12 February 2018
EMA/CHMP/91430/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 12 February 2018

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

12 February 2018, 09:30–12:30, 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. 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 12 February 2018 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of 12 February 2018 meeting will be adopted at the February 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

Draft agenda for SWP meeting to be held face-to-face on 13-14 February 2018 (EMA/CHMP/SWP/40675/2018)

Action: For information

Final minutes for SWP meeting held face-to-face on 3-4 October 2017 (EMA/CHMP/SWP/667387/2017)

Action: For information

Final minutes for SWP meeting held by teleconference on 21 November 2017 (EMA/CHMP/SWP/773822/2017)

Action: For information

SWP response to CMDh Question - Acceptability of statement on potential residues of latex in the Product information of products packed in containers with synthetic rubber stopper (EMA/CHMP/SWP/652246/2017)

Presentation by Jan Willem Van der Laan

Action: For adoption

PRAC questions to SWP regarding prenatal exposure to paracetamol and impact on the urogenital apparatus or impact on neurodevelopment (EMA/CHMP/SWP/80160/2018)

Action: For adoption

- Signal assessment report about prenatal exposure to paracetamol and impact on the urogenital apparatus or impact on neurodevelopment (EMA/45689/2018)

Action: For information

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Co-processed excipients – Letter to EDQM (EMA/CHMP/CVMP/64280/2018)

Action: For adoption

Nomination of new UK member & alternate

Action: For adoption

CMDh Question to QWP on Paclitaxel Hetero (PT/H/1256/001/DC) (EMA/CMDh/64913/2018)

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

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

Work plan for the Geriatric Expert Group (GEG) for 2018 (EMA/633939/2017)

Action: For adoption

2.1.7. Committees

CHMP 2018 Work Plan (EMA/CHMP/55038/2018)

Action: For adoption

Call for nomination of 5th co-opted member at the Committee on Herbal Medicinal Products HMPC

Agreed area of expertise: Clinical pharmacology (widened scope to clinical assessment/trials in general). Either general or focused on the most common areas herbal medicinal products are used.

Action: For information

2.1.8. International Council on Harmonisation (ICH)

Nomination of experts to contribute to guidelines:

- – ICH E19 EWG (Guideline in development on Optimisation of Safety Data Collection) – Deputy Topic Lead
- – ICH S5(R3) EWG (Guideline on reproductive toxicology: detection of toxicity to reproduction for human pharmaceuticals) - Deputy Topic Lead - Temporary replacement
- – ICH E17 IWG (Guideline on General principles for planning and design of Multi-Regional Clinical Trials) - Topic Lead
- – ICH E17 IWG (Guideline on General principles for planning and design of Multi-Regional Clinical Trials) - Deputy Topic Lead

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

JEG3Rs (J3RsWG) Annual Report 2017 (EMA/CHMP/CVMP/3Rs/502136/2017)

Action: For adoption

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

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Niklas Ekman

Overview of comments received on 'Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues' (EMEA/CHMP/BMWP/42832/2005 Rev. 1), (EMA/772616/2013)

Action: For information

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from December face-to-face meeting held 4-6 December 2017 (EMA/CHMP/BWP/810336/2017)

Action: For information

Draft agenda for BWP face-to-face meeting to be held 12-14 March 2018 (EMA/CHMP/BWP/27089/2018)

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Nomination of additional assessor (observer) to VWP

Action: For adoption

Follow-up item from January

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Final Minutes of the BPWP 16-17th November 2017 (EMA/CHMP/BPWP/759445/2017)

Action: For information

Agenda and time schedule of the F2F meeting 8-9th February 2018 (EMA/CHMP/BPWP/13936/2018)

Action: For information

TC with FDA 5th February 2018 (EMA/CHMP/BPWP/48972/2018)

Action: For information

TC with FDA to discuss the treatment of direct or indirect factor Xa(FXa) inhibitor when reversal of anticoagulation is needed (13th February 2018; date TBC)

Action: For information

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Guideline on good pharmacogenomic practice (EMA/CHMP/268544/2016)

Rapporteur: Krishna Prasad

Action: For adoption

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder

Final agenda for CVSWP meeting held by teleconference on 7 February 2018 (EMA/29049/2018)

Action: For information

Final minutes for CVSWP meeting held face-to-face on 22 November 2017 (EMA/775601/2017)

Action: For information

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich/André Elferink

Guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease and other dementias (CPMP/EWP/553/95 Rev.2)

Action: For adoption

Follow-up item from January Plenary

Nomination of an additional expert to the CNSWP

Action: For adoption

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

Ibuprofen 200 - 800 mg oral use immediate release formulations product-specific bioequivalence guidance (EMA/CHMP/356876/2017)

Rapporteur: Susan Cole

Action: For adoption

- Overview of comments received on 'Ibuprofen 200 – 800 mg oral use, immediate release formulations product-specific bioequivalence guidance' (EMA/CHMP/730723/2017)
  Action: For information

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

Nomination of new additional assessor

Action: For adoption

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

No items

2.3.8. Scientific Advisory Groups (SAGs)

No items

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Elmer Schabel

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

No items

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

No items

3.2. Meeting organisation / templates

3.2.1. Discussion on additional assessors (so called observers) to working parties and drafting groups

CHMP: Tomas Salmonson

Action: For discussion

Follow-up item from January Plenary