20 December 2018
EMA/848375/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 4 December 2018

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

4 December 2018, 14:00-17:00 UK time, room 2E

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.

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 4 December 2018 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of 4 December 2018 meeting will be adopted at the December 2018 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

No items

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Letter to EDQM from QWP (EMA/CHMP/QWP/785196/2018)

Action: For adoption

2.1.3. Scientific Advice Working Party (SAWP)

Chair: Robert Hemmings

No items

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

Co-chair: Kaisa Immonen

Summary of the PCWP Plenary Meeting held on 25 September 2018 (EMA/717595/2018)

Action: For information

Summary of the PCWP/HCPWP Joint Meeting held on 25 September 2018 (EMA/717794/2018)

Action: For information

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

Co-chair: Gonzalo Calvo

See 2.1.4

2.1.6. Geriatric Expert Group (GEG)

Chair: Katarina Vučić

No items

2.1.7. Committees

CHMP 2019 Draft Work Plan

Action: For adoption

2.1.8. International Council on Harmonisation (ICH)

No items

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 items

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

Chair: Nienke Rodenhuis

No items

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

Chair: Gérard Moulin

No items

2.1.12. Modelling and Simulation Working Party (MSWP)

Chair: Kristin Karlsson/Flora Musuamba Tshinanu

Call for nomination for 3 new MSWP members:

The following expertise areas need to be filled with 3 new members:

- PBPK modelling
- Exposure-response (PKPD) modelling
- Quantitative systems pharmacology (QSP) modelling
- Non-linear mixed effects modelling

Nominations should be sent by **25 January 2018**.

Action: For information

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Niklas Ekman

No items

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from October face-to-face meeting held 8-9 October 2018 (EMA/CHMP/BWP/700986/2018)

Action: For information

Draft agenda for BWP face-to-face meeting to be held 3-4 December 2018 (EMA/CHMP/BWP/730346/2018)

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

No items

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

No items

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

No items

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder/Alar Irs

No items

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich/André Elferink

No items

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections, Rev 3

Action: For adoption for 6 months public consultation

Presented by Mair Powell

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

Concept paper on the revision of the guideline on the evaluation of anticancer medicinal products in man (EMA/CHMP/755489/2018)

Action: For adoption for public consultation

Draft agenda for the Adobe meeting on 7 November 2018 (EMA/760743/2018)

Action: For information

Draft minutes for the Adobe meeting on 10 October 2018 (EMA/706854)

Action: For information

Question from PDCO to ONCWP: use of extrapolation for adolescent patients with metastatic, unresectable melanoma

Action: For adoption

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

Guideline on the reporting of physiologically based pharmacokinetic (PBPK) modelling and simulation (EMA/CHMP/658647/2017)

Rapporteur: Susan Cole

Action: For adoption

Product-specific bioequivalence guidance, Batch 9 and 10

Batch 9 (Final):

- Aliskiren film-coated tablet 150 mg and 300 mg product-specific bioequivalence guidance (EMA/CHMP/291450/2018)
- Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance (EMA/CHMP/257298/2018)
- Pegylated liposomal doxorubicin hydrochloride concentrate for solution 2 mg/ml product-specific bioequivalence guidance (EMA/CHMP/800775/2017)

Action: For adoption

Batch 10 (Draft):

- Alectinib hard capsule 150 mg product-specific bioequivalence guidance (EMA/CHMP/790261/2018)
- Cabozantinib tablet 20 mg, 40 mg and 60 mg, capsule 20 mg and 80 mg product-specific bioequivalence guidance (EMA/CHMP/790333/2018)
- Ezetimibe tablet 10 mg product-specific bioequivalence guidance product-specific bioequivalence guidance (EMA/CHMP/802491/2018)
- Palbociclib hard capsule 75 mg, 100 mg and 125 mg product-specific bioequivalence guidance (EMA/CHMP/802679/2018)

Action: For adoption for 6 months public consultation

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

Guideline on the investigation of subgroups in confirmatory clinical trials

Action: For adoption

Question and answer on adjustment for cross-over in estimating effects in oncology trials (EMA/713584/2018)

Action: For adoption

BSWP Draft Minutes of BSWP virtual meeting on 19 June 2018

Action: For information

BSWP Draft Minutes of the BSWP virtual meeting on 11 September 2018

Action: For information

Nomination of additional assessors

Action: For adoption

Composition of BSWP

Action: For discussion

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus/Romaldas Mačiulaitis

Concept paper on a Guideline for allergen products development in moderate to low-sized study populations (EMA/CHMP/251023/2018)

Presented by Andreas Bonertz via Adobe

Action: For adoption for public consultation

2.3.8. Scientific Advisory Groups (SAGs)

No items

2.3.9. Drafting Groups (DGs)

No items

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No items

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No items

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

No items

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

No items

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

EC request for EMA opinion on the definitions of pharmacological, immunological, metabolic and medical diagnosis

Action: For discussion

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No items

2.3.10.3. IPRF Nano Working Group

Chair: Harald Enzmann

No items

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

3.1.1. Proposal to harmonise the rules for chairmanship across WPs (two-term rule)

Presentation

Action: For discussion / adoption

4. Any Other Business

4.1. EMA emerging health threats plan

EMA emerging health threats plan (EMA/262604/2016)

Presentation

Action: For information

4.2. Ebola in Democratic Republic of the Congo (DRC)

Presentation

Action: For information