10 April 2017
EMA/CHMP/206179/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 10 April 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

10 April 2017, 09.30 – 12.30 (UK time), 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.

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

[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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adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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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 10 April 2017 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of April 2017 meeting will be adopted at the April 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

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Closure of the EMA-FDA QbD pilot program. Joint report for publication on the EMA and FDA websites

Action: For information

Question from Estonia to the QWP core team on sodium triphosphate pentabasic

Action: For agreement

2.1.3. Scientific Advice Working Party (SAWP)

Chair: Robert Hemmings

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

Co-chair: Kaisa Immonen

Minutes of the PCWP meeting with all eligible organisations - 30 November 2016 (EMA/801985/2016)

Action: For information

See also 2.1.5.2 Agenda of the PCWP/HCPWP joint meeting

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

Co-chair: Gonzalo Calvo

Agenda of the Workshop on personalised medicines: role of patients, consumers and healthcare professionals - 14 March 2017 (EMA/762357/2016)

Action: For information

Agenda of the PCWP/HCPWP joint meeting – 15 March 2017 (EMA/69326/2017)

Action: For information

2.1.6. Geriatric Expert Group (GEG)

Chair: Niccolo Marchionni

2.1.7. Committees

2.1.8. International Council on Harmonisation (ICH)

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 (JEG 3Rs)

Chair: Sonja Beken/ Ellen-Margrethe Vestergaard

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

Chair: Nienke Rodenhuis

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

Chair: Gérard Moulin

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Martina Weise

Nomination of additional PK expert to BMWP

Nominations received

• Current list of members

Action: For adoption

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse/Ilona Reischl

Draft agenda for BWP face-to-face meeting to be held 10-11 May 2017 (EMA/CHMP/BWP/209322/2017)

Action: For information

Final minutes from face-to-face meeting held 13-15 February 2017 (EMA/CHMP/BWP/112435/2017)

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell

Nomination of Daniel Brasseur (BE) as an observer to VWP

• Current list of members

Action: For adoption

Minutes of VWP virtual meetings on 03 February and 03 March 2017

Action: For information

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Nomination of Sophie Barbou Des Courieres (FR) and Mary-Ann Eichmann (PEI Germany) as new members to the BPWP

Action: For adoption

Nomination of Anneliese Hilger (PEI Germany) as BPWP additional expert

Action: For adoption

BPWP Work Plan 2017, revision

Action: For adoption

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Final minutes for PGWP meeting held by Adobe on 12 December 2017 (EMA/848583/2016)

Action: For information

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Final minutes for CVSWP meeting held face-to-face on 23 November 2016 (EMA/789887/2016)

Action: For information

Appointment of a new CVSWP core member replacing Karsten Bruins Slot

Nomination received

Action: For adoption

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

Final minutes for CNSWP meeting held face-to-face on 2 December 2016 (EMA/811433/2016)

Action: For information

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

Concept paper on a guideline on the evaluation of medicinal products indicated for treatment of influenza (EMA/CHMP/EWP/808940/2016)

Action: For adoption

2.3.4. Oncology Working Party (ONCWP)

Chair: Pierre Demolis/Paolo Foggi

Minutes of ONCWP virtual meeting held on 15 February 2017 (EMA/112280/2017).

Action: For information

Nomination of Sigrid Klaar (SE) as additional expert to ONCWP

• Current list of members and observers

Action: For adoption

Nomination of Ingrid Wang (NO) as an observer to ONCWP

Action: For adoption

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Concept paper on the revision of the Guideline on the role of pharmacokinetics in the development of medicinal products in the paediatric population (EMA/CHMP/448599/2016)

Action: For adoption for 3 months public consultation

CHMP request for PKWP input into PK aspects of biosimilarity

Action: For adoption

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Minutes of BSWP virtual meeting held on 14 March 2017 (EMA/177185/2017)

Action: For information

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

2.3.8. Scientific Advisory Groups (SAGs)

2.3.9. Drafting Groups (DGs)

2.3.9.1 Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

2.3.9.2 Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

Final minutes for RDG meeting held face-to-face on 15-16 September 2016 (EMA/621110/2016)

Action: For information

2.3.9.3 Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

2.3.9.4 Excipients Drafting Group

Chair: Dominique Masset

2.3.10. Additional agenda points

2.3.10.1 Innovation Task Force

ITF briefing meeting

Meeting date: 26 April 2017

Action: For discussion and agreement

2.3.10.2 Guideline Consistency Group (GCG)

Chair: Barbara van Zwieten-Boot

2.3.10.3 IPRF Nano Working Group

Chair: Harald Enzmann/Jean Louis Robert

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

3.2. Meeting organisation / templates

3.3. Pharmacovigilance

3.3.1. Patient Registry Initiative: Update and Workshops on Cystic Fibrosis (CF) and Multiple Sclerosis (MS)

The Patient Registry Initiative published recently the workshop report held last October 2016 including some recommendations. Following these recommendations, one of the proposed activities is to organise two workshops, one on CF and another one on MS with the following objectives:

- To agree on implementable recommendations on core data elements to be collected, protocols, consents, governance supporting registry interoperability.
- Workplan for the further development and finalisation of recommendations to be used by registry holders and MAHs/MAAs.

The workshops are taking place on 14th June (CF) and 7th July (MS). PRAC (co-) Rapporteurs have been invited as being key to the success of the workshop.

Action: For information

4. Any Other Business

4.1 EMA/FDA strategic document on Gaucher disease

Action: For adoption