22 January 2019
EMA/CHMP/332463/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 21 January 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

21 January 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 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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Table of contents

1. Agenda and Minutes

1.1. Welcome and declarations of interest of members, alternates and experts

1.2. Adoption of agenda

The CHMP ORGAM agenda for 21 January 2019 meeting was adopted.

1.3. Adoption of the minutes

CHMP Orgam Minutes of 21 January 2019 meeting will be adopted at the January 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

- Final minutes for SWP meeting held face-to-face on 9-10 October 2018 (EMA/CHMP/SWP/701534/2018)

  Action: For information

  The CHMP noted the minutes

- Final minutes for SWP meeting held by teleconference on 7 November 2018 (EMA/CHMP/SWP/786552/2018)

  Action: For information

  The CHMP noted the minutes

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Action: For information

2.1.3. Scientific Advice Working Party (SAWP)

Vice-chairs: Petr Mol and Kolbeinn Gadmundsson

Call for nomination for a new SAWP Chair

Following the resignation of Robert Hemmings in December 2018, the election of a new SAWP Chair will take place during the February 2019 CHMP plenary meeting.

Nominations should be submitted by **15 February 2019**.

Candidates shall submit a CV and letter of motivation in support of their candidature at the time of the nomination.

Action: For information

The CHMP noted the call.

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

Co-chair: Kaisa Immonen

- DRAFT Mandate, objectives and composition of the Patients and Consumers Working Party (PCWP) (EMA/563123/2018 Rev. 3)

  Action: For adoption

  The CHMP adopted the Mandate, objectives and composition of PCWP.

- DRAFT Rules of procedure for the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) (EMA/109591/2018)

  Action: For adoption

  The CHMP adopted the Rules of procedures of PCWP.

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

Co-chair: Gonzalo Calvo

- DRAFT Mandate, objectives and composition of the Healthcare Professionals Working Party (HCPWP) (EMA/109592/2018, Rev 1)

  Action: For adoption

  The CHMP adopted the Mandate, objectives and composition of HCPWP

- DRAFT Rules of procedure for the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) (EMA/109591/2018)

  Action: For adoption

  The CHMP adopted the rules of procedures for the HCPWP.

- Meeting summary - EMA Human Scientific' Committees Working Party with Healthcare Professionals' Organisations (HCPWP) 26 September 2018 (EMA/721409/2018)

  Action: For information

The CHMP noted the meeting summary.

2.1.6. Geriatric Expert Group (GEG)

Chair: Katarina Vučić

No items

2.1.7. Committees

- DRAFT Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials (EMA/CAT/852602/2018)

  Action: For adoption for public consultation

  The CHMP adopted the draft guideline for public consultation.

- Regulatory consideration on medical products composed of, or produced using genome editing component

  Action: For discussion

  The CHMP agreed - CHMP members could provide comments on the proposal for one week and to continue the discussion during the CHMP 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 (J 3RsWG)

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

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

2.1.12. Modelling and Simulation Working Party (MSWP)

Chair: Kristin Karlsson/Flora Musuamba Tshinanu

No items

2.1.13. SmPC Advisory Group

Launch of the first chapter of the product information review curriculum; an eLearning course to review efficacy information in product information

Action: For information

The CHMP noted the proposal. The Chair thanked the contributors.

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Niklas Ekman

No items

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

- Nomination of a new member to BWP

  Jaana Vesterinen (FI) - replacing Sirkku Saarela

  Action: For adoption

  The CHMP agreed on the nomination of Jaana Vesterinen as BWP member for Finland.

- Nomination of a new alternate to BWP

  Monta Emersone (LV)

  Action: For adoption

  The CHMP agreed on the nomination of Monta Emersone as BWP alternate for Latvia.

- Adopted minutes from the November 2018 BWP meeting

  Action: For information

  The CHMP noted the minutes from the November meeting.

- Agenda for the January 2019 BWP meeting (21-23 January 2019)

  Action: For information

  The CHMP noted the agenda for the January meeting.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

First VWP report on yearly influenza vaccines effectiveness data (EMA/CHMP/332463/2019)

Action: For information

The CHMP noted the report.

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

No items

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Action: For information

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder/Alar Irs

No items

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich/André Elferink

No items

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

No items

2.3.4. Oncology Working Party (ONCWP)

Chair: Pierre Demolis/Paolo Foggi

No items

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

Product-specific bioequivalence guidances:

- Alectinib hard capsule 150 mg product-specific bioequivalence guidance (EMA/CHMP/790261/2018) - *extent dose reduction steps described in the SmPC may be consideration for the acceptance criteria of generic products.*
- Palbociclib hard capsule 75 mg, 100 mg and 125 mg product-specific bioequivalence guidance (EMA/CHMP/802679/2018) - *extent dose reduction steps described in the SmPC may be consideration for the acceptance criteria of generic products.*
  Rapporteur: Malin Filler

- Levothyroxine tablet 12.5 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg (and 200 mcg) product-specific bioequivalence guidance (EMA/CHMP/790333/2018) – *classification as NTI*

  Action: For discussion

  The CHMP adopted the alectinib and palbociclib guidances for a 3-month public consultation. The guidance on levothyroxine needs further discussion and input from endocrinologists and cardiovascular clinicians.

- Octreotide acetate depot powder and solvent for suspension for injection 10 mg, 20 mg or 30 mg product-specific bioequivalence guidance (EMA/CHMP/291571/2018)

  Action: For adoption

  The CHMP adopted the final octreotide acetate guidance.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

Nomination of additional assessors:

- Maria Grünewald, Swedish Medical Products Agency;
- Flavia Lombardo, Italian AIFA.

As explained to CHMP at ORGAM in December 2018, BSWP is accepting these nominations for additional assessors in anticipation of the loss of members and additional assessors. BSWP composition will be reviewed again after March 2019 to comply with the rules on the number of delegates set by CHMP at its March 2018 plenary.

Action: For information

The CHMP agreed the nomination of the proposed additional assessors.

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus/Romaldas Mačiulaitis

- Draft guideline on clinical investigation of medicinal products for the treatment of gout (EMA/CHMP/771815/2011, Rev. 2)

  Rapporteur: Liesbeth Rook (NL)

  Action: for adoption for 6 month public consultation

  The CHMP adopted the draft guideline for public consultation.

- Appointment of a new core member following resignation of Kristiina Airola (FI).

  Nominations received:

  Action: For adoption

  The CHMP nominated Candida Silva as RIWP core member.

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

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

Minutes from the ITF Briefing Meetings held on 10th October, 27th November and 4th December 2018

Action: for information

The CHMP noted the minutes.

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No items

2.3.10.3. IPRF Nano Working Group

Chair: Harald Enzmann

No items

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

3.1.1. Report on the referral roadmap

Presentation and report

Action: For information

The CHMP noted the roadmap report.

3.1.2. Preparedness of the system and capacity increase

Presentation

Action: for information

The CHMP was updated on the actions taken by EMA to get prepared for the UK withdrawal from the EU.

3.2. Meeting organisation / templates

3.2.1. Topic

No items

3.3. Pharmacovigilance

3.3.1. Topic

No items

4. Any Other Business

4.1.1. Lartruvo – olaratumab – Conditional marketing authorisation – EMEA/H/C/004216

Eli Lilly Nederland B.V.

Indicated in combination with doxorubicin for the treatment of adult patients with advanced soft tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin.

Rapporteur: Jorge Camamero, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Menno van der Elst

Scope: Update on specific obligations.

Action: For discussion

The CHMP was updated on specific obligations and discussed the way forward. CHMP strategic, review and learning meeting under the Romanian presidency of the Council of the European Union

The CHMP was informed that the coming CHMP strategic, review and learning meeting (SRLM) would not take place in Romania. List of participants

5. List of participants

CHMP Chair:

Harald Enzmann

CHMP members:

Bruno Sepodes (Vice-Chair)

Agnes Gyurasics

Andrea Laslop

Concepcion Prieto Yerro

Daniela Melchiorri

Emilia Mavrokordatou

Ewa Balkowiec Iskra

Greg Markey

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Katarina Vučić

Martina Weise

Outi Mäki-Ikola

Sinan B. Sarac

CHMP alternate members:

Christophe Focke

Fátima Ventura

Milena Stain

Dana Gabriela Marin

Jorge Camarero Jiménez

Mark Ainsworth

Natalja Karpova

Selma Arapovic Dzakula

Experts:

Ilona G. Reischl

Malin Filler

Martina Schussler-Lenz

Mette Toftegaard Madsen

Mette Tranholm

Milena Peraita Ezcurra

Patricia Diaz Ramos

Sabine Mayrhofer

A representative from the European Commission attended the meeting

The meeting was run with support from the relevant EMA staff