



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 May 2020
EMA/CHMP/54321/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP) ORGAM¹ minutes for the meeting on 20 April 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

20 April 2020, 09:30–12:30, virtual 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 20 April 2020 meeting was adopted.

1.3. Adoption of the minutes

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

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.1.1. Guidance on remote GCP inspections

Action: For information

The CHMP noted the draft guidance on the steps to be followed during remote GCP inspections during crises like the COVID-19 pandemic. The guidance will be further discussed and adopted by the GCP inspectors working group. Any further comments can be provided.

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 adopted the learnings document with the agreed amendments.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. Nomination of experts for ICH groups

- ICH Guideline Q9(R1) on quality risk management
- ICH Guideline M12 on Drug interaction studies

Action: For adoption

The CHMP nominated the proposed experts for the ICH guidelines.

3.1.2. ICH Guideline Q3C(R8) on Impurities: guideline for residual solvents

Step 2b

Action: For adoption for 3-month public consultation

It was noted that this document only contains the Permissible Daily Exposure (PDE) levels for three solvents: 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol that were agreed to be included in the ICH Q3C(R8) revision. Further to reaching Step 4, these PDEs would be integrated into a complete Q3C(R8) Guideline document.

The CHMP adopted the draft ICH guideline Q3C(R8) on Impurities for 3-months public consultation.

3.2. Guideline Consistency Group (GCG)

Chair(s): Aranzazu Sancho-Lopez

No topics

3.3. Summary of product characteristics Advisory Group

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 17-19 February 2020
- Draft agenda for BWP meeting to be held by teleconference on 20-22 April 2020

Action: For information

The agenda and minutes were noted.

4.1.2. Call for nomination of BWP Vice-chair

Nanna Aaby Kruse's second term will expire in April 2020. The election is scheduled at the April 2020 CHMP Plenary meeting.

Nomination(s) received

Action: For information

The CHMP noted the nomination(s) received for the BWP vice-chair election.

4.1.3. EMA response to AskEMA question

Action: For adoption

The CHMP noted the EMA response. The document will be adopted at the April CHMP Plenary.

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 24 February 2020
- Final minutes for SWP ad-hoc meeting on nitrosamines held by teleconference on 10 February 2020

Action: For information

The agenda and minutes were noted.

4.2.2. SWP response to CMDh question on Nitrosamines MeNP

SWP Rapporteur: Roland Froetschl/Bodo Haas (BfArM)

- Final response

Action: For adoption

The CHMP adopted the SWP response.

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair(s): Elena Wolff-Holz/Niklas Ekman

4.3.1. Open call for nomination of a new member with clinical and/or PK expertise

Nominations have to be sent together with a CV and a brief motivation letter by 14 May 2020.

The CHMP noted the call for nomination.

4.4. Biostatistics Working Party (BSWP)

Chair(s): Jörg Zinserling

4.4.1. Call for nomination of new BSWP Chair and new member

Nominations have to be sent together with a CV and a brief motivation letter by 31 May 2020.

Action: For Information

The CHMP noted the call for nominations.

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/Carolien Versantvoort

4.7.1. Product-specific guidelines

Revision of product-specific guidelines (batch number 1)

- Dasatinib product-specific bioequivalence guidance (EMA/CHMP/675838/2014/Rev.1)
Draft for 3-month public consultation

Action: For adoption

The CHMP adopted the revision.

4.7.2. Question from pharmaceutical industry association to PKWP on clarification for demonstration of bioequivalence for dabigatran etexilate and response from PKWP

Action: For adoption

The CHMP adopted the response from PKWP.

4.7.3. Update on Q & A (7.1) on the key pharmacokinetic considerations in the assessment of biosimilarity

Action: For adoption

The CHMP adopted the Q&A update.

4.7.4. Update on PKWP Q & A (3.8) on the recommendations on for demonstration of bioequivalence of gastro-resistant preparations (e.g. omeprazole)

Action: For adoption

The CHMP adopted the Q&A update.

4.7.5. Question from pharmaceutical industry association to PKWP on biowaivers for additional strengths of immediate release fixed combinations.

Action: For adoption

The CHMP noticed the question. It was proposed to work on a Q&A. The CHMP endorsed the involvement of PKWP.

4.7.6. Changes to PKWP composition

A call for nomination of new PKWP members was launched in February 2020 with deadline of 11 March 2020.

Nominations received

Action: For adoption

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): To be appointed/Karri Penttilä

5.1.1. Election of the BPWP chair

Jacqueline Kerr's first term expired in March 2020. The election is scheduled at the April 2020 CHMP Plenary meeting.

Nomination(s) received

Action: For information

The CHMP noted the nomination(s) received for the BPWP chair election.

5.1.2. Agenda of the Blood Products cluster TC held on 3 April 2020

Action: For information

The agenda was noted.

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

No topics

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(s): Blanka Hirschlerova

7.1.1. QWP Core Team- March minutes

Meeting date: 18 March 2020

Action: For information

The minutes were noted.

7.1.2. Election of QWP Vice Chair

Previous vice chair Blanka Hirschlerova has become the chair of QWP. The election is scheduled at the April 2020 CHMP Plenary meeting.

Nomination(s) received

Action: For information

The CHMP noted the nomination(s) received for the QWP vice-chair election.

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

8.1.1. Change of membership

Action: For adoption

The CHMP adopted the change in membership.

8.1.2. Appointment of CHMP peer review for SA

Action: For information

The CHMP noted the information.

8.1.3. Rapid Scientific Advice process to address COVID-19

Action: For adoption

The CHMP noted that a COVID-EMA Task Force has been established, which meets virtually on a weekly basis as well as ad-hoc. For scientific advice requests to address COVID-19 there are no specific submission deadlines and no fees will be charged. ETF will contribute to scientific advice on products for treatment or prophylaxis of COVID-19 by commenting on the draft scientific advice. The review time in SAWP and CHMP should be as quickly as possible (keeping the overall process as short as total 20 days if feasible) including, as necessary, an up-front Joint Report from SAWP co-ordinators and parallel concurrent peer review from SAWP and CHMP. An adoption of the final scientific advice documents will be done via written procedure or an ad-hoc virtual meeting, unless the adoption coincides with an upcoming CHMP Meeting. The CHMP acknowledged the importance and endorsed the process.

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 21 April 2020

Action: For adoption

The CHMP endorsed the meeting.

8.2.2. ITF meeting

Meeting date: 04 April 2020

Action: For adoption

The CHMP endorsed the meeting.

8.2.3. ITF meeting

Meeting date: 18 May 2020

Action: For adoption

The CHMP endorsed the meeting.

9. Any Other Business

9.1.1. Update on collaboration with HTA bodies after CHMP opinion

Action: For information

The CHMP acknowledged the update. The members were informed about the increased number of products subject to relative effectiveness assessment (REA) related exchange. Not only the number of procedures but also a wider range of therapeutic areas has been covered. This provides a good opportunity to engage more with HTA authors. Webinars were identified as a crucial milestone for the collaboration. With the gained experience further analysis and learnings will be performed. The CHMP will be kept updated on the progress.

9.1.2. Final report of Workshop on the role of registries in the monitoring of cancer therapies based on genetic and molecular features

The CHMP noted the [final report](#) of the workshop held on 29 November 2019 that was published on the EMA website on 3 April 2020.

10. List of Participants

CHMP Chair

Harald Enzmann

CHMP Members

Bruno Sepodes (Vice-chair)

Andrea Laslop

Björg Bolstad

Blanka Hirschlerova

Christian Gartner

Daniela Melchiorri

Ewa Balkowiec Iskra

Frantisek Drafi

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Koenraad Norga

Konstantinos Markopoulos

Kristina Dunder

Maria Concepcion Prieto Yerro

Martina Weise

Martine Trauffler

Melinda Sobor

Outi Mäki-Ikola

Simona Badoi

CHMP alternate members:

Agnes Gyurasics

Christophe Focke

Dana Gabriela Marin

Elita Poplavska

Fátima Ventura

Giuseppa Pistritto

Ingrid Wang

Janet Koenig

Mark Ainsworth

Milena Stain

Nevenka Trsinar Brodt

Selma Arapovic Dzakula

Tomas Radimersky

Experts:

Alfredo Garcia-Arieta

Anja Schiel

Carolien Versantvoort

Hernike Potthast

Jan Willem van der Laan

Maria Victoria Tudanca Pacios

Mette Toftegaard Madsen

Milena Peraita Ezcurra

Noelia Fernández Bodas

Sabine Mayrhofer

A representative from the European Commission attended the meeting

The meeting was run with support from the relevant EMA staff