15 May 2020
EMA/CHMP/54387/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 18 May 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

18 May 2020, 09:30–12:30, virtual meeting

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 18 May 2020 meeting

1.3. Adoption of the minutes

CHMP ORGAM Minutes of May 2020 meeting will be adopted at the May 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 discussion

2.2.2. Rapporteurs assessment report template- similarity Revision

This template has been updated in order to integrate the guidance for assessors on similarity assessment (available in the CHMP welcome pack) to reach assessors more efficiently.

Action: For discussion

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

No topics

3.2. Guideline Consistency Group (GCG)

Chair(s): Aranzazu Sancho-Lopez

No topics

3.3. Summary of product characteristics Advisory Group

3.3.1. Scientific guidelines with SmPC recommendations

- List of Scientific guidelines with SmPC recommendations updated in May 2020 (EMA/813125/2012 rev. 6)

Action: For adoption

3.3.2. SmPC Advisory Group Members

- Update with new PRAC representatives

Action: For adoption

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 by Adobe meeting on 16-18 March 2020
- Draft agenda for BWP meeting to be held by Adobe meeting on 18-20 May 2020

Action: For information

4.2. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan/Susanne Brendler-Schwaab

No topics

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair(s): Elena Wolff-Holz/Niklas Ekman

4.3.1. Open call for nomination of a new member with clinical and/or PK expertise

Nominations have to be sent together with a CV and a brief motivation letter by 30 June 2020.

4.4. Biostatistics Working Party (BSWP)

Chair(s): Jörg Zinserling

No topics

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

Product-specific guidelines for public consultation

- Abiraterone tablets 250 mg and 500 mg product-specific bioequivalence guidance
- Levothyroxine tablets 12.5 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg (and additional strengths) and 200 mcg product-specific bioequivalence guidance

Action: For adoption

4.7.2. PKWP questions to QWP on levothyroxine product potency specifications

Action: For adoption

4.7.3. PKWP request for CVSWP input regarding acenocoumarol as Narrow Therapeutic Index drug

- Question from PKWP to CVSWP whether acenocoumarol as the basis for Product-Specific Bioequivalence Guidance (PSBG) should be considered a narrow therapeutic index drug

Action: For adoption

4.7.4. Response from PKWP to question from pharmaceutical industry association on biowaivers for additional strengths of immediate release fixed combinations

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): André Elferink

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

No topics

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)

No topics

6. Drafting groups

6.1. Excipients Drafting Group

No topics

6.2. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No topics

6.3. Geriatric Expert Group (GEG)

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. Agenda and minutes of April QWP Core Team meeting

Action: For information

7.1.2. Guideline on the quality of water for pharmaceutical use

- Revised Guideline on the quality of water for pharmaceutical use (EMA/CHMP/CVMP/QWP/496873/2018)
- Overview of comments received on the draft 'Guideline on the quality of water for pharmaceutical use' (EMA/CHMP/CVMP/QWP/230700/2020)

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)

Meeting Summary form the PCWP/HCPWP Joint meeting on 3-4 March 2020

Action: For information

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

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

8.1.2. CHMP digital therapeutics group

Action: For information

Presentation on the final draft of: *Questions and Answers - Qualification of digital technology-based methodologies to support approval of medicinal products.*

8.2. Innovation Task Force

8.2.1. Feedback from ITF meeting

Action: For discussion

8.2.2. ITF meeting

Meeting date: 5 June 2020

Action: For adoption

8.2.3. ITF meeting

Meeting date: 17 June 2020

Action: For adoption

8.2.4. ITF meeting

Meeting date: TBC 22 or 23 June 2020

Action: For adoption

8.2.5. ITF meeting

Meeting date: 24 June 2020

Action: For adoption

8.2.6. ITF meeting

Meeting date: 3 July 2020

Action: For adoption

9. Any Other Business

9.1.1. EMA H-Division organigram

Action: For information

10. List of Participants