18 June 2018
EMA/CHMP/412142/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 18 June 2018

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

18 June 2018, time 9:30 – 12:30, room 2D

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 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 June 2018 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of June 2018 meeting will be adopted at the June 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

Final minutes for SWP face-to-face meeting on 13-14 February 2018 (EMA/CHMP/SWP/101516/2018)

Action: For information

SWP report on anaesthetics and sedatives in young children and pregnant women (EMA/CHMP/SWP/172599/2018)

Action: For adoption

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Minutes from QWP Core team from January to May 2018:

Minutes of January (EMA/6919/2018); Minutes of February (EMA/76839/2018); Minutes of March (EMA/140220/2018); Minutes of April (EMA/227324/2018); Minutes of May (EMA/270742/2018)

Action: For information

Guideline on the quality of water for pharmaceutical use (EMA/CHMP/CVMP/QWP/383481/2018)

Action: For adoption for 6 months public consultation

Nomination of new QWP Core Team member – Laivi Saaremäel

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

No items

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

Co-chair: Gonzalo Calvo

No items

2.1.6. Geriatric Expert Group (GEG)

Chair: Katarina Vučić

No items

2.1.7. Committees

No items

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

Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken (EMA/CHMP/CVMP/3Rs/677407/2015)

Action: For adoption

- Background note for CHMP - J3RsWG - Review of EMA GLs considering 3Rs - report on actions taken (EMA/292206/2018)

  Action: For information

- Overview of comments received - JEG 3Rs - best practise (EMA/CHMP/CVMP/3Rs/731086/2016)

  Action: For information

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 (acting): Flora Musuamba Tshinanu

No items

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Niklas Ekman

Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant erythropoietins

Action: For adoption

Guidance on similar medicinal products containing somatropin

Action: For adoption

2.2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from April face-to-face meeting held 16-18 April 2018 (EMA/CHMP/BWP/243354/2018)

Action: For information

Draft agenda for BWP face-to-face meeting to be held 16-18 July 2018 (EMA/CHMP/BWP/333696/2018)

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

BPWP virtual meeting 14th June 2018: agenda (EMA/CHMP/BPWP/345658/2018) and timeschedule (EMA/CHMP/BPWP/395902/2018)

Action: For information

Draft Agenda – EMA-FDA-HC Blood Cluster teleconference 14th June 2018 (EMA/374189/2018)

Action: For information

Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) and related core SmPC

Rapporteur: Jacqueline Kerr

Action: For adoption

Haemophilia registries workshop: Final agenda (EMA/138425/2018) and presentations

Action: For information

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

No items

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

No items

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

Draft PKWP Q&A on Appendix I of the modified release guideline (EMA/CPMP/EWP/280/96 Corr1; clarification on sensitisation and irritation test for transdermal products) (EMA/CHMP/365909/2018)

Rapporteur: Henrike Potthast

Action: For adoption

CMDh question to PKWP/MSWP on Perlinring 0.015mg/0.12mg/ 24 hours Vaginal Delivery System - UK/H/6234/001/DC (EMA/CMDh/379205/2018):

- Background information (EMA/398716/2018)

Action: For information

Rapporteur: Sotiris Michaleas

Action: For adoption

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

Call for nomination of a new core member to BSWP

Following the resignation of one the core members, BSWP opens a call for nomination of new core member.

Please send the nominations to the Agency **by 10th July 2018**. Eligible experts, who wish to apply for the member position are requested to submit a brief letter in support of their candidature together with a brief CV, highlighting their expertise.

Action: For information

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

Call for nomination of a new core member to RIWP

One new member is envisaged, for the development of a “Concept paper on development strategies for allergen products intended for allergies with low prevalence”, experts with regulatory and/or clinical expertise for this topic are sought.

Please send the nominations to the Agency by **22nd June 2018**.

Action: For information

Concept paper on the need to develop a reflection paper on development of medicinal products to prevent and treat acute kidney injury (EMA/CHMP/171100/2018)

Rapporteur: Romaldas Maciulaitis

Action: For adoption 3 months public consultation

2.3.8. Scientific Advisory Groups (SAGs)

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth, Paediatric: Peter Szitanyi

To be presented by Mark Ainsworth at 11.00

Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis (CHMP/EWP/18463/2006) Rev.1

Action: For adoption

- Overview of comments received on ''Draft guideline on the development of new medicinal products for the treatment of Ulcerative Colitis' (EMA/CHMP/EWP/18463/2006 Rev. 1) EMA/CHMP/354664/2017

  Action: For information

Guideline on the development of new medicinal products for the treatment of Crohn's Disease (CPMP/EWP/2284/99) Rev. 2

Action: For adoption

- Overview of comments received on 'Draft guideline on the development of new medicinal products for the treatment of Crohn's Disease' (EMA/CPMP/EWP/2284/99 Rev. 2) EMA/CHMP/261409/2017

  Action: For information

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

ITF Briefing Meeting - Meeting date: 28th June 2018

Action: For discussion and agreement

ITF Briefing Meeting - Meeting date: 19th July 2018

Action: For discussion and agreement

ITF Briefing Meeting - Meeting date: 27th June or 2nd July 2018

Action: For discussion and agreement

ITF Briefing Meeting - Meeting date: 25th June 2018

Action: For discussion and agreement

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Barbara van Zwieten-Boot

No items

2.3.10.3. IPRF Nano Working Group

Chair: Harald Enzmann/Jean Louis Robert

No items

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

3.1.1. Abolishment of physical signatures for divergent positions for centrally authorised products (CAPs)

The divergent position members will be approached to confirm the agreed final wording for the divergent position electronically.

Action: For information

3.1.2. EMA Implementation plan of the new medical device and in vitro diagnostic regulation

Action: For information

4. Any Other Business

4.1.2. Understanding the training needs of NCA assessors involved in the work of the CHMP: Priority needs and plans for training 2018 – 2020

Action: For discussion

Linked to the Network 2020 objective to reinforce the scientific and regulatory capacity and capability of the network: specifically identification of gaps in scientific and regulatory expertise based on current and future needs, and meeting these needs through corresponding training development offered through the EU Network Training Centre.