



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Committee for medicinal products for human use (CHMP) Final ORGAM¹ agenda for the meeting on 20 April 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

20 April 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).....	5
4.3.	Biosimilar Medicinal Product Working Party (BMWP)	6
4.4.	Biostatistics Working Party (BSWP)	6
4.5.	Modelling and Simulation Working Party (MSWP)	6
4.6.	Pharmacogenomics Working Party (PGWP).....	6
4.7.	Pharmacokinetics Working Party (PKWP).....	6
5.	Therapeutic-area-specific working parties and SAGs	7
5.1.	Blood Products Working Party (BPWP).....	7
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).....	8
5.8.	Scientific Advisory Groups (SAGs)	8
6.	Drafting groups	8
6.1.	Excipients Drafting Group.....	8
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)	9
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

CHMP ORGAM agenda for 20 April 2020 meeting.

1.3. Adoption of the minutes

CHMP ORGAM minutes of April 2020 meeting will be adopted at the April 2020 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.1.1. Guidance on remote GCP inspections

Action: For information

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

- Process to collect and record CHMP learnings
CHMP: Outi Mäki-Ikola

Action: For discussion

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
- ICH Guideline M12 on Drug interaction studies

Action: For adoption

3.1.2. ICH Guideline Q3C(R8) on Impurities: guideline for residual solvents

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

No topics

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 face-to-face on 17-19 February 2020
- Draft agenda for BWP meeting to be held by teleconference on 20-22 April 2020

Action: For information

4.1.2. Call for nomination of BWP Vice-chair

Nanna Aaby Kruse's second term will expire in April 2020. The election is scheduled at the April 2020 CHMP Plenary meeting.

Nomination(s) received

Action: For information

4.1.3. EMA response to AskEMA question

Action: For adoption

4.2. Safety Working Party (SWP)

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

4.2.1. Agenda(s) and minutes

- Final minutes for SWP meeting held by teleconference on 24 February 2020
- Final minutes for SWP ad-hoc meeting on nitrosamines held by teleconference on 10 February 2020

Action: For information

4.2.2. SWP response to CMDh question on Nitrosamines MeNP

SWP Rapporteur: Roland Froetschl/Bodo Haas (BfArM)

- Final response

Action: For adoption

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 14 May 2020.

4.4. Biostatistics Working Party (BSWP)

Chair(s): Jörg Zinserling

4.4.1. Call for nomination of new BSWP Chair and new member

Nominations have to be sent together with a CV and a brief motivation letter by 31 May 2020.

Action: For Information

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

4.7.1. Product-specific guidelines

Revision of product-specific guidelines (batch number 1)

- Dasatinib product-specific bioequivalence guidance (EMA/CHMP/675838/2014/Rev.1)
Draft for 3-month public consultation

Action: For adoption

4.7.2. PKWP Q & A on BCS classification and requirements for biowaiver for chloroquine and hydroxychloroquine products

Action: For adoption

4.7.3. Question from pharmaceutical industry association to PKWP on clarification for demonstration of bioequivalence for dabigatran etexilate and response from PKWP

Action: For adoption

4.7.4. Update on Q & A (7.1) on the key pharmacokinetic considerations in the assessment of biosimilarity

Action: For adoption

4.7.5. Update on PKWP Q & A (3.8) on the recommendations on for demonstration of bioequivalence of gastro-resistant preparations (e.g. omeprazole)

Action: For adoption

4.7.6. Question from pharmaceutical industry association to PKWP on biowaivers for additional strengths of immediate release fixed combinations.

Action: For adoption

4.7.7. Changes to PKWP composition

A call for nomination of new PKWP members was launched in February 2020 with deadline of 11 March 2020.

The PKWP is looking for 2 experts with specific expertise in the following areas (in addition to the general PK and/or biopharmaceutics expertise):

- Bioequivalence/biowaivers
- PBPK modelling

Nominations received

Action: For adoption

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): TBC/Karri Penttilä

5.1.1. Election of the BPWP chair

Jacqueline Kerr's first term expired in March 2020. The election is scheduled at the April 2020 CHMP Plenary meeting.

Nomination(s) received

Action: For information

5.1.2. Agenda of the Blood cluster TC held on 3 April 2020

Action: For information

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. QWP Core Team- March minutes

Meeting date: 18 March 2020

Action: For information

7.1.2. Election of QWP Vice Chair

Previous vice chair Blanka Hirschlerova has become the chair of QWP. The election is scheduled at the April 2020 CHMP Plenary meeting.

Nomination(s) received

Action: For information

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 of membership

Action: For adoption

8.1.2. Appointment of CHMP peer review for SA

Action: For information

8.1.3. Rapid Scientific Advice process to address COVID-19

Action: For adoption

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 21 April 2020

Action: For adoption

8.2.2. ITF meeting

Meeting date: 04 April 2020

Action: For adoption

8.2.3. ITF meeting

Meeting date: 18 May 2020

Action: For adoption

9. Any Other Business

9.1.1. Update on collaboration with HTA bodies after CHMP opinion

Action: For information

9.1.2. Final report of Workshop on the role of registries in the monitoring of cancer therapies based on genetic and molecular features

The report of the workshop held on 29 November 2019 has been finalised and will be published on the EMA website. We would like to inform the CHMP about the outcome and follow-up actions.

Action: For information

10. List of Participants