4 September 2020
EMA/CHMP/404263/2020 Rev.1
Human Medicines Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 7 September 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

07 September 2020, 09:30–12:30, room 9A

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 07 September 2020 meeting

1.3. Adoption of the minutes

CHMP ORGAM Minutes of September 2020 meeting will be adopted at the September 2020 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.2. CHMP organisation / templates

2.2.1. CHMP learnings

Process to collect and record CHMP learnings

CHMP: Outi Mäki-Ikola

Action: For discussion

2.2.2. CHMP Co-opted membership

The 3-year mandate for the CHMP co-opted member Jan Mueller-Berghaus ends on 13 November 2020. The CHMP should discuss and agree on area of expertise needed at their September CHMP ORGAM.

Action: For discussion

2.2.3. Structure and procedure for remote CHMP meetings

For discussion on how to adapt to the current, pandemic induced situation.

Action: For discussion

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. Nomination of experts for ICH groups

- ICH Guideline E6(R2) – Good Clinical Practice

Nomination of Deputy Topic Lead.

Action: For adoption

- ICH Model-Informed Drug development (MIDD) Discussion Group

Nomination

Action: For adoption

3.1.2. ICH Q3D (R2) Guideline on Elemental Impurities

Step 2b

Action: For adoption for 3-month 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 by teleconference on 15-17 June 2020
- Draft agenda for BWP meeting to be held by teleconference on 7-9 September 2020

Action: for information

4.1.2. Change in membership

Nomination received for a new alternate.

Action: For endorsement

4.2. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan/Susanne Brendler-Schwaab

4.2.1. Change in membership

Nomination received for a new alternate.

Action: For endorsement

4.2.2. Agenda(s) and minutes

Final minutes for SWP meeting held by Adobe meeting on 25 May 2020

Action: For information

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): Kit Roes/Jörg Zinserling

4.4.1. Question and Answer on Data Monitoring Committee issues

BSWP is seeking CHMP adoption for the revised document accounting for the stakeholder comments received during the 1-year public consultation.

The aim of this question-and-answer document is to supplement the CHMP Data Monitoring Committee Guideline (EMEA/CHMP/EWP/5872/03) by providing clarification on the role and necessity for a Data Monitoring Committee (DMC) in different phases of drug development and throughout the product lifecycle as well as with regard to the responsibilities for implementing DMC decisions.

Action: For adoption

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

No topics

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

5.1.1. BPWP TC held on 8 June 2020

- Final agenda
- Final minutes

Action: For information

5.1.2. Blood cluster meeting to be held on 17 July 2020

- Final agenda

Action: For information

5.1.3. Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg) and Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)

- Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg))
- Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)

Action: For adoption

5.1.4. PPTA letter

- PPTA letter

Action: For discussion

5.1.5. EC lines to take: Covid-19 Convalescent Plasma in the EU – 28 August 2020

- EC lines to take

Action: For information

5.1.6. COVID-19 meeting of the Competent Authorities for Blood and Blood Components – 17 September 2020

- Draft agenda

Action: For information

5.2. Central Nervous System Working Party (CNSWP)

Chair(s): Vacant/Andre 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. Change in membership

Nomination(s) received for a new member

Action: For endorsement

5.5.2. Anticancer Guideline Revision 6

For release for 3 months public consultation

Action: For adoption

5.6. Rheumatology / Immunology Working Party (RIWP)

Chair(s): Vacant/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

Chair: Vacant

No topics

6.2. Gastroenterology Drafting Group (GDG)

Chair: Vacant

No topics

6.3. Geriatric Expert Group (GEG)

Chair: Vacant

No topics

6.4. Radiopharmaceuticals Drafting Group (RadDG)

Chair: 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)

Chair(s): Blanka Hirschlerova/Laivi Saaremäel

7.1.1. QWP Response to EDQM on Q&A on Use of Peptones in the manufacture of active substances

Action: For discussion

7.1.2. QWP Core Team

Agenda and minutes from July QWP CT meeting

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)

7.2.1. Meeting report PCWP HCPWP meeting - 2 June 2020

Action: For information

7.2.2. Meeting report PCWP HCPWP meeting (ICH) - 3 June 2020

Action: For information

7.2.3. Meeting report PCWP HCPWP meeting - 24 June 2020

Action: For information

7.2.4. Draft Agenda Workshop on the application of the General Data Protection Regulation (GDPR) in the area of health and Secondary Use of Data for Medicines and Public Health Purposes - 23 September 2020

Action: For information

7.2.5. Draft Agenda Workshop on benefit-risk of medicines used during pregnancy and breastfeeding – 22 September 2020

Action: For information

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

7.5.1. CHMP-PRAC Collaboration Group

Presentation on planned actions

Action: For discussion

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

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 14 September 2020 at 14:00 – 15:30

Action: For adoption

8.2.2. ITF meeting

Meeting date: 14 September 2020 at 15:00 – 16:30

Action: For adoption

8.2.3. ITF meeting

Meeting date: 21 September 2020 at 15:00 – 16:30

Action: For adoption

8.2.4. ITF meeting

Meeting date: 5 October 2020 at 12:30 – 14:00

Action: For adoption

9. Any Other Business

9.1.1. Presentation of the CONSING project

Presentation by the contractor of the EMA funded study on the impact of COVID-19 infection and medicines in pregnancy, including the ongoing international collaboration. Call for expression of interest of CHMP members to be involved.

Action: For information

9.1.2. EMA responses to the IPRP nanomedicines working group survey on liposomal products

Action: For information

9.1.3. Working Parties review

Discussion of CHMP perspective

Harald Enzmann

Action: For discussion

10. List of Participants