21 April 2017
EMA/CHMP/267964/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes of the meeting on 10 April 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 document is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this 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 minutes 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 10 April 2017 meeting was adopted.

1.3. Adoption of the minutes

CHMP Orgam Minutes of April 2017 meeting were adopted at the April 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

No items

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Closure of the EMA-FDA QbD pilot program. Joint report for publication on the EMA and FDA websites

Action: For information

The CHMP noted the Report from the EMA-FDA QbD pilot program which was launched in March 2011. The report was adopted by the CHMP for publication on the EMA website.

Question from Estonia to the QWP core team on sodium triphosphate pentabasic

Action: For agreement

The members were informed about the request by Estonia on sodium triphosphate pentabasic and agreed to refer the question to the QWP.

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

Minutes of the PCWP meeting with all eligible organisations - 30 November 2016 (EMA/801985/2016)

Action: For information

See also 2.1.5. Agenda of the PCWP/HCPWP joint meeting

The CHMP noted the minutes.

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

Co-chair: Gonzalo Calvo

Agenda of the Workshop on personalised medicines: role of patients, consumers and healthcare professionals - 14 March 2017 (EMA/762357/2016)

Action: For information

The CHMP noted the agenda**.**

Agenda of the PCWP/HCPWP joint meeting – 15 March 2017 (EMA/69326/2017)

Action: For information

The CHMP noted the agenda**.**

2.1.6. Geriatric Expert Group (GEG)

Chair: Niccolo Marchionni

No items

2.1.7. Committees

No items

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

Nomination of additional PK expert to BMWP

Nominations received

• Current list of members

Action: For adoption

The CHMP noted the nominations received. It was discussed whether both experts should be considered. The CHMP agreed to further liaise with the BMWP chair and to postpone the decision on the additional PK expert to the April 2017 plenary meeting.

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 May 2017 (EMA/CHMP/BWP/209322/2017)

Action: For information

The CHMP noted the draft agenda**.**

Final minutes from face-to-face meeting held 13-15 February 2017 (EMA/CHMP/BWP/112435/2017)

Action: For information

The CHMP noted the minutes.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell

Nomination of Daniel Brasseur (BE) as an observer to VWP

• Current list of members

Action: For adoption

The CHMP nominated Daniel Brasseur (BE) as an observer to the VWP.

Minutes of VWP virtual meetings on 03 February and 03 March 2017

Action: For information

The CHMP noted the minutes.

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Nomination of Sophie Barbou Des Courieres (FR) and Mary-Ann Eichmann (PEI Germany) as new members to the BPWP

Action: For adoption

The CHMP appointed Sophie Barbou Des Courieres (FR) and Mary-Ann Eichmann (PEI Germany) as new members to the BPWP.

Nomination of Anneliese Hilger (PEI Germany) as BPWP additional expert

Action: For adoption

The CHMP appointed Anneliese Hilger (PEI Germany) as additional expert to the BPWP.

BPWP Work Plan 2017, revision

Action: For adoption

The CHMP was informed about the addition of the Guideline on core SmPC for human albumin solution and adopted the revised BPWP work plan 2017.

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Final minutes for PGWP meeting held by Adobe on 12 December 2017 (EMA/848583/2016)

Action: For information

The CHMP noted the minutes.

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Final minutes for CVSWP meeting held face-to-face on 23 November 2016 (EMA/789887/2016)

Action: For information

The CHMP noted the minutes.

Appointment of a new CVSWP core member replacing Karsten Bruins Slot

Nomination received

Action: For adoption

Postponed as input from the CVSWP chair had not yet been received.

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

Final minutes for CNSWP meeting held face-to-face on 2 December 2016 (EMA/811433/2016)

Action: For information

The CHMP noted the minutes.

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

Concept paper on a guideline on the evaluation of medicinal products indicated for treatment of influenza (EMA/CHMP/EWP/808940/2016)

Action: For adoption

The CHMP noted the comments from the GCG. The CHMP discussed the concept paper, which proposes the development of a guideline on the clinical evaluation of medicinal products indicated for the treatment of influenza for which there is no regulatory guidance currently available within the EU. The members agreed to rephrase the wording on the study design. The adoption of the concept paper was postponed.

2.3.4. Oncology Working Party (ONCWP)

Chair: Pierre Demolis/Paolo Foggi

Minutes of ONCWP virtual meeting held on 15 February 2017 (EMA/112280/2017).

Action: For information

The CHMP noted the minutes.

Nomination of Sigrid Klaar (SE) as additional expert to ONCWP

• Current list of members and observers

Action: For adoption

The CHMP appointed Sigrid Klaar (SE) as additional expert to the ONCWP.

Nomination of Ingrid Wang (NO) as an observer to ONCWP

Action: For adoption

The CHMP nominated Ingrid Wang (NO) as an observer to the ONCWP.

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Concept paper on the revision of the Guideline on the role of pharmacokinetics in the development of medicinal products in the paediatric population (EMA/CHMP/448599/2016)

Action: For adoption for 3 months public consultation

The Committee discussed the concept paper outlining the revision of the guideline reflecting the experience gained over the last decade and developments in science. It was highlighted that the revision is to be seen in the context of other on-going initiatives. The CHMP proposed some re-wording in order to clarify the focus on PK. The adoption of the concept paper for public consultation was postponed.

CHMP request for PKWP input into PK aspects of biosimilarity

Action: For adoption

The members discussed the list of questions to the PKWP on key considerations and limitations in the assessment of biosimilarity. The list was adopted by the CHMP.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Minutes of BSWP virtual meeting held on 14 March 2017 (EMA/177185/2017)

Action: For information

The CHMP noted the minutes.

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

No items

2.3.9.2 Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

Final minutes for RDG meeting held face-to-face on 15-16 September 2016 (EMA/621110/2016)

Action: For information

The CHMP noted the minutes.

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: 26 April 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

No items

3.2. Meeting organisation / templates

No items

3.3. Pharmacovigilance

3.3.1. Patient Registry Initiative: Update and Workshops on Cystic Fibrosis (CF) and Multiple Sclerosis (MS)

The Patient Registry Initiative published recently the workshop report held last October 2016 including some recommendations. Following these recommendations, one of the proposed activities is to organise two workshops, one on CF and another one on MS with the following objectives:

- To agree on implementable recommendations on core data elements to be collected, protocols, consents, governance supporting registry interoperability.
- Workplan for the further development and finalisation of recommendations to be used by registry holders and MAHs/MAAs.

The workshops are taking place on 14th June (CF) and 7th July (MS). PRAC (co-) Rapporteurs have been invited as being key to the success of the workshop.

Action: For information

The CHMP noted the update on the patient registry initiative and the planned disease specific workshops following up on the recommendations from the patient registries workshop held on 28 October 2016. The members were informed about the new composition of the cross Committee task force, which will also be extended to the PDCO. The CHMP agreed to provide specific questions in relation to patient registry data for those diseases for further discussion at the planned workshops. Further discussion is expected at the May 2017 CHMP Plenary.

4. Any Other Business

4.1. EMA/FDA strategic document on Gaucher disease

Action: For adoption

The members were informed about the EMA/FDA strategic document on Gaucher disease. Although the document focuses on Gaucher disease as a disease model, the underlying principles may be extended to other areas of drug development in rare diseases. The CHMP agreed to the document. Further comments can be sent by 14 April 2017. The final adoption is expected in May 2017.

5. List of participants

CHMP Chairman:

Tomas Salmonson

CHMP members:

Andrea Laslop

Greg Markey

Harald Enzmann

Jan Mueller-Berghaus

Jean-Louis Robert

Johann Lodewijk Hillege

Katarina Vučić

Kristina Dunder

Nela Vilceanu

Outi Mäki-Ikola

Robert James Hemmings

CHMP alternate members:

Bjorg Bolstad

Dana Gabriela Marin

Fátima Ventura

Melinda Sobor

Milena Stain

Natalja Karpova

Experts:

Kristina Bech Jensen

Maria Escudero Galindo

Maria Romero Guerra

Valerie Lescrainier

EC representative