15 February 2019
EMA/CHMP/203261/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

Final ORGAM[1] agenda for the meeting on 18 February 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

18 February 2019, 09:30–12:30, room 2-D

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. Additional details on some of these procedures will be published in the CxMP <meeting highlights> <meeting reports> once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CxMP 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 February 2019 meeting

1.3. Adoption of the minutes

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

2. Working Parties, Committees, SAGs and Drafting Groups

2.1. General

2.1.1. Safety Working Party (SWP)

Chair: Jan Willem Van der Laan

CHMP List of questions to be addressed by the Safety Working Party (SWP) for NMBA impurities (EMA/CHMP/117995/2019)

Action: For adoption

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh / Blanka Hirschlerova

- Minutes from QWP Core team January 2019 and from July to December 2018:

Action: For information

- List of questions and answers that should be considered for inclusion on the Quality of medicines questions and answers at the EMA website

Action: For adoption

2.1.3. Scientific Advice Working Party (SAWP)

Co-Vice-Chairs: Peter Mol / Kolbeinn Gudmundsson

Revision of the SAWP mandate to include alternates as possible nominees for the position of Chair of the SAWP.

Action: For adoption

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

Joint Committee for Medicinal Products for Human Use (CHMP)/ Paediatric Committee (PDCO) membership

Procedure for appointing joint CHMP/PDCO members in PDCO

- Joint CHMP-PDCO membership presentation
- Draft letter from the CHMP Chair to Management Board Chair on CHMP PDCO joint membership

Action: For adoption

2.1.8. International Council on Harmonisation (ICH)

- Draft ICH M10 guideline on Bioanalytical Method Validation - Step 2b (EMA/115558/2019)

Action: For adoption for 6 months public consultation

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

Nomination of 3 new MSWP members to replace 3 leaving members

Five Candidatures were received:

Action: For adoption

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz / Niklas Ekman

No topics

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz / Nanna Aaby Kruse

- Final minutes from December face-to-face meeting held 3-4 December 2018

Action: For information

- Draft agenda for BWP face-to-face meeting to be held 18-20 February 2019

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell / Svein Rune Andersen

No topics

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

No topics

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad / Markus Paulmichl

No topics

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder / Alar Irs

No topics

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich / André Elferink

No topics

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

Participation of Dr. Stephanie Buchholz on behalf of EMA/CHMP at the EASL-AASLD meeting on HBV (London, UK) 8-9 March 2019

Action: For discussion

2.3.4. Oncology Working Party (ONCWP)

Chair: Pierre Demolis/Paolo Foggi

- Minutes for the F2F meeting on 11 January 2019 (EMA/5215/2019)

Action: for information

- Call for nomination for 2 new ONCWP members to replace Bertil Jonsson (SE) and Sinan Bardakci Sarac (DK) who stepped down as member to be additional expert.

  Nominations should be sent by **15th March 2019**.

Action: for information

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink / Henrike Potthast

- Products specific bioequivalence guidance:

  Drafts for 3 month public consultation

  Rapporteur: Henrike Potthast

  - Colchicine tablet 0.5 mg and 1 mg product-specific bioequivalence guidance (EMA/CHMP/35552/2019)
  - Etonogestrel and ethinylestradiol vaginal delivery system 0.12mg/0.015mg/day product-specific bioequivalence guidance (EMA/CHMP/97470/2019)

  Action: For adoption

Final (from batch 9)

Rapporteur: Malin Filler

- Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance (EMA/CHMP/257298/2018)

Action: For adoption

- PKWP revision of Q&A 3.6 on requirements for crushed tablets (EMA/CHMP/401006/2016)

  Rapporteur: Henrike Potthast

  Action: For adoption

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel / Jörg Zinserling

No topics

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus / Romaldas Mačiulaitis

No topics

2.3.8. Scientific Advisory Groups (SAGs)

Adoption of a LoQ to MAHs as a follow-up to the SAG-O meeting

Action: For adoption

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 Briefing Meeting

Action: For discussion and agreement

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No topics

2.3.10.3. IPRF Nano Working Group

Chair: Harald Enzmann

No topics

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

Amendments to Regulation (EC) No 726/2004 – presentation of changes and introduction of proposal for related template updates to be adopted via written procedure.

Action: For information

3.2. Meeting organisation / templates

No topics

3.3. Pharmacovigilance

No topics

4. Any Other Business

4.1. Relocation of EMA to the Netherlands – Q&A session on Delegates manual and Spark building

Action: For information

4.2. May 2019 CHMP plenary: 3-day meeting

Action: For information