03 September 2021
EMA/CHMP/429582/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 06 September 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

06 September 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 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 4
1.1. Welcome and declarations of interest of members, alternates and experts 4
1.2. Adoption of agenda 4
1.3. Adoption of the minutes 4
2. Non therapeutic-area-specific working parties 4
2.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP) 4
2.2. Biologics Working Party (BWP) 4
2.3. Quality Working Party (QWP) 5
2.4. Safety Working Party (SWP) 5
2.5. Biosimilar Medicinal Product Working Party (BMWP) 5
2.6. Biostatistics Working Party (BSWP) 5
2.7. Modelling and Simulation Working Party (MSWP) 5
2.8. Pharmacogenomics Working Party (PGWP) 5
2.9. Pharmacokinetics Working Party (PKWP) 5
3. Therapeutic-area-specific working parties and SAGs 6
3.1. Blood Products Working Party (BPWP) 6
3.2. Central Nervous System Working Party (CNSWP) 6
3.3. Cardiovascular Working Party (CVSWP) 6
3.4. Infectious Diseases Working Party (IDWP) 6
3.5. Oncology Working Party (ONCWP) 6
3.6. Rheumatology/Immunology Working Party (RIWP) 6
3.7. Vaccines Working Party (VWP) 7
3.8. Scientific Advisory Groups (SAGs) 7
4. Drafting groups 7
4.1. Excipients Drafting Group 7
4.2. Gastroenterology Drafting Group (GDG) 7
4.3. Geriatric Expert Group (GEG) 7
4.4. Radiopharmaceuticals Drafting Group (RadDG) 7
4.5. Respiratory Drafting Group (RDG) 7
5. Harmonisation and consistency groups 7
5.1. International Council on Harmonisation (ICH) 7
5.2. Guideline Consistency Group (GCG) 8
5.3. Summary of product characteristics Advisory Group 8

6. Joint groups and collaboration with other Scientific committees 8
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) 8
6.2. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG) 8
6.3. Collaboration with other Scientific committees 8
7. Regulatory / Organisational matters 8
7.1. Regulatory Issues / new legislation 8
7.2. CHMP organisation / templates 9
8. Product development support 10
8.1. Scientific Advice Working Party (SAWP) 10
8.2. Innovation Task Force 10
9. Product related topics 10
10. Any Other Business 12

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 06 September 2021 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of 06 September 2021 meeting will be adopted at the September 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. Agenda

- Draft agenda from joint PCWP/HCPWP meeting to be held by WebEx on 21-22 September 2021

Action: For information

2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by WebEx on 14-16 June 2021
- Draft agenda for BWP meeting to be held by WebEx on 6-8 September 2021

Action: For information

2.2.1. Call for nomination for the election of the BWP vice chair

Nanna Aaby Kruse (DK) has resigned from her position as BWP vice-chair following the September 2021 meeting. Nominations should be sent together with a CV and a brief motivation letter by 6 October 2021.

Action: For information

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Agenda and minutes

- Final minutes from QWP Core Team meeting held by teleconference on 14 July 2021
- Draft agenda for QWP meeting to be held by WebEx on 22-24 September 2021

Action: For information

2.4. Safety Working Party (SWP)

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

2.4.1. Workshop on Nitrosamine Impurities in Human Drugs

The workshop will address the Safety Assessment of Potential Risks Associated with Nitrosamine Impurities in Human Drugs and will take place on 20-21 September 2021. Day 1 will address aspects related to hazard identification whereas day 2 will cover elements related to risk assessment.

Action: For information

2.4.2. Minutes

- Final minutes for SWP meeting held by teleconference on 21 June 2021

Action: For information

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. Product-specific guidelines

Revision of product-specific guidelines - Abiraterone acetate product-specific bioequivalence guidance.

Action: For adoption

2.9.2. PKWP response to CMDh request on pirfenidone tablet formulations

Updated response following discussion of draft at CHMP PROM 12 July 2021.

Action: For adoption

2.9.3. PKWP response to CMDh request on tadalafil orodispersible tablet

PKWP response to CMDh regarding input on bioequivalence requirements for tadalafil orodispersible tablet.

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)

Chair(s): Vacant

No topics

3.3. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs

No topics

3.4. Infectious Diseases Working Party (IDWP)

Chair(s): Vacant

No topics

3.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

No topics

3.6. Rheumatology/Immunology Working Party (RIWP)

Chair: Romaldas Mačiulaitis

No topics

3.7. Vaccines Working Party (VWP)

Chair: Mair Powell

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. Nomination of experts for ICH groups

- ICH Guideline Q3C on Residual solvents
- ICH Guideline Q3D on Elemental impurities

Action: For adoption

5.1.2. ICH M7(R2) - Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk

Step2b - ICH M7(R2) guideline and addendum to be adopted for a 60-day public consultation.

These updated documents include: Identified Acceptable intake levels (Permitted daily intake levels) for the following selected known mutagenic impurities: Acetaldehyde; Formaldehyde; 1,2-Dibromoethane; Epichlorohydrin; Ethyl bromide; Styrene; Vinyl Acetate. In addition, the guideline is updated with a new classification of anti-HIV therapeutics as medicines for life-long treatment, with impact on AI levels. These two draft documents are proposed for adoption and release for a 60-day public consultation.

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 30/08-02/09 2021.

Action: For information

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. Report from Scientific Coordination Board meeting (SciCoBo) meeting

Information on the report from Scientific Coordination Board meeting (SciCoBo) meeting.

CHMP: Harald Enzmann

Action: For information

7.2.3. Pilot – Relaunch of face to face Scientific Committee Meetings

Next steps on the relaunch of face to face Scientific Committee Meetings

Action: For discussion

7.2.4. CHMP rules of procedure - update

Adoption of changes to the CHMP rules of procedure

Action: For adoption

7.2.5. Election of new CHMP chairperson

Harald Enzmann has served as Chair of the CHMP since 21 September 2018 and his first 3-year mandate will shortly come to an end.

The election of a new Chairperson will take place at the end of the September 2021 CHMP plenary meeting as previously communicated to the Committee.

Candidates for the position of CHMP Chair are now invited to indicate their interest in standing for this position. Although candidates can express their interest until the start of the September 2021 CHMP meeting, we would appreciate receiving nominations **by Wednesday, 8 September 2021** EOB to facilitate preparation of the meeting.

Candidates should declare their interest by circulating a letter, indicating their intention to stand, together with a motivation for so doing, as well as a brief résumé to the EMA

Any questions regarding the election can be addressed.

Action: For information

7.2.6. Template updates for PAMs procedures

Presentation on the draft update to the PAMs procedures templates.

Action: For information

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel Appointment of CHMP peer review for SA

Action: For information

8.1.1. Scientific Advice Working Party (SAWP) Products Related

Qualification Opinion

Action: For discussion

8.1.2. Scientific Advice Working Party (SAWP) call for interest for nomination of a replacement SAWP member

Call for interest for nomination of a replacement SAWP member following departure of Kolbeinn Gudmundsson (alternate Hrefna Guðmundsdóttir).

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting:

Meeting date: 20th September 2021

Action: For adoption

8.2.2. Amendment of ITF webpage to focus on 3Rs innovative methods

Information on the amendment of ITF webpage to focus on 3Rs innovative methods.

Action: For information

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. BRILIQUE – Ticagrelor - EMEA/H/C/001241/II/0049

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Menno van der Elst

Scope: Extension of indication to include, in co-administration with acetylsalicylic acid (ASA), the prevention of stroke in adult patients with acute ischaemic stroke or transient ischaemic attack (TIA), based on the final results of study D5134C00003 (THALES), a phase III, international, multicentre, randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of ticagrelor and ASA compared with ASA in the prevention of stroke and death in patients with acute ischaemic stroke or transient ischaemic attack; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13 of the RMP has also been submitted.

Request by the applicant for an extension of the clock stop to respond to the request for supplementary information adopted in June 2021.

Action: For adoption

Request for Supplementary Information adopted on 24.06.2021, 28.01.2021, 17.09.2020.

9.1.4. Teriparatide Cinnagen - teriparatide - EMEA/H/C/005543

treatment of osteoporosis

Scope: Request by the applicant for an extension to the clock stop to respond to the list of questions adopted in March 2021.

Action: For adoption

List of Questions adopted on 25.03.2021.

9.1.5. Nouryant - istradefylline - EMEA/H/C/005308

Kyowa Kirin Holdings B.V.; indicated as an adjunctive treatment to levodopa-based regimens in patients with Parkinson's disease

Scope: Draft timetable, call for re-examination rapporteurs

Action: For information

New active substance (Article 8(3) of Directive No 2001/83/EC)

Opinion adopted on 22.07.2021. List of Outstanding Issues adopted on 25.02.2021. List of Questions adopted on 30.04.2020.

9.1.6. Nexviadyme - avalglucosidase alfa - Orphan - EMEA/H/C/005501

Genzyme Europe BV; for long-term enzyme replacement therapy for the treatment of patients with Pompe disease.

Scope: Notification of re-examination, draft timetable, call for re-examination rapporteurs

Action: For information

Known active substance (Article 8(3) of Directive No 2001/83/EC)

Opinion adopted on 23.07.2021. List of Outstanding Issues adopted on 20.05.2021. List of Questions adopted on 28.01.2021.

9.1.7. Rapporteurship overview

Action: For information

10. Any Other Business

10.1.1. Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus Drafting Group

Adoption of the composition of the drafting group to revise the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus.

Action: For adoption

10.1.2. Updated Guideline on registry-based studies

Presentation on the changes made to the Guideline on Registry-based studies following the public consultation.

Action: For information

10.1.3. Response to Letter from third party

Action: For information

10.1.4. EMA Introduction into IRIS for Scientific Committees

EMA training to Committees on IRIS system.

Action: For information