08 October 2020
EMA/526005/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 5th October 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

05 October 2020, 09:30–13:30, room 9-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

CHMP ORGAM agenda for 05 October 2020 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of October 2020 meeting will be adopted at the October 2020 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

CHMP: Outi Mäki-Ikola

Action: For discussion

The topic was postponed.

2.2.2. Organisation of future virtual CHMP meetings

CHMP: Harald Enzmann

Action: For discussion

The CHMP was presented with the issue of long virtual meeting running for four consecutive days with long hours. This is attributed to an increased CHMP workload derived from the build-up of CAPs over time and more complex procedures resulting in the need for additional cooperation with internal and external stakeholders. Different options on meeting organisation were proposed.

2.2.3. CHMP meeting dates for the period 2022-2024

Action: For adoption

A proposed calendar including CHMP meeting dates for the period 2022-2024 was presented. Additional discussion on the meeting dates is needed and the topic will be brought in upcoming CHMP ORGAM meetings.

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

4.1.1. Agenda(s) and minutes

- Final minutes for BWP meeting held virtually on 13-15 July 2020
- Draft agenda for BWP meeting to be held virtually on 5-8 October 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 virtually on 20 July 2020

Action: For information

The CHMP noted the minutes.

4.2.2. Response to CMDh questions on Chlorobutanol

Action: For adoption

Response to CMDh questions triggered by renewal procedure. The CHMP adopted the response from SWP to CMDh.

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz/Niklas Ekman

4.3.1. Template for Master Biosimilar Product Guidance

- Presentation of planned template
- Discuss what is best process to obtain input from other experts/Working Parties/Committees

Action: For discussion

The CHMP was presented with a template for Master Biosimilar Product Guidance which aims to provide guidance for Assessors involved in Scientific advice procedures on how to answer frequently asked questions on a particular Biosimilar product (candidate). This will also ensure consistency in answering these questions.

The template shall be a compendium of all (pre-)clinical aspects addressed in the past including a summary table of previous SA procedures.

In addition, it should be a platform to challenge current scientific thinking/guidelines in the biosimilar area, where appropriate.

CHMP noted the value of this proposal and agreed to support the development of the guidance.

4.4. Biostatistics Working Party (BSWP)

Chairs: Kit Roes/Jörg Zinserling

4.4.1. Call for drafting group participants

Call for drafting group participants in reflection paper on the importance of randomisation for confirmatory evidence.

Action: For information

The CHMP noted the progress on the first draft of the reflection paper on the importance of randomisation for confirmatory evidence.

4.4.2. BSWP response to CAT questions on the Guideline on quality, non-clinical and clinical requirements for medicines containing genetically modified cells

During the consultation of the guideline consistency group (GCG), it was proposed to consult the BSWP on the clinical efficacy section (statement on target of estimation; alignment with ICH E9(R1) on estimation and sensitivity analysis).

Action: For adoption

The CHMP endorsed the proposal.

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)

Chairs: Henrike Potthast/Carolien Versantvoort

4.7.1. Product-specific guidelines

Draft product-specific guidelines

- acenocoumarol product-specific bioequivalence guidance

Action: For adoption for public consultation

The CHMP adopted the draft Acenocoumarol product-specific bioequivalence guideline with no additional comments.

Final product-specific guidelines

- Dasatinib product-specific bioequivalence guidance and overview of comments

Action: For adoption

The CHMP adopted the final product-specific guideline.

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

No topics

5.2. Central Nervous System Working Party (CNSWP)

Chair(s): vacant

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. Guideline on the clinical evaluation of anticancer medicinal products

Anticancer products guideline – Revision 6.

Action: For adoption

The CHMP adopted Revision 6 of the Guideline on the clinical evaluation of anticancer medicinal products for release for 3 months' public consultation.

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. Reflection Paper on the pharmaceutical development of medicines for use in the older population

Final version updated following public consultation.

Action: For adoption

The CHMP adopted Reflection Paper on the pharmaceutical development of medicines for use in the older population.

7.1.2. QWP Core Team

Agenda and minutes from September QWP CT meeting.

Action: For information

The CHMP noted the agenda and minutes.

7.1.3. Nomination of new member

Nomination of new member in replacement of Marina Popescu.

Nomination of new alternate for PT.

Action: For endorsement

The CHMP endorsed the nomination of Carmen Purdel in replacement of Marina Popescu as QWP member for Romania and Tiago Vistulo de Abreu as alternate for Portugal.

7.1.4. QWP response to CMDh – vancomycin strength

Action: For adoption

Following receipt of the letter from CMDh, the QWP discussed their question on a possible correction of the expression of strength of Vancomycin products and provided a response. The CHMP adopted the response from SWP to CMDh.

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

No topics

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

No topics

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 15 October 2020

Action: For adoption

The meeting was endorsed.

8.2.2. ITF meeting

Meeting date: 23 October 2020

Action: For adoption

The meeting was endorsed.

9. Any Other Business

9.1.1. Name Review Group (NRG)

NRG naming proposal

Action: For adoption

NRG naming proposal was adopted.

9.1.2. Presentation on EMA`s strategy for vaccines outreach

Presentation on EMA`s strategy for vaccines outreach.

Action: For information

EMA presented the vaccines outreach strategy with the aim to increase knowledge of and trust in the quality, safety and effectiveness of vaccines, and empower the EU public and healthcare professionals to take well-informed vaccination decisions.

9.1.3. Workshop on Guideline on registry-based studies

Action: For information

The CHMP noted the upcoming workshop on Guideline on registry-based studies.

9.1.4. Update of GVP XVI and new addendum II

Update of GVP XVI:

- Additional risk minimisation measures – selection of tools and effectiveness indicators
- Addendum II on methods for effectiveness
- evaluation

Action: For information

The CHMP noted the updated on GVP XVI and new addendum II.

9.1.5. Discussion on CHMP co-opted membership

Following resignation of Koen Norga as CHMP co-opted member, discussion on the nomination process of a new co-opted member.

Action: For Discussion

CHMP co-opted member Koenrad Norga resigned in September 2020. Consequently, the CHMP Quorum is now set at 21 members and majority set at 16; quorum for remote meetings under COVID is set at 16. The CHMP should discuss and agree of area of expertise needed with regards to the vacant seat at their November CHMP ORGAM.

The members were asked to send suggestions on the required area of expertise for discussion in November.

9.1.6. Clarification on authorised indication of melanoma products

CHMP letter to third party on clarification regarding the authorised indication of melanoma products.

CHMP: Harald Enzmann

Action: For information

CHMP noted the letter to third party on clarification regarding the authorised indication of melanoma products and requested additional discussion during the upcoming October CHMP plenary meeting.

9.1.7. Collaboration with other committees - COMP

CHMP: Bruno Sepodes

Following resignation of Bruno Sepodes as member of the COMP committee nominated by EC on recommendation of the EMA, the CHMP discussed options for keeping the collaboration with COMP.

10. List of Participants

CHMP Chair

Harald Enzmann

CHMP Members

Bruno Sepodes (Vice-chair)

Andrea Laslop

Armando Genazzani

Bjorg Bolstad

Blanka Hirschlerova

Christian Gartner

Christophe Focke

Elita Poplavska

Ewa Balkowiec Iskra

Frantisek Drafi

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

John Joseph Borg

Konstantinos Markopoulos

Kristina Dunder

Maria Concepcion Prieto Yerro

Martina Weise

Outi Mäki-Ikola

Sinan B. Sarac

CHMP alternate members

Agnes Gyurasics

Dana Gabriela Marin

Dorota Distlerova

Edward Laane

Emilia Mavrokordatou

Fátima Ventura

Ingrid Wang

Janet Koenig

Karin Janssen van Doorn

Kristine Moll Harboe

Milena Stain

Nevenka Trsinar Brodt

Selma Arapovic Dzakula

Simona Stankeviciute

Tomas Radimersky

Experts

Anja Schiel

Bodo Haas

Carolien Versantvoort

Christian B. (Kit) Roes

Elena Wolff-Holz

Janet Mifsud

Kristina Bech Jensen

Maria Victoria Tudanca Pacios

Martina Schussler-Lenz

Michal Zwiewka

Nora Cascante Estepa

Sabine Mayrhofer

Susanne Brendler-Schwaab

A representative from the European Commission attended the meeting.

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