laan/Susanne Brendler-Schwaab

2.4.1. Minutes

- Final minutes for SWP meeting held by teleconference on 22 February 2021

Action: For information

CHMP noted the Minutes.

2.4.2. SWP position on pyrrolizidine alkaloids

SWP position on draft HMPC public statement on herbal medicinal products containing pyrrolizidine alkaloids.

Action: For adoption

CHMP was presented with the SWP position on the draft HMPC public statement herbal medicinal products containing pyrrolizidine alkaloids. The scientific considerations proposed by SWP regarding the use of BMDL10 as a point of departure to establish an AI for pyrrolizidine alkaloids were endorsed by the CHMP. However, CHMP questioned the option to apply different approaches to safety assessment based on a distinction between "type of medicinal product", i.e. using different standards for herbal medicinal products, chemically defined medicines, biologicals, standards of safety for compounds affecting herbal and pharmaceutical medicinal products. This topic requires further discussion at the next CHMP plenary meeting before the SWP's position can be adopted.

2.4.3. Composition of the Nitrosamine expert group

The Nitrosamine expert group is being established to discuss nitrosamine issues with Industry.

Action: For information

CHMP noted the establishment and composition of the Nitrosamine expert group with no further comments.

2.4.4. EFSA scientific opinion on TiO2

SWP (together with QWP core group) is foreseen to review the EFSA opinion on TiO2 and available evidence.

Action: For information

CHMP was presented with the historical background related to the evaluation of TiO2 which started in 2016. CHMP was informed regarding the new assessment by EFSA on TiO2

requested by the Commission which takes into account literature data of the last 5 years with additional studies submitted by business operators.

2.5. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz/Niklas Ekman

2.5.1. Agenda and minutes

- Agenda of BMWP meeting held virtually on 31 March 2021
- Final minutes for BMWP meetings held by Adobe Connect on 22 October 2020 and 3 February 2021

Action: For information

CHMP noted Agenda and Minutes.

2.6. Biostatistics Working Party (BSWP)

No topics

2.7. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

2.7.1. Agenda and minutes

- Agenda of MSWP meeting held virtually on 7 April 2021
- Table of Decisions of MSWP meeting held virtually on 3 March 2021

Action: For information

CHMP noted Agenda and ToD.

2.7.2. Call for nominations for MSWP chair and MSWP vice-chair

The mandate of MSWP chair Kristin Karlsson and MSWP vice-chair Flora Musuamba Tshinanu will expire on 28 June 2021.

Action: For information

CHMP noted call for nominations for MSWP chair and MSWP vice-chair. Nominations should be sent to the Agency by **6 May 2021**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Elections will take place at the May CHMP Plenary meeting.

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair: Caroline Versantvoort

2.9.1. Product-specific guidelines

Final product-specific guidelines

- Lapatinib product-specific bioequivalence guidance (EMA/CHMP/257298/2018) and Overview of comments (Note: there were two public consultations in the development of this guideline and therefore the overview includes comments from both consultations)

  CHMP adopted final Lapatinib product-specific bioequivalence guidance (EMA/CHMP/257298/2018) with no additional comments.

- Acenocoumarol product-specific bioequivalence guidance (EMA/CHMP/512475/2020) (Note: no Overview as no comments received in public consultation)

Action: For adoption

CHMP adopted final Acenocoumarol product-specific bioequivalence guidance (EMA/CHMP/512475/2020) with no additional comments.

Revision of product-specific guidelines

- Palbociclib product-specific bioequivalence guidance (EMA/CHMP/802679/2018 Rev.1) and Overview of comments

Action: For adoption

CHMP adopted Palbociclib product-specific bioequivalence guidance (EMA/CHMP/802679/2018 Rev.1) and Overview of comments with no additional comments.

2.9.2. PKWP composition

- Iva Klarica Domjanović (HR) to change status from Member to Additional Assessor
- Current Additional Assessor to replace Iva Klarica Domjanović (HR) as Member in line with nomination pending vacancy in April 2019

Action: For endorsement

CHMP endorsed Victor Mangas Sanjuan (ES) to replace Iva Klarica Domjanović (HR) as PKWP member and for Iva Klarica Domjanović (HR) to change status from Member to Additional Assessor.

3. Therapeutic-area-specific working parties and SAGs

3.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

3.1.1. Agenda and minutes

- Minutes of the BPWP TC held virtually on 11 March
- Final agenda of the Blood cluster TC held virtually on 19 March
- Draft minutes of the Blood cluster TC held virtually on 19 March

Action: For information

CHMP noted Agenda and Minutes.

3.1.2. Third party (PPTA and IPFA) request to discuss matters related to plasma for fractionation and plasma-derived medicinal product

Third party (PPTA and IPFA) request for a TC to discuss matters related to plasma for fractionation and plasma-derived medicinal products.

Action: For discussion

CHMP noted third party (PPTA and IPFA) request for a TC to discuss matters related to plasma for fractionation and plasma-derived medicinal products and also the specific request of having an EMA position on the acceptability of UK plasma for fractionation. This will be discussed at the BWP at their May meeting.

3.2. Central Nervous System Working Party (CNSWP)

No topics

3.3. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs

3.3.1. Call for nominations for CVS WP chair and CVS WP vice-chair

The mandate of CVS WP chair Kristina Dunder expired in December 2020 and CVS WP vice-chair Alar Irs will expire on 18 April 2021.

EMA: Anna Baczynska

Action: For information

Nominations should be sent to the Agency by **6 May 2021**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Elections will take place at the May CHMP Plenary meeting.

3.4. Infectious Diseases Working Party (IDWP)

Chair(s): Vacant

No topics

3.5. Oncology Working Party (ONCWP)

No topics

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. Public consultation for Guideline ICH S1B Step 2b - Testing for Carcinogenicity of Pharmaceuticals - S1B Addendum

Start of 5-month public consultation of the draft Guideline ICH S1B Step 2b - Testing for Carcinogenicity of Pharmaceuticals - S1B Addendum.

Action: For adoption

CHMP endorsed start of 5-month public consultation of draft Guideline ICH S1B Step 2b - Testing for Carcinogenicity of Pharmaceuticals - S1B Addendum with no further comments.

5.2. Action: For adoption 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 06-09 April 2021.

Action: For information

The CHMP noted the Summary of recommendations and advice.

6.4. Regulatory Issues / new legislation

No topics

6.5. CHMP organisation / templates

6.5.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

CHMP endorsed learning.

6.5.2. Revision of assessment report templates

Revision of the following templates:

- Rapporteurs Assessment report on the claim of new active substance (NAS)
- Full batch of initial marketing authorisation assessment report templates.

Action: For discussion

CHMP noted revision of assessment report templates. CHMP provided comments to consider how to streamline the templates in order to promote the focused work of assessors while keeping the current high standards of quality.

6.5.3. Management of Written Procedures in emergency situations

Discussion on timelines and logistics for written procedures.

CHMP: Harald Enzmann, Sinan B. Sarac

Action: For discussion

CHMP discussed the current process and timelines for management of written procedures.

6.5.4. Resourcing of Covid-19 applications: Follow up from February and March CHMP meetings

Update to the CHMP on the progress and next steps on resourcing of Covid-19 applications following discussion at February and March CHMP meetings.

Action: For discussion

Following discussion in the extraordinary CHMP on the 4th of March and Management Board on the 11th of March, EMA was requested to bring up a first proposal to address the resources issue. CHMP was presented with two proposals on scenarios where two assessment reports (rapporteur and co-rapporteur assessment reports) will be drafted. CHMP endorsed option 1: COVID related applications and exceptions. This approach is also applicable to extension of indication applications.

6.5.5. Update of Working Parties Review Project

Update on the progress of the Working Party Review Project.

CHMP: Harald Enzmann

Action: For information

CHMP was informed on the latest discussions of the Management Board Review Group concerning the Working party operating model. An HMA satellite meeting was organised under the Portuguese Presidency to address concerns and to review the plan in more detail. This took place on 2nd March and facilitated subsequent discussions and endorsement at the 11th March 2021 Management Board meeting. The letter of invitation to the WP chairs to take part into a transitional implementation of the domain governance and co-develop detailed implementation plans was presented to the CHMP. Additionally, working party members will be updated on the current status in writing. CHMP noted this update and endorsed the letters and next steps.

7. Product development support

7.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

7.1.1. Appointment of CHMP peer review for SA

Action: For information

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

7.2. Innovation Task Force

7.2.1. ITF meeting

Meeting date: 21 April 2021

Action: For adoption

CHMP endorsed the meeting.

7.2.2. ITF meeting

Meeting date: 23 April 2021

Action: For adoption

CHMP endorsed the meeting.

7.2.3. ITF meeting

Meeting date: 28 April 2021

Action: For adoption

CHMP endorsed the meeting.

8. Product related topics

8.1.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

Preview of CHMP plenary.

8.1.2. 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 list of currently COVID-19 ongoing and upcoming procedures

8.1.3. zanubrutinib - Orphan - EMEA/H/C/004978

BeiGene Ireland Ltd; treatment of Waldenström's macroglobulinaemia (WM)

Scope: Update on the status of this application

Action: For information

CHMP was updated with the status of this procedure.

8.1.4. evinacumab - EMEA/H/C/005449

treatment of homozygous familial hypercholesterolemia (HoFH)

Scope: Update on the status of this application

Action: For information

CHMP was updated with the status of this procedure.

9. Any Other Business

9.1.1. Data Standards Strategy survey and workshop

As announced at the EU big data stakeholder virtual forum in December 2020, one of the 10 priority recommendations of the HMA-EMA joint Big Data Task Force (BDTF) is to engage in international initiatives related to data standardisation. This will be critical to realise the full potential of big data to drive regulatory evaluations. With a view to address these BDTF recommendations, the Big Data Steering Group has launched an initiative to develop a **Data Standards Strategy** that will enable the Network to more effectively leverage data to deliver evidence in support of benefit-risk decision-making on the development, authorisation and use of medicines.

Action: For discussion

CHMP noted Data Standards Strategy survey and workshop.

9.1.2. Results of EMA study on RWE in marketing authorisation applications and extensions of indication

EMA has studied the use of real-world data (RWD) to support centralised MAA and extensions of indication submitted in 2018 and 2019. The primary objective of this study is to characterise RWD/RWE and its contribution to benefit-risk decision-making.

Action: For discussion

CHMP was briefed on methodology and result of EMA study on RWE in marketing authorisation applications and extensions of indication submitted in 2018 and 2019.

9.1.3. Aspects that influence the communication of safety issues

Presentation on the aspects that influence the communication of safety issues with the aim to get insight into which aspects are relevant for regulators in the decision to communicate about safety issues.

CHMP: Hans Hillege

Action: For discussion

CHMP noted the initiative to determine the Aspects that influence the communication of safety issues. CHMP members were invited to participate in an online survey regarding this initiative.

10. 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	
Andrea Laslop	Member	Austria	No interests declared	
Daniela Philadelphy	Alternate	Austria	No interests declared	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Ilko Getov	Member	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Kirstine Moll Harboe	Alternate	Denmark	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	
Konstantinos Markopoulos	Member	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Kolbeinn Gudmundsson	Member	Iceland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jayne Crowe	Member	Ireland	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No participation in final deliberations and voting on	Covid-19
Simona Stankeviciute	Alternate	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
Carola de Beaufort	Alternate	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Ingrid Wang	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 participation in final deliberations and voting on	Covid-19
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No restrictions applicable to this meeting	
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	
Christian Gartner	Co-opted member	Austria	No restrictions applicable to this meeting	
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	
Jan Willem van der Laan	Expert - via Webex*	Netherlands	No interests declared	
Erika Fredriksson	Expert - via Webex*	Sweden	No interests declared	
Anja Schiel	Expert - via Webex*	Norway	No interests declared	
Michal Zwiewka	Expert - via Webex*	Germany	No interests declared	
Conception Gimenez Rebollo	Expert - via Webex*	Spain	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Valerie Lescrainier	Expert - via Webex*	Belgium	No interests declared	
Deirdre Mannion	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert - via Webex*	Spain	No restrictions applicable to this meeting	
Nora Cascante Estepa	Expert - via Webex*	Germany	No interests declared	
Susanne Høpner Rasmussen	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	

Dis *Experts were evaluated against the product(s) they have been invited to talk about