13 March 2017
EMA/CHMP/174281/2017 Rev.0
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for 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.

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 13 March 2017 meeting

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

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

Action: For information

Final minutes for SWP meeting held by Adobe connect on 31 January 2017

(EMA/CHMP/SWP/70344/2017)

Action: For information

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 adoption

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

QWP comments on Chapter 7 (Pediatric formulations) of ICH E11 (EMA/CHMP/QWP/163838/2017 & EMA/CHMP/QWP/163852/2017)

Action: For Adoption

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

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

Co-chair: Gonzalo Calvo

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 nomineés

Action: For adoption

2.1.7. Committees

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

Action: For information

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

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

Action: For information

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

Action: For information

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

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

Action: For information

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

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

Action: For information

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

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

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell

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

Action: For adoption

Meeting with LFB to discuss the guideline on immunoglobulin specifically the inclusion of multifocal motor neuropathy (MMN), chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) indications, 17th March 2017

Action: For information

Draft Agenda of the meeting

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

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

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

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

Action: For information

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

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

Action: For adoption 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

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

Action: For adoption for 6-months public consultation

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

Action: For adoption

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

- Current membership list

Action: For adoption

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.

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

Action: For information

2.3.8. Scientific Advisory Groups (SAGs)

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Elmer Schabel

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

Minutes of 2-Feb-17 meeting via TC

Action: For information

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

Action: For information

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF briefing meeting

Meeting date: 31 March 2017

Action: For adoption

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

3.1.1. EMA/FDA strategic document on Gaucher disease

Action: For adoption

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)

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