29 November 2019
EMA/CHMP/614413/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 2 December 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

2 December 2019, 09:30 – 12:30, room 0E

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, agendas and minutes are working documents primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda/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 2nd December 2019 meeting

1.3. Adoption of the minutes

CHMP ORGAM Minutes of December 2019 meeting will be adopted at the December 2019 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.1.1. New medical devices Regulation (EU) 2017/745

- EMA procedural guidance for consultation to the European Medicines Agency by a notified body on substance-based medical devices

  Action: For adoption

- EMA workshop on implementation of Article 117 of the medical devices regulation which introduces changes for medicinal products with an integral medical device

  Action: For information

2.2. CHMP organisation / templates

2.2.1. CHMP Workplan 2020

- Draft Workplan 2020

  Action: For discussion

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

No topics

3.2. Guideline Consistency Group (GCG)

Chair(s): Aranzazu Sancho-Lopez

No topics

3.3. Summary of product characteristics Advisory Group

No topics

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chair(s): Sol Ruiz/Nanna Aaby Kruse

4.1.1. Agenda(s) and minutes

- Final minutes for BWP meeting held face-to-face on 7-9 October 2019
- Draft agenda for BWP meeting to be held face-to-face on 2-4 December 2019

Action: For information

4.1.2. Call for nomination for the election of the BWP chair

Sol Ruiz second term will expire in February 2020. Nominations have to be sent together with a CV and a brief motivation letter by 19th February 2020.

Action: For information

4.1.3. CMDh questions to BWP

- Questions on DCP application for medicinal product

Action: For adoption

4.2. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan/Susanne Brendler-Schwaab

4.2.1. Agenda(s) and minutes

- Final minutes for SWP meeting held by teleconference on 16 September 2019

Action: For information

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair(s): Elena Wolff-Holz/Niklas Ekman

No topics

4.4. Biostatistics Working Party (BSWP)

Chair(s): Anja Schiel/Jörg Zinserling

4.4.1. Changes in BSWP Composition

- Call of interest for a new member

  Sought expertise: professionally qualified senior assessor within the European regulatory network, with relevant expertise in the field of biostatistics. Additional preferred criteria are SAWP membership, in order to support BSWP-SAWP interaction, and representing another European country to those of current members (see list). CVs to be sent by 20 January 2020.

  Action: For information

- Nomination of a new additional assessor

  The Spanish Agency (AEMPS) has nominated an additional assessor to the BSWP

  Action: For adoption

4.5. Modelling and Simulation Working Party (MSWP)

Chair(s): Kristin Karlsson/Flora Musuamba Tshinanu

4.5.1. Changes in MSWP Composition

- Nomination of new additional assessors

  The Norwegian Medicines Agency (NOMA) has nominated additional assessors to the MSWP.

  Action: For adoption

4.6. Pharmacogenomics Working Party (PGWP)

Chair(s): Markus Paulmichl

No topics

4.7. Pharmacokinetics Working Party (PKWP)

Chair(s): Henrike Potthast

4.7.1. Product-specific guidelines

Final product-specific guidelines (batch 10)

- Overview of comments received on 'Alectinib hard capsule 150 mg product-specific bioequivalence guidance' (EMA/CHMP/790261/2018) (EMA/CHMP/582874/2019)

Action: For information

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

5.1.1. BPWP request for BWP input regarding a query on heparins

- Question from BPWP to BWP

Action: For adoption

5.2. Central Nervous System Working Party (CNSWP)

Chair(s): André Elferink

No topics

5.3. Cardiovascular Working Party (CVSWP)

Chair(s): Kristina Dunder/Alar Irs

No topics

5.4. Infectious Diseases Working Party (IDWP)

Chair(s): Maria Jesus Fernandez Cortizo

5.4.1. Nomination for the election of the EU regulatory (IDWP member) representative in HIV Forum for HIV PreP activities

Nominations should be sent by 6 December 2019.

For background information see:

https://forumresearch.org/hiv-forum/226-hiv-forum-overview/1605-hiv-forum-overview

Action: For information

5.5. Oncology Working Party (ONCWP)

Chair(s): Sinan B. Sarac/Paolo Foggi

5.5.1. Agenda(s) and minutes

- Final minutes for the ONCWP Adobe meeting held on 22nd October 2019

Action: For information

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair(s): Romaldas Mačiulaitis

No topics

5.7. Vaccines Working Party (VWP)

Chair(s): Mair Powell

No topics

5.8. Scientific Advisory Groups (SAGs)

No topics

6. Drafting groups

6.1. Excipients Drafting Group

Chair:

No topics

6.2. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No topics

6.3. Geriatric Expert Group (GEG)

Chair:

No topics

6.4. Radiopharmaceuticals Drafting Group (RadDG)

Chair: Anabel Cortes Blanco

No topics

6.5. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No topics

7. Joint groups and collaboration with other committees

7.1. Quality Working Party (QWP)

Chair(s): Keith Pugh/Blanka Hirschlerova

7.1.1. QWP response to CMDh question on azacitidine powder for suspension for injection generics

QWP response to CMDh question on assessment of the pharmaceutical development and finished product specifications for azacitidine powder for suspension for injection generics

Action: For adoption

7.2. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

PCWP: Co-chair: Kaisa Immonen Co-chair: Juan Garcia Burgos (EMA)

HCPWP: Co-chair: Gonzalo Calvo Co-chair: Juan Garcia Burgos (EMA)

7.2.1. Agenda(s) and minutes

- Meeting Summary PCWP Plenary Meeting 24 Sep 2019
- Meeting Summary HCPWP Plenary Meeting 24 Sep 2019
- Meeting Summary PCWP/HCPWP Joint Meeting 25 Sep 2019
- Agenda for the Annual PCWP/HCPWP meeting with all eligible organisations, 20 November 2019

Action: For information

7.3. 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(s): Ellen-Margrethe Vestergaard/Susanne Brendler-Schwaab

No topics

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

Chair: Nienke Rodenhuis

No topics

7.5. Collaboration with other committees

7.5.1. CHMP-PRAC cooperation group

Call for volunteers

Action: For information

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair(s): Anja Schiel

8.1.1. Appointment of CHMP peer review for SA

Action: For information

8.1.2. SAWP composition re-examination – March 2020

Action: For information

8.2. Innovation Task Force

No topics

9. Any Other Business

9.1. Direct healthcare professional communication (DHPC) – proposal for publication on the EMA website

Action: For information

9.2. Report from steering group on opioids

Action: For information

9.3. EU NTC proposal for training on pharmacoepidemiology

Action: For information

10. List of Participants