12 July 2021
EMA/CHMP/363904/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on July 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

12 July 2021, 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 12 July 2021 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 12 July 2021 meeting will be adopted at the July 2021 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. Minutes

- Minutes from joint PCWP/HCPWP meeting held by Webex on 1-2 June 2021

Action: For information

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 10 May 2021
- Draft agenda for BWP meeting to be held by WebEx on 10 May 2021

Action: For information

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Minutes

- Final minutes from QWP Core Team meeting held by teleconference on 16 June 2021

Action: For information

2.3.2. Guideline on quality documentation for medicinal products when used with a medical device (EMEA/CHMP/QWP/BWP/259165/2019)

Public consultation on the draft guideline: June-August 2019; Revised guideline adopted by QWP, BWP and CAT: April 2021

Action: For adoption

2.3.3. Interim feedback from QWP to the EC request to evaluate the impact of the removal of titanium dioxide from the list of authorised food additives on medicinal products

On 6 May 2021, the European Food Safety Authority (EFSA) published its opinion on the safety of food additive titanium dioxide. On 17 May 2021, the European Commission (EC) requested the European Medicines Agency (EMA) to provide an analysis with the aim to define the technical purpose of titanium dioxide in medicinal products. Interim feedback from QWP to the EC request to evaluate the impact of the removal of titanium dioxide from the list of authorised food additives on medicinal products.

Action: For adoption

2.3.4. Change in nomination of member in the QWP

New Croatian member to replace Koraljka Mestrovic.

Action: For endorsement

2.4. Safety Working Party (SWP)

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

2.4.1. Minutes

- Final minutes for SWP/EFSA meeting dedicated to TiO2 held by teleconference on 10 May 2021
- Final minutes for SWP meeting held by teleconference on 17 May 2021

Action: For information

2.4.2. CMDh question to SWP regarding methodology for setting limits for multiple genotoxic impurities including nitrosamines

The CMDh has requested that the SWP (where appropriate with consultation of the QWP) - propose a methodology for setting limits for genotoxic impurities when both one or multiple nitrosamine impurities and other genotoxic impurities are present.

Action: For adoption

2.4.3. CMDh request on the AI for the nitrosamine N-Nitrosodi-n-propylamine (NDPA)

The CMDh has requested that the SWP provide a position on the AI for NDPA.

Action: For adoption

2.4.4. SWP response to HMPC request for feedback on public statement on the use of herbal medicinal products containing estragole

SWP response to HMPC on final public statement on the use of herbal medicinal products containing estragole.

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. Reflection paper on Statistical Issues in Quality Assessment

Reflection paper on the topic of "Statistical Issues in Quality Assessment" and high-level overview of how the comments received were taken into consideration. Follow up from discussion at June 2021 PROM meeting.

Action: For adoption

2.7. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

2.7.1. Agenda and Minutes

- Draft agenda of MSWP meeting held virtually via Webex on 30 June 2021
- Table of Decisions of MSWP meeting held virtually via Webex on 30 June 2021

Action: For information

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

2.9.1. Minutes

- Final minutes of PKWP meeting held via Webex on 01 July 2021

Action: For information

2.9.2. PKWP response to CMDh request on Megestrol acetate

Questions have been raised in regard to the interpretation of CPMP/EWP/QWP/1401/98 Rev. 1/ Corr ** (chapter 4.1.4 Fasting or fed conditions) in terms of the general study requirements of micronised suspension generic applications.

Action: For adoption

2.9.3. PKWP response to CMDh request on pirfenidone tablet formulations

PKWP response to CMDh request on pirfenidone tablet formulations over bioequivalence requirements.

Action: For adoption

2.9.4. CMDh request for PKWP input on bioequivalence waiver for an oily parenteral (i.m.) solution

CMDh request for PKWP input on bioequivalence waiver for an oily parenteral (i.m.) solution to clarify if viscosity and/or what other in vitro comparative data are needed to demonstrate comparable physicochemical characteristics of oily solutions too, sufficient to support a biowaiver.

Action: For adoption

2.9.5. PKWP request to CHMP to draft a Q&A on expectations for how to conduct bootstrapping to calculate the 90% CI of f2

PKWP proposes to clarify how to conduct the f2 CI bootstrapping and how to report this as related issues have arisen in a number of procedures. The input of QWP and BSWP is also sought.

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)

Chair(s): Vacant

3.4.1. Call for nomination of IDWP Chair

The mandate of the Chair Maria Jesús Fernández Cortizo expired in November 2020. The election is scheduled at the July CHMP Plenary meeting.

Nominations received.

Action: For information

3.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

3.5.1. Minutes

- Final minutes of ONCWP meeting held via Webex on 10 June 2021

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)

3.8.1. SAG re-nominations

Draft list of SAG candidates.

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 groups

- Appointment of one expert for the ICH M4Q(R2) Common Technical Document on Quality Guideline

Expressions of interest received.

Action: For adoption

5.1.2. ICH E19 Safety data collection - update

The draft ICH E19 guideline explores under what circumstances a targeted approach to safety data collection in some late-stage pre-marketing or post-marketing studies would be appropriate and how to implement such an approach.

The draft guidance has been released for public consultation in 2019. Since then, the dedicated ICH working group has discussed and negotiated amendments to the draft guideline. The main objective of this update is to present the updated ICH E19 Guideline and to highlight the changes implemented to address the concerns expressed by European regulators during the public consultation.

Action: For discussion

5.1.3. ICH Q13 Continuous Manufacturing of Drug Substances and Drug Products

Step2b- New draft guidance ICH Q13 Continuous Manufacturing of Drug Substances and Drug Products to be adopted for public consultation until 22 December 2021

Action: For adoption

5.1.4. ICH report from meeting in Incheon, Republic of Korea (May-June 2021)

- Presentation

Action: For information

- Report

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 05-08 July 2021

Action: For information

6.3.2. Draft Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells

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.

The core SmPC has been agreed with CAT/QRD and EC and is brought to the CHMP for adoption prior to a 3-month external consultation.

Action: For adoption

7. Regulatory / Organisational matters

7.1. Regulatory Issues / new legislation

7.1.1. Status update on the Companion Diagnostics (CDx) consultation working group

To provide a progress update on interactions of CHMP-CAT-EMA experts with Notified Bodies (NBs) to develop the NB consultation procedure on CDx suitability with EMA.

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 Survey on resource bottleneck

EMA will start a survey to NCAs to better understand the issues with finding rapporteurs for COVID-19 and Non-COVID products. The survey will be sent to the NCA resource contact points mid of July asking for responses by end of July. Each NCA will receive one link via the EU survey tool (which is also used for elections).

Action: For information

7.2.3. Progress on CHMP Work Plan 2021

Update on the progress of the 2021 CHMP Work Plan

Action: For information

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

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 12 July 2021

Action: For adoption

8.2.2. ITF meeting

Meeting date: 27 July 2021 (proposed)

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. tanezumab - EMEA/H/C/005189

Treatment of moderate to severe chronic pain associated with osteoarthritis (OA) in adult patients for whom treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and/or an opioid is ineffective, not tolerated or inappropriate

Scope: Update on the status of this application.

Action: For discussion

10. Any Other Business

10.1.1. Introduction of IRIS for Inspections: upcoming changes affecting documents tabled for CHMP

With the implementation of IRIS for inspections, planned to go live in Q3/Q4 2021, EMA's Inspections Office is making changes to the inspection-related documents tabled/circulated to CHMP.

Action: For information

10.1.2. Collaboration with HTA bodies – Report on the experience

EMA and the European Network for Health Technology Assessment (EUnetHTA) have recently published a report on their achievements since 2017 (Report on the implementation of the EMA-EUnetHTA work plan 2017 – 2021 (EMA/265469/2021)). The report covers the latest phase of an open and successful collaboration that began in 2010 and demonstrated the synergies between regulatory evaluation and health technology assessment (HTA) along the lifecycle of a medicine can be harnessed to speed up patients'

access to innovative medicines. The positive experience over the past decade highlights the importance of a sustainable European cooperation between EMA and HTA bodies to facilitate cross-fertilisation and collaborative work on methodologies and products. A list of priority areas for future cooperation is currently being established.

Action: For information

10.1.3. CHMP strategic, review and learning meeting under the Portuguese presidency of the Council of the European Union

Presentations of the SRLM meeting held virtually on 27 May 2021 under the Portuguese presidency.

CHMP: Bruno Sepodes, Fatima Ventura

Action: For information

10.1.4. Call for interest for nomination of CHMP members to join temporary ad-hoc group on complex trials Q&A - call for experts

The European Commission (DG Santé B4) has initiated the development of a question and answer document on 'complex clinical trials' in collaboration with EMA and the clinical trials facilitation group (CTFG). A first draft is now available, spanning a large scope of topics (master protocols, Bayesian methodology, use of external control, biomarkers, safety, transparency and study integrity). As the next important step, the EC/EMA/CTFG drafting group is now looking for volunteers from the network to contribute to this first draft and subsequent activities expected to span over the rest of 2021, and possibly beyond. Interested members should express interest 16 July 2021.

Action: For information