20 February 2020
EMA/244237/2020
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 17 February 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

17 February 2020, 09:30–12:30, room 09-A

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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Table of contents

1. Agenda and Minutes

1.1. Welcome and declarations of interest of members, alternates and experts

1.2. Adoption of agenda

The CHMP adopted the ORGAM agenda for 17 February 2020 meeting.

1.3. Adoption of the minutes

CHMP Orgam Minutes of February 2020 meeting will be adopted at the February 2020 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.1.1. Liaison with FDA on a new active substance status

Draft minutes from TC organised to discuss FDA position as well as the proposed United States Adopted Name (USAN)

Action: For discussion

The CHMP endorsed the scientific reasoning.

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

CHMP: Outi Mäki-Ikola

Process to collect and record CHMP learnings

Action: For discussion

- Records

Action: For adoption

The CHMP was satisfied with the process and format used to track CHMP learnings. CHMP members were encouraged to send cases they find interesting.

The information gathered during the pilot with a view of creating a regulatory/scientific memory repository was reviewed. CHMP members proposed a few amendments to the key words used to tag the cases. It was proposed to adjust the description to reflect new learnings falling under the same topic to evolve towards a more general wording.

The CHMP welcomed the proposal and adopted the document with the agreed amendments.

2.2.2. Revision of templates for Reader's Guidance

A revised draft update to the template for the reader's guidance has been prepared.

CHMP: Johann Lodewijk Hillege

Action: For discussion

Johann Lodewijk Hillege presented the latest changes to the documents. CHMP members were encouraged to use the revised guidance document.

2.2.3. Procedural Advice on the CHMP/CAT/PRAC (Co)-Rapporteur appointment

Action: For adoption

In 2017, the European Ombudsman opened an (OI/7/2017/KR) into the arrangements that the European Medicines Agency (EMA) has in place for engaging with individual medicine developers before they submit applications for authorisations to market their medicines in the EU, as well as the more general transparency of EMA's work concerning the authorisation of medicines. In the decision of 17th July 2019 (EO Decision OI/7/2017/KR), the Ombudsman made a number of suggestions for improvement to EMA.

In order to mitigate any perception of influence resulting from pre-submission involvement in Scientific Advice, the EO suggested that to the greatest extent possible, EMA should ensure that there is a separation between those responsible for providing scientific advice to a medicine developer and those subsequently involved in evaluating an MAA for the same medicine. In appointing rapporteurs to evaluate MAAs, EMA's CHMP should take into account whether individuals were already involved as coordinators in providing advice on the same medicine in the pre-submission stage. If exceptions are made, the reasons for the decision should be documented and the information published in the EPAR. EMA should ensure that at least one of the two rapporteurs had no prominent role in the pre-submission activities concerning that medicine.

Considering the above recommendation, as of February 2020, the EMA will systematic check if rapporteur/co-rapporteur candidates have been previously involved in pre-submission activities prior to their appointment by the CHMP with the aim of avoiding involvement of both rapporteur and co-rapporteur.

EMA's procedural document for rapporteurship appointment will be updated according to the EO's recommendations.

2.2.4. Change in the CHMP committee's quorum and majority following UK's withdrawal from the EU

Action: For information

The quorum and majority thresholds were recalculated with the new number of CHMP voting members (27 + 5 following Brexit). In contrary to what is indicated in the title, these number are not affected by the UK CHMP member departure: quorum and majority are reached with an attendance of 22 and 17 members respectively.

2.2.5. Parallel assessment for medicinal products under article 58 application and initial centralised application

Action: For information

EMA proposed to offer the possibility to have simultaneous submission / assessment of centralised marketing authorisation and Article 58 opinion when products are needed for EU and non-EU population.

Parallel submissions would be handled by same rapporteurs and co-rapporteurs and would result in two assessment reports (ARs) and separate opinions. The two ARs are expected to be identical, except where there would be different conditions of use. This would optimise the use of NCA resources, prevent assessment discrepancies and reduce the time to get an Article 58 opinion if the medicine is to be also used in EU.

The proposal is not expected to have any impact on fees as no changes are planned.

CHMP members were asked to send feedback on the proposal before the CHMP plenary. In the absence of comment the proposal will be considered adopted by CHMP.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1 Adoption of Guidelines

ICH **Q12** Step 5 - Guideline on Lifecycle Management (adopted January 2020)

- Note on EU implementation of ICH Q12

  Action: For adoption

The CHMP adopted the note on EU implementation.

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

- Final minutes for BWP meeting held face-to-face on 2-4 December 2019

  Action: For information

- Draft agenda for BWP meeting to be held face-to-face on 17-19 February 2020

Action: For information

The minutes and agenda were noted.

4.1.2. Change(s) to BWP composition

Nomination of new member

Action: For adoption

The CHMP adopted the nomination of Zsuzsanna Sasvari as BWP member for Hungary.

4.1.3. Election of the BWP chair

Nomination(s) received

The election will take place at the February 2020 CHMP plenary meeting.

Action: For information

The CHMP noted the nomination received. CHMP members were reminded about the deadline for nomination (19/02/2020).

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 9 December 2019

Action: For information

The minutes were noted.

4.2.2. Publication of SWP position on Genotoxicity and Contraception

SWP Q&A on Genotoxicity and Contraception

Action: For adoption

The CHMP adopted the Q&A on genotoxicity and contraception for publication.

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

4.4.1. Change(s) to BSWP composition

- Nomination(s) received following the call of interest for a new member launched in December 2019

  One nomination was received

  Action: For adoption

  The CHMP adopted the nomination of Finbarr Leacy as a new member of BSWP.

- Call of interest for a new member

  Nominations have to be sent together with a CV and a brief motivation letter as soon as possible or **at the latest by 31st March 2020** for an election during the April CHMP plenary meeting.

  Action: For information

  The call of interest was noted.

4.5. Modelling and Simulation Working Party (MSWP)

Chair(s): Kristin Karlsson/Flora Musuamba Tshinanu

4.5.1. Change(s) to MSWP composition

Nomination of a new additional assessor

Action: For adoption

The CHMP adopted the nomination of Margareta Bego as additional assessor in MSWP

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. PKWP Question and Answers

- PKWP Q&A for CMDh request on therapeutic equivalence for orally inhaled products containing beclomethasone diproprionate

  Action: For adoption

  The CHMP adopted the PKWP Q&A on therapeutic equivalence for orally inhaled products containing beclomethasone diproprionate for publication.

- PKWP Q&A for CMDh request on acceptable extent of release in comparative local in vivo availability studies for lozenges

Action: For adoption

The CHMP adopted the PKWP Q&A on acceptable extent of release in comparative local in vivo availability studies for lozenges for publication.

4.7.2. Product Specific Guidelines

Final Etonogestrel and ethinylestradiol vaginal delivery system 0.12mg/0.015mg/day product-specific bioequivalence guidance (EMA/CHMP/97470/2019)

No comments were received during the public consultation

Action: For adoption

The CHMP adopted the product specific bioequivalence guideline for publication.

4.7.3. Call for nomination for the election of PKWP vice chair

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. Nominations have to be sent together with a CV and a brief motivation letter as soon as possible or **at the latest by 28th February 2020** for an election during the March CHMP plenary meeting.

Action: For information

The CHMP noted the call for nomination.

4.7.4. Call of interest for new PKWP members

The following expertise areas need to be filled with 2 new members as a result of the departure of existing members.
The PKWP is looking for experts with specific expertise in the following areas (in addition to the general PK and/or biopharmaceutics expertise):

- Bioequivalence/biowaivers
- PBPK modelling

Nominations should be sent together with a CV and a brief motivation letter by **Wednesday 11th March 2020**

Action: For information

The CHMP noted the call of interest.

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

5.1.1. Agenda(s) and minutes

Final minutes from the blood cluster TC held on 11th October 2019

Action: For information

The minutes were noted.

5.1.2. 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 by 13th March 2020.

Action: For information

The CHMP noted the call for nomination.

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

Minutes and agenda will be tabled at the March ORGAM.

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. Agenda(s) and minutes

Minutes from January QWP Core Team

Action: For information

The minutes were noted.

7.2. Patients and Consumers Working Party (PCWP) and 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)

7.2.1. Agenda(s) and minutes

- Draft Agenda - PCWP and HCPWP joint meeting 3-4 March 2020
- Meeting Summary Annual PCWP-HCPWP meeting with all eligible organisations 20 November

Action: For information

The agenda and meeting summary were noted.

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

Appointment of CHMP peer review for SA

Action: For information

The CHMP noted the list.

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 02 March 2020

Action: For adoption

The meeting was adopted.

9. Any Other Business

9.1.1. Update on EMA organisational aspects

Action: For information

The CHMP noted the update.

10. List of Participants

CHMP Chair:

Harald Enzmann

CHMP members:

Bruno Sepodes (Vice-Chair)

Andrea Laslop

Bjørg Bolstad

Christian Gartner

Daniela Melchiorri

Ewa Balkowiec Iskra

Frantisek Drafi

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

John Joseph Borg

Koenraad Norga

Konstantinos Markopoulos

Kristina Dunder

Maria Concepcion Prieto Yerro

Martina Weise

Martine Trauffler

Melinda Sobor

Natalja Karpova

Outi Mäki-Ikola

Sinan B. Sarac

CHMP alternate members:

Agnes Gyurasics

Christophe Focke

Dana Gabriela Marin

Fátima Ventura

Ingrid Wang

Janet Koenig

Mark Ainsworth

Selma Arapovic Dzakula

Experts:

Anja Schiel

Maria Victoria Tudanca Pacios

Milena Peraita Ezcurra

Paolo Foggi

Sabine Mayrhofer

Trine Jensen

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