



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 June 2020
EMA/CHMP/56387/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP) ORGAM¹ minutes for the meeting on 15 June 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 June 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.



Table of contents

1.	Agenda and Minutes	4
1.1.	Welcome and declarations of interest of members, alternates and experts	4
1.2.	Adoption of agenda.....	4
1.3.	Adoption of the minutes	4
2.	Regulatory and organisational matters	4
2.1.	Regulatory Issues / new legislation	4
2.2.	CHMP organisation / templates	4
3.	Harmonisation and consistency groups	4
3.1.	International Council on Harmonisation (ICH)	4
3.2.	Guideline Consistency Group (GCG).....	5
3.3.	Summary of product characteristics Advisory Group	5
4.	Non therapeutic-area-specific working parties	5
4.1.	Biologics Working Party (BWP)	5
4.2.	Safety Working Party (SWP).....	6
4.3.	Biosimilar Medicinal Product Working Party (BMWP)	6
4.4.	Biostatistics Working Party (BSWP)	6
4.5.	Modelling and Simulation Working Party (MSWP)	7
4.6.	Pharmacogenomics Working Party (PGWP).....	7
4.7.	Pharmacokinetics Working Party (PKWP).....	7
5.	Therapeutic-area-specific working parties and SAGs	8
5.1.	Blood Products Working Party (BPWP).....	8
5.2.	Central Nervous System Working Party (CNSWP)	8
5.3.	Cardiovascular Working Party (CVSWP)	8
5.4.	Infectious Diseases Working Party (IDWP)	8
5.5.	Oncology Working Party (ONCWP)	8
5.6.	Rheumatology/Immunology Working Party (RIWP)	8
5.7.	Vaccines Working Party (VWP).....	9
5.8.	Scientific Advisory Groups (SAGs)	9
6.	Drafting groups	9
6.1.	Excipients Drafting Group.....	9
6.2.	Gastroenterology Drafting Group (GDG).....	9
6.3.	Geriatric Expert Group (GEG).....	9
6.4.	Radiopharmaceuticals Drafting Group (RadDG).....	9
6.5.	Respiratory Drafting Group (RDG).....	9

7.	Joint groups and collaboration with other committees	9
7.1.	Quality Working Party (QWP)	9
7.2.	Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)	10
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)	10
7.4.	Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)	10
7.5.	Collaboration with other committees.....	10
8.	Product development support	10
8.1.	Scientific Advice Working Party (SAWP).....	10
8.2.	Innovation Task Force	10
9.	Any Other Business	11
10.	List of Participants	11

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 15 June 2020 meeting

1.3. Adoption of the minutes

CHMP ORGAM Minutes of June 2020 meeting will be adopted at the June 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 adoption

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

2.2.2. Discussion on confidence intervals in labelling

Action: For discussion

The CHMP discussed the possibilities to include confidence intervals in the SmPC. The CHMP overall agreed to involve the BSWP in advising on the issue, but the framework needs to be further elaborated on.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. Nomination of experts for ICH groups

ICH Guideline Q9(R1) on quality risk management

Action: For adoption

3.1.2. ICH report from meeting in Vancouver (May 2020) – replaced by a virtual meeting

Report

Action: For adoption

The CHMP endorsed the report from the virtual ICH meeting.

3.1.3. ICH M7 Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk – Q&A

Step 2b

Action: For adoption for 3-month public consultation

The CHMP adopted the document 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. Scientific guidelines with SmPC recommendations

List of Scientific guidelines with SmPC recommendations updated in May 2020

Action: For adoption

The CHMP adopted the list of scientific guidelines.

3.3.2. SmPC Advisory Group Members

Update with new PRAC representatives

Action: For adoption

The CHMP endorsed the new members from PRAC (Adrien Inoubli and Željana Margan Koletić).

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 20-22 April 2020
- Draft agenda for BWP meeting to be held by teleconference on 15-17 June 2020

Action: For information

The minutes and agenda were noted.

4.2. Safety Working Party (SWP)

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

- Final minutes for SWP meeting held by teleconference on 23 March 2020

Action: For information

The minutes were noted.

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

BMWP is looking for a new member.

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

The CHMP noted the call for nominations.

4.4. Biostatistics Working Party (BSWP)

Chair(s): Jörg Zinserling

4.4.1. Change(s) to BSWP composition

Nomination received following a call of interest for a new member launched in February 2020

- Nomination(s) received

Action: For adoption

The CHMP endorsed Maria Grünwald (SE) as new member to the BSWP.

4.4.2. Election of the BSWP chair

- Nomination(s) received

The election will take place at the June 2020 CHMP plenary meeting.

Action: For information

The CHMP noted the nomination(s) received.

4.4.3. Training Curriculum on Biostatistics & Clinical Trial Methodology for regulators

- Presentation of training curriculum for statistical and non-statistical assessors in the EU network

- Priorities for 2020/2021 and launch of first training material in June 2020

Action: For adoption

The CHMP welcomed the proposal to establish a training curriculum on biostatistics and clinical trial methodology which will be established for different levels. The modules will be available through the EU NTC platform. The CHMP endorsed the members of steering committee as well as the proposed training priorities. Some modules already exist with further modules to be established in the next months and years.

4.4.4. Reflection paper on the importance of randomisation for confirmatory evidence

Action: For information

The CHMP noted the draft reflection paper. It was highlighted that the reflection paper will be an overarching document with separate sections or annexes for the different therapeutic areas to be added later. Members were asked to read the document and to provide comments. A presentation and further discussion are expected at the July ORGAM.

4.4.5. Points to consider on the impact of COVID-19 on methodological aspects of ongoing clinical trials

Action: For adoption

The CHMP was informed about the update of the document following the consultation phase. The CHMP adopted the document.

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

Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance

Action: For adoption for public consultation

The CHMP adopted the guidance for a second round of public consultation.

4.7.2. Overview of comments received on 'Guideline on the qualification and reporting of physiologically based pharmacokinetic (PBPK) modelling and simulation'

Action: For information

The CHMP was reminded that the guideline was published in December 2018 and noted the overview of comments.

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

5.1.1. Agenda(s) and minutes

- Final agenda BPWP TC 8 June 2020
- Draft minutes Blood cluster 3 April 2020

Action: For information

The minutes and agenda were noted.

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)

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(s) and minutes

Agendas and minutes from May QWP Core Team meeting

Action: For information

The minutes and agenda were noted.

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

No topics

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair(s): Anja Schiel

8.1.1. Change(s) to SAWP composition

Appointment of new SAWP member and alternate to replace Filip Josephson (SE)

- Proposed members

Action: For adoption

The CHMP endorsed Kristian Wennmalm as new SAWP member and Anders Lignell as new alternate to the SAWP.

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 17 July 2020

Action: For adoption

The meeting was endorsed.

8.2.2. ITF meeting

Meeting date: 20 July 2020

Action: For adoption

The meeting was endorsed.

9. Any Other Business

9.1.1. Guideline on registry-based studies

Action: For information

The members noted the draft guideline on registry-based studies with the scope to provide recommendations on key methodological aspects of registry-based studies and the relevant legal basis and regulatory requirements for MAAs/MAHs. Members were invited to send comments. A public consultation and possibly a stakeholder workshop are foreseen later this year.

9.1.2. Joint CHMP/SAWP Strategic Review and Learning Meeting under the Croatian EU presidency

To be held remotely on 17.06.2020

Action: For information

The members were invited to the remote Joint CHMP/SAWP Strategic Review and Learning Meeting under the Croatian EU presidency.

10. List of Participants

CHMP Chair

Harald Enzmann

CHMP Members

Bruno Sepodes (Vice-chair)

Andrea Laslop

Björg Bolstad

Blanka Hirschlerova

Christian Gartner

Daniela Melchiorri

Ewa Balkowiec Iskra

Frantisek Drafi

Jan Mueller-Berghaus

Jayne Crowe
Johann Lodewijk Hillege
John Joseph Borg
Konstantinos Markopoulos
Kristina Dunder
Margareta Bego
Maria Concepcion Prieto Yerro
Martina Weise
Martine Trauffler
Melinda Sobor
Outi Mäki-Ikola
Simona Badoi

CHMP alternate members

Agnes Gyurasics
Christophe Focke
Dana Gabriela Marin
Emilia Mavrokordatou
Fátima Ventura
Giuseppa Pistritto
Ingrid Wang
Kristine Moll Harboe
Milena Stain
Nevenka Trsinar Brodt
Simona Stankeviciute

Experts

Anja Schiel
Erika Fredriksson
Henrike Potthast
Maria Victoria Tudanca Pacios
Milena Peraita Ezcurra
Noelia Fernández Bodas
Nora Cascante Estepa

Sabine Mayrhofer

Sanne Bjørn Overgaard

A representative from the European Commission attended the meeting.

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