15 July 2019

EMA/CHMP/401816/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

DRAFT ORGAM[1] minutes for the meeting on 15 July 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 July 2019, 09:30 – 12:30, room 1B

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

The CHMP ORGAM agenda for the 15 July 2019 meeting was adopted.

1.3. Adoption of the minutes

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

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

No topics

2.2. CHMP organisation / templates

2.2.1. CHMP plenary: Half year remarks

Harald Enzmann

The second round of members' and alternates' consultation on CHMP organisation is about to start as initially planned. Participation to the consultation will be on a voluntary basis; a consolidated outcome will be presented at a future ORGAM.

Already identified suggestions to smoothen the organisational aspects of CHMP plenary were presented/reminded.

The Chair asked the topic leaders for activities listed in the CHMP 2019 work plan to get ready to report on their status in September.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. Nomination of experts for ICH groups

- E6(R3): Revision of ICH E6 Good Clinical Practice: Fergus Sweeney and Lisbeth Bregnhoj
- E2D (R1): Revision of ICH E2D Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting: Anja van Haren and Sabine Brosch
- S12: Biodistribution Studies for Gene Therapy Products: Rune Kjeken and Claire Beuneu

- Q5A(R2): Revision of ICH Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin: Johannes Blumel

Action: For adoption

The proposed EC expert nominations were endorsed. In addition, CHMP agreed with nominations for the following working groups:

- ICH E14/S7B The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs: Frank Holtkamp
- Pharmacoepidemiology Discussion Group : Xavier Kurtz and Brigitte Keller-Stanislawski

Next cycle will start in December. CHMP members were asked to identify NCA experts who could answer the next call for participants.

3.1.2. Report on ICH June 2019 meeting in Amsterdam, NL

Action: For adoption

CHMP noted the report. CHMP members asked for a possibility to provide comments on specific ICH guidelines. At present an interest in ICH E19 was identified, but in general a more systematic involvement of CHMP at the early stage of ICH guideline development was suggested.

3.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No topics

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz/Nanna Aaby Kruse

4.1.1. Agendas and minutes

- Final minutes for BWP meeting held face-to-face on 20-22 May 2019
- Draft agenda for BWP meeting to be held face-to-face on 15-17 July 2019

Action: For information

CHMP noted the agenda and minutes.

4.1.2. Workshop on quality support to PRIME-Breakthrough designation hosted by EMA (BWP, QWP, CAT & GMDP IWG) and FDA on 26 November 2018

Draft workshop report for adoption and compiled Industry comments for information

Presentation

Action: For adoption

The report was adopted for publication.

4.2. Safety Working Party (SWP)

Chair: Jan Willem Van der Laan

No topics

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz/Niklas Ekman

No topics

4.4. Biostatistics Working Party (BSWP)

Chairs: Anja Schiel/Jörg Zinserling

No topics

4.5. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

No topics

4.6. Pharmacogenomics Working Party (PGWP)

Chairs: Krishna Prasad/Markus Paulmichl

No topics

4.7. Pharmacokinetics Working Party (PKWP)

Chairs: Jan Welink/Henrike Potthast

4.7.1. Call for nomination for the election of PKWP chair in September 2019

Jan Welink's second 3-year term will expire in September 2019. An election will be organised during the September CHMP plenary meeting. Nominations have to be sent together with a CV and a brief motivation letter by 9 September 2019.

Action: For information

CHMP noted the call for nominations.

4.7.2. Nomination of 2 new additional assessors:

Action: For information

CHMP endorsed the nominations of Alessia Proietti (IT) and Yseult Brun (FR) as additional assessors in PKWP.

4.7.3. Adoption of the PKWP response to the CMDh question on acenocoumarol

Rapporteur

Action: For adoption

CHMP adopted the PKWP response to CMDh question on acenocoumarol.

4.7.4. Product-specific bioequivalence guidance

- Gefitinib film-coated tablet 250 mg product-specific bioequivalence guidance (EMA/CHMP/257026/2018) - Final
- Apixaban film-coated tablet 2.5 and 5 mg product-specific bioequivalence guidance (EMA/CHMP/291499/2018) - Final

  Overview of comments received on 'Apixaban film-coated tablet 2.5 and 5 mg product-specific bioequivalence guidance' (EMA/CHMP/681387/2018)
- Fingolimod capsules 0.25 and 0.5 mg product-specific bioequivalence guidance (EMA/CHMP/154812/2016) – Revision to reflect recent approval of a new lower strength.

Action: For adoption

CHMP adopted the above final documents.

4.7.5. 14th Workshop on Recent Issues in Bioanalysis (WRIB), to be held 30 March-3 April 2020 in Phoenix, AZ, USA

Proposal

Action: For adoption

CHMP agreed with Jan Welink representing CHMP/EMA at the workshop on his capacity of expert.

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

5.1.1. Agenda for the Blood cluster of 9th July 2019

Action: For information

CHMP noted the agenda.

5.2. Central Nervous System Working Party (CNSWP)

Chairs: Karl Broich/André Elferink

No topics

5.3. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder/Alar Irs

No topics

5.4. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

No topics

5.5. Oncology Working Party (ONCWP)

Chairs: Pierre Demolis/Paolo Foggi

5.5.1. Call for nomination for the election of ONCWP chair in September 2019

Pierre Demolis' first 3-year term will expire in September 2019. An election will be organised during the September CHMP plenary meeting. Nominations have to be sent together with a CV and a brief motivation letter by 9 September 2019.

Action: For information

CHMP noted the call for nominations.

5.6. Rheumatology/Immunology Working Party (RIWP)

Chairs: Jan Mueller-Berghaus/Romaldas Mačiulaitis

No topics

5.7. Vaccines Working Party (VWP)

Chair: Mair Powell

No topics

5.8. Scientific Advisory Groups (SAGs)

No topics

6. Drafting groups

6.1. Excipients Drafting Group

Chair: Dominique Masset

No topics

6.2. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No topics

6.3. Geriatric Expert Group (GEG)

Chair: Katarina Vučić

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)

Chairs: Keith Pugh/Blanka Hirschlerova

Minutes from ad-hoc QWP Core Team discussion

Action: For information

CHMP noted the minutes.

7.2. Patients and Consumers Working Party (PCWP)

Co-chair: Kaisa Immonen

No topics

7.3. Healthcare Professionals Working Party (HCPWP)

Co-chair: Gonzalo Calvo

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)

Chairs: 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)

Chairs: Anja Schiel

8.1.1. Appointment of CHMP peer reviewer for SA

Action: For information

CHMP members were encouraged to bid.

8.2. Innovation Task Force

No topics

8.2.1. ITF Meeting

Meeting date: 24th July 2019

Action: For adoption

CHMP agreed with the meeting.

8.2.2. ITF Meeting

Meeting date: 29th August 2019

Action: For adoption

CHMP agreed with the meeting.

8.2.3. ITF Meeting

Meeting date: 9th September 2019

Action: For adoption

CHMP agreed with the meeting.

8.2.4. ITF Meeting

Meeting date: 24th September 2019

Action: For adoption

CHMP agreed with the meeting.

8.2.5. ITF Meeting

Meeting date: 15th July

EMA launched an emergency call for interest for participation to this meeting agreed at the June ORGAM as a few experts were not able to join.

9. Any Other Business

9.1. Harmonisation of communication subject naming convention received from NCAs

Action: For information

EMA presented the new communication subject naming convention aiming at allowing the automation of the current process for circulation of assessment reports and comments received.

It was confirmed that the same naming convention will be followed by EMA PL as well.

10. List of participants

CHMP Chair:

Harald Enzmann

CHMP members:

Bruno Sepodes (Vice-Chair)

Alexandre Moreau

Andrea Laslop

Bjørg Bolstad

Christian Gartner

Daniela Melchiorri

Ewa Balkowiec Iskra

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Konstantinos Markopoulos

Kristina Dunder

Maria Concepcion Prieto Yerro

Martina Weise

Martine Trauffler

Melinda Sobor

Outi Mäki-Ikola

Sinan B. Sarac

CHMP alternate members:

Agnes Gyurasics

Fátima Ventura

Janet König

Maris Kodols

Milena Stain

Nithyanandan Nagercoil

Selma Arapovic Dzakula

Tuomo Lapveteläinen

Experts:

Keith Pugh

Kristina Bech Jensen

Pierre Demolis

Sabine Mayrhofer

Sotiris Michaleas

Valerie Lescrainier

A representative from the European Commission attended the meeting

The meeting was run with support from the relevant EMA staff