23 June 2017
EMA/402672/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes of the meeting on 12 June 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 12 June 2017 meeting

The CHMP adopted the ORGAM agenda.

1.3. Adoption of the minutes

CHMP Orgam Minutes of 12 June 2017 meeting were adopted at the June 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

Final minutes for SWP virtual meeting held on 24 April 2017 (EMA/CHMP/SWP/263253/2017)

Action: For information

The CHMP noted the minutes.

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

QWP Response to CMDh Questions on similarity of bortezomib versus ixazomib (EMA/CHMP/QWP354858/2017)

Action: For adoption

The CHMP adopted the QWP response to be sent to CMDh. It was considered in the response that bortezomib and ixazomib are not similar in the context of the orphan similarity exercise.

Q/As on Normal Operating Ranges (NORs) and Proven Acceptable Ranges (PARs) (EMA/CHMP/CVMP/QWP/354895)

Action: For information

The CHMP noted the Q/As on Normal Operating Ranges (NORs) and Proven Acceptable Ranges (PARs). The document will be published.

Reflection paper on the dissolution specification for generic solid oral immediate release products with systemic action (EMA/257304/2017)

Action: For adoption

- Overview of comments (EMA/257305/2017)

Action: For information

The adoption of the reflection paper was postponed for plenary discussion in case CHMP members have any comments.

Final minutes for QWP face-to face meeting held on 31st January – 2nd February (EMA/CHMP/CVMP/QWP/66148/2017)

Action: For information

The CHMP noted the minutes.

2.1.3. Scientific Advice Working Party (SAWP)

Chair: Robert Hemmings

SAWP Strategic Review and Learning Meeting, Malta 26 – 28 April 2017: feedback from the meeting to CHMP

Presentation by Robert Hemmings

Action: For information

The CHMP noted the feedback from the meeting. Experience and perspectives for the review of "PRIME requests" from SAWP perspective were discussed during the meeting. Opportunities for optimising the SAWP processes as well as several aspects of Estimands were discussed. Another topic was optimisation of the process for qualification of novel methodologies. The CHMP noted the detailed survey feedback and summary report from the meeting.

2.1.4. European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)

Co-chair: Kaisa Immonen

Draft Agenda of the PCWP/HCPWP joint meeting – 27/28 June (EMA/213892/2017)

Action: For information

The CHMP noted the draft agenda.

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

Co-chair: Gonzalo Calvo

Draft Agenda of the PCWP/HCPWP joint meeting

Action: For information

The CHMP noted the draft 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

Minutes of BMWP virtual meeting held on 26 April 2017 (EMA/286058/2017)

Action: For information

The CHMP noted the minutes.

Revised Minutes of BMWP face to-face meeting held on 08-09 March 2017 (EMA/CHMP/BMWP/169267/2017)

Action: For information

The CHMP noted the revised minutes.

Call for nomination of a new Vice-Chairperson following end of 2nd mandate in July 2017

Nominations should be sent by 31 July 2017.
Candidates should submit a brief résumé in support of their candidature. Election is going to take place at the September 2017 CHMP Plenary meeting.

Action: For information

The CHMP noted the call for nomination.

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from face-to-face meeting held 10-11 April 2017 (EMA/CHMP/BWP/241529/2017)

Action: For information

The CHMP noted the final minutes.

Draft agenda for BWP face-to-face meeting to be held 10-12 July 2017 (EMA/CHMP/BWP/332522/2017)

Action: For information

The CHMP noted the draft agenda.

Nomination of new member Helerin Margus (EE) to BWP

Action: For adoption

- CV
- Current membership list

The CHMP appointed Helerin Margus (EE) as member to BWP.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Nomination of Annette Lommel (PEI) as an observer to VWP

Action: For adoption

The CHMP nominated Annette Lommel (PEI) as an observer to VWP.

Draft Agenda of VWP face-to-face meeting held on 23-24 May 2017 (EMA/237022/2017)

Action: For information

The CHMP noted the draft agenda.

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Nomination of new member from Sweden in the BPWP Sofia Bosdotter Enroth to replace current member Eva Macrì

Action: For adoption

The CHMP appointed Sofia Bosdotter Enroth as new member to replace current member Eva Macrì (SE).

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Draft agenda for the TC meeting on Ethylmorphine to be held on 8 June 2017 (EMA/342953/2017)

Action: For information

The CHMP noted the draft agenda.

Pharmacogenomics drafting group on Addendum to the guideline on the Use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products on terminology in pharmacogenomics

Draft agenda for the TC meetings on 30 May 2017 (EMA/341732/2017)

Action: For information

The CHMP noted the draft agenda.

Concept paper on an Addendum on terms and concepts of pharmacogenomic features related to metabolism to the Guideline on the use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products (EMA/CHMP/37646/2009)

Rapporteurs: Marc Maliepaard, Adrian Llerena

Action: For adoption for 3 months public consultation

The CHMP discussed the concept paper and further discussions will be held at the June Plenary meeting.

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

Call for nomination of a Vice-Chairperson following end of 1st mandate in July 2017

Nominations should be sent by 1st September 2017.
Candidates should submit a brief résumé in support of their candidature. Election is going to take place at the September 2017 CHMP Plenary meeting.

Action: For information

The CHMP noted the call.

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

No items

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Response to CMDh Question to PKWP on BE studies for oral solution - Administration with or without water (EMA/CHMP/364793/2017)

Rapporteur: Sotiris Michaleas,

Action: For adoption

The CHMP discussed the response from PKWP to be sent to CMDh. It was agreed that more targeted response should be developed.

Product specific bioequivalence guidance: Batch 6, final:

- Crizotinib hard capsules 200 mg and 250 mg product-specific bioequivalence guidance (EMA/CHMP/805479/2016)

Rapporteur: Ridha Belaiba

- Elvitegravir 85 mg & 150 mg film-coated tablets product-specific bioequivalence guidance (EMA/CHMP/805507/2016)

Rapporteur: Susan Cole

- Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil film-coated tablets 150 mg/150 mg/200 mg/245 mg product-specific bioequivalence guidance (EMA/CHMP/805518/2016)

Rapporteur: Susan Cole

- Emtricitabine/rilpivirine/tenofovir disoproxil, film-coated tablets, 200 mg/25 mg/245 mg product-specific bioequivalence guidance (EMA/CHMP/805532/2016)

Rapporteur: Carolien Versantvoort

- Vortioxetine hydrobromide, 5 mg, 10 mg, 15 mg, and 20 mg immediate release tablets, vortioxetine lactate, oral drops solution 20 mg / ml product-specific bioequivalence guidance (EMA/CHMP/474974/2016)

Rapporteur: Henrike Potthast

Action: For adoption

The CHMP adopted the product specific bioequivalence guidance Batch 6. The documents will be published.

Product specific bioequivalence guidance: Batch 7, draft:

- Dolutegravir, film-coated tablets, 10 mg, 25 mg, 50 mg, product specific bioequivalence guidance

Rapporteur: Eva Berglund/Malin Filler

- Dronedarone, film-coated tablets, 400 mg product-specific bioequivalence guidance

Rapporteur: Carolien Versantvoort

- Paracetamol oral use, immediate release formulations, product-specific bioequivalence guidance

Rapporteur: Jan Welink

- Rilpivirine 25mg, product-specific bioequivalence guidance

Rapporteur: Carolien Versantvoort

Action: For adoption for 3 months public consultation

The CHMP adopted the product specific bioequivalence guidance Batch 7 for 3 months public consultation.

Nomination of Gro Dahlseng Håkonsen (NO) as an observer to PKWP

Action: For adoption

The CHMP nominated Gro Dahlseng Håkonsen (NO) as an observer to PKWP.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Minutes of BSWP virtual meeting held on 11 April 2017 (EMA/242120/2017)

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: Elmer Schabel

Final minutes for GDG F2F meeting held on 22 March 2017 (EMA/215695/2017)

Action: For information

The CHMP noted the minutes.

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: 29 June 2017

Action: For discussion and agreement

The CHMP agreed to the meeting. CHMP members were invited to express interest to participate. The meeting is related to HTA and PRIME.

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

3.2.1. Update to the CHMP templates

Updates to the CHMP templates:

1) CHMP and Rapporteurs' joint assessment report template on assessment of similarity;

2) Annex 1 - ASMF assessment report template;

3) (Co)-Rapp JAR of the grounds for re-examination template.

Action: For adoption

The updated templates were presented. The members were invited to send comments by 19 June. If no comments are received the templates will be considered as adopted. For any comments or suggestions on the CHMP AR templates, please send them.

4. Any Other Business

5. List of participants

CHMP Chairman:

Tomas Salmonson

CHMP members:

Agnes Gyurasics

Andrea Laslop

Concepcion Prieto Yerro

Daniela Melchiorri

Eleftheria Nikolaidi

Greg Markey

Harald Enzmann

Jan Mueller-Berghaus

Jean-Louis Robert

Johann Lodewijk Hillege

Katarina Vučić

Kolbeinn Gudmundsson

Kristina Dunder

Outi Mäki-Ikola

Robert James Hemmings

CHMP alternate members:

Dana Gabriela Marin

Fátima Ventura

Milena Stain

Natalja Karpova

Nithyanandan Nagercoil

Experts:

Jan Willem van der Laan

Maria Romero Guerra

Mette Toftegaard Madsen

Patricia Diaz Ramos

Valerie Lescrainier

A representative from the European Commission participated in the meeting

Meeting was run with support from the relevant EMA staff