



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP) Final ORGAM¹ agenda for the meeting on 17 February 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

17 February 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 17 February 2020 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of February 2020 meeting will be adopted at the February 2020 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.1.1. Liaison with FDA on a new active substance status

Draft minutes from TC organised to discuss FDA position as well as the proposed United States Adopted Name (USAN)

Action: For discussion

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

CHMP: Outi Mäki-Ikola

- Process to collect and record CHMP learnings

Action: For discussion

- Records

Action: For adoption

2.2.2. Revision of templates for Reader's Guidance

A revised draft update to the template for the reader's guidance has been prepared.

CHMP: Johann Lodewijk Hillege

Action: For discussion

2.2.3. Procedural Advice on the CHMP/CAT/PRAC (Co)-Rapporteur appointment

Action: For adoption

2.2.4. Change in the CHMP committee's quorum and majority following UK's withdrawal from the EU

Action: For information

2.2.5. Parallel assessment for medicinal products under article 58 application and initial centralised application

Action: For information

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1 Adoption of Guidelines

ICH **Q12** Step 5 - Guideline on Lifecycle Management (adopted January 2020)

- Note on EU implementation of ICH Q12

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

- Final minutes for BWP meeting held by face-to-face on 2-4 December 2019

Action: For information

- Draft agenda for BWP meeting to be held face-to-face on 17-19 February 2020

Action: For information

4.1.2. Change(s) to BWP composition

Nomination of new member Zsuzsanna Sasvari (HU) to the BWP

Action: For adoption

4.1.3. Election of the BWP chair

Nomination(s) received

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

Action: For information

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 9 December 2019

Action: For information

4.2.2. Publication of SWP position on Genotoxicity and Contraception

SWP Q&A on Genotoxicity and Contraception

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

4.4.1. Change(s) to BSWP composition

- Nomination(s) received following the call of interest for a new member launched in December 2019

One nomination was received

Action: For adoption

- Call of interest for a new member

Nominations have to be sent together with a CV and a brief motivation letter as soon as possible or **at the latest by 31st March 2020** for an election during the April CHMP plenary meeting.

Action: For information

4.5. Modelling and Simulation Working Party (MSWP)

Chair(s): Kristin Karlsson/Flora Musuamba Tshinanu

4.5.1. Change(s) to MSWP composition

Nomination of a new additional assessor

Action: For adoption

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. PKWP Question and Answers

- PKWP Q&A for CMDh request on therapeutic equivalence for orally inhaled products containing beclomethasone dipropionate
Action: For adoption
- PKWP Q&A for CMDh request on acceptable extent of release in comparative local in vivo availability studies for lozenges
Action: For adoption

4.7.2. Product Specific Guidelines

Final Etonogestrel and ethinylestradiol vaginal delivery system 0.12mg/0.015mg/day product-specific bioequivalence guidance (EMA/CHMP/97470/2019)

No comments were received during the public consultation

Action: For adoption

4.7.3. Call for nomination for the election of PKWP vice chair

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. Nominations have to be sent together with a CV and a brief motivation letter as soon as possible or **at the latest by 28th February 2020** for an election during the March CHMP plenary meeting.

Action: For information

4.7.4. Call for nomination for new PKWP members

The following expertise areas need to be filled with 2 new members as a result of the departure of existing members.

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

- Bioequivalence/biowaivers
- PBPK modelling

Nominations should be sent together with a CV and a brief motivation letter by **Wednesday 11th March 2020**

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. Agenda(s) and minutes

Final minutes from the blood cluster TC held on 11th October 2019

Action: For information

5.1.2. 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 by 13th March 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 5th February 2020 Adobe TC
- Minutes of the 15th 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)

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. Agenda(s) and minutes

Minutes from January QWP Core Team

Action: For information

7.2. Patients and Consumers Working Party (PCWP) and 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)

7.2.1. Agenda(s) and minutes

- Draft Agenda - PCWP and HCPWP joint meeting 3-4 March 2020
- Meeting Summary Annual PCWP-HCPWP meeting with all eligible organisations 20 November

Action: For information

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. Appointment of CHMP peer review for SA

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting:

Meeting date: 02 March 2020

Action: For adoption

9. Any Other Business

9.1.1. Update on EMA organisational aspects

Action: For information

10. List of Participants