08 December 2020
EMA/CHMP/647319/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 30 November 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

03 November 2020, 09:30–13:30, room 09-A

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 adopted ORGAM agenda for 30 November 2020 meeting.

1.3. Adoption of the minutes

CHMP ORGAM Minutes of November 2020 meeting will be adopted at the December 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

CHMP endorsed learnings.

2.2.2. CHMP meeting dates for the period 2022-2024

Action: For information

CHMP was informed of the proposal for meeting dates for the period 2022-2024 and took the opportunity to discuss if the current meeting duration considered for planning is still fit for purpose, given the increased CHMP workload derived from the build-up of CAPs over time and more complex procedures resulting in the need for additional cooperation with internal and external stakeholders without much adaptation being made to the way meetings are planned.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. ICH report from meeting in Greece (November 2020) – replaced by a virtual meeting

Report and presentation.

Action: For adoption

CHMP was updated on the progress of various active working groups and on ICH Assembly decisions.

3.1.2. Reflection Paper on Patient-Focused Drug Development (PFDD)

Reflection paper for endorsement.

Action: For adoption

CHMP adopted reflection paper on Patient-focused drug development to be published for public consultation on the ICH and EMA websites.

3.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No topics

3.3. Summary of product characteristics Advisory Group

3.3.1. Product information review curriculum

New chapter on pharmaceutical information.

CHMP Topic Leader: Blanka Hirschlerova

Action: For endorsement

eLearning product information review curriculum has been developed, based on the SmPC Advisory Group experience, to promote consistent review of product information within the network.

Chapters on efficacy and safety information are available on EU NTC LMS since 2018 and 2019 respectively.

A new Chapter on pharmaceutical information in SmPC, labelling and Package leaflet has been prepared under QWP Chair's supervision in 2020.

The CHMP endorsed and welcomed its release in the EU NTC Learning Management System.

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz/Nanna Aaby Kruse

4.1.1. Nomination of new member

Nomination of new BWP member.

Action: For endorsement

CHMP endorsed nomination of BWP member Francesca Luciani (IT) replacing Carlo Pini (IT).

4.1.2. Agenda(s) and minutes

- Final minutes for BWP meeting held by teleconference on 5-7 October 2020
- Draft agenda for BWP meeting to be held by teleconference on 30 November – 2 December 2020

Action: For information

CHMP noted agenda and minutes.

4.2. Safety Working Party (SWP)

Chairs: Jan Willem Van der Laan/Susanne Brendler-Schwaab

4.2.1. Agenda(s) and minutes

Final minutes for SWP meeting held by teleconference on 21-22 October 2020.

Action: For information

CHMP noted the minutes.

4.2.2. SWP response to CMDh question on DEA and coconut oil DEA

Action: For adoption

CHMP adopted SWP response to CMDh question on DEA and coconut oil DEA with no further comments.

4.2.3. Requests from EDQM and URPL to CHMP on colistimethate

Follow-up to discussion during November 2020 ORGAM meeting: update on possibility to trigger article 5(3) procedure.

Action: For information

The CHMP noted the next steps regarding this topic.

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz/Niklas Ekman

No topics

4.4. Biostatistics Working Party (BSWP)

Chairs: Kit Roes/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)

Chair: Markus Paulmichl

No topics

4.7. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

4.7.1. Minutes of PKWP meeting September 2020

Action: For information

CHMP noted the minutes.

4.7.2. Product-specific guidelines

Draft product-specific guidelines

- Deferisarox product-specific bioequivalence guidance (EMA/CHMP/472383/2020)

Rapporteur: Jan Neuhauser

Action: For adoption for public consultation

The CHMP adopted for public consultation the Deferisarox product-specific bioequivalence guidance with no additional comments.

Final product-specific guidelines

- Levothyroxine product-specific bioequivalence guidance (EMA/CHMP/176098/2020) and overview of comments

Rapporteur: Alfredo Garcia-Arieta

Action: For adoption

The CHMP adopted for adoption the Levothyroxine product-specific bioequivalence guidance (EMA/CHMP/176098/2020) and overview of comments without any further comment/feedback.

4.7.3. Changes to PKWP composition

Replacement of Henrike Potthast's following departure as Chair.

Action: For endorsement

CHMP endorsed the appointment of Carolien Versantvoort (Vice-Chair) to act as ad-interim Chair and Jutta Dedorath as a Member.

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

5.1.1. Blood cluster TC on 23 October 2020

- Draft minutes of the blood cluster TC held on 23 October 2020

Action: For information

CHMP noted the minutes.

5.2. Central Nervous System Working Party (CNSWP)

Chair(s): Vacant

No topics

5.3. Cardiovascular Working Party (CVSWP)

Chairs: 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: Sinan B. Sarac/Paolo Foggi

No topics

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair: 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(s): Vacant

No topics

6.2. Gastroenterology Drafting Group (GDG)

Chair(s): Vacant

No topics

6.3. Geriatric Expert Group (GEG)

Chair(s): Vacant

No topics

6.4. Radiopharmaceuticals Drafting Group (RadDG)

Chair(s): Vacant

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: Blanka Hirschlerova/Laivi Saaremäel

7.1.1. Agenda(s) and minutes

- Draft agenda for QWP meeting to be held by teleconference on 14-16 December 2020

Action: For information

CHMP noted the agenda

7.1.2. QWP Core Team

- Agenda and minutes from November 2020 QWP CT meeting
- Agenda and minutes from the ad hoc QWP CT meeting

Action: For information

CHMP noted the minutes.

7.1.3. CMDh question to QWP Septocaine and Septocaine forte

CMDh question to QWP on acceptability of proposed alternative reduced terminal sterilisation cycle for Septocaine (articaine HCl and epinephrine) and Septocaine forte (articaine HCl and adrenaline).

Action: For adoption

CHMP adopted CMDh question to QWP on acceptability of proposed alternative reduced terminal sterilisation cycle for Septocaine (articaine HCl and epinephrine) and Septocaine forte (articaine HCl and adrenaline) with no further comments.

7.1.4. CMDh question to QWP on extrapolation of stability data

Action: For adoption

CHMP adopted 7.1.4. CMDh question to QWP on extrapolation of stability data.

7.1.5. CMDh question to QWP on applicability Q5 of CMDh Q&As

CMDh question to QWP on whether Q5 of the CMDh Q&As on QP declaration could also be applicable to intermediate manufacturers.

Action: For adoption

CHMP adopted CMDh question to QWP on applicability Q5 of CMDh Q&As.

7.1.6. QWP responses to PKWP on product specifications for levothyroxine

Rapporteur: Carolien Versantvoort (PKWP) Jobst Limberg (QWP)

Action: For adoption

CHMP adopted 7.1.6. QWP responses to PKWP on product specifications for levothyroxine.

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)

Chairs: 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: Anja Schiel

8.1.1. Nomination of new member

Application(s) received following a call of interests for nomination of a replacement SAWP member and his/her alternate with the following expertise launched in November 2020:

- Rheumatology/ immunology
- General medicine/ clinical pharmacology
- Haematology

It is proposed that Drs Vikerfors and Sjöberg replace Drs Wakelkamp and Vikerfors. In addition, the SAWP proposes that Drs Abramavičius and Sosa fill the vacant position of the 2nd PRAC representative and alternate at the SAWP to account for the increasing SAWP workload which was further exacerbated by the COVID-19 pandemic. This proposal is contingent upon:

- the PRAC giving their endorsement towards this end

- the provision that the representative and alternate position will be promptly made available to the PRAC, should they decide to appoint PRAC members to these positions at any time and at the latest by the time of the next re-nomination of all SAWP members.

Action: For endorsement

CHMP endorsed the proposal pending agreement from PRAC Committee.

8.2. Innovation Task Force

8.2.1. ITF meeting

Action: For adoption

The meeting was endorsed.

8.2.2. ITF meeting

Action: For adoption

The meeting was endorsed.

8.2.3. ITF meeting

Action: For information

The meeting was endorsed.

9. Any Other Business

9.1.1. IRIS implementation in Scientific Advice Procedures

Update to CHMP on implementation of IRIS system in Scientific Advice and access to Scientific Advice documents through the new system for CHMP members.

Action: For information

9.1.2. Updates on the CONSIGN and ACCESS projects

Generic protocols to assess the impact of Covid-19 and medicines (including vaccines) received from the EMA-funded CONSIGN (Covid-19 infectiON and medicineS In preGNancy) and ACCESS (vACCine covid-19 monitoring readinESS) projects.

Presentation

Action: For information (CONSIGN protocol) and for discussion (ACCESS effectiveness and safety protocols)

CHMP noted Generic protocols to assess the impact of Covid-19 and medicines (including vaccines) received from the EMA-funded CONSIGN (Covid-19 infectiON and medicineS In preGNancy) and ACCESS (vACCine covid-19 monitoring readinESS) projects, coordinated by Utrecht University with additional clarification that that ACCESS has been funded by the EMA to prepare for vaccines monitoring by developing protocols that will be published and that can then be used by any stakeholders. The project does not aim at conducting these studies and delivering results but to make available protocols.

9.1.3. Joint CHMP-CAT membership

Nomination by CHMP of joint members to CAT.

Action: For adoption

CHMP adopted nomination of Romaldas Mačiulaitis, Sol Ruiz, Bruno Sepodes, Jan Mueller-Berghaus and John Borg to continue as joint CHMP-CAT members in CAT committee, together with their proposed alternates in CAT, for a new 3 year mandate starting on 18 December 2020.

9.1.4. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

9.1.5. CHMP Work Plan 2021

Discussion on draft CHMP Work Plan 2021.

Action: For discussion

CHMP noted the proposed draft CHMP Work Plan 2021 including topics being carried over to 2021 and new proposed topics. CHMP members are invited to send comments by 16 of December 2020.

9.1.6. Covid-19 EMA pandemic Task Force (COVID-ETF)

Overview of ETF objectives and activities regarding COVID crisis. Overview of ongoing and upcoming procedures. Overview on Scientific Advice.

Action: For information

CHMP noted the overview of ETF objectives and activities regarding COVID crisis, the overview of ongoing and upcoming rolling review procedures and the overview on Scientific Advice procedures.

9.1.7. Covid-19 pandemic; COVID-19: update on vaccines in review

Overview on MA submissions and timetables; update on timelines.

Action: For information

CHMP noted the timetables for submission of marketing authorisations and for upcoming procedures.

9.1.8. mRNA-1273 - EMEA/H/C/005791

Active immunisation against coronavirus disease 2019 (COVID-19) caused by the SARSCoV-2 virus in persons 18 years of age and older.

Scope: Initial Marketing Authorisation Timetable.

Action: For adoption

The CHMP adopted the timetable.

9.1.9. Covid-19 mRNA vaccine - H0005735

Indicated for prophylactic vaccination against Severe Acute Respiratory Syndrome (SARS)-CoV-2.

Scope: Initial Marketing Authorisation Timetable

Action: For adoption

The CHMP adopted the timetable.

10. List of Participants

CHMP Chair

Harald Enzmann

CHMP Members

Bruno Sepodes (Vice-chair)

Alar Irs

Andrea Laslop

Armando Genazzani

Bjorg Bolstad

Blanka Hirschlerova

Christian Gartner

Christophe Focke

Edward Laane

Elita Poplavska

Ewa Balkowiec Iskra

Frantisek Drafi

Ilko Getov

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

John Joseph Borg

Kolbeinn Gudmundsson

Konstantinos Markopoulos

Kristina Dunder

Margareta Bego

Martina Weise

Martine Trauffler

Outi Mäki-Ikola

Simona Badoi

Sinan B. Sarac

CHMP alternate members

Agnes Gyurasics

Alexandre Moreau

Blanca Garcia-Ochoa

Dana Gabriela Marin

Dorota Distlerova

Emilia Mavrokordatou

Fátima Ventura

Hrefna Gudmundsdottir

Ingrid Wang

Janet Koenig

Karin Janssen van Doorn

Kirstine Moll Harboe

Milena Stain

Nevenka Trsinar Brodt

Simona Stankeviciute

Tomas Radimersky

Experts

Alfredo García-Arieta

Anja Schiel

Anne Hasle Buur

Carolien Versantvoort

Concepcion Gimenez Rebollo

Irene Bachmann

Jan Neuhauser

Jobst Limberg

Maria Victoria Tudanca Pacios

Milena Peraita Ezcurra

Nora Cascante Estepa

Sabine Mayrhofer

Sonja Beken