10 February 2022
EMA/CHMP/57793/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 14 February 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

14 February 2022, 09:00–16:00, 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 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 14 February 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 14 February 2022 meeting will be adopted at the February 2022 CHMP plenary.

2. Non therapeutic-area-specific working parties

2.1. 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)

2.1.1. Agenda and meeting summary

- Meeting Summary of the PCWP/HCPWP joint meeting with all eligible organisations held by Webex on 24 November 2021
- Draft Agenda of the upcoming PCWP/HCPWP joint meeting to be held by Webex 2 and 3 March 2022

Action: For information

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Agenda and minutes

- Final minutes for the BWP meeting held by Webex on 6-8 December 2021
- Draft agenda for the BWP meeting to be held by Webex on 14-16 February 2022

Action: For information

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova Minutes

2.3.1. Agenda and minutes

- Final minutes from QWP Core Team meeting held by teleconference on 19 January 2022

Action: For information

2.4. Safety Working Party (SWP)

Chairs: Susanne Brendler-Schwaab/Günter Waxenecker

2.4.1. Minutes

- Minutes from SWP meeting held by Webex on 13 December 2021

Action: For information

2.4.2. CMDh Question to SWP regarding medicinal products with genotoxic potential

SWP answered questions from CMDh in 2020 on how to deal with the duration of contraception after completion of a therapy using potentially genotoxic medicines. Member states are now receiving variations with regards to these recommendations. CMDh proposed an amendment to the published Q&A.

Action: For adoption

2.4.3. CMDh request on the acceptable intake for nitrosamine N-nitroso diisopropanolamine

CMDh request to SWP to determine the acceptable intake for N-nitroso-diisopropanolamine based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

2.4.4. CMDh request on the acceptable intake for nitrosamine Nitroso-STG-19

CMDh request to SWP to determine the acceptable intake for Nitroso-STG-19 (7-Nitroso-3-(trifluoromethyl)-5,6,7,8-tetrahydro[1,2,4]triazolo-[4,3- a]pyrazine) based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

2.5. Biosimilar Medicinal Product Working Party (BMWP)

No topics

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

- Table of Decisions for MSWP meeting held by teleconference on 14 January 2022
- Agenda for MSWP meeting to be held by teleconference on 02 February 2022

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)

Chairs: Sinan B. Sarac/Paolo Foggi

3.5.1. Agenda

- Agenda of the ONCWP meeting held by Webex on 10 February 2022

Action: For information

3.6. Rheumatology/Immunology Working Party (RIWP)

No topics

3.7. Vaccines Working Party (VWP)

No topics

3.8. Scientific Advisory Groups (SAGs)

No topics

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)

No topics

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)

No topics

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

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 07-10 February 2022.

Action: For information

6.3.2. Joint CHMP-PDCO membership

CHMP members are invited to express interest for the joint CHMP-PDCO membership as required by the Paediatric Regulation. Candidatures should be submitted until 4 March 2020.

Action: For information

6.3.3. EMA Advice on the designation of antimicrobials reserved for treatment of certain infections in humans

Regulation (EU) 2019/6 on veterinary medicinal products allows the European Commission to adopt implementing acts designating antimicrobials or groups of antimicrobials to be reserved for the treatment of certain infections in humans only. These antimicrobials (antibiotics, antivirals, antifungals and antiprotozoals) shall not be used in any animals under any circumstances. The CVMP, with assistance from colleagues at ECDC, EFSA and external experts, prepared advice for the Commission on this topic.

Action: For discussion

7. Regulatory/Organisational matters

7.1. Regulatory Issues/new legislation

7.1.1. Revision of the Pharmaceutical legislation

Follow-up on implementation of Pharmaceutical Strategy.

Action: For information

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

Experience of the implementation of Co-Rapporteur critique in initial marketing authorisation applications.

Action: For discussion

7.2.3. Presentation of the CPAS group (Classification of Post-Authorisation Studies)

Presentation of the mandate of the CPAS.

Action: For discussion

7.2.4. Accelerating Clinical Trials in the EU (ACT EU)

Accelerating Clinical Trials in the EU (ACT EU) is an EC-HMA-EMA co-led initiative that aims to optimise the environment for clinical research in Europe. This business change initiative will use the momentum of the Clinical Trials Regulation to further promote the conduct of bigger and better clinical trials. This session will outline the initiative's priorities for 2022-2023.

Action: For information

7.2.5. New Working Parties Operating Model (WOM)

Call for nominations and 3-year workplans for workings parties in clinical (excluding ONCWP), non-clinical and methodology domain.

Progressing in the implementation of the WOM, the CHMP is presented with the call for nominations and drafts 3-year workplans for workings parties in clinical (excl. ONCWP), non-clinical and methodology domain.

Clinical domain

- Central Nervous System Working Party (CNSWP)
- Cardiovascular Woking Party (CSSWP)
- Haematology Working Party (HAEMWP)
- Infectious Disease Working Party (IDWP)
- Rheumatology and Immunology Working Party (RIWP)
- Vaccines Working Party (VWP)

Non-Clinical domain

- Non-Clinical Working Party (NCWP)
- Joint 3Rs Working Party (J3RsWP)

Methodology domain

- Methodology Working Party (MWP)

Action: For adoption

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

8.1.2. 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 change of role of Paolo Foggi (alternate Cristina Migali).

Required areas of expertise: oncology, genetic disorders (focus on metabolic and neurological ones), infectious diseases, clinical trial methodology and/or pharmacoepidemiology.

The new SAWP member and his/her alternate starting date will immediately follow their nomination by the CHMP PROM (14 March 2022).

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 14 February 2022

Action: For information

8.2.2. ITF meeting

Meeting date: 09 March 2022

Action: For information

9. Product related topics

9.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

9.2. 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

9.3. Covid-19 Vaccine (recombinant) – EMEA/H/C/005754/000

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

Scope: Rolling review 3rd interim opinion

Action: For information

10. Any Other Business

10.1. Update on proof-of-concept raw data pilot

Update on the proof-of-concept raw data pilot. The pilot, which is expected to start in summer 2022, will analyse individual patient data (raw data) from selected marketing authorisation applications. The pilot aims to generate relevant learnings about accessing and analysing raw data during the assessment process.

The proof-of-concept raw data pilot is part of EMA's Lifecycle Regulatory Submissions Raw Data project, which is focusing on utilising raw data to support regulatory decision-making and was listed as an action in CHMP's work plan for 2022.

Action: For discussion

10.2. CHMP additional experts

CHMP members and experts needs, extend of attendance and participation to CHMP meetings.

Action: For discussion

10.3. 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 adoption

10.4. Rapporteurships

Update

Action: For information