17 January 2020
EMA/CHMP/53952/2021
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

Final ORGAM[1] agenda for the meeting on 20 January 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

20 January 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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Table of contents

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 January 2020 meeting

1.3. Adoption of the minutes

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

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.1.1. Letter to WHO on INNs for ATMPs

Draft letter to WHO on INN for ATMPs for discussion and adoption

- BWP and CAT input and adoption planned at their January meeting

Action: For adoption

2.2. CHMP organisation / templates

2.2.1. Revision of templates for accelerated assessment requests

Following up from discussions at October 2019 ORGAM meeting, a revised draft update to the template for the briefing note on accelerated assessment requests has been prepared, addressing comments from CHMP sponsors.

CHMP: Johann Lodewijk Hillege, CHMP/CAT: Jan Mueller-Berghaus

Action: For discussion

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. CHMP work plan 2020

Draft work plan for adoption in January plenary meeting

Action: For discussion

2.2.4. 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. ICH report from meeting in Singapore (November 2019)

- Presentation

  Action: For discussion

- Report

  Action: For adoption

3.1.2. Adoption of Guidelines

- ICH **Q12** Step 5 - Guideline on Lifecycle Management
- ICH **S5(R3)** Step 5 - Guideline on reproductive toxicology: detection of toxicity to reproduction for human pharmaceuticals
- ICH **M9** Step 5 - Guideline on Biopharmaceutics Classification System-based biowavers
- ICH **E9(R1)** Step 5 – Addendum to Guideline on Statistical Principles for Clinical Trials

Action: For adoption

3.1.3. Nomination of experts for ICH groups

- ICH M7(R2) Addendum to guideline on Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk
- ICH M13 Guideline on Bioequivalence for Immediate-Release Solid Oral Dosage Forms
- ICH Q3E Guideline on Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics
- ICH Q5A(R2) guideline on Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin

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 face-to-face on 4-6 November 2019
- Draft agenda for BWP meeting to be held face-to-face on 20-22 January 2020

Action: For information

4.1.2. Change(s) to BWP composition

Nomination of a new member for Portugal

Action: For adoption

4.2. Safety Working Party (SWP)

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

4.2.1. Agendas and minutes

- Final minutes for SWP meeting held by teleconference on 11 November 2019

Action: For information

4.2.2. Response from SWP to CMDh regarding Genotoxicity and Contraception

- Final SWP response to CMDh regarding Genotoxicity and Contraception

Action: For adoption

4.2.3. Change(s) to SWP composition

Nomination of a new Swedish alternate member:

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

No topics

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

5.1.1. BPWP request for BWP input regarding a query on heparins

Draft response for discussion and agreement

- BWP input
- BPWP draft response to the external query received

Action: For adoption

5.1.2. Agendas and minutes

Draft minutes Blood cluster TC held on 11th October 2019

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): Keith Pugh/Blanka Hirschlerova

7.1.1. Agendas and minutes

Minutes December 2019 QWP Core Team

Action: For information

7.2. Patients and Consumers Working Party (PCWP)

Co-chair: Kaisa Immonen Co-chair: Juan Garcia Burgos (EMA)

No topics

7.3. Healthcare Professionals Working Party (HCPWP)

Co-chair: Gonzalo Calvo Co-chair: Juan Garcia Burgos (EMA)

No topics

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

7.6.1. Correspondence with European Commission on assessment of orphan medicinal products and proposal for fostering collaboration between CHMP and COMP

Correspondence with European Commission on the scientific assessment of the orphan medicinal products by the COMP and the CHMP is included for information. In this regard, EMA has prepared a corresponding proposal for fostering the scientific collaboration between CHMP and COMP.

Action: For discussion

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: 04 February 2020

Action: For adoption

8.2.2. ITF meeting

Meeting date: 19 February 2020

Action: For adoption

9. Any Other Business

9.1.1. Nitrosamines Art 5(3) - Involvement of Industry as part of the procedure

Action: For discussion

10. List of Participants