08 April 2022
EMA/CHMP/183772/2022 Rev.1
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 11 April 2022

Vice-Chair: Bruno Sepodes, deputising for the Chair Harald Enzmann

11 April 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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Table of contents

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 11 April 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 11 April 2022 meeting will be adopted at the April 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. Re-nomination of members of the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP)

Re-nomination of Fátima Ventura and Maria Concepcion Prieto Yerro as members of the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP).

Action: For endorsement

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Joint QWP/BWP Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME and certain marketing authorisation applications targeting an unmet medical need (EMA/CHMP/BWP/QWP/IWG/694114/2019)

Joint QWP/BWP guideline.

The Guideline (GL) was developed as a follow-up from the joint EMA/FDA workshop on PRIME/BT, held in London in November 2018. The draft GL was published in February 2021 for public consultation. All comments received were reviewed and the final guideline prepared, which has been adopted by BWP, QWP, IWG and CAT in their February/March plenaries and which is now presented to PROM/CHMP.

Overview of comments received during public consultation and outcomes.

Action: For adoption

2.2.2. Revision of the EU pharmaceutical legislation

Follow-up on new Pharmaceutical Strategy.

Action: For adoption

2.2.3. Agenda and minutes

- Draft agenda of BWP meeting to be held virtually on 11-13 April 2022
- Final minutes of BWP meeting held virtually on 14-16 February 2022

Action: For information

2.2.4. Joint QWP/BWP Launch call for nominations to Quality Innovation Group

Joint QWP/BWP request.

In the context of the new operational model of working parties and Operational Expert Group (OEGs) that was agreed at the EMA Management Board in April 2021, this is a request to launch the call for nominations for the Quality Innovation Group. Nominations should be sent by 27 May 2022.

Action: For information

CHMP noted the call for nominations to the Quality Innovation Group.

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Agenda and minutes

- Agenda from the QWP Core Team meeting held by teleconference on 16 March 2022
- Minutes from the QWP Core Team meeting held by teleconference on 16 March 2022

Action: For information

2.4. Safety Working Party (SWP)

Chair: Susanne Brendler-Schwaab

2.4.1. Minutes

- Final minutes for SWP meeting held by teleconference on 16 February 2022

Action: For information

2.4.2. SWP position on the AI for N-nitrosomethyphenidate (NMPH)

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

SWP response to CMDh.

Action: For adoption

2.4.3. CMDh request on the AI for N-nitroso-pseudoephedrine

The CMDh requests the SWP to determine the acceptable intake for N-nitroso-pseudoephedrine based on lifetime daily exposure including information on the points of departure and methodology used (structurally similar to sotalol, salbutamol etc.).

Action: For adoption

2.4.4. CMDh request on the AI for N-Nitroso-hydrochlorothiazide

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

Action: For adoption

2.4.5. CMDh request on the AI for N-Nitroso-quinapril

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

In addition, as ACE-Inhibitors share a similar chemical structure, SWP might consider if a class specific AI would be appropriate.

Action: For adoption

2.5. Biosimilar Medicinal Product Working Party (BMWP)

No topics

2.6. Biostatistics Working Party (BSWP)

Chair: Kit Roes

2.6.1. Draft BSWP statement on the impact of the war in Ukraine on methodological aspects of ongoing clinical trials

BSWP is drafting a statement addressing the potential impact of the crisis in Ukraine on methodological aspects of affected ongoing clinical trials.

Action: For adoption

2.7. Modelling and Simulation Working Party (MSWP)

No topics

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

2.9.1. Product-specific guidelines

Draft product-specific guideline for public consultation

- Lanreotide acetate, prolonged-release solution for injection in prefilled syringe 60, 90 and 120 mg product-specific bioequivalence guidance (EMA/CHMP/559891/2021)

Action: For adoption

2.9.2. PKWP response to CMDh Question on interpretation of the Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms

At the February 2022 CMDh meeting, the CMDh discussed comments raised during a repeat-use procedure for Venlafaxine on the interpretation of the Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms (EMA/CHMP/EWP/280/96 Rev1). In order to come to a harmonised EU position in this respect, the CMDh forwarded a question to PKWP. The PKWP response is now provided.

Action: For adoption

2.9.3. PKWP response to CHMP question on rosuvastatin BCS classification

PKWP response is provided to the question from CHMP adopted at the March PROM on the BCS classification of rosuvastatin in the context of the ongoing Synchron Research Services (EMEA/H/A-31/1515) referral procedure.

Action: For adoption

2.9.4. Minutes

- Final minutes for PKWP meeting held by teleconference on 04 February 2022

Action: For information

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)

No topics

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)

Chair: Vacant

5.2.1. Call for volunteers to join the Guideline Consistency Group

Call for volunteers to join the group.

Action: For discussion

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-PDCO membership

6.2.1. Appointment of joint CHMP/PDCO members

The paediatric legislation foresees 5 joint CHMP/PDCO members and alternates to be appointed by CHMP into PDCO. The mandates of the currently appointed joint CHMP/PDCO members and alternates expire on 23 June 2022. CHMP were asked to express interest to step into a joint CHMP/PDCO membership position for the next 3-year term. The following joint CHMP/PDCO members and alternates are proposed for the next mandate as from 24 June 2022.

- Agnes Gyurasics (HU): CHMP alternate and PDCO member
- Robert Porszasz (HU): CHMP member and PDCO alternate
- Dana Gabriela Marin (RO): CHMP alternate and PDCO member
- Simona Badoi (RO): CHMP member and PDCO alternate

Action: For adoption

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 04-07 April 2022.

Action: For information

7. Regulatory/Organisational matters

7.1. Regulatory Issues/new legislation

No topics

7.2. CHMP organisation/templates

7.2.1. Revision of the procedure for nomination and appointment of co-opted members

Background

- Legislation allows CHMP, CVMP and HMPC to appoint up to 5 co-opted members to complement the committee with specific scientific expertise.
- The procedure describes the steps for the committee's decision on the number of co-opted members and their expertise, the nomination of candidates and the appointment by the committee, as well as provides some guidance on the participation of co-opted members in the committee.
- The procedure was last revised in 2016.

Next steps

- Agreement of revised procedure by CHMP, CVMP and HMPC.
- Set date for entry into force (month after agreement from last committee)

Action: For adoption

7.2.2. Return to Committees face-to-face meetings

Update on the preparation for holding the May CHMP plenary as face-to-face/Webex hybrid.

Action: For information

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

8.1.1. Appointment of CHMP peer review for SA

Action: For information

8.1.2. Election of Scientific Advice Working Party vice-chair

The second mandate of Scientific Advice Working Party vice-chair Peter Mol will expire in May 2022.

Nomination(s) received.

The election will take place at the April CHMP plenary meeting.

Action: For information

8.1.3. Scientific Advice Working Party (SAWP) call for interest for nomination of two replacement SAWP members

Call for interest for nomination of two replacement SAWP members following resignation of Markku Pasanen (alternate Juha Kolehmainen) and Aaron Sosa (alternate Svein Rune Andersen).

Required areas of expertise: non-clinical, oncology, biosimilars, vaccines.

Applications should be sent by 29 April 2022.

The new SAWP member and his/her alternate starting date will immediately follow their nomination by the CHMP PROM (10 May 2022).

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 19 April or 17 May 2022 (TBC)

Action: For adoption

8.2.2. ITF meeting

Meeting date: May 2022 (TBC)

Action: For adoption

8.2.3. ITF meeting

Meeting date: May 2022 (TBC)

Action: For adoption

9. Product related topics

9.1. Preview CHMP Plenary

CHMP: Bruno Sepodes

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

10. Any Other Business

10.1. Rapporteurships

Update.

Action: For information

10.2. Data Analysis and Real-World Interrogation Network (DARWIN EU) and RWE Pilot with CHMP

This is an update on the launch and start of establishment of DARWIN EU. In line with the CHMP workplan 2022 to "Identify use cases of RWE and establish processes in order to start a pilot on RWE studies to support CHMP decision-making (including feasibility to provide RWE on disease epidemiology and standard of care in the elderly)"; this will be a first discussion on the RWE pilot.

Action: For discussion

10.3. Complex clinical trials Q&A

A questions-and-answers (Q&A) document on 'complex clinical trials' has been drafted in collaboration by the Clinical trials coordination group (CTCG), EMA, the European Commission and experts from CHMP, SAWP, COMP, BSWP, PDCO, CAT. A first complete draft is now shared with these Committees and WPs as well as the PRAC and the GCP-IWG.

The Q&A has been mandated by the Commission/Clinical Trial Expert Group (CTEG) and is sponsored by the ACT EU Steering Group (SG). It is important that the Q&A reflects the views of the Committees/WPs. Subsequently, the Q&A will be adopted by the ACT EU SG as an ACT EU Q&A.

The CHMP is invited to send comments by 28 April 2022.

Action: For information

10.4. New Working Parties Operating Model (WOM) - Call for nominations for additional expertise for the Methodology Working Party (MWP)

The CHMP is presented with the call for nominations for additional expertise required for the Methodology Working Party. Nominations should be sent by 4 May 2022.

Action: For information