



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 November 2020
EMA/CHMP/615039/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP) ORGAM¹ agenda for the meeting on 30 November 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

03 November 2020, 09:30–13:30, 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 30 November 2020 meeting

1.3. Adoption of the minutes

CHMP ORGAM Minutes of November 2020 meeting will be adopted at the December 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

2.2.2. CHMP meeting dates for the period 2022-2024

Action: For information

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. ICH report from meeting in Greece (November 2020) – replaced by a virtual meeting

Report and presentation.

Action: For adoption

3.1.2. Reflection Paper on Patient-Focused Drug Development (PFDD)

RP for endorsement.

Action: For adoption

3.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No topics

3.3. Summary of product characteristics Advisory Group

3.3.1. Product information review curriculum:

New chapter on pharmaceutical information.

CHMP Topic Leader: Blanka Hirschlerova

Action: For endorsement

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz/Nanna Aaby Kruse

4.1.1. Nomination of new member

Nomination of new BWP member.

Action: For endorsement

4.1.2. Agenda(s) and minutes

- Final minutes for BWP meeting held by teleconference on 5-7 October 2020
- Draft agenda for BWP meeting to be held by teleconference on 30 November – 2 December 2020

Action: For information

4.2. Safety Working Party (SWP)

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

4.2.1. Agenda(s) and minutes

Final minutes for SWP meeting held by teleconference on 21-22 October 2020.

Action: For information

4.2.2. SWP response to CMDh question on DEA and coconut oil DEA

Action: For adoption

4.2.3. Requests from EDQM and URPL to CHMP on colistimethate

Follow-up to discussion during November 2020 ORGAM meeting: update on possibility to trigger article 5(3) procedure.

Action: For information

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz/Niklas Ekman

No topics

4.4. Biostatistics Working Party (BSWP)

Chairs: Kit Roes/Jörg Zinserling

No topics

4.5. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

No topics

4.6. Pharmacogenomics Working Party (PGWP)

Chair: Markus Paulmichl

No topics

4.7. Pharmacokinetics Working Party (PKWP)

Chairs: Vacant/Carolien Versantvoort

4.7.1. Minutes of PKWP meeting September 2020

Action: For information

4.7.2. Product-specific guidelines

Draft product-specific guidelines

- Deferisarox product-specific bioequivalence guidance (EMA/CHMP/472383/2020)

Rapporteur: Jan Neuhauser

Action: For adoption for public consultation

Final product-specific guidelines

- Levothyroxine product-specific bioequivalence guidance (EMA/CHMP/176098/2020) and overview of comments

Rapporteur: Alfredo Garcia-Arieta

Action: For adoption

4.7.3. Changes to PKWP composition

Replacement of Henrike Potthast's following departure as Chair.

Action: For endorsement

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

5.1.1. Blood cluster TC on 23 October 2020

- Draft minutes of the blood cluster TC held on 23 October 2020

Action: For information

5.2. Central Nervous System Working Party (CNSWP)

Chair(s): Vacant

No topics

5.3. Cardiovascular Working Party (CVSWP)

Chairs: Kristina Dunder/Alar Irs

No topics

5.4. Infectious Diseases Working Party (IDWP)

Chair(s): Vacant

No topics

5.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

No topics

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair: Romaldas Mačiulaitis

No topics

5.7. Vaccines Working Party (VWP)

Chair: Mair Powell

No topics

5.8. Scientific Advisory Groups (SAGs)

No topics

6. Drafting groups

6.1. Excipients Drafting Group

Chair: Vacant

No topics

6.2. Gastroenterology Drafting Group (GDG)

Chair(s): Vacant

No topics

6.3. Geriatric Expert Group (GEG)

Chair(s): Vacant

No topics

6.4. Radiopharmaceuticals Drafting Group (RadDG)

Chair(s): Vacant

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

- Draft agenda for QWP meeting to be held by teleconference on 14-16 December 2020

Action: For information

7.1.2. QWP Core Team

- Agenda and minutes from November 2020 QWP CT meeting

Action: For information

- Agenda and minutes from the ad hoc QWP CT meeting

Action: For information

7.1.3. CMDh question to QWP on Septocaine and Septocaine forte

CMDh question to QWP on acceptability of proposed alternative reduced terminal sterilisation cycle for Septocaine (articaine HCl and epinephrine) and Septocaine forte (articaine HCl and adrenaline).

Action: For adoption

7.1.4. QWP responses to PKWP on product specifications for levothyroxine

Rapporteur: Carolien Versantvoort (PKWP) Jobst Limberg (QWP)

Action: For adoption

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)

Chairs: 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: Anja Schiel

8.1.1. Nomination of new member

Application(s) received following a call of interests for nomination of a replacement SAWP member and his/her alternate with the following expertise launched in November 2020:

- Rheumatology/ immunology
- General medicine/ clinical pharmacology
- Haematology

Action: For endorsement

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 1 December 2020 at 11:00 – 12:30

Action: For adoption

8.2.2. ITF meeting

Meeting date: 14 December 2020 at 10:00 – 11:30

Action: For adoption

8.2.3. ITF meeting

Meeting date: 17 December 2020 at 11:00 – 12:30

Action: For information

9. Any Other Business

9.1.1. IRIS implementation in Scientific Advice Procedures

Update to CHMP on implementation of IRIS system in Scientific Advice and access to SAWP documents through the new system for CHMP members.

Action: For information

9.1.2. Updates on the CONSIGN and ACCESS projects

Generic protocols to assess the impact of Covid-19 and medicines (including vaccines) received from the EMA-funded CONSIGN (Covid-19 infectiON and medicineS In preGNancy) and ACCESS (vACCine covid-19 monitoring readinESS) projects.

Action: For information (CONSIGN protocol) and for discussion (ACCESS effectiveness and safety protocols)

9.1.3. Joint CHMP-CAT membership

Nomination by CHMP of joint members to CAT.

Action: For adoption

9.1.4. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

9.1.5. CHMP Work Plan 2021

Discussion on draft CHMP Work Plan 2021

Action: For discussion

9.1.6. Covid-19 EMA pandemic Task Force (COVID-ETF)

Overview of ETF objectives and activities regarding COVID crisis. Overview of ongoing and upcoming procedures. Overview on Scientific Advice.

Action: For information

10. List of Participants