22 October 2020
EMA/534390/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP)

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

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

05 October 2020, 09:30–13:30, virtual meeting/ 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

No topics

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

CHMP: Outi Mäki-Ikola

Action: For discussion

2.2.2. Organisation of future virtual CHMP meetings

CHMP: Harald Enzmann

Action: For discussion

2.2.3. CHMP meeting dates for the period 2022-2024

Action: For adoption

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

Chair(s): TBC

No topics

3.2. Guideline Consistency Group (GCG)

Chair(s): Aranzazu Sancho-Lopez

No topics

3.3. Summary of product characteristics Advisory Group

Chair(s): TBC

No topics

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chair(s): 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

4.2. Safety Working Party (SWP)

Chair(s): 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

4.2.2. Response to CMDh questions on Chlorobutanol

Action: For adoption

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair(s): 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

4.4. Biostatistics Working Party (BSWP)

Chair(s): 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

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

Action: For adoption

4.5. Modelling and Simulation Working Party (MSWP)

Chair(s): Kristin Karlsson/Flora Musuamba Tshinanu

No topics

4.6. Pharmacogenomics Working Party (PGWP)

Chair(s): Markus Paulmichl

No topics

4.7. Pharmacokinetics Working Party (PKWP)

Chair(s): Henrike Potthast

4.7.1. Product-specific guidelines

Draft product-specific guidelines

- Acenocoumarol product-specific bioequivalence guidance

Action: For adoption for public consultation

Final product-specific guidelines

- Dasatinib product-specific bioequivalence guidance and overview of comments

Action: For adoption

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

No topics

5.2. Central Nervous System Working Party (CNSWP)

Chair(s): Karl Broich

No topics

5.3. Cardiovascular Working Party (CVSWP)

Chair(s): Kristina Dunder/Alar Irs

No topics

5.4. Infectious Diseases Working Party (IDWP)

Chair(s): Maria Jesus Fernandez Cortizo

No topics

5.5. Oncology Working Party (ONCWP)

Chair(s): 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

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair(s): Romaldas Mačiulaitis

No topics

5.7. Vaccines Working Party (VWP)

Chair(s): Mair Powell

No topics

5.8. Scientific Advisory Groups (SAGs)

Chair(s): TBC

No topics

6. Drafting groups

6.1. Excipients Drafting Group

Chair(s): TBC

No topics

6.2. Gastroenterology Drafting Group (GDG)

Chair(s): TBC

No topics

6.3. Geriatric Expert Group (GEG)

Chair(s): TBC

No topics

6.4. Radiopharmaceuticals Drafting Group (RadDG)

Chair: Anabel Cortes Blanco

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)

Chair(s): Blanka Hirschlerova

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

7.1.2. QWP Core Team

Agenda and minutes from September QWP CT meeting

Action: For information

7.1.3. Nomination of new member

Nomination of new members

Action: For endorsement

7.1.4. QWP response to CMDh – vancomycin strength

Action: For adoption

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)

Chair(s): 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

Chair(s): TBC

No topics

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair(s): Anja Schiel

8.1.1. Appointment of CHMP peer review for SA

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 15 October 2020

Action: For adoption

8.2.2. ITF meeting

Meeting date: 23 October 2020

Action: For adoption

9. Any Other Business

9.1.1. Name Review Group (NRG)

NRG naming proposal

Action: For adoption

9.1.2. Presentation on EMA's strategy for vaccines outreach

Presentation on EMA's strategy for vaccines outreach

Action: For information

9.1.3. Workshop on Guideline on registry-based studies

Action: For information

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

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