13 September 2019
EMA/CHMP/121051/2020
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 9 September 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

09 September 2019, 09:30 –12:30, room 0-D

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 09 September 2019 meeting was adopted.

1.3. Adoption of the minutes

CHMP ORGAM minutes of September 2019 meeting will be adopted at the September 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 work plan 2019

Reports from topic leads on the status of activities listed in the CHMP work plan.

Action: For information

CHMP noted the reports. The topic will be back at the October ORGAM.

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

Overview of comments received from CHMP members

Action: For discussion

CHMP members were asked to send further feedback focusing on the concepts developed in the document in order to consolidate the position of the Committee before the next ICH meeting.

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. Agendas and minutes

- Draft agenda for BWP meeting to be held face-to-face on 9-11 September 2019
- Final minutes for BWP meeting held face-to-face on 17-19 June 2019

Action: For information

CHMP note the documents.

4.1.2. Change(s) to BWP composition

Nomination of a BWP member for Slovenia

Action: For adoption

CHMP agreed on the nomination of Suzana Vidic as BWP member for Slovenia.

4.2. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan

4.2.1. CMDh request to SWP on genotoxicity and contraception

Action: For adoption

CHMP agreed on the CMDh consulting SWP on genotoxicity and contraception.

4.2.2. Change(s) to SWP composition

Nomination of new members:

- Slovenia
- Cyprus – replacing Sofia Petridou

Action: For adoption

CHMP agreed on the nomination of Gaja Leseničar Pučko and Panagiotis Psaras as SWP members for Slovenia and Cyprus respectively.

4.2.3. Call for nomination for the election of SWP vice-chair in October 2019

Mikael Andersson'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.

Action: For information

CHMP noted the call for nomination.

4.2.4. Response to CMDh request on nitrosamine acceptable intake for non-sartans

Action: For adoption

The SWP response to CMDh request on NDBA and nitrosamine impurities temporary limits will be adopted by CHMP following the October plenary meeting if no comments are received.

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 BMWP chair in October 2019

Elena Wolff-Holz'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 together with a CV and a brief motivation letter by 11 October 2019.

Action: For information

CHMP noted the call for nomination.

4.4. Biostatistics Working Party (BSWP)

Chair(s): Anja Schiel/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): Krishna Prasad/Markus Paulmichl

No topics

4.7. Pharmacokinetics Working Party (PKWP)

Chair(s): Jan Welink/Henrike Potthast

4.7.1. Product-specific guidelines

Final product-specific guidelines (batch 10)

- Ezetimibe tablet 10 mg product-specific bioequivalence guidance (EMA/CHMP/802491/2018) and Overview of comments

- Cabozantinib tablet 20 mg, 40 mg and 60 mg, capsule 20 mg and 80 mg product-specific bioequivalence guidance (EMA/CHMP/790333/2018)
- Alectinib hard capsule 150 mg product-specific bioequivalence guidance (EMA/CHMP/790261/2018)
- Palbociclib hard capsule 75 mg, 100 mg and 125 mg product-specific bioequivalence guidance (EMA/CHMP/802679/2018)

Action: For adoption

CHMP adopted the final four product-specific bioequivalence guidelines mentioned above for publication.

Product-specific guideline requested by CMDh

- Colchicine tablet 0.5 mg and 1 mg product-specific bioequivalence guidance (EMA/CHMP/35552/2019)

Action: For adoption

CHMP adopted the product-specific bioequivalence guideline on colchicine tablets.

Product-specific guideline for revision (batch 1)

- Dasatinib film-coated tablets 20, 50, 70, 80, 100 & 140 mg product-specific bioequivalence guidance (EMA/CHMP/675838/2014)

Action: For discussion

In light of data submitted with recent applications, PKWP is considering to revise the currently published product-specific guideline on dasatinib film-coated tablets

CHMP agreed with the approach.

4.7.2. Update on PKWP Question and Answers

Question 3.6 on requirements for BE with 'crushed' tablets in light of new data for a (non-centralised) deferisarox generic

Action: For adoption

Some data for deferasirox show that bioequivalence may not be demonstrated under certain conditions related to food intake. It was agreed that for now, there are no implications on the ongoing deferasirox centralised application and on Q & A 3.6, but that PKWP would develop a product-specific guideline for deferasirox.

4.7.3. Change(s) to PKWP composition

- Nomination by AEMPS (ES) of an additional assessor to the PKWP

Action: For adoption

CHMP agreed on the nomination of Susana Morales as additional assessor to the PKWP.

- Sotiris Michaleas stepped down as PKWP member and will be replaced by Paulo Paixão who was nominated as PKWP member in April 2019 in anticipation of the next membership vacancy.

Action: For information

CHMP agreed to the change in PKWP membership.

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

Jan Welink's second 3-year term is expiring in September 2019.

Action: For information

CHMP agreed on an extension to the call for nomination until 11 October 2019 for an election during the October CHMP plenary meeting. Nominations have to be sent together with a CV and a brief motivation letter.

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr

No topics

5.2. Central Nervous System Working Party (CNSWP)

Chair(s): Karl Broich/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): Pierre Demolis/Paolo Foggi

5.5.1. Agendas and minutes

Final minutes for ONCWP Adobe meeting held on 12 June 2019 (EMA/395871/2019)

Action: For information

CHMP noted the minutes.

5.5.2. Election of ONCWP chair

The Chair's first 3-year term is expiring in September 2019. The election will take place during the CHMP September plenary meeting.

The following nominations were received (deadline 9 September 2019 EOB):

Action: For information

CHMP noted the nominations.

5.5.3. Call for nomination for the election of ONCWP vice-chair in October 2019

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.

CHMP noted the call for nomination.

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair(s): Jan Mueller-Berghaus/Romaldas Mačiulaitis

No topics

5.7. Vaccines Working Party (VWP)

Chair(s): Mair Powell

5.7.1. Change(s) to VWP composition

Nomination by NOMA (NO) of an additional assessor to the VWP

Action: For adoption

CHMP agreed on the nomination of Maja Sommerfelt Grønvold as additional assessor to VWP.

5.7.2. Call for nomination for the election of VWP chair in October 2019

Mair Powell'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.

Action: For information

CHMP noted the call for nomination.

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)

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. Call of interest for a QWP core-team member

Nominations have to be sent together with a CV and a brief motivation letter highlighting the candidate's areas of expertise by 19 September 2019.

Action: For information

CHMP noted the call of interest.

7.1.2. Change(s) to QWP composition

Nomination of a QWP member for the Netherlands, replacing Diana van Riet–Nales.

Action: For adoption

CHMP agreed on the nomination of Kim Notenboom as the new Dutch representative to QWP.

7.1.3. QWP response to IGDRP

QWP response to IGDRP on NIR and RAMAN analysis techniques for identification and quantification of all raw materials and the quantification of finished drug products within MAA procedures

Action: For adoption

The QWP response to IGDRP (International Generic Drug Regulators Programme) group was considered adopted unless CHMP members send comments before the September plenary meeting.

7.2. Patients and Consumers Working Party (PCWP)

7.2.1. Work plan

2019-2022 joint PCWP/HCPWP work plan

Action: For adoption

CHMP adopted the work plan. CHMP representatives in PCWP and HCPWP will make sure there is no overlap with CHMP work plan.

7.2.2. Agendas

- Draft Agenda - Patients and Consumers Working Party (PCWP) meeting
- Draft Agenda - Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) joint meeting

Action: For information

CHMP noted the agendas.

7.3. Healthcare Professionals Working Party (HCPWP)

- Draft Agenda - Healthcare Professionals Working Party (HCPWP) meeting

Action: For information

CHMP noted the agenda.

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

The CHMP noted the list.

8.1.2. Change(s) to SAWP composition

- Following the nomination of Christian Gartner (AGES) as CHMP member

Action: For adoption

CHMP adopted the nomination of Andreas Kirisits (SAWP alternate) as SAWP member replacing Christian Gartner recently elected as CHMP co-opted member.

- Vacant Alternate positions for NCA nominations

Action: For information

CHMP noted the call for nomination.

- Preparation to the SAWP composition re-examination.

Action: For information

CHMP was informed that the SAWP composition would be re-examinated in March 2020.

8.2. Innovation Task Force

8.2.1. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004

Action: For information

CHMP was informed of changes that were proposed to the previously adopted definitions of Pharmacological, Immunological, Metabolic and Medical diagnosis. CHMP members can send further comments if needed. The amended definitions have been shared with Industry; the

outcome of this consultation will be shared with CHMP. Once agreed, the definitions will be published as part of the medical device guidance currently being developed.

9. Any Other Business

9.1. Notice to sponsors of clinical trials on requirements for the qualification of vendors of e-systems and the validation of such systems used in clinical trials

Action: For adoption

CHMP adopted the document.

9.2. Guidance for assessors for Post Authorisation Safety Study (PASS)

Action: For discussion

CHMP members were invited to send comments before the September plenary meeting.

9.3. GMO consultation

Presentation of the streamlined consultation process

Action: For discussion

The revision was triggered by the CAT. The new consultation process was presented to CHMP. CHMP members were invited to send comments and questions they may have before September CHMP plenary.

9.4. Nitrosamine impurities

Presence of nitrosamine impurities in human medicinal products containing chemically synthesised active pharmaceutical ingredients

Action: For information

CHMP was informed about next steps.

10. List of Participants

CHMP Chair:

Harald Enzmann

CHMP members:

Bruno Sepodes (Vice-Chair)

Alar Irs

Blanka Hirschlerova

Bjørg Bolstad

Christian Gartner

Daniela Melchiorri

Ewa Balkowiec Iskra

Frantisek Drafi

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Kristina Dunder

Maria Concepcion Prieto Yerro

Margareta Bego

Martina Weise

Martine Trauffler

Melinda Sobor

Natalja Karpova

Outi Mäki-Ikola

Simona Badoi

CHMP alternate members:

Agnes Gyurasics

Christophe Focke

Dana Gabriela Marin

Emilia Mavrokordatou

Fátima Ventura

Janet König

Mark Ainsworth

Nevenka Trsinar Brodt

Selma Arapovic Dzakula

Tomáš Radiměřský

Experts:

Anja Schiel

Carolien Versantvoort

Henrike Potthast

Lisbeth Bregnhoj

Milena Peraita Ezcurra

Mirjam Hinterleitner

Sabine Mayrhofer

Theis Moeslund Jensen

Ulla Wändel Liminga

A representative from the European Commission attended the meeting.

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