8 May 2017
EMA/CHMP/293225/2017 Rev.0
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda of the meeting on 8th May 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

8 May 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. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CxMP <meeting highlights> <meeting reports> once the procedures are finalised and start of referrals will also be available.

Of note, this agenda 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 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 8 May 2017 meeting

1.3. Adoption of the minutes

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

Nomination of new observer Christine Siezen (NL) – replacing Wilhelm Johan de Waard

Action: For adoption

- Current membership list

SWP position paper on 'Opportunities to access and view SEND files for the EU regions' (EMA/CHMP/SWP/258499/2017)

Action: For information

Minutes of SWP face-to-face meeting held on 14-15 February 2017 (EMA/CHMP/SWP/110749/2017)

Action: For information

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Outcome from April QWP Core Team discussion on the questions from Estonia on whether sodium triphosphate pentabasic is to be considered a novel excipient in case of parenteral administration (EMA/249961/2017)

Action: For information

Revision of the Guideline on the pharmaceutical quality of inhalation and nasal products (EMEA/CHMP/QWP/49313/2005 Corr) – inclusion of TGA (Australian medicine authority) to act as an observer

Action: For information

Call for nomination of QWP Chairperson

CHMP/CVMP Members, and QWP Members and Alternates are eligible for the position of QWP Chairperson. Eligible experts, who wish to apply for the Chairperson position are requested to submit a brief resume in support of their candidature together with a brief resume, highlighting the expertise.

Nominations should be sent to the EMA by 12 June 2017.

Action: For information

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

2.1.7. Committees

Minutes of Strategic Review and Learning meeting in Malta 1-2 March 2017 (EMA/166340/2017)

Action: For adoption

2.1.8. International Council on Harmonisation (ICH)

E2B (R3) Step 5 Electronic transmission of individual case safety reports (ICSRs) - data elements and message specification - implementation guide

Action: For adoption

E2B (R3) Step 5 Questions and Answers: Data Elements for Transmission of Individual Case Safety Reports

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 (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

Guideline on Immunogenicity assessment of biotechnology-derived therapeutic proteins (EMEA/CHMP/BMWP/14327/2006 Rev1)

Action: For adoption

Minutes of BMWP face-to-face meeting held on 08-09 March 2017 (EMA/169167/2017)

Action: For information

Minutes of BMWP virtual meeting held on 29 March 2017 (EMA/249100/2017)

Action: For information

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Nomination of Katalin Szalay as new HU member to BWP

Action: For adoption

Q&A on haemagglutination inhibition (HI) assay - for influenza vaccines.

Action: For adoption

Final minutes from face-to-face meeting held 13-15 March 2017 (EMA/CHMP/BWP/179791/2017)

Action: For information

Draft agenda for BWP face-to-face meeting to be held 12-14 June 2017 (EMA/CHMP/BWP/261436/2017)

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Concept paper for the revision of the Guideline on Clinical evaluation of new vaccines (EMEA/CHMP/VWP/164653/05)

Action: For adoption for 3 months public consultation

Minutes of VWP virtual meeting held on 31 March 2017 (EMA/222130/2017)

Action: For information

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) and related core SmPC

Rapporteur: Jacqueline Kerr

Action: For discussion

Minutes of BPWP February 2017 meeting

Action: For information

Agenda and draft minutes of BPWP April 2017 meeting

Action: For information

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

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

Minutes of ONCWP virtual meeting held on 15 March 2017 (EMA/181212/2017)

Action: For information

Draft Agenda of ONCWP meeting to be held face-to-face held on 10 May 2017 (EMA/249901/2017)

Action: For information

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Question from CMDh to PKWP on bioequivalence studies for oral solutions administration with or without water

Action: For adoption

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

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

Concept paper on the need for the development of a Reflection Paper on regulatory requirements for the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH) (EMA/CHMP/197320/2017)

Rapporteur: Elmer Schabel

Action: For adoption for 3 months public consultation

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

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF briefing meeting

Meeting date: 16 May 2017

Action: For adoption

ITF briefing meeting

Meeting date: 13 June 2017

Action: For adoption

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Barbara van Zwieten-Boot

Call for nominations of GCG Chairperson

Expression of interest for the Chairperson position should include a brief letter in support of the candidature together with a brief CV, highlighting the expertise of the candidate, should be sent **by 11 May 2017**. Election will take place at May 2017 CHMP Plenary.

Action: For information

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 framework of collaboration with academia

Action: For information

3.1.2. Revision of the Commission Regulation (EC) No 847/2000 of April 2000 laying down the provisions for implementation of the Criteria for designation of a medicinal product as an orphan medicinal product and definitions of the Concept 'similar medicinal product and 'clinical superiority'

Overview of comments and proposed amended text

Action: For discussion

3.1.3. Draft Acceptability Criteria for Combination packs

Explanatory Note on Combination packs medicinal product in the CP (EMA/43584/2014)

Action: For discussion

3.2. Meeting organisation / templates

3.2.1. Update to the CHMP Assessment Report templates for Initial MAA and line extensions to include guidance on PSUR submission requirements

Action: For adoption