



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2020
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Human Medicines Division

Committee for medicinal products for human use (CHMP) ORGAM¹ minutes for the meeting on 7 September 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

07 September 2020, 09:30–12:30, room 9A

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
2.3.	International Council on Harmonisation (ICH)	5
2.4.	Guideline Consistency Group (GCG).....	5
2.5.	Summary of product characteristics Advisory Group	5
3.	Non therapeutic-area-specific working parties	5
3.1.	Biologics Working Party (BWP)	5
3.2.	Safety Working Party (SWP).....	6
3.3.	Biosimilar Medicinal Product Working Party (BMWP)	6
3.4.	Biostatistics Working Party (BSWP)	6
3.5.	Modelling and Simulation Working Party (MSWP)	7
3.6.	Pharmacogenomics Working Party (PGWP).....	7
3.7.	Pharmacokinetics Working Party (PKWP).....	7
4.	Therapeutic-area-specific working parties and SAGs	7
4.1.	Blood Products Working Party (BPWP).....	7
4.2.	Central Nervous System Working Party (CNSWP)	8
4.3.	Cardiovascular Working Party (CVSWP)	9
4.4.	Infectious Diseases Working Party (IDWP)	9
4.5.	Oncology Working Party (ONCWP)	9
4.6.	Rheumatology/Immunology Working Party (RIWP)	9
4.7.	Vaccines Working Party (VWP).....	9
4.8.	Scientific Advisory Groups (SAGs)	9
5.	Drafting groups	9
5.1.	Excipients Drafting Group.....	9
5.2.	Gastroenterology Drafting Group (GDG)	10
5.3.	Geriatric Expert Group (GEG).....	10
5.4.	Radiopharmaceuticals Drafting Group (RadDG)	10
5.5.	Respiratory Drafting Group (RDG)	10

6.	Joint groups and collaboration with other committees	10
6.1.	Quality Working Party (QWP)	10
6.2.	Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)	10
6.3.	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)	11
6.4.	Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)	11
6.5.	Collaboration with other committees.....	11
7.	Product development support	12
7.1.	Scientific Advice Working Party (SAWP)	12
7.2.	Innovation Task Force	12
8.	Any Other Business	13
9.	List of Participants	13

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 CHMP ORGAM agenda for the 07 September 2020 meeting

1.3. Adoption of the minutes

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

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

Process to collect and record 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. 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 discussion

The CHMP discussed the area of expertise for the 5th co-opted member and agreed on "Quality, safety and efficacy of biological medicinal products, including advanced therapies and with specific emphasize on vaccines".

2.2.3. Structure and procedure for remote CHMP meetings

For discussion on how to adapt to the current, pandemic induced situation.

Action: For discussion

The members were reminded that the CHMP meeting will be held remotely for the rest of the year 2020. The members discussed how to make the remote meetings more efficient. Harmonisation and consistency groups.

2.3. International Council on Harmonisation (ICH)

2.3.1. Nomination of experts for ICH groups

- ICH Guideline E6(R2) – Good Clinical Practice

Nomination of Deputy Topic Lead.

Action: For adoption

The CHMP endorsed the nomination of Gabriele Schwarz (BfArM) as Deputy Topic Lead.

- ICH Model-Informed Drug development (MIDD) Discussion Group

Nomination

Action: For adoption

The CHMP endorsed the nominations of Kristin Karlsson (MPA) and Flora Musuamba-Tshinanu (FAGG).

2.3.2. ICH Q3D (R2) Guideline on Elemental Impurities

Step 2b

Action: For adoption for 3-month public consultation

The appendices set up limits for elemental impurities by cutaneous and transcutaneous route. Furthermore permitted daily exposures for nickel, gold and silver were revised and the gold and silver monographs were corrected.

The CHMP adopted the guideline for 3-month public consultation

2.4. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No topics

2.5. Summary of product characteristics Advisory Group

No topics

3. Non therapeutic-area-specific working parties

3.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz / Nanna Aaby Kruse

3.1.1. Agenda(s) and minutes

- Final minutes for BWP meeting held by teleconference on 15-17 June 2020
- Draft agenda for BWP meeting to be held by teleconference on 7-9 September 2020

Action: for information

The agenda and minutes were noted.

3.1.2. Change in membership

Nomination received for a new alternate

Action: For endorsement

The CHMP endorsed Andreea Barbu as new Swedish alternate.

3.2. Safety Working Party (SWP)

Chairs: Jan Willem Van der Laan / Susanne Brendler-Schwaab

3.2.1. Change in membership

Nomination received for a new alternate

Action: For endorsement

The CHMP endorsed Marianne Schmidt as new Danish alternate.

3.2.2. Agenda(s) and minutes

Final minutes for SWP meeting held by Adobe meeting on 25 May 2020

Action: For information

The minutes were noted.

3.3. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz / Niklas Ekman

No topics

3.4. Biostatistics Working Party (BSWP)

Chairs: Kit Roes / Jörg Zinserling

3.4.1. Question and Answer on Data Monitoring Committee issues

BSWP is seeking CHMP adoption for the revised document accounting for the stakeholder comments received during the 1-year public consultation.

The aim of this question-and-answer document is to supplement the CHMP Data Monitoring Committee Guideline (EMA/CHMP/EWP/5872/03) by providing clarification on the role and necessity for a Data Monitoring Committee (DMC) in different phases of drug development

and throughout the product lifecycle as well as with regard to the responsibilities for implementing DMC decisions.

Action: For adoption

The CHMP adopted the question and answer document.

3.5. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson / Flora Musuamba Tshinanu

No topics

3.6. Pharmacogenomics Working Party (PGWP)

Chair: Markus Paulmichl

No topics

3.7. Pharmacokinetics Working Party (PKWP)

Chairs: Henrike Potthast / Carolien Versantvoort

No topics

4. Therapeutic-area-specific working parties and SAGs

4.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr / Karri Penttilä

4.1.1. BPWP TC held on 8 June 2020

- Final agenda
- Final minutes

Action: For information

The agenda and minutes were noted.

4.1.2. Blood cluster meeting to be held on 17 July 2020

- Final agenda

Action: For information

The agenda was noted.

4.1.3. Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg) and Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)

- Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg)
- Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)

Action: For adoption

The core SmPC has been revised to include the indication of measles post-exposure prophylaxis for susceptible persons in whom active immunisation is contraindicated.

The guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) has been revised to provide recommendation to use immunoglobulins for the treatment of measles post-exposure prophylaxis for susceptible persons in whom active immunisation is contraindicated.

The CHMP adopted the revised guidelines.

4.1.4. PPTA letter

- PPTA letter

Action: For discussion

The CHMP noted the letter.

4.1.5. EC lines to take: Covid-19 Convalescent Plasma in the EU – 28 August 2020

- EC lines to take

Action: For information

The CHMP noted the lines to take.

4.1.6. COVID-19 meeting of the Competent Authorities for Blood and Blood Components – 17 September 2020

- Draft agenda

Action: For information

The agenda was noted.

4.2. Central Nervous System Working Party (CNSWP)

Chairs: Vacant / Andre Elferink

No topics

4.3. Cardiovascular Working Party (CVSWP)

Chairs: Kristina Dunder / Alar Irs

No topics

4.4. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

No topics

4.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac / Paolo Foggi

4.5.1. Change in membership

Nomination(s) received for a new member

Action: For endorsement

The CHMP endorsed Michal Zwienka as new member.

4.5.2. Anticancer Guideline Revision 6.

For release for 3 months public consultation

Action: For discussion

The members noted the revised guideline. The members were asked to send comments. Further discussion expected at the October ORGAM.

4.6. Rheumatology/Immunology Working Party (RIWP)

Chairs: Vacant / Andre Elferink

No topics

4.7. Vaccines Working Party (VWP)

Chair: Mair Powell

No topics

4.8. Scientific Advisory Groups (SAGs)

No topics

5. Drafting groups

5.1. Excipients Drafting Group

Chair: Vacant

No topics

5.2. Gastroenterology Drafting Group (GDG)

Chair: Vacant

No topics

5.3. Geriatric Expert Group (GEG)

Chair: Vacant

No topics

5.4. Radiopharmaceuticals Drafting Group (RadDG)

Chair: Vacant

No topics

5.5. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No topics

6. Joint groups and collaboration with other committees

6.1. Quality Working Party (QWP)

Chairs: Blanka Hirschlerova / Laivi Saaremäel

6.1.1. QWP Response to EDQM on Q&A on Use of Peptones in the manufacture of active substances

Action: For discussion

The CHMP endorsed the QWP response to EDQM.

6.1.2. QWP Core Team

Agenda and minutes from July QWP CT meeting

Action: For information

The agenda and minutes were noted.

6.2. 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)

6.2.1. Meeting report PCWP HCPWP meeting - 2 June 2020

Action: For information

The meeting report was noted.

6.2.2. Meeting report PCWP HCPWP meeting (ICH) - 3 June 2020

Action: For information

The meeting report was noted.

6.2.3. Meeting report PCWP HCPWP meeting - 24 June 2020

Action: For information

The meeting report was noted.

6.2.4. Draft Agenda Workshop on the application of the General Data Protection Regulation (GDPR) in the area of health and Secondary Use of Data for Medicines and Public Health Purposes - 23 September 2020

Action: For information

The draft agenda was noted.

6.2.5. Draft Agenda Workshop on benefit-risk of medicines used during pregnancy and breastfeeding – 22 September 2020

Action: For information

The draft agenda was noted.

6.3. 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)

Chairs: Ellen-Margrethe Vestergaard / Susanne Brendler-Schwaab

No topics

6.4. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

Chair: Nienke Rodenhuis

No topics

6.5. Collaboration with other committees

6.5.1. CHMP-PRAC Collaboration Group

Presentation on planned actions

Action: For discussion

The members were informed that the collaboration group was set up to facilitate the collaboration between CHMP and PRAC, to discuss RMP aspects and to find process improvements and provide clarification on the Committees' roles. Comments were invited to be sent.

7. Product development support

7.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

7.1.1. Appointment of CHMP peer review for SA

Action: For information

The CHMP noted the information.

7.2. Innovation Task Force

7.2.1. ITF meeting

Meeting date: 14 September 2020 at 14:00 – 15:30

Action: For adoption

The meeting was endorsed.

7.2.2. ITF meeting

Meeting date: 14 September 2020 at 15:00 – 16:30

Action: For adoption

The meeting was endorsed.

7.2.3. ITF meeting

Meeting date: 21 September 2020 at 15:00 – 16:30

Action: For adoption

The meeting was endorsed.

7.2.4. ITF meeting

Meeting date: 5 October 2020 at 12:30 – 14:00

Action: For adoption

The meeting was endorsed.

8. Any Other Business

8.1.1. Presentation of the CONSING project

Presentation by the contractor of the EMA funded study on the impact of COVID-19 infection and medicines in pregnancy, including the ongoing international collaboration. Call for expression of interest of CHMP members to be involved.

Action: For information

The CHMP noted the presentation on the CONSING project. The CHMP will be kept updated once first results are available.

8.1.2. EMA responses to the IPRP nanomedicines working group survey on liposomal products

Action: For information

The CHMP was informed about the IPRP nanomedicines working group survey on liposomal products. The members noted the EMA response to the questions. The CHMP will be kept updated on the outcome of the survey and the next steps.

8.1.3. Working Parties review

Discussion of CHMP perspective.

Action: For discussion

The CHMP noted the draft CHMP perspective on the working party review. Members were asked to read the document. Further discussion is expected.

9. List of Participants

CHMP Chair

Harald Enzmann

CHMP Members

Bruno Sepodes (Vice-chair)

Andrea Laslop

Armando Genazzani

Bjorg Bolstad

Blanka Hirschlerova

Christian Gartner

Christophe Focke

Ewa Balkowiec Iskra

Frantisek Drafi
Johann Lodewijk Hillege
Jan Mueller-Berghaus
Jayne Crowe
Margareta Bego
Maria Concepcion Prieto Yerro
Martina Weise
Martine Trauffler
Melinda Sobor
Outi Mäki-Ikola
Sinan B. Sarac

CHMP Alternates

Agnes Gyurasics
Dana Gabriela Marin
Dorota Distlerova
Fatima Ventura
Ingrid Wang
Janet Koenig
Karin Janssen van Doorn
Milena Stain
Nevenka Tršinar Brodt
Simona Stankeviciute

Experts

Anja Schiel
Christian B. Roes
Giuseppa Pistritto
Kitty Bloemenkamp
Maria Victoria Tudanca Pacios
Martina Schuessler-Lenz
Mette Tranholm
Miriam Sturkenboom
Nora Cascante Estepa
Sabine Mayrhofer

