15 March 2019
EMA/CHMP/349980/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda 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 this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda 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 18 March 2019 meeting

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

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

  Action: For information

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

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)

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

  Action: For adoption

- Expert nomination for ICH E9 (R1) guideline

  Action: For adoption

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

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

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

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

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

- 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

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

  Rapporteur: Henrike Potthast

  Action: For adoption

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

  Rapporteur: Janet Mifsud

  Action: For adoption

- Nomination of a new additional assessor:

  Joelle Warlin (BE)

  Action: For information

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

ITF Meeting

Action: For adoption

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

3.2. Meeting organisation / Templates

No topics

3.3. Pharmacovigilance

No topics

4. Any Other Business

Handling of confidential information within the EU network

Action: For discussion