25 January 2021
EMA/CHMP/51258/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 16 March 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

16 March 2020, 09:30–12:00, room 09-A/remotely

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 16 March 2020 meeting was adopted.

1.3. Adoption of the minutes

CHMP ORGAM minutes of 16 March 2020 meeting will be adopted at the March 2020 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

No topics

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

Process to collect and record CHMP learnings

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP noted that there is no new learning this month for validation. Some of the learnings will be for validation upon conclusion of the concerned procedure at the CHMP Plenary.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. Nomination of experts for ICH groups

Draft ICH MedDRA M1 Points to consider

Action: For adoption

The CHMP appointed the Kenneth Nieleboch (DK) as new expert to the ICH.

3.1.2. Draft ICH S11 Nonclinical Safety Testing in Support of Development of Paediatric Medicines

Step 5 draft

Action: For adoption

The members noted the update of the guideline. The purpose of this document is to recommend international standards for, and promote harmonisation of, the nonclinical safety assessments to support the development of pharmaceuticals intended for paediatric use. Following further discussion at the March PDCO meeting, the document will be for adoption that the March CHMP Plenary.

3.2. Guideline Consistency Group (GCG)

Chair(s): Aranzazu Sancho-Lopez

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

- Draft agenda for BWP meeting to be held via F2F on 16-18 March 2020
- Final minutes for BWP meeting held via F2F on 20-22 January 2020

Action: For information

The agenda and minutes were noted.

4.1.2. Call for nomination for the election of the BWP Vice-Chair

Nanna Aaby Kruse's second term will expire in April 2020. Nominations have to be sent together with a CV and a brief motivation letter by 16th April 2020.

Action: For information

The CHMP noted the call for nominations.

4.1.3. Use of live fly larvae as medicinal products

BWP Response to CMDh questions

Action: For adoption

The BWP response to CMDh questions on live fly larvae was presented. The CHMP adopted the response.

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 27 January 2020

Action: For information

The CHMP noted the minutes**.**

4.2.2. Mutagenic impurity from promazine

SWP responses to CMDh

SWP: Fabien Lavergne/Dominique Masset

Action: For adoption

The SWP response to CMDh questions on mutagenic impurity from promazine was presented. The CHMP adopted the SWP response.

4.2.3. Change(s) to SWP composition

Nomination of a new alternate to the SWP

Action: For adoption

The CHMP endorsed Ana Cláudia Figueiredo as new Portuguese alternate to the SWP.

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): Jörg Zinserling

No topics

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. Election of PKWP Vice Chair in March 2020

Previous vice chair Henrike Potthast has now become the chair of PKWP and therefore an election for vice chair will be organised during the March CHMP plenary meeting. The last day for nomination was 28th February 2020.

Nomination(s) received

Action: For information

The election of the PKWP vice chair will take place at the March 2020 CHMP Plenary. The CHMP noted the nomination(s) received.

4.7.2. Change(s) to PKWP composition

A call for nomination of new PKWP members was launched in February ORGAM) with a deadline on 11th March 2020.

The PKWP is looking for 2 experts with specific expertise in the following areas (in addition to the general PK and/or biopharmaceutics expertise):

- Bioequivalence/biowaivers
- PBPK modelling

Nominations received

Action: For information

The CHMP noted the nominations.

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

5.1.1. Call for nomination for the election of the BPWP chair

Jacqueline Kerr's first term will expire in March 2020. Nominations have to be sent together with a CV and a brief motivation letter.

The call is extended until 15th April 2020.

Action: For information

The CHMP noted the call for nominations.

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. Agenda(s) and minutes

- Agenda of the 5th February 2020 Adobe TC
- Minutes of the 15th January 2020 Adobe TC

Action: For information

The agenda and minutes were noted**.**

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

No topics

6.2. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No topics

6.3. Geriatric Expert Group (GEG)

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: Blanka Hirschlerova

7.1.1. QWP position on the Ph. Eur. Commission proposal to introduce requirements for the detection and control of N-nitrosamine impurities and the application of such requirements to all substances for pharmaceutical use (general monograph 2034)

- Letter to EDQM

  Action: For adoption

- Letter from EDQM

  Action: For information

  The CHMP noted the letter from EDQM and agreed to the response letter.

7.1.2. CMDh request whether it is possible to approve only one manufacturing site included in an ASMF in relation to a specific medicinal product.

- EMA-QWP response to CMDh

Action: For adoption

The EMA-QWP response to CMDh questions was presented. The CHMP adopted the EMA-QWP response.

7.1.3. Minutes from February 2020 QWP Core Team meeting

Action: For information

The minutes were noted.

7.1.4. Election of QWP Vice Chair

A call of interest was launched in February (CHMP SoO) with a deadline on 13th March 2020.

Action: For information

The members noted the call for nominations.

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

No topics

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

No topics

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair(s): Anja Schiel

SAWP composition re-nomination

Action: For adoption

The CHMP noted the new SAWP composition proposed by the SAWP chair. The CHMP was informed about the increased workload of scientific advice over time. The CHMP adopted the proposal for the SAWP composition.

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: 30 March 2020

Action: For adoption

The CHMP endorsed the meeting.

8.2.2. ITF meeting

Meeting date: 31 March 2020

Action: For adoption

The CHMP endorsed the meeting.

8.2.3. ITF meeting

Meeting date: 06 April 2020

Action: For adoption

The CHMP endorsed the meeting.

9. Any Other Business

9.1.1. Joint HMA/EMA network strategy 2025

Action: For information

The CHMP noted the work ongoing to draft the next Joint HMA/EMA network strategy to 2025. Early consultation has taken place with EMA Committees/Working Parties, HMA Working Groups/Task Forces, and external stakeholder groups. According to current plans a draft will be put for adoption to HMA and EMA Management Board via written procedure in mid-April. On 4th May, a 2-month external written consultation is planned. The finalisation of the document is targeted for October 2020.

9.1.2. Art 5 (3) referral part I Nitrosamines call for review

Selection of Rapporteurs when risk assessment is required for specific cases.

Action: For discussion

The CHMP noted the need to agree on a process for the management and risk assessment of responses from the step 2 of the nitrosamine call for review. This includes modalities of selection of lead rapporteur in case of issues impacting multiple products. EMA agreed to work on a proposal for the process. Any proposals on the best suitable process for NCAs are welcome.

9.1.3. CHMP statement on increase efficiency and coordination of clinical trials in EU against COVID-19

Action: For adoption

The CHMP discussed and endorsed the statement.

10. List of Participants

CHMP Chair:

Harald Enzmann

CHMP Members:

Bruno Sepodes (Vice-chair)

Alar Irs

Andrea Laslop

Bjørg Bolstad

Blanka Hirschlerova

Christian Gartner

Daniela Melchiorri

Ewa Balkowiec Iskra

Frantisek Drafi

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Konstantinos Markopoulos

Kristina Dunder

Maria Concepcion Prieto Yerro

Margareta Bego

Martine Trauffler

Melinda Sobor

Outi Mäki-Ikola

Simona Badoi

Sinan B. Sarac

Sol Ruiz

CHMP alternate members:

Agnes Gyurasics

Christophe Focke

Dana Gabriela Marin

Elita Poplavska

Fátima Ventura

Giuseppa Pistritto

Ingrid Wang

Janet Koenig

Milena Stain

Simona Stankeviciute

Tomas Radimersky

Tuomo Lapvetelainen

Experts:

Anja Duchting

Anja Schiel

Fabien Lavergne

Jan Willem van der Laan

Kristina Bech Jensen

Maria Victoria Tudanca Pacios

Sabine Mayrhofer

The meeting was run with support from the relevant EMA staff.