04 October 2019
EMA/CHMP/518388/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on October 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

07 October 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 the 7 October 2019 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of October 2019 meeting will be adopted at the October 2019 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.1.1. Wording of Therapeutic Indication: A guide to assessors of Centralised Application

CHMP: Kristina Dunder

Action: For adoption

2.2. CHMP organisation / templates

2.2.1. Revision of the template for briefing note on accelerated assessment requests

CHMP Lead: to be nominated

Further to previous discussions, revisions to the template for the briefing note on accelerated assessment requests and the corresponding template for applicant's request are proposed.

Action: For discussion

2.2.2. Revision of the template for (Co)Rapporteur AR for initial MAA

Update to the D80 nonclinical AR and the D80 AR Overview /D120 LOQ template for initial MAA with regards to guidance on biosimilars proposed by the BMWP.

Action: For adoption

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. ICH guideline E19 on Optimisation of safety data collection – Step 2b

Lead: Alar Irs (EE)

Following the previous discussion at the September CHMP ORGAM, further comments were forwarded by CHMP Members. In addition, PRAC finalised a consolidated set of comments.

Action: For adoption

3.1.2. ICH M8 - electronic Common Technical Document (eCTD)

Nomination.

Action: For adoption

3.2. Guideline Consistency Group (GCG)

Chair(s): Aranzazu Sancho-Lopez

No topics

3.3. Summary of product characteristics Advisory Group

Launch of the second chapter of the product information review curriculum; an eLearning course to review safety information in product information, and update of SmPC AG membership.

Action: For information

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chair(s): Sol Ruiz/Nanna Aaby Kruse

4.1.1. Agendas and minutes

- Final minutes for BWP meeting held face-to-face on 15-17 July 2019.

  Action: For information

- Draft agenda for BWP meeting to be held face-to-face on 7-9 October 2019.

  Action: For information

4.2. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan/Mikael Andersson

4.2.1. Call for nomination for the election of the SWP vice-chair

Mikael Andersson's first 3-year term will expire in October 2019. Nominations have to be sent together with a CV and a brief motivation letter by 11 October 2019.

Election of SWP vice-chair will take place at the October CHMP Plenary meeting.

Action: For information

4.3. Biosimilar Medicinal Product Working Party (BMWP)

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

4.3.1. Call for nomination for the election of the BMWP Chair

Elena Wolff-Holz's first 3-year term will expire in October 2019. Nominations have to be sent together with a CV and a brief motivation letter by 11 October 2019.

Election of BMWP chair will take place at the October CHMP Plenary meeting.

Action: For information

4.4. Biostatistics Working Party (BSWP)

Chair(s): Anja Schiel/Jörg Zinserling

4.4.1. Call for nomination for BSWP Chair

Anja Schiel's first 3-year term will expire in December 2019. Nominations have to be sent together with a CV and a brief motivation letter by 2nd December 2019.

Action: For information

4.5. Modelling and Simulation Working Party (MSWP)

Chair(s): Kristin Karlsson/Flora Musuamba Tshinanu

No topics

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. Call for nomination for the election of PKWP Chair in October 2019

Jan Welink's second 3-year term expired in September 2019. Nominations have to be sent together with a CV and a brief motivation letter by 11 October 2019.

Election of PKWP chair will take place at the October CHMP Plenary meeting.

Action: For information

4.7.2. Bioequivalence for orally inhaled products containing beclomethasone diproprionate

Rapporteurs: Susan Cole, Nithyanandan Nagercoil and Prashant Dalvi

PKWP response to the CMDh question on bioequivalence for orally inhaled products containing beclomethasone dipropionate

Action: For adoption

4.7.3. Product-specific guideline for acenocoumarol

Proposal from PKWP to develop a product-specific guideline for acenocoumarol

Action: For adoption

4.7.4. Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms (EMA/CPMP/EWP/280/96 Corr1)

Overview of comments received on the draft guideline for publication

Action: For adoption

4.7.5. CMDh question to PKWP

To what extent active ingredients should be released in order to allow a conclusion of comparable local exposure for lozenges

Action: For adoption

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

5.1.1. Agendas and minutes

- Minutes of the Blood cluster TC held on 9 July 2019

  Action: For information

- Draft agenda of the Blood cluster TC to be held on 11 October 2019

  Action: For information

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

No topics

5.5. Oncology Working Party (ONCWP)

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

5.5.1. Call for nomination for the election of the ONCWP vice-chair

Paolo Foggi's first 3-year term will expire in October 2019. An election will be organised during the October CHMP plenary meeting. Nominations have to be sent together with a CV and a brief motivation letter by 11 October 2019.

Election of ONCWP vice-chair will take place at the October CHMP Plenary meeting

Action: For information

5.5.2. Update on membership

Official nomination of Sinan B. Sarac as member of ONCWP.

Action: For information

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair: Romaldas Mačiulaitis

No topics

5.7. Vaccines Working Party (VWP)

Chair(s): Mair Powell

5.7.1. Call for nomination for the election of the VWP chair

Mair Powell's first 3-year term will expire in October 2019. Nominations have to be sent together with a CV and a brief motivation letter by 11 October 2019.

Election of VWP chair will take place at the October CHMP Plenary meeting

Action: For information

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:

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. Change(s) to QWP composition

Nomination of a new member to the QWP core-group: Olaf Ludek (IS) – replacing Diana van Riet-Nales (NL)

Action: For information

7.2. Patients and Consumers Working Party (PCWP)

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

No topics

7.3. Healthcare Professionals Working Party (HCPWP)

Co-chair: Ulrich Jaeger Co-chair: Juan Garcia Burgos (EMA)

No topics

7.4. 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

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

Chair: Nienke Rodenhuis

No topics

7.6. Collaboration with other committees

No topics

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

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 16th October

Action: For adoption

8.2.2. ITF meeting

Meeting date: 5th Novbember

Action: For adoption

8.2.3. ITF meeting

Meeting date: 6th November

Action: For adoption

8.2.4. ITF meeting

Meeting date: 16th October

Action: For adoption

8.2.5. ITF meeting

Meeting date: 20th November

Action: For adoption

9. Any Other Business

9.1. Draft recommendations from the joint EMA-HMA Big Data Taskforce

Action: For information

9.2. Name Review Group (NRG)

Revision of the Mandate, objectives and rules of procedure for the Name Review Group (NRG).

Action: For adoption

9.3. Digital devices and health technology

Action: For discussion

9.4. MNAT procedural guidelines for Rapporteurs and coordinators

Action: For information

10. List of Participants