11 March 2022
EMA/CHMP/121881/2022 Rev.2
Human Medicines Division

Committee for medicinal products for human use (CHMP)

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

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

14 March 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 March 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 14 March 2022 meeting will be adopted at the March 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. Nomination of representatives to the PCWP and HCPWP

Nomination of a representative (and alternate) for each working party for the mandate June 2022 to May 2025.

Action: For endorsement

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Agenda and minutes

- Draft agenda of BWP meeting to be held virtually on 14-16 March 2022
- Final minutes of BWP meeting held virtually on 17-19 January 2022

Action: For information

2.2.2. Nomination of BWP members

- Nomination of Marie Louise Vindvad Kristensen as the BWP Member representing Denmark
- Nomination of Nanna Aaby Kruse (current Member) as the BWP Alternate representing Denmark

Action: For endorsement

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Minutes

- Final minutes for QWP-CT meeting held virtually on 16 February 2022
- Final minutes from 98th QWP plenary meeting held virtually on 22-23 November 2021

Action: For information

2.3.2. Titanium Dioxide update

Update on workplan.

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 19 January 2022

Action: For information

2.4.2. CMDh request on the AI for N-nitroso-salbutamol

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

In addition, the CMDh requests the SWP to consider if a class specific AI would be more appropriate for the N-nitrosamines with the substructure 1-[tert-butyl(nitroso)amino]-2-propanol (salbutamol-like).

Action: For adoption

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

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

In addition, the CMDh requests the SWP to consider if a class specific AI would be more appropriate for the N-nitrosamines with the substructure 1-[Isopropyl(nitroso)amino]-2-propanol (sotalol-like).

Action: For adoption

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

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

Action: For adoption

2.4.5. Requests for CHMP/EMA external representation

Action: For adoption

2.5. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

2.5.1. Agenda and minutes

- Agenda of BMWP meeting held virtually on 02 March 2022
- Final minutes of BMWP meeting held virtually on 17 November 2021

Action: For information

2.6. Biostatistics Working Party (BSWP)

No topics

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

Revision of product-specific guidelines

- Ibuprofen oral use immediate release formulations 200 - 800 mg product-specific bioequivalence guidance (EMA/CHMP/356876/2017) Revision 1
- Paracetamol oral use immediate release formulations product-specific bioequivalence guidance (EMA/CHMP/356877/2017) Revision 1
- Tadalafil film-coated tablets 2.5 mg, 5 mg, 10 mg and 20 mg product-specific bioequivalence guidance (EMA/CHMP/315234/2014/Rev.1) Revision 2

Action: For adoption

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

In the February 2022 CMDh meeting, the CMDh discussed comments 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 has agreed to forward a question to PKWP.

Action: For adoption

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)

Chair(s): vacant

3.5.1. Call for nominations for ONCWP member

Following the resignation of Sinan B. Sarac, nominations for an additional ONCWP member should be sent to the Agency by **13 March 2022**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Action: For endorsement

3.6. Rheumatology/Immunology Working Party (RIWP)

No topics

3.7. Vaccines Working Party (VWP)

No topics

3.8. Scientific Advisory Groups (SAGs)/Ad-hoc Expert Groups (AHEGs)

3.8.1. Proposal for single nominated chairperson for all AHEGs

A proposal from EMA for a single nominated AHEG chairperson.

Action: For adoption

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 group

Quality Discussion Group (QDG).

Action: For adoption

5.1.2. ICH Q2(R2) – Validation of analytical methods

Step 2b - ICH Q2(R2) to be adopted for a 4-month public consultation.

Action: For adoption

5.1.3. ICH Q14 – Analytical procedure development

Step 2b - ICH Q14 to be adopted for a 4-month public consultation.

Action: For adoption

5.1.4. ICH E11A – Paediatric extrapolation

Step 2b - ICH E11A to be adopted for a 4-month public consultation.

Action: For adoption

5.1.5. ICH Q3D(R2) – Guideline for elemental impurities

Step 5 - The ICH Q3D(R2) Regulatory experts are completing the step 3 sign-off of the guideline and 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. The guideline will be implemented 6 months after adoption.

Action: For adoption

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 March 2021.

Action: For information

7. Regulatory/Organisational matters

7.1. Regulatory Issues/new legislation

7.1.1. Pharma Strategy

Revision of the Pharmaceutical legislation: update

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-opted membership

The 3-year co-opted member mandate for Christian Gartner comes to an end on 23.06.2022. His area of expertise is medical statistics.

The nomination procedure foresees that the CHMP should decide on whether a new co-opted member should be appointed and if so, on the required specific complementary scientific expertise (there could be more than one area). Afterwards a call for nominations will be launched.

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. Nomination of new member and alternate to the Scientific Advice Working Party

Nomination of new SAWP member and alternate.

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

Nomination(s) received.

Action: For endorsement

8.1.3. Call for nominations for Scientific Advice Working Party vice-chair(s)

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

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 25 March 2022

Action: For information

8.2.2. ITF meeting

Meeting date: 28 March 2022

Action: For adoption

8.2.3. ITF meeting

Meeting date: 01 April 2022

Action: For adoption

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. Synchron Research Services – various – EMEA/H/A-31/1515

Article 31 procedure triggered by the Federal Agency for Medicines and Health Products (FAMHP) in Belgium, the Danish Medicines Agency (DKMA), the Finnish Medicines Agency (Fimea), the Medicines Evaluation Board (MEB) in the Netherlands and the Medical Products Agency (MPA) in Sweden concerning the contract research organisation (CRO) Synchron Research Services, located in Ahmedabad, Gujarat, India.

Referral Rapporteur: Kristina Dunder, Referral Co-Rapporteur: Janet Koening

Scope: List of questions to PKWP

Action: For adoption

10. Any Other Business

10.1. Data protection notice (DPN) – processing of scientific Committees (CxMP) members/alternates' contact details

Introduction of the DPN, developed to allow to share CXMP contact details in MMD.

Action: For information

10.2. Rapporteurships

Update.

Action: For information