06 May 2022
EMA/CHMP/228709/2022 Rev.1
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 10 May 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

10 May 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 Preparatory and Organisational Matters (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 10 May 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 10 May 2022 meeting will be adopted at the May 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)

Chair: Sol Ruiz

2.2.1. Agenda and minutes

- Draft agenda of BWP meeting to be held virtually on 10-12 May 2022
- Final minutes of BWP meeting held virtually on 14-16 March 2022

Action: For information

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Agenda

- Final Agenda for QWP-CT meeting held by Webex on 13 April 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 13 April 2022

Action: For information

2.4.2. SWP positions on requests on new nitrosamines

- SWP position on NTTP (7-nitroso-3-(trifluoromethyl)-5,6,7,8-tetrahydro[1,2,4]triazolo-[4,3- a]pyrazine) acceptable intake in Sitagliptin
- SWP position on N-nitrosonortryptiline (NNORT) acceptable intake
- SWP position on N-nitroso diisopropanolamine (NDIPLA) acceptable intake
- SWP position on N-nitrosorasagilene acceptable intake

Action: For adoption

2.5. Non-clinical Working Party (NcWP)

Chairs: Susanne Brendler-Schwaab and Karen van Malderen

2.5.1. Agenda

- Draft agenda for NcWP meeting to be held by teleconference on 10-11 May 2022

Action: For information

2.5.2. CMDh requests to SWP/NcWP on new nitrosamines

- The CMDh requests that the SWP/NcWP determines the acceptable intake for N-nitroso-metoprolol based on lifetime daily exposure including information on the points of departure and methodology used.
- The CMDh requests that the SWP/NcWP determines the acceptable intake for N-nitroso-aryl piperazine based on lifetime daily exposure including information on the points of departure and methodology used.
- The CMDh requests that the SWP/NcWP determines the acceptable intake for N-Nitrosodiethanolamine (NDELA) based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

2.6. Biosimilar Medicinal Product Working Party (BMWP)

No topics

2.7. Methodology Working Party (MWP)

Chairs: Christian Roes and Kristin Karlsson

2.7.1. Agenda and minutes

- Agenda and Minutes for MWP meeting held by teleconference on 28 April 2022

Action: For information

2.7.2. Nominations for additional expertise for MWP

Presentation of nominations received.

Action: For discussion

3. Therapeutic-area-specific working parties and SAGs

3.1. Haematology Working Party (HaemWP)

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)

Chair: Maria Jesus Fernandez Cortizo

3.4.1. Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections, (CPMP/EWP/558/95 Rev 3)

This Guideline merges, revises and adds to the guidance previously included in the *Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections* (CPMP/EWP/558/95 Rev 2) and the Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections (EMA/CHMP/351889/2013).

Action: For adoption

3.4.2. Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements (EMA/CHMP/187859/2017)

This addendum to the *Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections* (CPMP/EWP/558/95 rev 3) has been developed to provide guidance on clinical development programmes that are required to support the authorisation of antibacterial agents for treatment of infectious diseases in paediatric patients.

Action: For adoption

3.5. Oncology Working Party (ONCWP)

Chairs: Pierre Demolis and Sigrid Klaar

3.5.1. Call for nominations ESEC Oncology

The membership of the ESEC will be composed of experts that are assessors working for a National Competent Authority, members of the different working parties with a special interest or expertise in oncology and members from academia in institutions/universities that are relevant for the Oncology ESEC. The experts will need to be nominated by a Committee member (COMP, PDCO, PRAC, CAT and CHMP). Committee members, Oncology WP members and SAG Oncology members can request access to the ESEC automatically.

The expert will need to provide their CV and a valid DoI to be included in the expert database. Therefore, any expert who is in the expert database can be proposed to be part of the ESEC.

The appointment of the ESEC member will be agreed by the Oncology Working Party and a list of new memberships will be presented to the CHMP for adoption.

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)

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

4.6. Diabetes Drafting Group

4.6.1. Reflection Paper on the data required in confirmatory studies of medicinal products for the treatment of type 2 diabetes (EMA/240473/2022)

The CHMP has agreed previously that the revision of the "Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus" CPMP/EWP/1080/00 Rev. 2" can be continued and the Diabetes drafting Group was established in 2021.

Based on recent discussions in the CHMP, it has been decided to consider (in addition to implementing external comments) if the data requirements with respect to confirmatory studies for certain claims in the wording of the therapeutic indication would benefit from revisions. In addition to internal discussions within the regulatory system, it was considered that input from external stakeholders would be valuable. The draft Reflection Paper tabled is the proposal from the Group that is currently put for the discussion at the CHMP.

Action: For adoption

5. Harmonisation and consistency groups

5.1. International Council on Harmonisation (ICH)

5.1.1. Adoption of guidelines

ICH Guideline M7(R2): Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk - Questions and Answers. Implementation 6 months after publication.

Action: For adoption

5.2. Guideline Consistency Group (GCG)

Chair: Vacant

5.2.1. Second call for volunteers to join the Guideline Consistency Group

Call for volunteers (CHMP, SAWP members and experienced assessors) to join the group. Nominations to be sent by 20 May 2022, with a summary of experience and expertise.

Action: For discussion

5.3. Summary of product characteristics Advisory Group

5.3.1. SmPC Advisory Group Membership update

CHMP representative to join the SmPC Advisory Group.

Action: For adoption

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 and Working Groups

6.3.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 2-5 May 2022.

Action: For information

6.3.2. Call for volunteer for COMP expert meeting

Chair: Violeta Stoyanova-Beninska

Request for volunteer to take part in the clinical and patients consultation COMP expert meeting about orphan conditions in Inherited Retinal Dystrophies (IRD) on behalf of the CHMP.

Action: For information

6.3.3. Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells EMA/CAT/CHMP/158266/2021

In October 2020, to account for inconsistencies in the product information of ATMPs containing genetically modified cells, the CAT, in agreement with the CAT EC representative and QRD group initiated a review of the QRD template to introduce additional wording and guidance specific to these products. Due to the extent of changes required, the work has culminated in the creation of a core SmPC, labelling and package leaflet for ATMPs containing genetically modified cells, to be read in conjunction with the SmPC guideline and QRD template.

After a 3-month external consultation period, the core SmPC has been agreed with CAT/QRD and EC and is brought to the CHMP for adoption prior to publication, together with the overview of comments.

Action: For adoption

7. Regulatory/Organisational matters

7.1. Regulatory Issues/new legislation

7.1.1. Revision of the EU pharmaceutical legislation

Final CHMP position on new Pharmaceutical Strategy.

Action: For adoption

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. Return to Committees face-to-face meetings

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

Action: For information

7.2.3. 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 3-year co-opted member mandate for Sol Ruiz comes to an end on 21.07.2022. Her area of expertise is quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies).

CHMP decided at the March PROM that the two co-opted member positions should be filled again. A discussion is expected on the area(s) of expertise for the two co-opted member positions.

Action: For discussion

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 members and alternates to the Scientific Advice Working Party

Nomination of new SAWP members and alternates.

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

Action: For endorsement

8.2. Innovation Task Force

No topics

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

10. Any Other Business

10.1. Rapporteurships

Update.

Action: For information

10.2. Update on the upcoming proof-of-concept raw data pilot

Update on the proof-of-concept raw data pilot including information on how to participate in the pilot. The pilot, which is expected to start in Q3 2022, will analyse individual patient data in electronic structured format (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

10.3. Embedding the outcome of GCP inspections into the B/R assessment and modernisation of the inspection process

Action: For discussion

10.4. (Vice)chair presentations for Working Parties

The candidates for the remaining chair/vice-chair positions of the working parties are asked to present themselves at the PROM. The election is planned at the May CHMP plenary meeting.

Nominations received.

Action: For discussion

10.5. RMP Publications – future activities

Experience with Covid-19 related products RMP publication is already gained and EMA would like to further progress with publishing the RMPs of new active substances (Art 8.3 of DIR). The RMP summary is published for all products; RMP (main body and Annexes 4 and 6, as single PDF) will replace the RMP summary (in EPAR), in due course. This is aiming at further increasing transparency of safety information for public/stakeholders.

Action: For information

10.6. CHMP opinion on an interchangeability of biosimilars statement

Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. From a scientific perspective, once a biosimilar is approved in the EU it is considered interchangeable, which may concern replacing a reference product with a its biosimilar (or vice versa) or replacing one biosimilar with another biosimilar of the same reference product. Decisions regarding substitution (the practice of dispensing one medicine instead of another medicine without consulting the prescriber), are not within the remit of the EMA and are managed by individual member states.

Action: For adoption