



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 July 2020
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Human Medicines Division

Committee for medicinal products for human use (CHMP) ORGAM¹ agenda for the meeting on 13 July 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

13 July 2020, 09:30–12:30, room 09A

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 13 July 2020 meeting

1.3. Adoption of the minutes

CHMP ORGAM Minutes of July 2020 meeting will be adopted at the July 2020 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.1.1. 2020 GCP inspections strategy

Action: For adoption

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

CHMP: Outi Mäki-Ikola

Action: For discussion

2.2.2. Rapporteurs assessment report templates for initials

Revision of the following templates:

- Rapporteurs Assessment report on the claim of new active substance (NAS) status;
- Informed consent application - joint assessment report / list of questions / list of outstanding issues template.

Action: For discussion

2.2.3. CHMP Co-opted membership

The 3-year mandate for the CHMP co-opted member Jan Mueller-Berghaus ends on 13 November 2020. The CHMP should discuss and agree on the area of expertise needed at their September CHMP ORGAM.

Action: For information

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. ICH E14/S7B IWG Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential – Question and Answers

Step 2b

Action: For adoption for 3-month public consultation

3.2. Guideline Consistency Group (GCG)

Chair(s): Aranzazu Sancho-Lopez

No topics

3.3. Summary of product characteristics Advisory Group

3.3.1. Draft ONCWP/SmPC AG Mock-up of SmPC section 4.8 for anticancer medicines

Action: For discussion

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chair(s): Sol Ruiz/Nanna Aaby Kruse

No topics

4.1.1. Agenda(s) and minutes

- Final minutes for BWP meeting held by teleconference on 18-20 May 2020
- Draft agenda for BWP meeting to be held by teleconference on 13-15 July 2020

Action: For information

4.1.2. Nomination of new member and alternate

Nominations received for new Dutch member and alternate

Action: For endorsement

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. Nomination of new members

Nominations received following a call of interests for two new members with clinical and/or PK expertise launched in April 2020

Action: For endorsement

4.4. Biostatistics Working Party (BSWP)

Chair(s): Kit Roes/Jörg Zinserling

4.4.1. Importance of randomisation

Overview of comments received

Presentation by Kit Roes

Action: For discussion

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/Carolien Versantvoort

No topics

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): Vacant/Andre 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

5.5.1. Call for nomination of a new member with expertise in haematology

ONCWP is looking for a new member with expertise in haematology.

Nominations should be sent together with a CV and a brief motivation letter by 25 August 2020.

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair(s): Vacant/Romaldas Mačiulaitis

No topics

5.7. Vaccines Working Party (VWP)

Chair(s): Mair Powell

5.7.1. Nomination of new additional assessors

Action: For endorsement

5.8. Scientific Advisory Groups (SAGs)

No topics

6. Drafting groups

6.1. Excipients Drafting Group

Chair: Vacant

No topics

6.2. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No topics

6.3. Geriatric Expert Group (GEG)

Chair: Vacant

No topics

6.4. Radiopharmaceuticals Drafting Group (RadDG)

Chair: 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)

Chair(s): Blanka Hirschlerova/Laivi Saaremäel

7.1.1. QWP Core Team: June meeting Agenda and minutes

Action: For information

7.1.2. CMDh questions to QWP

CMDh questions to QWP on acceptability

Action: For endorsement

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

7.3.1. Agenda(s) and minutes

Action: For information

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. Final proposal for fostering collaboration between CHMP and COMP

Final proposal for fostering the scientific collaboration between CHMP and COMP taking into account comments from both Committees.

Action: For discussion

7.5.2. Fee waiver for protocol assistance by academia (COMP)

Link to [EMA website](#)

Action: For information

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: 23 July 2020

Action: For adoption

8.2.2. ITF meeting

Meeting date: 24 July 2020

Action: For adoption

9. Any Other Business

9.1.1. Update on ACCESS project (vACcine Covid-19 monitoring ReadinESS)

Action: For information

9.1.2. Name Review Group (NRG)

Presentation on NRG decisions on INN+ MAH naming proposals for insulin products

Action: For adoption

10. List of Participants