16 May 2017
EMA/CHMP/312260/2017 Rev.0
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

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

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann (chaired this meeting)

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

The CHMP adopted the ORGAM agenda.

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

The CHMP nominated Christine Siezen (NL) as observer to SWP.

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

Action: For information

Presentation about Standards for Exchange of Nonclinical Data (SEND) was given by Peter van Meer (CBG/MEB). SEND was initiated by FDA in 2002 to improve predictability, consistency and efficiency of the review process and is based in part on Guidance for Industry on Electronic Source Data in Clinical Investigations. It allows increased reliability, quality, integrity and traceability of e-data. It requires companies to submit, in addition to non-clinical study reports, specific additional files in a standardized electronic format that allow re-analysis of raw data through use of specific software. Of note, this is already mandatory from FDA submissions and PMDA is currently implementing a similar approach. It was highlighted that all EU member states need to consider this paper and should discuss potential benefits/costs associated with it and recommend a way forward. Furthermore, it

was suggested that SWP together with EMA should further discuss this proposal to better define practical implementation aspects.

The CHMP noted the proposal.

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

Action: For information

The CHMP noted the minutes.

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

QWP CT agreed that the excipient should be considered novel and this would be in line with the Excipients in the dossier for application for marketing authorisation of a medicinal product guideline.

The CHMP noted the outcome of April QWP Core Team discussion.

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

Action: For information

The CHMP agreed that TGA is involved as observer in the revision of the guideline.

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

The CHMP noted the information.

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

No items

2.1.7. Committees

Minutes of Strategic Review and Learning meeting 1-2 March 2017 and of the meeting "Making Article 58 and other EMA outputs more relevant for non-EU regulators" 2-3 March 2017 in Malta (EMA/166340/2017)

Action: For adoption

The CHMP adopted the Minutes.

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

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

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

Action: For adoption

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

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

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

Action: For adoption

Presentation on guideline content and changes done was given by Pekka Kurki. The document is a revision of the Guideline on Immunogenicity assessment of therapeutic proteins on the basis of experience from marketing authorisation applications, scientific advices, and other new information. It includes, among others, more specific guidance for assays for immunogenicity, and integrated analysis of the clinical significance of immunogenicity. In order to facilitate the risk assessment, the guideline contains a list of

issues to be considered, a multidisciplinary summary of immunogenicity, including risk assessment that should be included in the marketing authorization application. It was noted that it could be clarified in the scope that the guideline does not cover immunoglobulins.

The CHMP adopted the guideline.

Post-meeting note: the guideline has been updated to reflect that it does not apply to coagulation factors, vaccines, or heterogeneous immunoglobulin preparations, such as human immunoglobulins purified from plasma.

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

Action: For information

The CHMP noted the minutes.

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

Action: For information

The CHMP noted the minutes.

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

The CHMP appointed Katalin Szalay as new member.

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

Action: For adoption

The CHMP agreed to the drafting of the Q&A on haemagglutination inhibition (HI) assay - for influenza vaccines.

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

Action: For information

The CHMP noted the minutes.

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

Action: For information

The CHMP noted the agenda.

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

The Working Party recommends revising the guideline on clinical development of vaccines. In summary, the objective of the revision is to update the guideline based on current knowledge, including further reflection on immunogenicity studies and correlates of protection, vaccination of special populations including elderly and pregnant women, comparative studies, safety consideration by vaccine type and population and vaccine effectiveness studies.

The CHMP adopted the concept paper for 3 months public consultation.

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

Action: For information

The CHMP noted the minutes.

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

Presentation on revision of the guideline was given by Jacqueline Kerr. The CHMP agreed to the next steps and for BPWP to continue with the revision of the guideline as proposed. The CHMP noted the correspondence. A workshop with all stakeholders will be organised in Q4 2017. The guideline will later come back to CHMP for discussions.

Minutes of BPWP February 2017 meeting

Action: For information

The CHMP noted the minutes.

Agenda and draft minutes of BPWP April 2017 meeting

Action: For information

The CHMP noted the agenda and draft minutes.

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

No items

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

The CHMP noted the minutes.

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

Action: For information

The CHMP noted the draft agenda.

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

The CHMP agreed to send the question from CMDh to PKWP.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

No items

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: 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

The proposed Reflection Paper is intended to discuss the difficulties and opportunities for drug development in the field of chronic liver disease. It is intended to define “landmarks” with the aim to increase consistency in future regulatory decisions. The Reflection Paper is considered a first step before more detailed regulatory guidance can follow.

It was discussed and agreed that Biostatistics Working Party will be involved in the review of the reflection paper and also in earlier phase of drafting. The draft Reflection Paper is planned to be published for public consultation 2nd quarter 2018.

The CHMP adopted the concept paper for 3 months public consultation.

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

ITF briefing meeting

Meeting date: 16 May 2017

Action: For adoption

The CHMP agreed to the meeting.

ITF briefing meeting

Meeting date: 13 June 2017

Action: For adoption

The CHMP agreed to the meeting.

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

The CHMP noted the information. It was noted that one nomination was received during the meeting.

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 framework of collaboration with academia

Action: For information

The EMA Management Board adopted a framework for collaboration between EMA and academia in March 2017. Academics and researchers are encouraged to participate in the work of the Agency in several ways. The framework aims to reinforce and further develop the collaboration between the European Medicines Agency and academia by clarifying scope, formalising and structuring interactions in the wider context of the European medicines regulatory network. It describes the objectives and the working methodology that will be undertaken to this end, in line with the principles of transparency, independence and integrity, accountability, and broad representation.

The CHMP noted the 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

The CHMP noted the overview of comments and proposed amended text. There is a need for a subsequent update of the EC similarity guideline or some Q&A with more technical details (or transparency of similarity AR may address the point).

Adoption of final text by CAT/ CHMP has been planned for May plenaries.

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

The CHMP noted the explanatory Note on Combination packs medicinal product in the CP.

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

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

An update on the ongoing review of Rapporteurs Initial MAA Assessment Report templates was given. D80 AR templates and guidance documents are being merged into single documents and instructions added on how to delete green guidance text. A reduced number of documents will facilitate maintenance and update of AR templates. Draft AR templates are available in MMD and comments can be sent.

The CHMP noted the update.

4. List of participants

CHMP Vice-Chairman:

Harald Enzmann

CHMP members:

Agnes Gyurasics

Andrea Laslop

Greg Markey

Jan Mueller-Berghaus

Jean-Louis Robert

Johann Lodewijk Hillege

Katarina Vučić

Kristina Dunder

Nela Vilceanu

Outi Mäki-Ikola

Sol Ruiz

Svein Rune Andersen

CHMP alternate members:

Bjorg Bolstad

Christophe Focke

Dana Gabriela Marin

Fátima Ventura

Milena Stain

Nithyanandan Nagercoil

Selma Arapovic Dzakula

Experts:

Pekka Kurki

Jacqueline Kerr

Anne Hasle Buur

Elena Wolff-Holz

Jan Willem van der Laan

Peter Van Meer

A representative from the European Commission participated in the meeting

Meeting was run with support from the relevant EMA staff