5 June 2018
EMA/CHMP/257951/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

Minutes of ORGAM[1] meeting on 16 April 2018

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

Disclaimers

Some of the information contained in the minutes is considered commercially confidential or sensitive and therefore not disclosed. Of note, this document 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 minutes 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Table of contents

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 16 April 2018 meeting was adopted.

1.3. Adoption of the minutes

CHMP Orgam Minutes of 16 April 2018 meeting will be adopted at the April 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

Questions and answers on implementation of risk based prevention of cross contamination in production and 'Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities' (EMA/CHMP/CVMP/SWP/169430/2012)

Action: For adoption

The Questions and answers document was presented. The document went through public consultation and comments received from workshop and public consultation were taken into account. Prior to circulation to the CHMP, the document had been reviewed by SWP-h, SWP-v and the GMP/GDP Inspectors Working Group.

The CHMP adopted the document. The document will be published on the EMA website.

Final minutes for SWP meeting held by teleconference on 19 December 2017 (EMA/CHMP/SWP/844162/2017)

Action: For information

The CHMP noted the final minutes.

Final minutes for SWP meeting held by teleconference on 16 January 2018 (EMA/CHMP/SWP/32544/2018)

Action: For information

The CHMP noted the final minutes.

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Letter to EDQM - paromomycin sulfate monograph request (EMA/CHMP/CVMP/QWP/126810/2018)

Action: For adoption

The CHMP adopted the letter to EDQM.

Nomination of a new member – Katerina Savvidou (CY) replacing Maria Vassiliou (CY)

- Nomination Letter Katerina Savvidou (CY)
- E-CV – Katerina Savvidou

Action: For adoption

The CHMP appointed Katerina Savvidou (CY) as new member to QWP.

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)

ICH S9 Guideline: Nonclinical Evaluation for Anticancer Pharmaceuticals - Questions and Answers – Step5

Action: For adoption

The CHMP adopted the Questions and Answers – Step5.

ICH Q3D Guideline for Elemental Impurities – Cadmium – Step2b

Action: For adoption

The CHMP adopted the guideline.

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 (JRsWG)

Chair: Ellen-Margrethe Vestergaard, Co-Chair: Susanne Brendler-Schwaab

BWP nomination to the J3RsWG of a new core member Dijana Derganc from Croatia, replacing Svein Andersen

- E-CV – Dijana Derganc
- Background note on the election of a new core member of J3RsWG (EMA/200108/2018)

Action: For adoption

The CHMP appointed Dijana Derganc from Croatia as new core member to the J3RsWG.

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 Group (MSWG)

Chair (acting): Flora Musuamba Tshinanu

Conversion of MSWG to MSWP

In view of the current and anticipated impact of M&S approaches in drug development and regulatory review it is proposed to convert the EMA MSWG to a CHMP temporary working party.

Action: For adoption

The topic was postponed to the April CHMP Plenary meeting.

Call for interest for Chair/Vice-Chair

Action: For adoption

The topic was postponed to the April CHMP Plenary meeting.

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

CMDh question to BWP on requirements for Module 3 for the transfer of test methods to already approved QC testing site for a biological MP (EMA/CMDh/188925/2018)

Action: For adoption

The CHMP adopted the CMDh question to BWP.

Final minutes from February face-to-face meeting held 12-14 February 2018 (EMA/CHMP/BWP/91627/2018)

Action: For information

The CHMP noted the final minutes.

Draft agenda for BWP face-to-face meeting to be held 22-23 May 2018 (EMA/CHMP/BWP/171873/2018)

Action: For information

The CHMP noted the draft agenda.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Revised Guideline on clinical evaluation of new vaccines, draft (EMA/406830/2017)

Action: For adoption for 6 months public consultation

The guideline was presented by Mair Powell. The guideline addresses the clinical evaluation of vaccines intended for the prevention of infectious diseases. It includes considerations for trials intended to document the safety, immunogenicity and efficacy of new candidate vaccines and to support changes in the prescribing information of licensed vaccines. It also considers the need for and use of vaccine effectiveness studies.

The CHMP adopted the guideline for 6 months public consultation.

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Final Minutes Blood Cluster EMA-FDA-HC Teleconference 1st March, 2018 (EMA/CHMP/BPWP/198925/2018)

Action: For information

The CHMP noted the final minutes.

Final agenda and time schedule for BPWP virtual meeting on 10th April 2018 (EMA/CHMP/BPWP/160880/2018 and EMA/CHMP/BPWP/184535/2018)

Action: For information

The CHMP noted the final agenda.

Workshop on haemophilia registries: draft agenda and pre-work packages (EMA/138425/2018 and EMA/183154/2018)

Action: For discussion

The CHMP noted the information about the workshop on haemophilia registries, taking place 8th June 2018 in EMA premises.

Letter from European Ombudsman on the European Medicines Agency's process for revising guidelines concerning normal human immunoglobulin

- European Ombudsman's Decision in case 2018/2/KR on the process followed by the European Medicines Agency for revising guidelines concerning the use of 'normal human immunoglobulin'

Action: For discussion

The CHMP noted the letter from the European Ombudsman concluding that there was no EMA maladministration in EMA's procedure for revising the guidelines concerning normal human immunoglobulin.

PRAC questions to BPWP on drug induced lupus erythematosus associated with immunoglobulins:

- Signal assessment report on lupus-like syndrome and related terms with Normal Human Immunoglobulin (EMA/PRAC/720440/2017)

Action: For adoption

The CHMP adopted the PRAC questions to BPWP.

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

No items

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich/André Elferink

Call for nomination of a new core member to CNSWP. Please send the nominations **by 18th May 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

The expertise should be related to the *"significant experience in guideline development and evaluation of CNS products, in particular in the field of depression and migraine"*. The CHMP noted the call.

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

Nomination of additional assessor (observer) to ONCWP

Action: For adoption

The CHMP nominated Hilke Zander from Germany (PEI) as additional assessor to ONCWP.

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

No items

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

No items

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Axial Spondyloarthritis (EMA/CPMP/EWP/4891/03 Rev.1, Corr 1*)

Action: For adoption

The CHMP adopted the guideline. There is only one change in the guideline, which relates to the change of the nomenclature from “moderate disease activity” to “low disease activity” (paragraphs 3 and 4 under Primary endpoints).

2.3.8. Scientific Advisory Groups (SAGs)

No items

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Mark Answorth

Draft Programme of the workshop on EMA stakeholder interaction on the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC and NASH).

The Workshop is planned for 3rd December 2018 to support the drafting process of the reflection paper. Speakers from academia, patient organisations and regulatory agencies

will be invited. The workshop is open for the public (subject to prior registration) and will be externally broadcasted and recorded.

Action: For information/discussion

The CHMP noted the information about the workshop.

Nomination of additional assessor to the GDG

Action: For adoption

The CHMP nominated Joost Romme (NL) as additional assessor to the GDG.

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. Requests for additional assessors to working parties and drafting groups

CHMP: Tomas Salmonson

Action: For discussion

Further discussions are expected to be held during the April CHMP Plenary. It was agreed that the communication sent to working parties regarding the composition rules should be sent to all CHMP members as well.

4. List of participants

CHMP Chair:

Tomas Salmonson

CHMP members:

Frantisek Drafi

Harald Enzmann

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Katarina Vučić

Outi Mäki-Ikola

Robert James Hemmings

Simona Badoi

CHMP alternate members:

Bjorg Bolstad

Christophe Focke

Dana Gabriela Marin

Mark Ainsworth

Milena Stain

Nithyanandan Nagercoil

Experts:

Claire-Li Ding

Gloria Calderon de la Barca

Irene Diaz Ortiz

Jan Willem van der Laan

Keith Pugh

Kristina Bech Jensen

Mair Powell

Maria Escudero Galindo

Milena Peraita Ezcurra

The meeting was run with support from the relevant EMA staff