15 March 2021
EMA/CHMP/161669/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 15 March 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 March 2021, 09:30–14:30, 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 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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Table of contents

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 15 March 2021 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of February 2021 meeting will be adopted at the March 2021 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

No topics

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings

CHMP: Outi Mäki-Ikola

Action: For discussion

CHMP endorsed learnings.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

No topics

3.2. Guideline Consistency Group (GCG)

No topics

3.3. Summary of product characteristics Advisory Group

No topics

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz/Nanna Aaby Kruse

4.1.1. Agenda and minutes

- Agenda of BWP meeting to be held by Adobe Connect on 15-17 March 2021
- Minutes of BWP meeting held by Adobe Connect on 18-20 January 2021

Action: For information

CHMP noted the Agenda and Minutes

4.2. Safety Working Party (SWP)

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

4.2.1. Agenda and minutes

- Draft agenda for SWP meeting in replacement of face-to-face to be held by Adobe Connect on 17-18 March 2021
- Final minutes for SWP meeting held by teleconference on 25 January 2021

Action: For information

CHMP noted Agenda and minutes

4.2.2. CMDh request to Safety Working Party (SWP) on acceptable intake for new nitrosamine (N-nitrosodiethanolamine (NDELA))

CMDh request to SWP on determination of acceptable intake for new nitrosamine. During ORGAM meeting in November 2020, the CHMP and CMDh adopted a generic question to the SWP which can be triggered when a "new nitrosamine" is identified without the need for adoption by CHMP.

Action: For information

CHMP noted CMDh request to Safety Working Party (SWP) on acceptable intake for new nitrosamine (N-nitrosodiethanolamine (NDELA)).

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

4.3.1. Call for nominations for BMWP Vice-Chair

The first mandate of the Vice-Chair Niklas Ekman expired in September 2020. The election is scheduled at the March CHMP Plenary meeting. Candidates were asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

One nomination was received.

Action: For information

CHMP noted call for nomination for BMWP and nominations received. The election is scheduled at the March CHMP Plenary meeting.

4.4. Biostatistics Working Party (BSWP)

Chair: Kit Roes

4.4.1. Call for nominations for BSWP Vice-Chair

The first mandate of the Vice-Chair Jörg Zinserling expired in January 2021. The election is scheduled at the March CHMP Plenary meeting. Candidates were asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

One nomination was received.

Action: For information

CHMP noted call for nomination for BSWP and nominations received. The election is scheduled at the March CHMP Plenary meeting.

4.4.2. Change to BSWP Composition

Philippe Zamia (FR) to step down as additional assessor. Proposal for nomination of an additional assessor (Bruno Delafont).

Action: For endorsement

CHMP endorsement of Bruno Delafont (FR) to replace Philippe Zamia (FR) as additional assessor.

4.5. Modelling and Simulation Working Party (MSWP)

No topics

4.6. Pharmacogenomics Working Party (PGWP)

No topics

4.7. Pharmacokinetics Working Party (PKWP)

No topics

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

5.1.1. Agendas

- Agenda of BPWP meeting held by teleconference on 11th March 2021
- Agenda for Blood cluster meeting to be held by teleconference on 19th March 2021

Action: For information

CHMP noted the Agenda.

5.2. Central Nervous System Working Party (CNSWP)

No topics

5.3. Cardiovascular Working Party (CVSWP)

No topics

5.4. Infectious Diseases Working Party (IDWP)

No topics

5.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

5.5.1. Agenda and minutes

- Agenda of ONCWP meeting held by teleconference on 11th March 2021
- Minutes of ONCWP meeting held by teleconference on 11th February 2021

Action: For information

CHMP noted the Agenda and minutes.

5.6. Rheumatology/Immunology Working Party (RIWP)

No topics

5.7. Vaccines Working Party (VWP)

No topics

5.8. Scientific Advisory Groups (SAGs)

6. Drafting groups

6.1. Excipients Drafting Group

No topics

6.2. Gastroenterology Drafting Group (GDG)

No topics

6.3. Geriatric Expert Group (GEG)

No topics

6.4. Radiopharmaceuticals Drafting Group (RadDG)

No topics

6.5. Respiratory Drafting Group (RDG)

No topics

7. Joint groups and collaboration with other committees

7.1. Quality Working Party (QWP)

Chair: Blanka Hirschlerova/Laivi Saaremäel

7.1.1. Minutes

- Minutes from QWP Core Team meeting held by Adobe Connect on 17 February 2021
- Minutes for QWP plenary meeting held by Adobe Connect on 14-16 December 2020

Action: For information

CHMP noted the Minutes.

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

No topics

7.3. 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

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

No topics

7.5. Collaboration with other committees

7.5.1. Committee for Advanced Therapies (CAT)

Chair: Martina Schüssler-Lenz

- Guideline on quality, non-clinical and clinical requirements for medicinal products containing genetically modified cells – Revision 1 (EMA/CAT/GTWP/671639/2008 Rev.1)

The Guideline was adopted by CAT in October 2020 and by CHMP during the November 2020 ORGAM meeting. In December 2020, comments were received from the ONCWP that necessitated an update of the Annex I (Clinical considerations for CAR-T cells). The updated Annex I to the guideline was adopted by CAT in January 2021.

Action: For adoption

CHMP adopted the Guideline on quality, non-clinical and clinical requirements for medicinal products containing genetically modified cells – Revision 1 (EMA/CAT/GTWP/671639/2008 Rev.1) with no further comments.

7.5.2. Pharmacovigilance Risk Assessment Committee (PRAC)

Chair: Sabine Straus

PRAC report to CHMP. Summary of recommendations and advice of PRAC meeting held on 08-11 March 2021

Action: For information

The CHMP noted the Summary of recommendations and advice.

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Outcome of the pilot of tailored biosimilar scientific advice

The outcome of the pilot of tailored scientific advice for biosimilars, which invited biosimilar developers to present extensive Quality and in vitro Non-Clinical data towards a tailored further development, is presented to the CHMP for information and for endorsement of the proposal to integrate such tailored scientific advice in regular SAWP operations. Towards this end, a minor update of the SAWP mandate updated scope of activities is also presented for adoption.

Action: For adoption

The proposal to integrate such tailored scientific advice in regular SAWP operations was endorsed by CHMP together with the update of point 31 of the SAWP mandate.

The CHMP requested that the committee is informed about any new scientific advice requests relating to a tailored biosimilar development proposal.

8.1.2. Appointment of CHMP peer review for Scientific Advice

Action: For information

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

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 19th March 2021

Action: For adoption

CHMP endorsed the meeting.

8.2.2. ITF meeting

Meeting date: 22nd March 2021

Action: For adoption

CHMP endorsed the meeting.

8.2.3. ITF meeting

Meeting date: 29th March 2021

Action: For adoption

CHMP endorsed the meeting.

9. Any Other Business

9.1.1. EMA draft pregnancy strategy

Since July 2020 EMA has started the international collaboration on building an infrastructure for drug safety in pregnancy studies (building on the work initiated for COVID & pregnancy), held a stakeholders workshop and published the report from this (available at https://www.ema.europa.eu/en/documents/report/report-workshop-benefit-risk-medicines-used-during-pregnancy-breastfeeding_en.pdf)

The presentation will give an update on what is done to further develop and implement the strategy and to obtain feedback on CHMP needs in this space.

Action: For discussion

CHMP noted developments on the activities related to the EMA draft pregnancy strategy aiming at improving information on B/R of medicine use in pregnancy & breastfeeding.

9.1.2. WebEx rollout plan for CHMP

Update to the CHMP on Webex rollout strategy

Action: For discussion

CHMP noted the upcoming rollout of Webex and next steps for implementation by the CHMP. CHMP plenary in May 2021 will be conducted using Webex.

9.1.3. Revised PROM Agenda template

Adaptation of the PROM agenda template following transition from ORGAM meeting

Action: For information

CHMP noted the revised PROM Agenda template.

9.1.4. Type II variations discussed at CHMP plenary

Type II variations discussed at the CHMP plenary: following topic presented in 2019 at CHMP ORGAM meetings (May and November), a proposal is presented to CHMP for endorsement on the type of variations discussed by default in the CHMP plenary.

Action: For endorsement

CHMP endorsed the type of Type II variations to be discussed at the CHMP plenary by default.

9.1.5. In vitro diagnostic regulation implementation for CDx–update on discussions with Notified Bodies and legacy IVDs

The IVDR will become fully effective as of 26 May 2022 and notified bodies need to seek a scientific opinion on the "suitability" of the device (CDx) in relation to the medicinal product concerned from a medicine authority/EMA. Proposal to ask interested CHMP members and/or assessors to join informal discussions with NBs to understand each other's requirements.

Action: For information

CHMP noted the progress on In vitro diagnostic regulation implementation for CDx and noted the update on discussions with Notified Bodies on legacy IVDs. CHMP members were invited to join a working group with NBs to discuss/understand the data required for conformity assessment of the IVD-CDx which will also form the basis of the scientific opinion required as part of the consultation procedure with NBs on CDx. EMA will continue dialogue to finalise draft procedural guidance and present to CHMP in due course. Kick-off meeting is planned towards end of April. CHMP also discussed the importance of regularly updating the CHMP committee on the progress of this initiative by participating members.

9.1.6. Call for interest for nomination of CHMP members to join temporary ad-hoc group on Lifecycle Regulatory Submissions Raw Data

Call for interest for nomination of CHMP members to join temporary ad-hoc group on raw data.

EMA's Lifecycle Regulatory Submissions Raw Data project is focusing on utilising raw data to generate evidence for better and more efficient regulatory decision making.

This project is part of the Data Analytics Programme also known as the Agency's vehicle for evolving to data-driven medicines regulation and constitutes one of the priority recommendations of the EMA-HMA Big Data Taskforce.

Action: For information

CHMP noted call for interest for nomination of CHMP members to join temporary ad-hoc group on raw data to generate evidence for better and more efficient regulatory decision making. CHMP requested to keep the Committee updated on the developments performed by this group. CHMP also stressed the importance of creating templates focused on drafting a brief outline of a prespecified raw data assessment process, expressing the research question, intended patient population, rationale for analysis and methods, intercurrent event strategy, degree of alpha-level control, methodological uncertainties and expected timelines, with the possibility of this ad-hoc templates to be shared with the company.

Interested members should contact directly by 22 March 2021.

9.1.7. New COVID application tracker

To improve oversight of ongoing and upcoming COVID-19 applications, EMA is introducing a tracking table. The table will be updated on a regular basis and brief updates will be provided at each PROM meeting.

Action: For information

CHMP noted new COVID application tracker

9.1.8. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

Preview of CHMP plenary. CHMP chair flagged some procedures for adoption in the upcoming plenary for possibly extended discussion. CHMP members involved or particularly interested in these procedures were encouraged to discuss in advance before the plenary meeting.

9.1.9. satralizumab - Orphan - EMEA/H/C/004788

Roche Registration GmbH; treatment of adult and adolescent patients from 12 years of age with neuromyelitis optica spectrum disorders (NMOSD).

Scope: Update on the status of this application.

Action: For discussion

CHMP was updated on the status of this application.

10. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on the genda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Christian Gartner	Co-opted member	Austria	No restrictions applicable to this meeting	
Daniela Philadelphy	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Ilko Getov	Member	Bulgaria	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Tomas Radimersky	Alternate	Czechia	No interests declared	
Kirstine Moll Harboe	Alternate	Denmark	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Janet Koenig	Alternate	Germany	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Konstantinos Markopoulos	Member	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Simona Stankeviciute	Alternate	Lithuania	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Bjorg Bolstad	Member	Norway	No restrictions applicable to this meeting	
Ingrid Wang	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on	COVID-19 vaccines
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Simona Badoi	Member	Romania	No interests declared	

Dorota Distlerova	Alternate	Slovakia	No restrictions applicable to this meeting	
Francisek Drafi	Member	Slovakia	No interests declared	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with the help of EMA staff				

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