



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 March 2017
EMA/CHMP/174289/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP) Final ORGAM¹ Minutes of the meeting on 13 March 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

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 13 March 2017 meeting was adopted

1.3. Adoption of the minutes

CHMP Orgam Minutes of March 2017 meeting will be adopted at the March 2017 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 meeting held by Adobe connect on 22 November 2016
(EMA/CHMP/SWP/788133/2016)

Action: For information

The CHMP noted the minutes.

Final minutes for SWP meeting held by Adobe connect on 20 December 2016
(EMA/CHMP/SWP/67183/2017)

Action: For information

The CHMP noted the minutes.

Final minutes for SWP meeting held by Adobe connect on 31 January 2017
(EMA/CHMP/SWP/70344/2017)

Action: For information

The CHMP noted the minutes.

Withdrawal of Questions and answers on the 'Guideline on the limits of genotoxic impurities'
(EMA/CHMP/SWP/431994/2007 Rev. 3) from EMA website:

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002907.pdf

Action: For information

The CHMP agreed to the withdrawal from the EMA website.

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

QWP comments on Chapter 7 (Pediatric formulations) of ICH
(EMA/CHMP/QWP/163838/2017 & EMA/CHMP/QWP/163852/2017)

Action: For adoption

The CHMP noted the QWP comments.

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: Niccolo Marchionni

Nomination of new members to the GEG:

- Barbro Westerholm: member of the Patients' and Consumers' Working Party (PCWP).
- Jean-Pierre Baeyens: member of Healthcare Professionals' Working Party (HCPWP).
- María Silvia de Orbe (Spain) : current National Expert on secondment working in the implementation of Geriatrics medicines strategy and Elderly population CHMP D80 AR Pilot, in order to have a continuation of the work.

- Current membership list
- CVs of the new nominees

Action: For adoption

The CHMP appointed new members Barbro Westerholm, Jean-Pierre Baeyens, María Silvia de Orbe (Spain). The CHMP noted involvement of Katarina Vučić (Croatia) and Arantxa Sancho (Spain) in this group.

2.1.7. Committees

Committee for Advanced Therapies (CAT): Draft Agenda of the March 2017 meeting (EMA/CAT/151495/2017)

Action: For information

The CHMP noted the agenda.

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 (JEG 3Rs)

Chair: Sonja Beken/ Ellen-Margrethe Vestergaard

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

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Martina Weise

Draft agenda of BMWP meeting held face to face on 08-09 March 2017 (EMA/61797/2017).

Action: For information

The CHMP noted agenda.

Draft minutes of BMWP virtual meeting held on 01 February 2017 (EMA/95489/2017).

Action: For information

The CHMP noted minutes.

Call for interests for one additional clinical pharmacokinetics expert.

Additional clinical pharmacokinetics expertise is needed to support the following activity:
Support PKWP discussion and Q&A development on pharmacokinetics aspects related to demonstration of biosimilarity.

The deadline for nominations is **15 March 2017**.

Please include a CV of the candidate(s) nominated.

Action: For information

The CHMP noted the call.

Final minutes of Biosimilar Cluster TC held on 15 November 2016 (EXT/69613/2017).

Action: For information

The CHMP noted the minutes.

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 April 2017
(EMA/CHMP/BWP/138843/2017)

Action: For information

The CHMP noted the agenda.

Final minutes from face-to-face meeting held 16-18 January 2017
(EMA/CHMP/BWP/36641/2017)

Action: For information

The CHMP noted the minutes.

Guideline on pharmaceutical and biological aspects of combined vaccines
(EMA/CHMP/BWP/151006/1999) – request for archiving the document on EMA website

Action: For information

The CHMP agreed to archive the guideline.

Thiomersal documents: Update of website

- Thiomersal: Implementation of the warning statement relating to sensitisation
EMEA/CHMP/VWP/19541/2007

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003905.pdf

- Reduction, elimination or substitution of thiomersal in vaccines CPMP/BWP/2517/00

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003929.pdf

- Thiomersal in vaccines for human use - recent evidence supports safety of thiomersal-containing vaccines EMEA/CPMP/VEG/1194/04

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003904.pdf

Action: For information

The CHMP agreed to include the statement that the content of these documents was reviewed in 2016 and it was considered that an update is not necessary.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell

No items

2.2.4. Blood Products Working Party (BPWP)

Chair: Anneliese Hilger

Nomination of Jacqueline Kerr as a member of the Blood Products Working Party as replacement to the current member Mary-Ann Eichmann, who is stepping down and nominated as an observer

Action: For adoption

The CHMP appointed Jacqueline Kerr as a member and Mary-Ann Eichmann was nominated as an observer to the Blood Products Working Party.

Meeting with LFB to discuss the guideline on immunoglobulin specifically the inclusion of multifocal motor neuropathy (MMN), chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) indications, 16th March 2017

Action: For information

Draft Agenda of the meeting

The CHMP noted the meeting. The purpose of this meeting is to discuss comments related to the guideline.

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: Pieter de Graeff/Kristina Dunder

No items

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

No items

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

Draft agenda of IDWP meeting held face to face on 29-30 March 2017

Action: For information

The CHMP noted the agenda.

2.3.4. Oncology Working Party (ONCWP)

Chair: Pierre Demolis/Paolo Foggi

Nomination of Bjørg Bolstad (NO) and Mette Linnert Jensen (DK) as an observers to ONCWP

- Current membership list

Action: For adoption

The CHMP nominated Bjørg Bolstad (NO) and Mette Linnert Jensen (DK) as observers to ONCWP.

Minutes of ONCWP virtual meeting held on 18 January 2017 (EMA/37669/2017).

Action: For information

The CHMP noted the minutes.

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Guideline on equivalence studies for the demonstration of therapeutic equivalence for products that are locally applied locally acting in the gastrointestinal tract as addendum to

the guideline on the clinical requirements for locally applied, locally acting products containing known constituents (CPMP/EWP/239/95 Rev. 1)

Action: For adoption for 6 months public consultation

Further discussions will be held during the March Plenary. The CHMP noted the comments from GCG.

Concept paper on a revision of the Guideline on the investigation of drug interactions (EMA/CHMP/694687/2016)

Action: For adoption for 3 months public consultation

The CHMP noted the comments from GCG. The CHMP adopted the concept paper for 3 months public consultation.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Nomination of Anne Louise Svendsen (DK) as an observer to BSWP

- Current membership list

Action: For adoption

The CHMP nominated Anne Louise Svendsen (DK) as an observer to BSWP.

Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development

Action: For adoption for 6-months public consultation

Further discussions will be held at the March Plenary. The CHMP noted the reflection paper and comments from GCG. It was acknowledged that the reflection paper is well written and methodologically sound. However, there are concerns that the "reflection" paper format (which can be understood as providing some recommendations) may be too prescriptive about the EMA position on this topic, while this document is rather seen as a "discussion" or "white" paper. Discussions on whether organising an EMA workshop before release for public consultation would be beneficial. BSWP should emphasize that it is merely a "discussion paper" and should consider a longer consultation phase (i.e. longer than 6 months as currently proposed). An updated version of the reflection paper should be provided to CHMP and discussed at the March Plenary.

Nomination of 2 additional experts: Andreas Brandt (BfArM) and Cecilia Hedlund (MPA) to the BSWP.

Action: For adoption

The CHMP appointed 2 additional experts Andreas Brandt (BfArM) and Cecilia Hedlund (MPA) to the BSWP.

Nomination of Kit Roes (NL) as observer to the BSWP

- Current membership list

Action: For adoption

The CHMP nominated Kit Roes (NL) as observer to the BSWP.

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

Call for nomination for RIWP core member after resignation of Nils Feltelius

Action: For information

Nominations for a RIWP core member should be sent to by 31 March 2017.

The CHMP noted the call.

Draft agenda of RIWP meeting held face to face on 08-09 March 2017 (EMA/93534/2017).

Action: For information

The CHMP noted the agenda.

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

Minutes of 2-Feb-17 meeting via TC

Action: For information

The CHMP noted the minutes.

Harmonisation of the package leaflet statements of the excipients revised between 2014 and 2016

Action: For information

The CHMP noted the harmonisation proposal.

2.3.10. Additional agenda points

2.3.10.1. *Innovation Task Force*

No items

ITF briefing meeting

Meeting date: 31 March 2017

Action: For adoption

The CHMP agreed to the meeting.

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. EMA/FDA strategic document on Gaucher disease

Action: For adoption

Postponed

3.2. Meeting organisation / templates

3.2.1. Experts attending plenary meetings via Adobe Connect

Action: For discussion

New release of Adobe Connect and its guidance (EMA/CHMP/162173/2017)

The CHMP noted the information.

3.3. Pharmacovigilance

No items

4. Any Other Business

First-in-Human (FIH) clinical trials guideline revision experts group:

Nomination of Joelle El-Khoury as new expert following Philippe Vella's resignation (ANMS, France)

Action: For adoption

The CHMP nominated Joelle El-Khoury as new expert following Philippe Vella's resignation (ANMS, France). Furthermore, update on the revision of the guideline should be given at the March Plenary.

5. List of participants

CHMP Chairman:

Tomas Salmonson

CHMP members:

Agnes Gyurasics

Alexandre Moreau

Andrea Laslop

Concepcion Prieto Yerro

Greg Markey

Jan Mueller-Berghaus

Jean-Louis Robert

Katarina Vučić

Martina Weise

Nela Vilceanu

Outi Mäki-Ikola

Robert James Hemmings

CHMP alternate members:

Bjorg Bolstad

Dana Gabriela Marin

Nithyanandan Nagercoil

Paula Boudewina van Hennik

Experts:

Maria Escudero Galindo

Maria Romero Guerra

Patricia Diaz Ramos

Theis Moeslund Jensen

Valerie Lescrainier