30 October 2020
EMA/CHMP/555821/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 3 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 ORGAM agenda for the 03 November 2020 meeting

1.3. Adoption of the minutes

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

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

No topics

3.2. Guideline Consistency Group (GCG)

Chair: 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)

Chairs: Sol Ruiz/Nanna Aaby Kruse

No topics

4.1.1. Agenda(s) and minutes

- Final minutes for BWP meeting held by Adobe Connect on 07-09 September 2020
- Draft agenda for BWP meeting to be held by Adobe Connect on 03-05 November 2020

Action: For information

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 14 September 2020

Action: For information

4.2.2. Requests from EDQM and URPL to CHMP on colistimethate powder for injection

The European Pharmacopoeia Group of Experts 7 addressed a request to CHMP on colistimethate sodium (CMS) powder for injection.

Polish Agency (URPL) request to EMA Executive Director to consider asking CHMP on the need of amending the European Pharmacopoeia monograph on CMS.

Action: For confirmation

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

4.3.1. Draft Biosimilar Guideline by MHRA

MHRA guideline on requirements for the biosimilars development and the main difference compared to EU guidance in the area of confirmatory efficacy trials.

Presenter: Elena Wolff-Holtz

Action: For information

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)

Chairs: Henrike Potthast/Carolien Versantvoort

4.7.1. Product-specific guidelines

Final product-specific guidelines (revision)

- Abiraterone tablets 250 mg and 500 mg product-specific bioequivalence guidance (EMA/CHMP/474712/2016 Rev. 1) and Overview of comments

Action: For adoption

Draft product-specific guidelines (revision)

- Palbociclib hard capsule 75 mg, 100 mg and 125 mg and film-coated tablet 75 mg, 100 mg and 125 mg product-specific bioequivalence guidance (EMA/CHMP/555821/2020/Rev.1)

Action: For adoption

Overview of comments

- Overview of comments (from first consultation 27 June 2018 to 30 September 2018) for Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance (EMA/CHMP/257298/2018) (second public consultation ended 30 October 2020). Proposal to publish draft overview now and to extend public consultation by 2 months.

Action: For information

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 17 July 2020

- Final minutes of the blood cluster TC held on 17 July

Action: For information

5.1.2. Blood cluster TC on 23 October 2020

- Draft agenda of the blood cluster TC 23rd October

Action: For information

5.1.3. PPTA/IPFA letter on regulatory flexibility relief for EMA PMF process

- Letter received from PPTA/IPFA dated 28 August 2020
- EMA response to PPTA/IPFA

Action: For information

5.2. Central Nervous System Working Party (CNSWP)

Chair: André Elferink

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

5.5.1. Agenda(s) and minutes

- Final minutes for ONCWP held by Adobe Connect on 23 September 2020
- Final agenda for ONCWP meeting held by Adobe Connect on 22 October 2020

Action: For information

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

- Final minutes for 91st meeting held by teleconference on 5-6 February 2020
- Final minutes for 92nd meeting held by teleconference on 4-6 May 2020

Action: For information

7.1.2. Nomination of members/alternates

Nomination of new QWP alternate.

Action: for endorsement

7.1.3. QWP Core Team

- Agenda and minutes from October 2020 QWP CT meeting

Action: For information

7.1.4. CMDh question to QWP on applicability of Q5 to intermediate manufacturers

CMDh question to QWP on possibility to expand the applicability of Q5 of the CMDh Q&A on QP declaration (CMDh/340/2015/Rev.6, July 2020) to also include the intermediate manufacturers.

Action: For information

7.1.5. CMDh question to QWP on extrapolation of stability data

CMDh question to QWP on extension of shelf-life of the finished product or retest period of the active substance via extrapolation of stability data.

Action: For information

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

7.5.1. Committee for Advanced Therapies (CAT)

Chair: Martina Schüssler-Lenz

- Guideline on quality, non-clinical and clinical requirements for medicinal products containing genetically modified cells – Revision 1 (EMA/CAT/GTWP/671639/2008 Rev.1)

Action: for adoption

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Call for interest for nomination of member and alternate

Call for interest for nomination of a replacement SAWP member and his/her alternate.

Required area of expertise:

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

The letters of candidacy together with the CVs of both member and alternate, as per the SAWP Rules of Procedure, should be sent directly to the SAWP Secretariat by **23 November 2020.**

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Action: For adoption

8.2.2. ITF meeting

Action: For adoption

9. Any Other Business

9.1.1. CHMP Work Plan 2020 – Status Report

Update on the progress of the 2020 CHMP Work Plan

Action: For information

9.1.2. (Re)nomination of CHMP representative for ENCePP Steering Group 2021-2023

Discussion on nomination of a CHMP representative as part of ENCePP Steering Group (SG) for the period 2021-2023 following end of mandate for current member Johann Lodewijk Hillege.

Action: For discussion

Nominations should be sent to the ENCePP Secretariat **by 13 November 2020.**

9.1.3. Big Data Training Signpost

Introduction to Big Data Training Signpost as a collection of external training courses on Big Data skills as a previous step to Big Data curriculum.

Action: For information

9.1.4. Discussion on CHMP co-opted memberships

- Discussion on area of expertise in light of Koenraad Norga's resignation as CHMP co-opted member as of 31 September 2020 following proposals received.

Action: For discussion

- Update on call for nomination of CHMP co-opted member in light of the end of the mandate of Jan Mueller-Berghaus as co-opted member on 13 November 2020.

Action: For discussion

9.1.5. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

9.1.6. Invitation to participate in a MCDA (Multi Criteria Decision Analysis) exercise for benefit risk

CHMP: Johann Lodewijk Hillege

Action: For information

9.1.7. IRIS implementation in Scientific Advice Procedures

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

Action: For information