18 January 2021
EMA/CHMP/689695/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 18 January 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

18 January 2021, 09:30–14:30, virtual meeting/ 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 18 January 2021 meeting.

1.3. Adoption of the minutes

CHMP ORGAM Minutes of January 2021 meeting will be adopted at the January 2021 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

2.2.2. CHMP Co-opted membership

The 3-year mandate for the CHMP co-opted member Blanka Hirschlerova ends on 18 March 2021. The CHMP should discuss and agree on area of expertise needed at their January CHMP ORGAM.

Action: For discussion

2.2.3. Organisational information on January 2021 plenary meeting

CHMP plenary meeting in January 2021 is being extended for an additional day to Friday 29 January. Organisation implication on the time-schedule being explained to the committee.

Action: For information

2.2.4. Revision of Accelerated Assessment Request/Briefing Note template

The revision of the AA briefing note template discussed at the January 2020 CHMP ORGAM has now been finalised and is ready for release.

CHMP: Jan Müller-Berghaus

Action: For information

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

4.1.1. Agenda(s) and minutes

- Final minutes for BWP meeting held by teleconference on 3-5 November 2020
- Draft agenda for BWP meeting to be held by teleconference on 18-20 January 2021

Action: For information

4.1.2. Joint BWP/QWP/IWG Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME marketing authorisation applications

This toolbox guidance follows on from the Workshop with stakeholders on support to quality development in early access approaches (i.e. PRIME, Breakthrough Therapies) held jointly with the US Food and Drug Administration (FDA) in November 2018.

Action: For adoption

4.2. Safety Working Party (SWP)

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

No topics

4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

4.3.1. WHO plan to revise the General GL on SBP (Similar Biologic Products)

Introduction of WHO initiative to review its General GL on SBP (Similar Biologic Products) in line with the current scientific evidence and experience.

Action: For information

4.4. Biostatistics Working Party (BSWP)

Chairs: Kit Roes/Jörg Zinserling

4.4.1. Question and Answer on Data Monitoring Committee issues – Stakeholder comments and responses

BSWP is seeking CHMP adoption for the responses to the stakeholder comments received during the public consultation phase. The final Q&A accounting for these comments was adopted by CHMP on 17 September 2020 and published on the EMA website on 8 October 2020. For completeness, the stakeholder comments and responses should also be published on the dedicated website.

Action: For adoption

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. Product-specific guidelines

Revision of product-specific guidelines

- Sorafenib product-specific bioequivalence guidance (EMA/CHMP/315232/2014) Revision 1 (text amendments, no change in requirements, not for public consultation)

  Rapporteur: Erika Fredriksson

Action: For adoption

4.7.2. PKWP response to CHMP on splitting modified-release tablets

PKWP response to CHMP question on use of bioequivalence studies to support splitting modified-release (MR) tablets.

Rapporteur: Paulo Paixao/Iva Klarica Domjanović

Action: For adoption

4.7.3. Change(s) to PKWP composition

Nomination by BfArM (DE) of an additional assessor to the PKWP.

Action: For adoption

4.7.4. 15th Workshop on Recent Issues in Bioanalysis (WRIB)

Proposal to have Jan Welink representing CHMP/EMA at the workshop to be held 27 September – 1 October 2021 in Orlando, FL, USA.

Action: For adoption

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

No topics

5.2. Central Nervous System Working Party (CNSWP)

Chair(s): Vacant

No topics

5.3. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs

No topics

5.4. Infectious Diseases Working Party (IDWP)

Chair(s): Vacant

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 meeting held by Adobe Connect on 16 December 2020
- Final agenda for ONCWP meeting held by Adobe Connect on 13 January 2021

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair: Romaldas Mačiulaitis

No topics

5.7. Vaccines Working Party (VWP)

Chair: Mair Powell

5.7.1. VWP report on influenza vaccines effectiveness

VWP report on the influenza effectiveness data from the DRIVE consortium covering the 2019-2020 season endorsed by CHMP following written procedure ending on 18 December 2020.

Action: For information

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

- Minutes from September QWP plenary meeting held 16-18 September 2020

Action: For information

7.1.2. QWP Core Team

- Minutes from December QWP CT meeting held 2 December 2020

Action: For information

7.1.3. Change(s) to QWP composition

Nomination received for a new member and alternate from SE.

Action: For endorsement

7.1.4. QWP response to CMDh on referral

Feedback on acceptability on an alternative shortened (121°C / ≥ 8 min) sterilization cycle

Action: For adoption

7.1.5. QWP response to CMDh on extrapolation of stability data

Following receipt of the letter from CMDh EMA/575938/2020, dated 30 October 2020, the QWP discussed their question on the extension of shelf-life/re-test period in variation applications using extrapolation at the December 2020 QWP plenary meeting.

Action: For adoption

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)

7.3. 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. PRAC report to CHMP

Summary of recommendations and advice of PRAC meeting held on 11-14 January 2021.

Action: For information

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: 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: 08 January 2021 at 15:00 – 16:30 CET

Action: For adoption

8.2.2. ITF meeting

Meeting date: 20 January 2021 at 11:00 – 12:30 CET

Action: For adoption

9. Any Other Business

9.1.1. Proposal to update ORGAM meeting structure

CHMP: Harald Enzmann

Action: For information

9.1.2. Cross-Committee Task Force on Registries

Call for interest of a new CHMP representative.

Action: For information

9.1.3. Update on Aplidin Court Case

Update on the status on Aplidin (plitidepsin) following Court Case *T-594/18, Pharma Mar v Commission*

Action: For information

9.1.4. CHMP Work Plan 2021

Discussion on draft CHMP Work Plan 2021.

Action: For discussion

Draft CHMP Work Plan 2021 document intended for publication. CHMP members are invited to volunteer as contributors in individual activities or send comments on the wording of the document by 24 January 2021.

9.1.5. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

9.1.6. GCP IWG justification paper for the need to update the CHMP guideline on Data Monitoring Committees (DMCs)

Need for CHMP guideline on Data Monitoring Committees (DMCs) to be harmonised with current legal and regulatory framework as well as the necessity for additional guidance.

Action: For endorsement

9.1.7. Comirnaty - COVID-19 mRNA vaccine (nucleoside-modified) - H0005735

BioNTech Manufacturing GmbH; active immunisation against COVID-19 disease.

Rapporteur: Filip Josephson, Co-Rapporteur: Jean-Michel Race PRAC Rapporteur: Menno van der Elst

Scope: Update on upcoming post-authorisation submission.

Action: For discussion