01 October 2021
EMA/CHMP/529450/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 04 October 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

04 October 2021, 09:00–17:30, virtual meeting/room 08-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 PReparatoy and Organisational Matter (PROM) is a meeting to discuss CHMP organisational matters and other topics in preparation for the CHMP Plenary meeting. 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 PROM topics can be discussed at the CHMP Plenary.

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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 PROM agenda for 04 October 2021 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of 04 October 2021 meeting will be adopted at the October 2021 CHMP plenary.

2. Non therapeutic-area-specific working parties

2.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

No topics

2.2. Biologics Working Party (BWP)

Chairs: Sol Ruiz/Nanna Aaby Kruse

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by Webex on 12-14 July 2021
- Draft agenda for BWP meeting to be held by Webex on 4-6 October 2021

Action: For information

2.2.2. Nomination of new BWP member and alternate

Nomination of new BWP member following the resignation of Maeve Lally representing Ireland.

Nomination of new BWP alternate replacing Agnes Mambole-Dema representing France.

Action: For endorsement

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Minutes

- Final minutes from QWP Core Team meeting held by teleconference on 8 September 2021
- Final minutes for QWP meeting held by Webex on 25-27 May 2021

Action: For information

2.3.2. QWP responses to CMDh questions on medicinal product monographs

Recently Ph. Eur. includes Monographs on Medicinal Products containing chemically defined active substances. This has resulted in several questions from MAHs on how to comply with these monographs. QWP provides responses to CMDh on this topic.

Action: For adoption

2.4. Safety Working Party (SWP)

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

2.4.1. Minutes

- Final minutes for SWP meeting held by teleconference on 19 July 2021

Action: For information

2.4.2. CMDh question on novel nitrosamine in methylphenidate

The CMDh requests the SWP to determine the acceptable intake for Nitrosomethylphenidate based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

2.4.3. Election of the SWP chair

Jan Willem van der Laan's second term (after the introduction of a maximum of two 3-year terms in the RoP) will expire on 18 October 2021. Elections will take place at the October CHMP plenary. Candidatures received

Action: For information

2.5. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

2.5.1. Agenda and minutes

- Final minutes for BMWP meeting held by Webex on 26 May 2021.
- Agenda for BMWP meeting held by Webex on 22 September 2021.

2.6. Biostatistics Working Party (BSWP)

No topics

2.7. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

2.7.1. Agenda and Table of decisions

- Agenda of the MSWP meeting held by Webex on 22 September 2021
- Table of decisions of the MSWP meeting held by Webex on 2 September 2021
- Draft Table of decisions of the MSWP meeting held by Webex on 22 September 2021

Action: For information

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

No topics

3. Therapeutic-area-specific working parties and SAGs

3.1. Blood Products Working Party (BPWP)

No topics

3.2. Central Nervous System Working Party (CNSWP)

No topics

3.3. Cardiovascular Working Party (CVSWP)

No topics

3.4. Infectious Diseases Working Party (IDWP)

No topics

3.5. Oncology Working Party (ONCWP)

3.5.1. Agenda

- Agenda of the ONCWP meeting held by Webex on 22 September 2021

Action: For information

3.5.2. Reflection paper on the use of measurable residual disease (MRD) as a clinical endpoint in multiple myeloma (MM) studies - (EMA/554633/2021)

Final draft version of reflection paper on the use of measurable residual disease as a clinical endpoint in multiple myeloma studies. Reflection paper is intended for publication after adoption.

Action: For adoption

3.6. Rheumatology/Immunology Working Party (RIWP)

No topics

3.7. Vaccines Working Party (VWP)

No topics

3.8. Scientific Advisory Groups (SAGs)

3.8.1. Appointment of SAG Oncology (SAG-O) Chair and Vice-chair

Appointment of SAG Oncology (SAG-O) Chair and Vice-Chair based on outcome of the election organised by the SAG, in accordance to the SAG-O rules of procedure.

Action: For endorsement

4. Drafting groups

4.1. Excipients Drafting Group

No topics

4.2. Gastroenterology Drafting Group (GDG)

No topics

4.3. Geriatric Expert Group (GEG)

No topics

4.4. Radiopharmaceuticals Drafting Group (RadDG)

No topics

4.5. Respiratory Drafting Group (RDG)

No topics

5. Harmonisation and consistency groups

5.1. International Council on Harmonisation (ICH)

5.1.1. Nomination of experts for ICH groups

- ICH Guideline E21 on General principles on planning and designing pharmacoepidemiological studies that utilize real-world data for safety assessment of a medicine

Action: For adoption

5.1.2. ICH E8(R1) step 5 - General considerations for clinical studies

ICH E8(R1) step 5 - General considerations for clinical studies final version for adoption. Once the sign-off by the E8(R1) Regulatory experts is completed, the Regulatory Members of the Assembly will be invited to adopt as final under Step 4 this document, which would subsequently be published on the ICH public website.

Action: For adoption

5.1.3. ICH New Topics

Introduction to new ICH Topics.

Action: For information

5.2. Guideline Consistency Group (GCG)

No topics

5.3. Summary of product characteristics Advisory Group

No topics

6. Joint groups and collaboration with other Scientific committees

6.1. 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

6.2. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

Chair: Nienke Rodenhuis

No topics

6.3. Collaboration with other Scientific committees

6.3.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 27-30 September 2021.

Action: For information

7. Regulatory / Organisational matters

7.1. Regulatory Issues / new legislation

7.1.1. Pharmaceutical Strategy –Revision of general pharmaceutical acts

Update from CHMP contact points on the Revision of general pharmaceutical acts

CHMP: Harald Enzmann

Action: For information

7.1.2. EMA pre-submission meetings- new ways of working

CHMP advice is sought on potential joint meetings with the Rapporteurs

Action: For discussion

7.2. CHMP organisation / templates

7.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

7.2.2. CHMP Co-rapporteur critique

First experience of the implementation of Co-Rapp Critique in initial marketing authorisation applications.

Action: For discussion

7.2.3. Structured guidance on reflection of use of extrapolation - development of an assessor's guidance template

This document reflects on the published reflection paper on the use of extrapolation of efficacy and safety data in the development of medicines, with a focus on paediatrics.

Action: For discussion

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Agenda and Table of decisions

- Agenda from 27-30 September 2021 SAWP meeting held by Webex

- Draft Table of decisions from 27-30 September SAWP meeting held by Webex

Action: For information

8.1.2. Appointment of CHMP peer review for SA

List of procedures for discussion.

Action: For information

8.1.3. Nomination of new SAWP member and alternate

The required areas of expertise: Cardiovascular, Endocrinology, Diabetes, Nephrology, Internal medicine, Immunology, Clinical pharmacology.

Action: For endorsement

8.1.4. Scientific Advice Working Party (SAWP) call for interest for nomination of a replacement SAWP member

Call for interest for nomination of a replacement SAWP member following departure of Ferran Torres (alternate Rosalía Ruano Camps).

Required areas of expertise: rare diseases (esp. neurological and metabolic), ATMPs, statistics, clinical pharmacology, internal medicine, endocrinology, gynaecology.

Action: For information

8.1.5. Call for nominations for Scientific Advice Chair

The mandate of Scientific Advice Working Party Chair Anja Schiel will expire on 28 February 2022.

Nominations should be sent to the Agency by 7 January 2022.

Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Elections expected to take place at the 24-27 January 2022 CHMP Plenary meeting.

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 18 October 2021

Action: For adoption

8.2.2. ITF meeting

Meeting date: 21 October 2021

Action: For adoption

9. Product related topics

9.1.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

9.1.2. COVID-19 ongoing and upcoming procedures

List of currently ongoing and upcoming (imminently, i.e. expected within the next 2 months) applications for COVID-19 vaccines and therapeutics.

Action: For information

9.1.3. COVID-19 vaccine (recombinant, adjuvanted) - EMEA/H/C/005754

Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.

Scope: Presentation to CHMP RR1 on non-clinical

Action: For discussion

9.1.4. Avacopan - Orphan - EMEA/H/C/005523

Vifor Fresenius Medical Care Renal Pharma France; Treatment of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)

Scope: Update on the status of this application

Action: For information

10. Any Other Business

10.1.1. EMA press releases: presentation and discussion

Presentation to inform of current practice for COVID-19 public communications and activities to coordinate such information within the EU Regulatory Network.

Action: For discussion

10.1.2. EMA new emergency notification system FACT24

The previous notification system, RapidReach, has been decommissioned. The FACT24 system allows the Agency to send out emergency alerts to all members and delegates in the event of a crisis situation, disruption to business-critical infrastructure or other emergency event, in order to ensure your safety.

Action: For information

10.1.3. EMA lessons learned from COVID-19 pandemic

An update on the current status of and considerations identified in the ongoing exercise of EMA lessons learned from the COVID-19 pandemic.

Action: For information

10.1.4. Nitrosamines Multidisciplinary Expert Group (NMEG)

Update on Rifampicin nitrosamine contamination: preparation for follow -up meeting on 15 October (after January 2021 NMEG).

Action: For information

10.1.5. Supplementary Urgency Procedures for Regulatory Assessment (SUPRA)

Update on the progress of SUPRA initiative which is currently part of the CHMP WP 2021. Feedback from Workshop which took place on 22nd September 2021.

Action: For information