14 January 2022
EMA/CHMP/6647/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 17 January 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

17 January 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 the 17 January 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 17 January 2022 meeting will be adopted at the January 2022 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. Nomination of new member

Nomination of new BWP member representing Finland (following the resignation of Jaana Vesterinen).

Action: For endorsement

2.2.2. Agenda and minutes

- Final minutes for BWP meeting held virtually on 3-5 November 2021
- Draft agenda for BWP meeting to be held virtually on 17-19 January 2022

Action: For information

2.2.3. Revision of the Guideline on the requirements for quality documentation concerning biological investigational medicinal products (IMPs) in clinical trials - EMA/CHMP/BWP/534898/2008

Request from European Commission related to Clinical Trial Regulation. QWP working in parallel on the guideline for chemical IMPs (see 2.3.2).

Updates are proposed to the classification of changes to IMPs which require substantial modification of the IMPD (guideline chapter 6).

Final guideline proposal to be published on 31 January 2022.

Action: For adoption

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Agenda

- Final agenda from the QWP Core Team meeting held by teleconference on 8 December 2021

Action: For information

2.3.2. Revision of the Guideline on requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products (IMPs) in clinical trials - EMA/CHMP/QWP/545525/2017

Request from European Commission related to Clinical Trial Regulation. BWP working in parallel on the guideline for biological IMPs (see 2.2.3).

Updates are proposed to the classification of changes to IMPs which require substantial modification of the IMPD (guideline chapter 9).

Final guideline proposal to be published on 31 January 2022.

Action: For adoption

2.3.3. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005, EMA/CPMP/QWP/2819/00, EMA/CVMP/814/00, Rev. 3)

Third revision of the Guideline on quality of herbal medicinal products/traditional herbal medicinal products which takes into account other new and revised guidelines, questions and answers and the Ph. Eur. revised general monograph "Herbal Drug Extracts" as well as experiences gained over the years with the application of the guideline.

Action: For adoption

2.3.4. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products /traditional herbal medicinal products (EMA/HMPC/162241/2005, EMA/CPMP/QWP/2820/00, EMA/CVMP/815/00, Rev. 3)

Third revision of the Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products which takes into account other new and revised guidance documents.

Action: For adoption

2.4. Safety Working Party (SWP)

Chair: Susanne Brendler-Schwaab; vice-chair: Günter Waxenecker

2.4.1. Minutes

- Final minutes for SWP virtual meeting held on 8 November 2021

Action: For information

2.4.2. CMDh request on the AI for the nitrosamine N-nitroso-Mefanamic acid (NO-MFA)

CMDh question to SWP to determine the acceptable intake for nitrosamine N-nitroso-Mefanamic acid (NO-MFA) based on lifetime daily exposure including information on the points of departure and methodology used.

Action: For adoption

2.4.3. Corrigendum of the Ethanol report (EMA/CHMP/43486/2018)

Third party pointed out to EMA some calculation inconsistencies in the ethanol background report (EMA/CHMP/43486/2018) that was published in Nov 2019 by the Excipients DG. SWP has agreed on the correction.

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)

No topics

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

2.9.1. PKWP Q&A on expectations for bootstrapping to calculate the 90% CI of f2 (EMA/410839/2021)

Following discussion at CHMP July 2021 PROM, PKWP has drafted a Q&A with the input of BSWP and QWP to clarify the conduct and reporting of f2 Confidence Interval bootstrapping for dissolution similarity.

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: Maria Cortizo

3.4.1. Product Information of the HIV products

Follow-up from December 2021 discussion at PROM on the update of the Product Information of HIV products in what refers to the risk of transmission of HIV either due to sexual activity or breastfeeding.

Action: For adoption

3.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

3.5.1. Agenda and Minutes

- Agenda of the ONCWP meeting held by Webex on 13 January 2022
- Minutes of the ONCWP meeting held by Webex on 02 December 2021

Action: For information

3.5.2. Launch call for nominations for Oncology Working Party

In the context of the new operational model of working parties that was agreed at the EMA Management Board in April 2021, this is a request to launch the call for nominations for the Oncology Working Party.

Action: For information

3.5.3. Revision of the Anticancer Guideline (EMA/593364/2020) – Appendix 3

Revision to the Appendix 3 of the Anticancer guideline. The Appendix 3 relates to section 4.8 of the SmPC for the Anticancer Medicinal products. The revised guideline is brought to the CHMP for adoption after 3-month external public consultation.

Action: For adoption

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)

5.1.1. ICH E14/S7B Q&As step 5 - Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential

The E14/S7B IWG Regulatory experts have completed step 3 sign-off of the Q&As 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.

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 10-13 January 2022.

Action: For information

6.3.2. CMDh question to CHMP on the HMPC statement on the use of herbal medicinal products containing estragole

Following the adoption of the SWP response to HMPC in July 2021 PROM and subsequent HMPC public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005, Rev 1), CMDh seeks information on whether the recommendations set in the Public Statement are applicable to all medicinal products containing estragole either as excipient or as part of the active substance.

Action: For adoption

7. Regulatory / Organisational matters

7.1. Regulatory Issues / new legislation

No topics

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

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. Qualification procedures in 2021 - Digital technologies

Overview of qualification procedures from Scientific Advice (SA) involving digital technologies received by the Agency in 2021. This activity was performed within the context of the CHMP Workplan 2021.

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 07 January 2022

Action: For information

8.2.2. ITF meeting

Meeting date: 31 January 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

10. Any Other Business

10.1. 5-year review of PRIME experience

Presentation of the main findings and recommendations of the experience with the PRIME scheme since its launch in March 2016.

Action: For information

10.2. Introduction to the Lifecycle Regulatory Submissions Metadata Project

The purpose of the project is to deliver effective generation of evidence in support of benefit/risk decision making from data-driven interrogation of scientific information within regulatory submissions.

Action: For information