22 March 2019
EMA/CHMP/349981/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 18 March 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

18 March 2019, 09:30–12:30 (CET), room 0-F

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 the minutes is considered commercially confidential or sensitive and therefore not disclosed.

Of note, the minutes are a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned these 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

The CHMP agenda for 18 March 2019 ORGAM was adopted with the addition of two topics by the Chair under A.O.B.

1.3. Adoption of the minutes

CHMP Orgam Minutes of 18 March 2019 meeting will be adopted at the March 2019 CHMP plenary.

2. Working Parties, Committees, SAGs and Drafting Groups

2.1. General

2.1.1. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan

- SWP response to CHMP List of questions for NMBA, DIPNA and EIPNA impurities (EMA/CHMP/SWP/141787/2019)

  Action: For adoption

  The response to CHMP List of questions for NMBA, DIPNA and EIPNA impurities was adopted.

- Final minutes of the SWP meeting held by teleconference on 11 December 2018 (EMA/CHMP/SWP/874038/2018)

  Action: For information

  The CHMP noted the minutes from the virtual SWP meeting held on 11 December 2018.

2.1.2. Quality Working Party (QWP)

Chair(s): Keith Pugh/Blanka Hirschlerova

EU Experts report from ICH Q12 (Lifecycle Management) interim EWG meeting 11-15 February 2019 (Tokyo)

Presented by: Jean-Louis Robert

Action: For information

The CHMP noted the status of ICH Q12 guideline.

2.1.3. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

No topics

2.1.4. European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)

Co-chair: Kaisa Immonen

No topics

2.1.5. European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP)

Co-chair: Gonzalo Calvo

No topics

2.1.6. Geriatric Expert Group (GEG)

Chair: Katarina Vučić

No topics

2.1.7. Committees

No topics

2.1.8. International Council on Harmonisation (ICH)

- Draft ICH E19 – step 2b guideline on Optimisation of Safety Data Collection

  Action: For adoption (6 months public consultation)

  The CHMP adopted the draft ICH E19 guideline for a 6-month public consultation.

- Draft ICH Q3D (R1) - step 5 guideline on Elemental Impurities

  Action: For adoption

  The CHMP adopted the draft ICH Q3D (R1) guideline.

- Expert nomination for ICH E9 (R1) guideline

  Action: For adoption

  The CHMP agreed on the nomination of Norbert Benda (BfArM) to support the ICH E9(R1) expert working group in the finalisation of the guideline, as a replacement of Rob Hemmings (MHRA). The last face-to-face meeting of this group is planned in June 2019.

- Expert nomination for ICH E20 – Adaptive clinical trials

  The CHMP also agreed on the nomination of Armin Koch (Hannover Medical School) and Frank Petavy (EMA) to support the ICH E20 expert working group in developing a guideline on adaptive clinical trials. The first face-to-face meeting of this group is planned in November 2019.

2.1.9. 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 topics

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

Chair: Nienke Rodenhuis

No topics

2.1.11. Joint CVMP-CHMP antimicrobial advice ad hoc expert group (AMEG)

Chair: Gérard Moulin

No topics

2.1.12. Modelling and Simulation Working Party (MSWP)

Chair: Kristin Karlsson/Flora Musuamba Tshinanu

No topics

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

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

No topics

2.2.2. Biologicals Working Party (BWP)

Chair(s): Sol Ruiz/Nanna Aaby Kruse

- Final minutes of the BWP plenary meeting held on 18-20 February 2019
- Draft agenda of the BWP plenary meeting to be held on 18-20 March 2019

Action: For information

The CHMP noted the minutes from the BWP February 2019 meeting and the agenda from the March 2019 meeting.

2.2.3. Vaccines Working Party (VWP)

Chair(s): Mair Powell

Nomination of a new additional assessor:

Alicia Perez (ES) – replacing Marta Soler

Action: For information

The nomination of Alicia Perez as an additional assessor to the VWP was noted.

2.2.4. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr

No topics

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair(s): Krishna Prasad/Markus Paulmichl

No topics

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair(s): Kristina Dunder/Alar Irs

No topics

2.3.2. Central Nervous System Working Party (CNSWP)

Chair(s): Karl Broich/André Elferink

No topics

2.3.3. Infectious Diseases Working Party (IDWP)

Chair(s): Maria Jesus Fernandez Cortizo

Participation of Dr. Mair Powell on behalf of EMA/CHMP at the ASM-ECSMID Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance, Boston, US, 3-6 September 2019 (EMA/169173/2019)

Action: For discussion

The participation of Dr. Mair Powell to the above-mentioned conference on behalf of EMA/CHMP was agreed.

2.3.4. Oncology Working Party (ONCWP)

Chair(s): Pierre Demolis/Paolo Foggi

Nomination of two new core members following Bertil Jonsson's (SE) and Sinan Bardakci Sarac's (DK) resignations as members.

Nominations received:

Action: For adoption

The topic was postponed to the next ORGAM in April.

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair(s): Jan Welink/Henrike Potthast

- Call for nomination for two new PKWP members:

  The following expertise areas need to be filled with 2 new members as a result of departure of existing members, Susan Cole (UK) and Eva Gil-Berglund (SE). These should be special expertise areas in addition to general PK and/or biopharmaceutics:

  - PBPK modelling
  - Drug-Drug interactions

  Nominations should be sent by **Friday 12 April 2019**.

  Action: For information

  The CHMP noted the call for nomination.

- Products specific bioequivalence guidance:

  Draft for 3 month public consultation

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

  Action: For adoption

  Further discussions are needed before the document can be adopted. The PKWP secretariat will liaise with the RMS for the innovator.

- PKWP response to CMDh question - demonstration of bioequivalence for ezetimibe

  Rapporteur: Henrike Potthast

  Action: For adoption

  The CHMP adopted the PKWP response to CMDh.

- PKWP Q&A for CMDh request on PK characteristics of iron products – acceptable bridging/bioequivalence data

  Rapporteur: Janet Mifsud

  Action: For adoption

The CHMP adopted the PKWP Q&A on bioequivalence data for iron products.

- Nomination of a new additional assessor:

  Joelle Warlin (BE)

  Action: For information

  The CHMP noted the nomination of Joelle Warlin as additional assessor to PKWP.

2.3.6. Biostatistics Working Party (BSWP)

Chair(s): Anja Schiel/Jörg Zinserling

No topics

2.3.7. Rheumatology/Immunology Working Party (RIWP)

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

No topics

2.3.8. Scientific Advisory Groups (SAGs)

No topics

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No topics

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No topics

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

No topics

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

No topics

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

- **ITF Meeting**

  Action: For adoption

  The CHMP agreed on the purpose of the meeting and noted the meeting date.

- **ITF Meeting**

  Action: For adoption

  The CHMP agreed on the purpose of the meeting and noted the meeting date.

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No topics

3. Organisational, regulatory and methodological matters

3.1. Regulatory issues / New legislation

Regulatory Affairs training plan for 2019 - Summary of the feedback from the EU Network Regulatory awareness sessions in 2018 and proposal for the Regulatory Affairs Training Plan for 2019

Action: For information

The CHMP noted the report on Regulatory Affairs awareness sessions held in 2018 as well as the training plan for 2019. CHMP members welcomed the proposed training plan, which reflects topics identified by CHMP. CHMP members were asked to share their experience with EMA on the best format for assessor training, if possible, before the first session (10 May 2019). The process will be adjusted as needed.

3.2. Meeting organisation / Templates

No topics

3.3. Pharmacovigilance

No topics

4. Any Other Business

4.1. Handling of confidential information within the EU network

Action: For discussion

The discussion was postponed to the plenary meeting.

4.2 Feedback from consultation of CHMP members on CHMP organisation

Presented by Harald Enzmann

Action: For information

Following his first presentation during the February ORGAM the chair continued with the organisational topics identified during his one-to-one TCs with CHMP members.

The chair presented a training plan for 2019 and the SAWP chair presented proposals to optimise SAWP-CHMP interactions.

The SAWP chair will present the proposed changes at the March CHMP plenary.

4.3 CHMP-CAT collaboration

Presented by Harald Enzmann

Action: For information

The chair flagged that (EMEA/H/C/003691) will be discussed during the CAT March meeting and that CHMP members were invited by the CAT chair to attend the discussion (remotely).

5. List of participants

CHMP Chair:

Harald Enzmann

CHMP members:

Bruno Sepodes (Vice-Chair)

Agnes Gyurasics

Andrea LaslopConstantinos Markopoulos

Frantisek Drafi

Greg Markey

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Katarina Vučić

Kristina Dunder

Martina Weise

Natalja Karpova

Outi Mäki-Ikola

Simona Badoi

Sinan B. Sarac

CHMP alternate members:

Christophe Focke

Dana Gabriela Marin

Fátima Ventura

Ingrid Wang

Nithyanandan Nagercoil

Selma Arapovic Dzakula

Experts:

Anja SchielHenrike Potthast

Jean-Louis Robert

Keith Pugh

Maria Escudero Galindo

Mette Toftegaard Madsen

Milena Peraita Ezcurra

Patricia Diaz Ramos

Sabine Mayrhofer

The meeting was run with support from the relevant EMA staff