



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

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

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

13 July 2020, 09:30–12:30, room 09A, remotely

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 ORGAM agenda for 13 July 2020 meeting

1.3. Adoption of the minutes

The 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

The CHMP noted the 2020 GCP inspections strategy, which was already adopted by the GCP IWG. The strategy outlines alternative or complementary regulatory supervision approaches, which could be used exceptionally during the COVID-19 pandemic for the remaining period of 2020. In addition member states were invited to consider conducting national inspections of ongoing COVID-19 vaccine trials. EMA will collect information on such national GCP inspections. The CHMP adopted the strategy and noted that it will be for adoption at the CAT as a next step.

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP discussed the proposals and adopted the document with the agreed amendments.

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

The members noted the proposal to have a stand-alone assessment report on the claim of NAS status template throughout the initial MAA procedure. Furthermore, amendments were done to the informed consent application assessment report template to focus on module 1, to bring it in line with other assessment report templates and to clarify the roles of the different Rapporteurs. Members were asked to send comments by 31 August 2020. In case no major comments are received the templates are considered adopted. Otherwise another discussion will be scheduled at one of the next ORGAM meetings.

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 area of expertise needed at their September CHMP ORGAM.

Action: For information

The CHMP member noted the standard timetable.

Please send suggestions on the required area of expertise discussion in September.

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

The CHMP adopted the question and answer document for release 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

Following some concern raised of potential divergencies of section 4.8, especially for oncology products, the Oncology Working Party, together with the SmPC Advisory Group, developed guidance on the different parts of section 4.8. This mock-up was presented to the CHMP and it was discussed whether to use it internally for the day 10 review, have CHMP testing it in a pilot or whether to release it for public consultation as appendix to the

anticancer guideline. The CHMP in general supported the public consultation. However it was flagged that the CAT should be consulted and possibly separate guidance for ATMPs needs to be developed.

The CHMP was asked to send comments on the draft mock-up and to come back at the September CHMP ORGAM.

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

Action: For information

The agenda and minutes were noted.

4.1.2. Nomination of new member and alternate

Nominations received for new Dutch member and alternate

The CHMP endorsed Martijn van der Plas as new member and Marcel Hoefnagel as new alternate from the Netherlands to the BWP.

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

The CHMP appointed Henrik Wahlstrom and Rene Anour as new members of the BMWP.

4.3.2. Nomination of new additional assessor

Action: For endorsement

The CHMP endorsed Pavel Simek (CZ) as new additional assessor, replacing Tereza Bazantova in this role.

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

The CHMP noted the draft reflection paper on the importance of randomisation for confirmatory evidence. Members were asked to provide comments **until 23 July 2020 EOB**.

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**.

The CHMP noted the call for nominations for a new member.

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

The CHMP endorsed the nomination of Kateřina Pospíšilová (CZ) and Violette Dirix (BE) as new additional assessors.

The CHMP endorsed the nomination of as observer.

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: Vacant

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

The agenda and minutes were noted.

7.1.2. CMDh questions to QWP

CMDh questions to QWP on acceptability

Action: For endorsement

The CHMP endorsed the QWP consultation.

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

The agenda and minutes were noted.

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

Following discussions at the January 2020 ORGAM, the CHMP was reminded of the concrete steps to increase collaboration between CHMP and COMP through early exchange of information. Further proposals were made to proactively share the COMP assessment with the CHMP Rapporteurs and to include PRIME and derogation claims in case of orphan similarity in the scope. The members noted that EMA processes and templates have been updated accordingly. Training to EMA PLs and orphan coordinators was planned. The processes will be further fine-tuned as needed. The CHMP endorsed the proposals.

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

Link to [EMA website](#)

Action: For information

The CHMP noted the update.

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair(s): Anja Schiel

No topics

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 23 July 2020

Action: For adoption

The meeting was endorsed.

8.2.2. ITF meeting

Meeting date: 24 July 2020

Action: For adoption

The meeting was endorsed.

9. Any Other Business

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

Action: For information

The CHMP welcomed the information.

9.1.2. Name Review Group (NRG)

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

Action: For adoption

Therefore the CHMP did not endorse the proposal but asked for more information and further discussion.

9.1.3 Joint QWP/CMDh/Inspectors/EDQM discussion group

Setting up a joint QWP/CMDh/Inspectors/EDQM discussion group to deal with a procedural issue with CEP versions and what is valid in the dossier. This mostly concerns NAPs/DCPs though some CAPs are impacted.

The CHMP endorsed the formation of a joint QWP/CMDh/Inspectors/EDQM discussion group.

10. List of Participants

CHMP Chair

Harald Enzmann

CHMP Members

Bruno Sepodes (Vice-chair)

Alexandre Moreau

Andrea Laslop

Blanka Hirschlerova

Christian Gartner

Ewa Balkowiec Iskra

Frantisek Drafi

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

John Joseph Borg

Kolbeinn Gudmundsson

Konstantinos Markopoulos

Maria Concepcion Prieto Yerro

Martine Trauffler

Melinda Sobor

Outi Mäki-Ikola

Sinan B. Sarac

CHMP alternate members

Agnes Gyurasics

Blanca Garcia-Ochoa

Christophe Focke

Dana Gabriela Marin

Elita Poplavska

Fátima Ventura

Filip Josephson

Giuseppa Pistritto

Ingrid Wang
Janet Koenig
Kristine Moll Harboe
Milena Stain
Paula van Hennik
Selma Arapovic Dzakula
Simona Stankeviciute
Tomas Radimersky

Experts

Adriana Andrić
André Elferink
Anja Schiel
Brigitte Schwarzer-Daum
Carin Bergquist
Christian B. (Kit) Roes
Clemens Mittmann
Cristina Migali
Elena Wolff-Holz
Joerg Zinserling
Johanna Wernsperger
Johannes Hendrikus Ovelgonne
Kristina Bech Jensen
Larissa Higgins
Linda Trauffer
Maria Victoria Tudanca Pacios
Milena Peraita Ezcurra
Noelia Fernández Bodas
Nora Cascante Estepa
Paolo Foggi
Peter Mol
Rosalía Ruano Camps
Serena Marchetti

A representative from the European Commission attended the meeting.

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