



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) ORGAM¹ agenda for the meeting on 9 September 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

9 September 2019, 09:30–12:30, room 0-D

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 9 September 2019 meeting

1.3. Adoption of the minutes

CHMP ORGAM minutes of September 2019 meeting will be adopted at the September 2019 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

No topics

2.2. CHMP organisation / templates

2.2.1. CHMP work plan 2019

Reports from topic leaders on the status of activities listed in the CHMP work plan.

Action: For information

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. ICH guideline E19 on optimisation of safety data collection - Step 2b

Overview of comments received from CHMP members

Action: For discussion

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. Agendas and minutes

- Draft agenda for BWP meeting to be held face-to-face on 9-11 September 2019
- Final minutes for BWP meeting held face-to-face on 17-19 June 2019

Action: For information

4.1.2. Change(s) to BWP composition

Nomination of a BWP member for Slovenia

Action: For adoption

4.2. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan

4.2.1. CMDh request to SWP on genotoxicity and contraception

Action: For adoption

4.2.2. Change(s) to SWP composition

Nomination of new members:

- Slovenia
- Cyprus – replacing Sofia Petridou

Action: For adoption

4.2.3. Call for nomination for the election of SWP vice-chair in October 2019

Mikael Andersson's first 3-year term will expire in October 2019. An election will be organised during the October CHMP plenary meeting. Nominations have to be sent together with a CV and a brief motivation letter by 11 October 2019.

Action: For information

4.2.4.

Action: For adoption

4.3. Biosimilar Medicinal Product Working Party (BMWP)

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

4.3.1. Call for nomination for the election of BMWP chair in October 2019

Elena Wolff-Holz's first 3-year term will expire in October 2019. An election will be organised during the October CHMP plenary meeting. Nominations have to be sent together with a CV and a brief motivation letter by 11 October 2019.

Action: For information

4.4. Biostatistics Working Party (BSWP)

Chair(s): Anja Schiel/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): Krishna Prasad/Markus Paulmichl

No topics

4.7. Pharmacokinetics Working Party (PKWP)

Chair(s): Jan Welink/Henrike Potthast

4.7.1. Product-specific guidelines

Final product-specific guidelines (batch 10)

- Ezetimibe tablet 10 mg product-specific bioequivalence guidance (EMA/CHMP/802491/2018) and Overview of comments
- Cabozantinib tablet 20 mg, 40 mg and 60 mg, capsule 20 mg and 80 mg product-specific bioequivalence guidance (EMA/CHMP/790333/2018)
- Alectinib hard capsule 150 mg product-specific bioequivalence guidance (EMA/CHMP/790261/2018)
- Palbociclib hard capsule 75 mg, 100 mg and 125 mg product-specific bioequivalence guidance (EMA/CHMP/802679/2018)

Action: For adoption

Product-specific guideline requested by CMDh

- Colchicine tablet 0.5 mg and 1 mg product-specific bioequivalence guidance (EMA/CHMP/35552/2019)

Action: For adoption

Product-specific guideline for revision (batch 1)

- Dasatinib film-coated tablets 20, 50, 70, 80, 100 & 140 mg product-specific bioequivalence guidance (EMA/CHMP/675838/2014)

Action: For discussion

4.7.2. [Update on PKWP Question and Answers](#)

Question 3.6 on requirements for bioequivalence (BE) with ‘crushed’ tablets in light of new data for a (non-centralised) deferisarox generic

Action: For adoption

4.7.3. [Change\(s\) to PKWP composition](#)

- Nomination by AEMPS (ES) of an additional assessor to the PKWP

Action: For adoption

- Sotiris Michaleas will be replaced by Paulo Paixão who was nominated as PKWP member in April 2019 in anticipation of the next membership vacancy.

Action: For information

4.7.4. [Call for nomination for the election of PKWP chair in September 2019](#)

Jan Welink’s second 3-year term is expiring in September 2019. An election is planned during the September CHMP plenary meeting. Nominations have to be sent together with a CV and a brief motivation letter by 9 September 2019.

Action: For information

5. **Therapeutic-area-specific working parties and SAGs**

5.1. **Blood Products Working Party (BPWP)**

Chair(s): Jacqueline Kerr

No topics

5.2. **Central Nervous System Working Party (CNSWP)**

Chair(s): Karl Broich/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): Pierre Demolis/Paolo Foggi

5.5.1. Agendas and minutes

Final minutes for ONCWP Adobe meeting held on 12 June 2019 (EMA/395871/2019)

Action: for information

5.5.2. Election of ONCWP chair

The Chair's first 3-year term is expiring in September 2019. The election will take place during the CHMP September plenary meeting.

Action: For information

5.5.3. Call for nomination for the election of ONCWP vice-chair in October 2019

Paolo Foggi's first 3-year term will expire in October 2019. An election will be organised during the October CHMP plenary meeting. Nominations have to be sent together with a CV and a brief motivation letter by 11 October 2019.

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair(s): Jan Mueller-Berghaus/Romaldas Mačiulaitis

No topics

5.7. Vaccines Working Party (VWP)

Chair(s): Mair Powell

5.7.1. Change(s) to VWP composition

Nomination by NOMA (NO) of an additional assessor to the VWP

Action: For adoption

5.7.2. Call for nomination for the election of VWP chair in October 2019

Mair Powell's first 3-year term will expire in October 2019. An election will be organised during the October CHMP plenary meeting. Nominations have to be sent together with a CV and a brief motivation letter by 11 October 2019.

Action: For information

5.8. Scientific Advisory Groups (SAGs)

No topics

6. Drafting groups

6.1. Excipients Drafting Group

Chair: Dominique Masset

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): Keith Pugh/Blanka Hirschlerova

7.1.1. Call of interest for a QWP core-team member

Nominations have to be sent together with a CV and a brief motivation letter highlighting the candidate's areas of expertise by 19 September 2019.

Action: For information

7.1.2. Change(s) to QWP composition

Nomination of a QWP member for the Netherlands replacing Diana van Riet–Nales

Action: For adoption

7.1.3. QWP response to IGDRP

QWP response to IGDRP on NIR and RAMAN analysis techniques for identification and quantification of all raw materials and the quantification of finished drug products within MAA procedures

Action: For adoption

7.2. Patients and Consumers Working Party (PCWP)

7.2.1. Work plan

2019-2022 joint PCWP/HCPWP work plan

Action: For adoption

7.2.2. Agendas

- Draft Agenda - Patients and Consumers Working Party (PCWP) meeting
- Draft Agenda - Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) joint meeting

Action: For information

7.3. Healthcare Professionals Working Party (HCPWP)

- Draft Agenda - Healthcare Professionals Working Party (HCPWP) meeting

Action: For information

7.4. 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

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

Chair: Nienke Rodenhuis

No topics

7.6. 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

8.1.2. Change(s) to SAWP composition

- Following the nomination of Christian Gartner (AGES) as CHMP member

Action: For adoption

- Vacant Alternate positions for NCA nominations

Action: For information

- Preparation to the SAWP composition re-examination.

Action: For information

8.2. Innovation Task Force

8.2.1. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004

Action: For information

9. Any Other Business

9.1. Notice to sponsors of clinical trials on requirements for the qualification of vendors of e-systems and the validation of such systems used in clinical trials

Action: For adoption

9.2. **Guidance for assessors for Post Authorisation Safety Study (PASS)**

Action: For discussion

9.3. **GMO consultation**

Presentation of the streamlined consultation process

Action: For discussion

9.4. **Nitrosamine impurities**

Presence of nitrosamine impurities in human medicinal products containing chemically synthesised active pharmaceutical ingredients

Action: For information

10. **List of Participants**