



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 November 2020
EMA/CHMP/586023/2020 Rev. 1
Human Medicines Division

Committee for medicinal products for human use (CHMP) CHMP ORGAM¹ minutes for the meeting on 3 November 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

03 November 2020, 09:30–13:30, room 09-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 ORGAM is a meeting to discuss CHMP organisational matters. 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 ORGAM topics can be discussed at the CHMP Plenary. Please note that the ORGAM meeting is not taking place every month.

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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 CHMP ORGAM agenda for 03 November 2020 meeting.

1.3. Adoption of the minutes

CHMP Orgam Minutes of November 2020 meeting will be adopted at the November 2020 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

Process to collect and record CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For endorsement

The CHMP endorsed learnings.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

No topics

3.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

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

No topics

4.1.1. Agenda(s) and minutes

- Final minutes for BWP meeting held by Adobe Connect on 07-09 September 2020
- Draft agenda for BWP meeting to be held by Adobe Connect on 03-05 November 2020

Action: For information

The 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(s) and minutes

- Final minutes for SWP meeting held by teleconference on 14 September 2020

Action: For information

4.2.2. Requests from EDQM and URPL to CHMP on Colistimethate powder for injection

The European Pharmacopoeia Group of Experts 7 addressed a request to CHMP on Colistimethate sodium (CMS) powder for injection.

Polish Agency (URPL) request to the EMA Executive Director to consider asking CHMP for an opinion on the need to further amend the European Pharmacopoeia monograph on CMS.

Action: For confirmation

CHMP noted the request from EDQM to provide a response to define the safe range for the composition profile (degree of sulfomethylation) for Colistimethate sodium (CMS) powder for injection, and the letter from the Polish Agency (URPL) to the EMA Executive Director.

4.2.3. CHMP/CMDh request to Safety Working Party (SWP) on acceptable intake for new nitrosamine

CHMP/CMDh requests to SWP on determination of acceptable intake for new nitrosamine based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

The CHMP adopted CHMP/CMDh request to Safety Working Party (SWP) on acceptable intake for new nitrosamine with no additional comments.

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz/Niklas Ekman

4.3.1. Draft Biosimilar Guideline by MHRA

[MHRA guideline](#) on requirements for the biosimilars development and the main difference compared to EU guidance in the area of confirmatory efficacy trials

Presenter: Elena Wolff-Holtz

Action: For information

The CHMP noted the [MHRA guideline](#) on requirements for the biosimilars development. There are major differences compared to EU guidance in the area of confirmatory efficacy trials.

4.4. Biostatistics Working Party (BSWP)

Chairs: Kit Roes/Jörg Zinserling

No topics

4.5. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

No topics

4.6. Pharmacogenomics Working Party (PGWP)

Chair: Markus Paulmichl

No topics

4.7. Pharmacokinetics Working Party (PKWP)

Chair: Henrike Potthast

4.7.1. Product-specific guidelines

Final product-specific guidelines (revision)

- Abiraterone tablets 250 mg and 500 mg product-specific bioequivalence guidance (EMA/CHMP/474712/2016 Rev. 1) and Overview of comments

Action: For adoption

The CHMP adopted the Final-Product specific bioequivalence guideline for Abiraterone tablets 250 mg and 500 mg following approval of a new 500 mg strength.

Draft product-specific guidelines (revision)

- Palbociclib hard capsule 75 mg, 100 mg and 125 mg and film-coated tablet 75 mg, 100 mg and 125 mg product-specific bioequivalence guidance (EMA/CHMP/586023/2020/Rev.1)

Action: For adoption

The CHMP adopted the draft Palbociclib product-specific bioequivalence guideline to undertake public consultation.

Overview of comments

- Overview of comments (from first consultation 27 June 2018 to 30 September 2018) for Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance (EMA/CHMP/257298/2018) (second public consultation ended 30 October 2020).
Proposal to publish draft overview now and to extend public consultation by 2 months.

Action: For information

The CHMP noted the extension of deadline for consultation by two months of draft Lapatinib 250 mg film-coated tablet product-specific bioequivalence guideline and to publish draft overview of comments received during first consultation of the guidance undertaken in 2018 with no additional comments.

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

5.1.1. Blood cluster TC on 17th July 2020

- Final minutes of the blood cluster TC held on 17th July

Action: For information

The CHMP noted the minutes.

5.1.2. Blood cluster TC on 23rd October 2020

- Draft agenda of the blood cluster TC 23rd October

Action: For information

The CHMP noted the agenda.

5.1.3. PPTA/IPFA letter on regulatory flexibility relief for EMA PMF process

- Letter received from PPTA/IPFA dated 28th July 2020
- EMA response to PPTA/IPFA

Action: For information

The CHMP noted letter received from PPTA/IPFA dated 28th July 2020 and EMA response to PPTA/IPFA.

5.2. Central Nervous System Working Party (CNSWP)

Chair: André Elferink

No topics

5.3. Cardiovascular Working Party (CVSWP)

Chairs: Kristina Dunder/Alar Irs

No topics

5.4. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

No topics

5.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

5.5.1. Agenda(s) and minutes

- Final minutes for ONCWP held by Adobe Connect on 23 September 2020
- Final agenda for ONCWP meeting held by Adobe Connect on 22 October 2020

Action: For information

The CHMP noted the Agenda and Minutes.

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair: Romaldas Mačiulaitis

No topics

5.7. Vaccines Working Party (VWP)

Chair: Mair Powell

No topics

5.8. Scientific Advisory Groups (SAGs)

No topics

6. Drafting groups

6.1. Excipients Drafting Group

Chair(s): Vacant

No topics

6.2. Gastroenterology Drafting Group (GDG)

Chair(s): Vacant

No topics

6.3. Geriatric Expert Group (GEG)

Chair(s): Vacant

No topics

6.4. Radiopharmaceuticals Drafting Group (RadDG)

Chair(s): Vacant

No topics

6.5. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No topics

7. Joint groups and collaboration with other committees

7.1. Quality Working Party (QWP)

Chairs: Blanka Hirschlerova/Laivi Saaremäel

7.1.1. Agenda(s) and minutes

- Final minutes for 91st meeting held by teleconference on 5-6 February 2020
- Final minutes for 92nd meeting held by teleconference on 4-6 May 2020

Action: For information

The CHMP noted the minutes.

7.1.2. Nomination of members/alternates

Nomination of new QWP alternate.

Action: for endorsement

The CHMP endorsed the nomination of Bart Denayer to replace René Hanselaer as QWP alternate for Belgium.

7.1.3. QWP Core Team

- Agenda and minutes from October 2020 QWP CT meeting

Action: For information

The CHMP noted the agenda and minutes.

7.1.4. 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.

Action: For adoption

The CHMP adopted CMDh question to QWP on applicability of Q5 to intermediate manufacturers with no further comments.

7.1.5. CMDh question to QWP on extrapolation of stability data

CMDh question to QWP on extension of shelf-life of the finished product or retest period of the active substance via extrapolation of stability data.

Action: For adoption

The CHMP adopted CMDh question to QWP on extension of shelf-life of the finished product or retest period of the active substance via extrapolation of stability data with no further comments.

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

PCWP: Co-chair: Kaisa Immonen Co-chair: Juan Garcia Burgos (EMA)

HCPWP: Co-chair: Ulrich Jaeger Co-chair: Juan Garcia Burgos (EMA)

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)**

Chairs: Ellen-Margrethe Vestergaard/Susanne Brendler-Schwaab

No topics

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

Chair: Nienke Rodenhuis

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)

Action: for adoption

The committee adopted the guideline 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 additional comments.

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Call for interest for nomination of member and alternate

Call for interest for nomination of a replacement SAWP member and his/her alternate.

Required area of expertise:

- Rheumatology/ immunology
- General medicine/ clinical pharmacology
- Haematology

The letters of candidacy together with the CVs of both member and alternate, as per the [SAWP Rules of Procedure](#), should be sent directly to the SAWP Secretariat by **23 November 2020**

Action: For information

The CHMP noted the call for interest for nomination of member and alternate.

8.2. Innovation Task Force

8.2.1. ITF meeting

Action: For adoption

The meeting was endorsed.

8.2.2. ITF meeting

Action: For adoption

The meeting was endorsed.

9. Any Other Business

9.1.1. CHMP Work Plan 2020 – Status Report

Update on the progress of the 2020 CHMP Work Plan.

Action: For information

The CHMP noted the report on progress of the 2020 CHMP Work Plan and next steps for preparation of 2021 Work Plan

9.1.2. (Re)nomination of CHMP representative for ENCePP Steering Group 2021-2023

Discussion on nomination of a CHMP representative as part of ENCePP Steering Group (SG) for the period 2021-2023 following end of mandate for current member Johann Lodewijk Hillege

Action: For discussion

Nominations should be sent to the ENCePP Secretariat **by 13 November 2020.**

The CHMP noted the nomination process.

9.1.3. Big Data Training Signpost

Introduction to Big Data Training Signpost as a collection of external training courses on Big Data skills as a previous step to Big Data curriculum.

Action: For information

The CHMP noted this initiative with no further comments

9.1.4. Discussion on CHMP co-opted memberships

- Discussion on area of expertise in light of Koenraad Norga's resignation as CHMP co-opted member as of 30 September 2020 following proposals received.

Action: For discussion

The CHMP discussed the area of expertise for the co-opted member and agreed on "Pharmaco-Epidemiology; especially for methodology (bias, effect modifications, etc.) and interpretation of data, in particular study designs (observational studies, RWD, etc.), strengths and weaknesses".

- Update on call for nomination of CHMP co-opted member in light of the end of the mandate of Jan Mueller-Berghaus as co-opted member on 13 November 2020.

Action: For discussion

The CHMP noted nominations received following deadline for submission of nominations. Election CHMP co-opted member in light of the end of the mandate of Jan Mueller-Berghaus as co-opted member on 13 November 2020 will take place during November CHMP plenary.

9.1.5. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

The CHMP discussed organisational matters regarding the CHMP plenary.

9.1.6. Invitation to participate in a MCDA (Multi Criteria Decision Analysis) exercise for benefit risk

CHMP: Johann Lodewijk Hillege

Action: For information

This topic was postponed.

9.1.7. IRIS implementation in Scientific Advice Procedures

Update to CHMP on implementation of IRIS system in Scientific.

Action: For information

This topic was postponed.

10. List of Participants

CHMP Chair

Harald Enzmann

CHMP Members

Bruno Sepodes (Vice-chair)

Alar Irs

Andrea Laslop

Armando Genazzani

Bjorg Bolstad

Christian Gartner

Christophe Focke

Elita Poplavska

Ewa Balkowiec Iskra

Frantisek Drafi

Ilko Getov

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

John Joseph Borg

Konstantinos Markopoulos

Kristina Dunder

Margareta Bego

Maria Concepcion Prieto Yerro

Martina Weise

Martine Trauffer

Outi Mäki-Ikola

Simona Badoi

Sinan B. Sarac

CHMP alternate members

Agnes Gyurasics

Blanca Garcia-Ochoa

Dana Gabriela Marin

Dorota Distlerova
Edward Laane
Emilia Mavrokordatou
Fátima Ventura
Filip Josephson
Hrefna Gudmundsdottir
Ingrid Wang
Janet Koenig
Jean-Michel Race
Karin Janssen van Doorn
Kristine Moll Harboe
Milena Stain
Nevenka Trsinar Brodt
Paula van Hennik
Simona Stankeviciute
Tomas Radimersky

Experts

Alfredo García-Arieta
Elena Wolff-Holz
Erika Fredriksson
Irene Bachmann
Jan Willem van der Laan
Johanna Lähteenvu
Karri Penttila
Laivi Saaremäel
Maria Victoria Tudanca Pacios
Martina Schussler-Lenz
Milena Peraita Ezcurra
Niklas Ekman
Nora Cascante Estepa
Sabine Mayrhofer
Susanne Høpner Rasmussen

The meeting was run with support from the relevant EMA staff.