24 February 2017
EMA/CHMP/139584/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 13 February 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 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 February 2017 meeting was adopted

1.3. Adoption of the minutes

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

Draft agenda for WP/DG meeting to be held face-to-face on 14-15 February 2017 (EMEA/CHMP/SWP/85402/2017)

Action: For information

The CHMP noted the draft agenda.

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Final Minutes of the 81st QWP face-to-face meeting held on 29 November – 1 December 2016 (EMA/CHMP/CVMP/QWP/797355/2016)

Action: For information

The CHMP noted the minutes.

Draft Q/As on information on capsule shells and their components to be stated in the SmPC for dry powder inhalers (EMA/CHMP/QWP/83866/2017)

Action: For adoption

Guideline on the Pharmaceutical Quality of Inhalation and Nasal Products (EMEA/CHMP/QWP/49313/2005 Corr) Appendix II contain specific information on particulars

in the SmPC concerning inhalation products. However, nothing is mentioned on the declaration of the content of the capsule shells of dry powder inhalers. Therefore additional guidance on this is given in a question and answer document.

The CHMP adopted the question and answer document.

Draft Concept paper on revision of the guideline on the pharmaceutical quality of inhalation and nasal products (EMA/CHMP/QWP/83432/2017)

Action: For adoption for 3-month consultation

The current guideline on quality of inhalation and nasal products came into effect in 2006 and since then a lot of experience has been gained mainly with regard to establishment of therapeutic equivalence but also new combinations and new chemical entities. During review of applications and scientific advices several issues are frequently being discussed and some Question & Answers have been adopted which may be incorporated in the updated guideline. The main focus of the revision will be on the inhalation part. The revised guideline will not introduce new requirements on medicinal products already authorised and on the market, but it will clarify the regulatory expectations for new applications for medicinal products.

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

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

CHMP Draft Work plan 2017 (EMA/CHMP/67982/2017)

Action: For adoption

The document will be sent once more for review and written input to members. The CHMP noted the draft work plan and further discussions will be held during Plenary.

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

Overview of comments (EMA/CHMP/CVMP/JEG-3Rs/25975/2015) received on the guideline on regulatory acceptance of 3R (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012)

Action: For information

The CHMP noted the overview of comments.

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

Minutes of BMWP meeting held by Adobe connect on 16 November 2016

Action: For information

The CHMP noted the minutes.

Minutes of BMWP meeting held by Adobe connect on 10 January 2017

Action: For information

The CHMP noted the minutes.

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

The CHMP noted the current composition for BMWP and need for one additional PK expert. A call for interest will be made in this regard.

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse/Ilona Reischl

Nomination Maeve Lally (IE) as new member to BWP in replacement to Una Moore

Action: For adoption

The CHMP appointed Maeve Lally (IE) as new member to BWP in replacement to Una Moore.

Draft agenda for BWP face-to-face meeting to be held 13-15 February 2017 (EMA/CHMP/BWP/870331/2016)

Action: For information

The CHMP noted draft agenda.

Final minutes from face-to-face meeting held 5-7 December 2016 (EMA/CHMP/139584/2017)

Action: For information

The CHMP noted the final minutes.

Letter to CHMP - Further Revision of the European Pharmacopoeia monograph on Human plasma (pooled and treated for virus inactivation)

Action: For information

The CHMP noted the letter.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/vacant

Call for nomination for Vice-chair of the Vaccines Working Party following resignation of Daniel Brasseur.

Nominations, along with a short statement in support of candidature, should be sent by 31 March 2017.

Action: For information

The CHMP noted the call.

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

The CHMP noted the current composition and proposal. Further discussions will be held.

Participation of VWP Chair Mair Powell as CHMP representative in EMA-PMDA-FDA antimicrobial drug development meeting 26-27 April 2017 in Vienna, Austria

Action: For adoption

The CHMP agreed to the participation of VWP Chair Mair Powell as CHMP representative.

2.2.4. Blood Products Working Party (BPWP)

Chair: Anneliese Hilger

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

The CHMP noted the current composition of BPWP.

Draft agenda of BPWP meeting to be held on 17 February 2017

Action: For information

The CHMP noted the draft agenda.

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017. Two additional experts will be proposed.

Action: For discussion

The CHMP noted the current composition and proposal for inclusion of additional experts.

Nomination of two new additional experts: Sir Munir Pirmohamed (UK) and Wilko Weichert (DE) to PGWP.

Action: For discussion

The CHMP noted the need for additional experts for the development of guidelines. Further discussions will be held.

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

The CHMP noted the current composition of CVSWP.

Call for nomination of CVSWP core member following resignation of Karsten Bruins Slot

Nominations should be sent by 13th March 2017

Action: For information

The CHMP noted the call.

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

The CHMP noted the current composition of CNSWP.

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

The CHMP noted the current composition of IDWP.

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

Postponed.

Minutes of ONCWP meeting held by Adobe connect on 07 December 2016.

Action: For information

The CHMP noted the minutes.

Concept paper on a proposal to replace the reflection paper on the regulatory guidance for the use of health – related quality of life (HRQL) measures in the evaluation of medicinal products with a new PRO guideline.

Action: For adoption for public consultation

- Overview of GCG comments

  Action: For information

Recently, the Oncology Working Party published guidance on the evaluation of PROs (including HRQL) in the context of cancer clinical trials after an extensive consultation process, which involved a workshop with stakeholders to discuss Health Related Quality of Life and a public consultation (Appendix 2 to the guideline on the evaluation of anticancer medicinal products in man; The use of patient-reported outcome (PRO) measures in oncology studies).

Further discussions will be held on the concept paper. The CHMP noted the overview of comments.

Concept paper on the need to revise Condition – Specific guidance, Appendix 4 to the guideline on the evaluation of anticancer medicinal products in man on MRD as an endpoint in clinical studies in MM (EMA/102314/2017)

Action: For adoption for 3-months public consultation

The guideline on anticancer medicinal products as revised in early 2010 (rev.3) included disease specific guidance which was later expanded (rev. 4 published January 2013) to constitute a separate appendix (Appendix 4). The Appendix 4 was recently revised (rev 2 published February 2016). The concept paper describes and discusses the basis for the revision to the existing Appendix 4 in relation to the use of minimal residual disease (MRD) as a clinical endpoint in multiple myeloma (MM) clinical studies.

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

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Nomination of new Swedish additional expert Anita Andersson to the PKWP

Action: For adoption

The CHMP nominated additional expert Anita Andersson to work on biosimilar aspects and other guidelines.

Product specific bio equivalence guidance (PSBEG), 5th batch final

- Abiraterone tablets 250 mg product-specific bioequivalence guidance (EMA/CHMP/474712/2016)
- Exenatide powder and solvent for prolonged-release suspension for injection, 2 mg, and powder and solvent for prolonged-release suspension for injection in pre-filled pen, 2 mg product-specific bioequivalence guidance (EMA/CHMP/474782/2016)
- Paliperidone palmitate depot suspension for injection 25 mg, 50 mg, 75 mg, 100 mg and 150 mg product-specific bioequivalence guidance (EMA/CHMP/474825/2016)
- Vandetanib film-coated tablets 100 mg and 300 mg product-specific bioequivalence guidance (EMA/CHMP/474883/2016)
- Vemurafenib film-coated tablets 240 mg product-specific bioequivalence guidance (EMA/CHMP/476248/2016)

Action: For adoption

The CHMP adopted the 5 guidances for abiraterone, exenatide, paliperidone, vandetanib and vemurafenib. Altogether 31 PSBEGs have been finalised to this date.

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

The CHMP noted the current composition in PKWP and possible need for additional expert.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Minutes of BSWP meeting held by Adobe connect on 06 December 2016

Action: For information

The CHMP noted the minutes.

Minutes of BSWP meeting held by Adobe connect on 16 November 2016.

Action: For information

The CHMP noted the minutes.

Minutes of BSWP meeting held by Adobe connect on 17 January 2017

Action: For information

The CHMP noted the minutes.

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

The CHMP noted the current composition of BSWP.

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

Postponed. Further discussions will be held.

2.3.8. Scientific Advisory Groups (SAGs)

The revised mandate and rules of procedure for SAGs and ad hoc expert groups

Action: For adoption

Further discussions are needed on the proposed changes. Postponed.

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Elmer Schabel

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

The CHMP noted the current composition of GDG.

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

Concept paper on revision of the guideline on the requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of asthma and chronic obstructive pulmonary disease (COPD) in adults and for the treatment of asthma in children and adolescents (EMA/CHMP/267194/2016)

Action: For adoption for 3 month public consultation

This concept paper concerns a revision of the guideline directed to the requirements for demonstration of therapeutic equivalence between two inhaled products. The guideline focuses on hybrid applications but may be applicable also for other applications that are based on demonstration of therapeutic equivalence compared to a reference product, such as line extensions and variations. The guideline was originally published in September 2000 and was revised between September 2007 and January 2009 (henceforth referred to as Revision 1). Since the last revision, several MAAs with the aim to demonstrate therapeutic equivalence compared to a reference product concerning orally inhaled products have been submitted for regulatory review to the National Competent Authorities. The proposed revision is aimed at updating the guideline to reflect knowledge gained from regulatory experience.

The CHMP adopted the guideline for 3 months public consultation.

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

The CHMP noted the current composition of RDG.

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017.

Action: For discussion

The CHMP noted the current composition of RadDG.

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

Call for nomination of additional experts to contribute to revision of following excipients

- Dextrans (clinical)
- Maltose and sucrose (non-clinical + clinical)
- Maltodextrin (oral) (non-clinical + clinical)
- Polyethylene glycols and macrogols (non-clinical + clinical)
- Xylitol and maltitol (non-clinical + clinical)

Nominations should be sent

Action: For information

The CHMP noted the call for experts.

Minutes of ExcpDG meeting held face-to-face on 8-9 November 2016

Action: For information

The CHMP noted the minutes.

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF briefing meeting Meeting date: 27 February 2017

Action: For discussion and agreement

The CHMP agreed to the meeting.

ITF briefing meeting Meeting date: 13 March 2017

Action: For discussion and agreement

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. ATMP guideline on safety and efficacy follow-up and risk management (EMA/CHMP/65416/2016)

Action: For discussion

An update was given on the guideline development. Comments are awaited from the CHMP members by the 1st of March 2017.

The guideline will be updated by the drafting group based on the PRAC, CAT and CHMP members' comments. The main points for update were risks specific for ATMPs based on previous MAAs, a strengthened guidance on additional risk minimisation measures (e.g. educational materials for physicians, etc.). Guidance on safety and efficacy follow-up studies in terms of study objectives, ATMPs specific aspects to consider and study design has been provided. In addition, guidance is also provided in the management and reporting of Adverse Reactions (reporting of AEs related to administration procedures, pre-conditioning regimes for example).

In addition, CHMP sponsor is needed for the development of the RMP guidance template for ATMPs (practical implementation of the ATMP guideline which should aim at facilitating the workflow between 3 committees etc). Expressions of interest should be sent.

The CHMP noted the update.

3.1.2. SmPC Advisory Group 2016 activity report

Action: For information

Overview was given on SmPC Advisory Group activities in 2016. It was noted that SmPC webinars were held throughout 2016 and SmPC AG Q&As and useful support to Committees and working parties was provided. It was highlighted that the SmPC Advisory group activities are needed and should be maintained.

EC report is under development, however it will focus more on PL than on SmPC. Furthermore, Healthcare Professionals' need should be considered.

The CHMP noted the report and draft programme of 2017 SmPC AG webinars to be held.

3.2. Meeting organisation / templates

3.2.1. CHMP Plenary and ORGAM meeting dates

CHMP Plenary meeting dates 2019-2021 (EMA/391620/2016)

Action: For adoption

The CHMP noted the dates and will continue discussions in Plenary.

CHMP ORGAM meeting dates 2019-2021 (EMA/CHMP/69637/2017)

Action: For adoption

The CHMP noted the dates and will further discuss, whether to schedule additional ORGAM meetings for January and April 2019-2021. Further discussions will be held in Plenary.

4. Any Other Business

EU Network Regulatory Awareness Sessions for 2017

Action: For information

Altogether 7 regulatory awareness sessions were organised in 2016. The feedback from the attendants has been very good towards both – the training content and training format. However the number of participants from the NCAs could be increased, since the awareness sessions were considered as beneficial tool for learning and development.

Regulatory training plan for 2017 can be considered as part of the vision for the Agency to strengthen capacity and capability development across the Network through the EU NTC. The sessions were designed to address the needs for the network and EMA. EMA considers expertise available in the network by inviting NCA or Committee Members to give presentation during these awareness sessions. Aim is to support the EU Network Strategy to 2020.

The CHMP noted the EU Network Regulatory Awareness Sessions for 2017.

5. List of participants

CHMP Chairman:

Tomas Salmonson

CHMP members:

Daniela Melchiorri

Greg Markey

Harald Enzmann

Jean-Louis Robert

Johann Lodewijk Hillege

Katarina Vučić

Nela Vilceanu

CHMP alternate members:

Christophe Focke

Dana Gabriela Marin

Fátima Ventura

Milena Stain

Nithyanandan Nagercoil

Patrick Salmon

Selma Arapovic Dzakula

Experts:

Janet Schriever

Beata Ullrich

Anabel Cortés Blanco

Krishna Prasad

Maria Romero

Mette Tranholm

Patricia Diaz Ramos

Meeting was run with support from the relevant EMA staff