



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 June 2019
EMA/CHMP/447862/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP) ORGAM¹ minutes for the meeting on 17 June 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

17 June 2019, 09:30–12:30, room 1B

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 June 2019 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of June 2019 meeting will be adopted at the June 2019 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

No topic

2.2. CHMP organisation / templates

2.2.1. Appointment of joint CHMP/PDCO members

Proposed joint CHMP-PDCO membership

Action: For adoption

The paediatric legislation foresees 5 joint CHMP/PDCO members and alternates to be appointed by CHMP into PDCO. The mandates of the currently appointed joint CHMP/PDCO members and alternates expired on 29 May 2019. National competent authorities already involved agreed to take up the joint membership position for the next 3-year term. The CHMP agreed to appoint the following joint CHMP/PDCO members and alternates at their June CHMP plenary meeting:

- Agnes Gyurasics (HU): CHMP alternate and PDCO member;
- Melinda Sobor (HU): CHMP member and PDCO alternate;
- Martine Trauffler (LU): CHMP member and PDCO alternate;
- Carola de Beaufort (LU): CHMP alternate and PDCO member;
- Simona Badoi (RO): CHMP member and PDCO alternate;
- Dana Gabriela Marin (RO): CHMP alternate and PDCO member.

2.2.2. Handling of competing interests

Action: For information

The EMA Secretariat reminded the Committee of the principles on handling competing interests for Scientific Committees' members and experts as detailed in the corresponding EMA Policy on handling competing interests for Scientific Committees' members and experts (EMA/626261/2014, Rev. 1). In particular, the presentation detailed the types of interests to be declared in the electronic declaration of interests (eDOI) by a member or an expert, the corresponding restrictions in EMA activities if an interest is declared, the requirement to inform the EMA of any intention to become an employee in a pharmaceutical company and the breach of trust procedure in case an interest is not declared intentionally or through gross negligence. In case of any doubt, members and experts are advised to contact EMA for advice before agreeing on any involvement in non-EMA /non-NCAs activities that potentially could be considered as a competing interest and incompatible with involvement in EMA activities.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

No topic

3.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No topic

4. Non therapeutic-area-specific working parties

4.1. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

4.1.1. BWP response to CMDh questions on leeches

Action: For adoption

The BWP response to CMDh questions on leeches was presented. CHMP members were given until 17 June 2019 EOB to comment on the proposed response. In absence of comments, the document will be considered adopted.

4.1.2. Final BWP Minutes - 15-16 April 2019

Action: For information

The CHMP noted the minutes.

4.1.3. Draft BWP Agenda - 17-19 June 2019

Action: For information

The CHMP noted the agenda.

4.2. Safety Working Party (SWP)

Chair: Jan Willem Van der Laan

4.2.1. Final SWP Minutes 25 Feb 2019

Action: For information

The CHMP noted the minutes.

4.2.2. EMA speaker nomination to the 50th Annual Environmental Mutagenesis and Genomics Society (EMGS)

Proposal

Action: For adoption

The CHMP agreed the nomination of Roland Froetschl as EMA speaker.

4.2.3. Publication of SWP summary report on temporary interim limits for NMBA, DIPNA and EIPNA impurities in sartan blood pressure medicines

Action: For information

The CHMP endorsed the summary report.

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Niklas Ekman

No topic

4.4. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

4.4.1. Nomination of an additional assessor to the BSWP

Mats Økvist has been nominated by Norwegian medicines Agency (NoMA) as an additional assessor to the BSWP

Action: For adoption

The CHMP agreed to the nomination.

4.5. Modelling and Simulation Working Party (MSWP)

Chair: Kristin Karlsson/Flora Musuamba Tshinanu

No topic

4.6. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

No topic

4.7. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

4.7.1. Question from CMDh to PKWP on acenocumarol generics and need for chiral measures

Action: For adoption

The CHMP agreed the CMDh question to PKWP on acenocumarol generics.

4.7.2. PKWP response to CMDh question on Biowaiver for oral solutions with the "same concentration"

Action: For adoption

PKWP response to the CMDh question, on behalf of PKWP. The CHMP adopted the PKWP response to CMDh.

4.7.3. Question from CMDh to PKWP Bioequivalence for orally inhaled products containing beclomethasone dipropionate (BDP)

Action: For adoption

The CHMP agreed to CMDh consulting the PKWP

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

5.1.1. Election of BPWP Vice-Chair at June 2019 CHMP plenary

Nominations received:

Action: For information

The CHMP noted the list of candidates.

5.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich/André Elferink

No topic

5.3. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder/Alar Irs

No topic

5.4. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

No topic

5.5. Oncology Working Party (ONCWP)

Chair: Pierre Demolis/Paolo Foggi

5.5.1. Nomination of additional assessors to the ONCWP

- Liisa Pylkkänen has been nominated by the Finnish medicines Agency (Fimea) as an additional assessor to the ONCWP
- Lucia Lopez-Anglada Fernandez has been nominated by the Spanish medicines Agency (AEMPS) as an additional assessor to the ONCWP
- João de Oliveira Baptista Geraldes Freire has been nominated by the Portuguese medicines Agency (INFARMED) as an additional assessor to the ONCWP

Action: For adoption

The CHMP endorsed the nomination of the additional assessors to the ONCWP.

5.5.2. Guideline on MRD as an endpoint in clinical trials in Multiple Myeloma

Possible need for a consultation with the SAG Oncology

Action: For discussion

The CHMP agreed on the consultation of the SAG Oncology.

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus/Romaldas Mačiulaitis

No topic

5.7. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

No topic

5.8. Scientific Advisory Groups (SAGs)

No topic

6. Drafting groups

6.1. Excipients Drafting Group

Chair: Dominique Masset

No topic

6.2. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No topic

6.3. Geriatric Expert Group (GEG)

Chair: Katarina Vučić

No topic

6.4. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes Blanco

No topic

6.5. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No topic

7. Joint groups and collaboration with other committees

7.1. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

No topic

7.2. Patients and Consumers Working Party (PCWP)

Co-chair: Kaisa Immonen

No topic

7.3. Healthcare Professionals Working Party (HCPWP)

Co-chair: Gonzalo Calvo

No topic

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: Ellen-Margrethe Vestergaard, CoChair: Susanne Brendler-Schwaab

No topic

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

Chair: Nienke Rodenhuis

No topic

7.6. Committees

No topic

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Appointment of CHMP peer reviewer for SA

Action: For discussion

The new approach was presented. The experience will be reviewed after 3 months. The proposal was agreed.

8.2. Innovation Task Force

8.2.1. ITF Meeting

Meeting date: 17th June

Action: For adoption

The meeting was agreed.

8.2.2. ITF Meeting

Meeting date: 3rd July

Action: For adoption

The meeting was agreed.

8.2.3. ITF Meeting

Meeting date: 15th July

Action: For adoption

The meeting was agreed.

8.2.4. ITF Meeting

Meeting date: 25th September

Action: For adoption

The meeting was agreed.

9. Any Other Business

9.1. EMA Public engagement department: methodologies for consulting with patients and consumers

The CHMP was given an overview of the different methodologies for engagement with patients and consumers. CHMP welcomed the presentation.

9.2. Study update

Presentation

Action: For information

10. List of participants

CHMP Chair:

Harald Enzmann

CHMP members:

Andrea Laslop

Bjorg Bolstad

Blanka Hirschlerova

Ewa Balkowiec Iskra

Frantisek Drafi

Jayne Crowe

Johann Lodewijk Hillege

Kristina Dunder

Martina Weise

Melinda Sobor

Natalja Karpova

Sinan B. Sarac

CHMP alternate members:

Agnes Gyurasics

Christophe Focke

Fátima Ventura

Jorge Camarero Jiménez

Milena Stain

Nithyanandan Nagercoil

Selma Arapovic Dzakula

Tuomo Lapveteläinen

Experts:

Anja Schiel

Anne Hasle Buur

Carolien Versantvoort

Keith Pugh

Pierre Demolis

Sabine Mayrhofer

Wahiba Oualikene-Gonin

The meeting was run with support from the relevant EMA staff