18 January 2019
EMA/CHMP/140798/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda 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 this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Of note, this agenda 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 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 21 January 2019 meeting

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

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

Action: For information

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Call for nomination for a new QWP Chair

The election of a new QWP 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

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

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

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

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

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

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

Action: For information

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

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

Action: For discussion

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

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

replacing Sirkku Saarela

- CV
- Nomination letter

Action: for adoption

Nomination of a new alternate to BWP

- CV
- Nomination letter

Action: For adoption

Adopted minutes from the November 2018 BWP meeting

Action: For information

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

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

First VWP report on yearly influenza vaccines effectiveness data (EMA/CHMP/140798/2019)

Action: For information

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

Call for nomination for a new PGWP Chair

The election of a new PGWP 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

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 (will join the discussion)
- 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

- 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

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

Nomination of additional assessors:

- Maria Grünewald, Swedish Medical Products Agency (2nd additional assessor from MPA);
- Flavia Lombardo, Italian AIFA (replacing Marco Massari, only additional assessor from AIFA).

As explained to CHMP at ORGAM in December 2018, BSWP is accepting these nominations for additional assessors in anticipation of the loss of MHRA 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.

The list of BSWP participants is provided for information

Action: For information

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

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

Nominations received:

-

The list of RIWP participants is provided for information

Action: For adoption

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

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

3.1.2. Preparedness of the system and capacity increase

Presentation

Action: for information

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