



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 March 2020
EMA/CHMP/54201/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP) Final ORGAM¹ agenda for the meeting on 16 March 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

16 March 2020, 09:30–12:30, room 09-A

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the 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.



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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 16 March 2020 meeting

1.3. Adoption of the minutes

CHMP ORGAM minutes of 16 March 2020 meeting will be adopted at the March 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

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

Draft ICH MedDRA M1 Points to consider

Action: For adoption

3.1.2. Draft ICH S11 Nonclinical Safety Testing in Support of Development of Paediatric Medicines

Step 5 draft

Action: For adoption

3.2. Guideline Consistency Group (GCG)

Chair(s): Aranzazu Sancho-Lopez

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

- Draft agenda for BWP meeting to be held via F2F on 16-18 March 2020
- Final minutes for BWP meeting held via F2F on 20-22 January 2020

Action: For information

4.1.2. Call for nomination for the election of the BWP Vice-Chair

Nanna Aaby Kruse's second term will expire in April 2020. Nominations have to be sent together with a CV and a brief motivation letter by 16 April 2020.

Action: For information

4.1.3. Use of live fly larvae as medicinal products

BWP Response to CMDh questions

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 27 January 2020

Action: For information

4.2.2. Mutagenic impurity in Promazine

SWP responses to CMDh

SWP: Fabien Lavergne/Dominique Masset

Action: For adoption

4.2.3. Change(s) to SWP composition

Nomination of a new alternate to the SWP

Action: For adoption

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair(s): Elena Wolff-Holz/Niklas Ekman

No topics

4.4. Biostatistics Working Party (BSWP)

Chair(s): Jörg Zinserling

No topics

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. Election of PKWP Vice Chair in March 2020

Previous vice chair Henrike Potthast has now become the chair of PKWP and therefore an election for vice chair will be organised during the March CHMP plenary meeting. The last day for nomination was 28 February 2020.

Nomination received

Action: For information

4.7.2. Change(s) to PKWP composition

A call for nomination of new PKWP members was launched in February (ORGAM) with deadline on 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 information

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

5.1.1. Call for nomination for the election of the BPWP chair

Jacqueline Kerr's first term will expire in March 2020. Nominations have to be sent together with a CV and a brief motivation letter.

The call is extended until 15 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

5.5.1. Agenda(s) and minutes

- Agenda of the 5 February 2020 Adobe TC
- Minutes of the 15 January 2020 Adobe TC

Action: For information

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: Blanka Hirschlerova

7.1.1. QWP position on the Ph. Eur. Commission proposal to introduce requirements for the detection and control of N-nitrosamine impurities and the application of such requirements to all substances for pharmaceutical use (general monograph 2034)

- Letter to EDQM
Action: For adoption
- Letter from EDQM
Action: For information

7.1.2. CMDh request whether it is possible to approve only one manufacturing site included in an ASMF in relation to a specific medicinal product.

- EMA-QWP response to CMDh

Action: For adoption

7.1.3. Minutes from February 2020 QWP Core Team meeting

Action: For information

7.1.4. Election of QWP Vice Chair

A call of interest was launched in February (CHMP SoO) with a deadline on 13 March 2020. No nomination has been received so far.

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)

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

SAWP composition re-nomination

Action: For adoption

8.1.1. Appointment of CHMP peer review for SA

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 30 March 2020

Action: For adoption

8.2.2. ITF meeting

Meeting date: 31 March 2020

Action: For adoption

8.2.3. ITF meeting

Meeting date: 06 April 2020

Action: For adoption

9. Any Other Business

9.1.1. Joint HMA/EMA network strategy 2025

Action: For information

9.1.2. Art 5 (3) referral part I Nitrosamines call for review

Selection of Rapporteurs when risk assessment is required for specific cases.

Action: For discussion

9.1.3. CHMP statement on increase efficiency and coordination of clinical trials in EU against COVID19

Action: For adoption

10. List of Participants