26 February 2019
EMA/CHMP/343726/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 18 February 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

18 February 2019, 09:30–12:30, room 2-D

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 the minutes is considered commercially confidential or sensitive and therefore not disclosed.

Of note, the minutes are a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in these 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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 18 February 2019 meeting was adopted. A topic was added under A.O.B.

1.3. Adoption of the minutes

CHMP Orgam Minutes of 18 February 2019 meeting will be adopted at the February 2019 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

CHMP List of questions to be addressed by the Safety Working Party (SWP) for NMBA impurities (EMA/CHMP/117995/2019)

Action: For adoption

The list of questions to be addressed to SWP was adopted after minor amendments.

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh / Blanka Hirschlerova

- Minutes from QWP Core team January 2019 and from July to December 2018:

  Action: For information

  The CHMP noted the minutes.

- List of questions and answers that should be considered for inclusion on the Quality of medicines questions and answers at the EMA website

  Action: For adoption

  The new questions and answers were adopted for publication on the EMA website.

2.1.3. Scientific Advice Working Party (SAWP)

Co-Vice-Chairs: Peter Mol / Kolbeinn Gudmundsson

Revision of the SAWP mandate to allow the inclusion of alternates as possible nominees for the position of Chair of the SAWP. A change in the text has been made as below:

Extract (page 8): In keeping with the CHMP rules of procedures:

7. The chairperson of the SAWP shall be elected by the members of the CHMP for a term of 3 years, which may be renewed once. A CHMP member, a SAWP member **or an alternate of these working bodies** may be elected by the committee to fulfil this responsibility. Where the chairperson does not belong to the CHMP, he/she shall be invited to attend plenary CHMP meetings to report on the activities of the SAWP and ensure liaison with the work of the CHMP. The vice-chairperson of the SAWP shall be elected by the CHMP for a term of 3 years, which may be renewed once.

Action: For adoption

The CHMP adopted the revised SAWP mandate.

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

Co-chair: Kaisa Immonen

No topics

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

Co-chair: Gonzalo Calvo

No topics

2.1.6. Geriatric Expert Group (GEG)

Chair: Katarina Vučić

No topics

2.1.7. Committees

Joint Committee for Medicinal Products for Human Use (CHMP)/ Paediatric Committee (PDCO) membership

Procedure for appointing joint CHMP/PDCO members in PDCO

- Joint CHMP-PDCO membership presentation

Action: For adoption

The CHMP agreed with the proposed procedure for appointing joint CHMP/PDCO members in PDCO.

2.1.8. International Council on Harmonisation (ICH)

Draft ICH M10 guideline on Bioanalytical Method Validation - Step 2b (EMA/115558/2019)

Action: For adoption for 6 months public consultation

The CHMP adopted the draft ICH M10 guideline for public consultation.

EMA informed the CHMP of the proposal to set up an informal group on harmonisation of the standards for generic drugs to do exploratory work for 1 year.

The CHMP welcomed the initiative.

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 (J 3RsWG)

Chair: Ellen-Margrethe Vestergaard, CoChair: Susanne Brendler-Schwaab

No topics

2.1.10. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

Chair: Nienke Rodenhuis

No topics

2.1.11. Joint CVMP-CHMP antimicrobial advice ad hoc expert group (AMEG)

Chair: Gérard Moulin

No topics

2.1.12. Modelling and Simulation Working Party (MSWP)

Chair: Kristin Karlsson / Flora Musuamba Tshinanu

Nomination of 3 new MSWP members to replace 3 leaving MHRA members

Five Candidatures were received:

Action: For adoption

The CHMP nominated Peter Colin (BE), Jeroen Koomen (NL) and Pyry Välitalo (FI) as MSWP members and agreed to the proposal to have Isabel Garcia Gallego (ES) and Marina Senek (SE) as additional assessors (‘observers’).

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz / Niklas Ekman

No topics

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz / Nanna Aaby Kruse

- Final minutes from December face-to-face meeting held 3-4 December 2018

  Action: For information

  The CHMP noted the minutes.

- Draft agenda for BWP face-to-face meeting to be held 18-20 February 2019

  Action: For information

  The CHMP noted the agenda.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell / Svein Rune Andersen

No topics

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

No topics

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad / Markus Paulmichl

No topics

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder / Alar Irs

No topics

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich / André Elferink

No topics

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

Participation of Dr. Stephanie Buchholz on behalf of EMA/CHMP at the EASL-AASLD meeting on HBV (London, UK) 8-9 March 2019

Action: For discussion

The CHMP endorsed the participation of Dr. Stephanie Buchholz on behalf of EMA/CHMP.

2.3.4. Oncology Working Party (ONCWP)

Chair: Pierre Demolis / Paolo Foggi

- Minutes for the F2F meeting on 11 January 2019 (EMA/5215/2019)

  Action: for information

  The CHMP noted the minutes.

- Call for nomination for 2 new ONCWP members to replace Bertil Jonsson (SE) and Sinan Bardakci Sarac (DK) who stepped down as member to be additional assessor ('observer').

  Nominations should be sent by **15th March 2019**.

  Action: for information

  The ONCWP chair clarified that clinical and pharmacovigilance expertise would be needed. The CHMP noted the call for nomination.

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink / Henrike Potthast

- Products specific bioequivalence guidance:

  Drafts for 3 month public consultation

  - Colchicine tablet 0.5 mg and 1 mg product-specific bioequivalence guidance (EMA/CHMP/35552/2019)
  - Etonogestrel and ethinylestradiol vaginal delivery system 0.12mg/0.015mg/day product-specific bioequivalence guidance (EMA/CHMP/97470/2019)

  Action: For adoption

The product-specific bioequivalence guidance on colchicine was adopted for a 3-month public consultation.

The product-specific bioequivalence guidance on etonogestrel and ethinylestradiol was discussed. The adoption of the guidance is postponed for one month accordingly.

Final (from batch 9)

Rapporteur: Malin Filler

- Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance (EMA/CHMP/257298/2018)

Action: For adoption

The CHMP agreed to further work by the PKWP and, if needed, to consult BSWP on the proposed guidance and postponed its adoption.

- PKWP revision of Q&A 3.6 on requirements for crushed tablets (EMA/CHMP/401006/2016)

Rapporteur: Henrike Potthast

Action: For adoption

The CHMP adopted the revised Q&A and noted that it would be important to communicate the new approach to assessors and applicants.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel / Jörg Zinserling

No topics

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus / Romaldas Mačiulaitis

No topics

2.3.8. Scientific Advisory Groups (SAGs)

Adoption of a LoQ to MAHs to investigate the risk of early deaths with anti PD-1/PD-L1 as a follow-up to the SAG-O meeting

Action: For adoption

Daniela Melchiorri was adopted as lead Rapporteur for the procedure. The CHMP adopted the LoQ and the associated time table.

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No topics

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No topics

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

No topics

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

No topics

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF Briefing Meeting

Action: For discussion and agreement

The CHMP noted the meeting.

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No topics

2.3.10.3. IPRF Nano Working Group

Chair: Harald Enzmann

No topics

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

Amendments to Regulation (EC) No 726/2004 – presentation of changes and introduction of proposal for related template updates to be adopted via written procedure.

Action: For information

The CHMP noted the changes to Regulation (EC) No 726/2004 and their impact on EMA templates.

3.2. Meeting organisation / templates

No topics

3.3. Pharmacovigilance

No topics

4. Any Other Business

4.1. Relocation of EMA to the Netherlands – Q&A session on Delegates manual and Spark building

Action: For information

EMA presented the Orientation guide for delegates and highlighted changes to the travel booking process. The presentation was followed by a Q&A session.

4.2. May 2019 CHMP plenary: 3-day meeting

Action: For information

The CHMP was informed that the CHMP would be one day shorter in May 2019 due to EMA holidays. In order to make the best possible use of time during the meeting, EMA proposed to organise a pre-meeting Adobe-connect meeting on Friday before CHMP. The CHMP welcomed the proposal.

4.3 Feedback from consultation of CHMP members on CHMP organisation

Presented by Harald Enzmann

Action: For information

The CHMP chair reported from his one-to-one TCs with CHMP members. During these talks, areas for improvement of CHMP functioning have been identified. The chair presented proposals regarding the first few of these identified topics.

5. List of participants

CHMP Chair:

Harald Enzmann

CHMP members:

Bruno Sepodes (Vice-Chair)

Agnes Gyurasics

Alexandre Moreau

Bjorg Bolstad

Concepcion Prieto Yerro

Constantinos Markopoulos

Daniela Melchiorri

Emilia Mavrokordatou

Ewa Balkowiec Iskra

Frantisek Drafi

Jan Mueller-Berghaus

Johann Lodewijk Hillege

Katarina Vučić

Kristina Dunder

Martina Weise

Outi Mäki-Ikola

Sol Ruiz

CHMP alternate members:

Christophe Focke

Dana Gabriela Marin

Fátima Ventura

Jorge Camarero Jiménez

Milena Stain

Nithyanandan Nagercoil

Peter Kiely

Selma Arapovic Dzakula

Experts:

Blanka Hirschlerova

Flora Musuamba Tshinanu

Henrike Potthast

Maria Escudero Galindo

Patricia Diaz Ramos

Pierre Demolis

Sabine Mayrhofer

Theis Moeslund Jensen

A representative from the European Commission attended the meeting

The meeting was run with support from the relevant EMA staff