23 January 2020
EMA/CHMP/29856/2020
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 20 January 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

20 January 2020, 09:30–12:30, room 09-A

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

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 ORGAM is a meeting to discuss CHMP organisational matters. 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 ORGAM topics can be discussed at the CHMP Plenary. Please note that the ORGAM meeting is not taking place every month.

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Table of contents

1. Agenda and Minutes

1.1. Welcome and declarations of interest of members, alternates and experts

1.2. Adoption of agenda

CHMP ORGAM agenda for 20 January 2020 meeting

1.3. Adoption of the minutes

CHMP ORGAM Minutes of January 2020 meeting will be adopted at the January 2020 CHMP plenary.

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.1.1. Letter to WHO on INNs for ATMPs

Draft letter to WHO on INN for ATMPs for discussion and adoption

- BWP and CAT input and adoption planned at their January meeting

Action: For adoption

The CHMP was informed on the draft communication to be sent to WHO with regards to the INN for ATMPs in the context of an ongoing MAA validation. The CHMP agreed on the proposed approach.

2.2. CHMP organisation / templates

2.2.1. Revision of templates for accelerated assessment requests

Following up from discussions at October 2019 ORGAM meeting, a revised draft update to the template for the briefing note on accelerated assessment requests has been prepared, addressing comments from CHMP sponsors.

CHMP: Johann Lodewijk Hillege, CHMP/CAT: Jan Mueller-Berghaus

Action: For discussion

CHMP addressed questions raised during the revision of the accelerated assessment (AA) briefing note template.

Further comments can be sent by CHMP members until 7th February.

2.2.2. Revision of templates for Reader's Guidance

A revised draft update to the template for the reader's guidance has been prepared.

CHMP: Johann Lodewijk Hillege

Action: For discussion

The topic was postponed to the February ORGAM.

2.2.3. CHMP work plan 2020

Draft work plan for adoption in January plenary meeting

Action: For discussion

The latest amendments were presented to CHMP. Comments can be sent by 24th February.

2.2.4. CHMP learnings

Process to collect and record CHMP learnings

CHMP: Outi Mäki-Ikola

Action: For discussion

In May 2019, the CHMP agreed on a voluntary pilot to collect learnings from CHMP with a view of creating a regulatory/scientific memory repository that can be referred to for future decisions. Information collected during the pilot (that ended in September 2019) was compiled in a table and discussions started in Helsinki on formalising a process.

Based on the experience of the pilot, such repository may include scientific/regulatory learnings such as new policy issues and aspects relevant for robustness for future decisions, examples of decisions whether issues are to be major objections vs other concerns or examples of how the SmPC guideline is being implemented.

A process and format for identifying, validating and tracking learnings was proposed and agreed. It was highlighted that the focus will be on new learnings rather than matters and cases already covered in existing guidance documents. In order to keep the list manageable, for similar cases, it was suggested to avoid creating a new entry but to rather update the existing one.

The first scientific/regulatory learnings identified during the pilot will be discussed at the ORGAM in February.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

3.1.1. ICH report from meeting in Singapore (November 2019)

- Presentation

  Action: For discussion

  The CHMP was informed on guidelines discussed in Singapore.

- Report

Action: For adoption

The report was adopted.

3.1.2. Adoption of Guidelines

- ICH **Q12** Step 5 - Guideline on Lifecycle Management
- ICH **S5(R3)** Step 5 - Guideline on reproductive toxicology: detection of toxicity to reproduction for human pharmaceuticals
- ICH **M9** Step 5 - Guideline on Biopharmaceutics Classification System-based biowavers
- ICH **E9(R1)** Step 5 – Addendum to Guideline on Statistical Principles for Clinical Trials

Action: For adoption

The CHMP adopted the guidelines.

3.1.3. Nomination of experts for ICH groups

- ICH M7(R2) Addendum to guideline on Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk
- ICH M13 Guideline on Bioequivalence for Immediate-Release Solid Oral Dosage Forms
- ICH Q3E Guideline on Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics
- ICH Q5A(R2) guideline on Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin

Action: For adoption

The proposed nominations were adopted.

3.2. Guideline Consistency Group (GCG)

No topics.

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chair(s): Sol Ruiz/Nanna Aaby Kruse

4.1.1. Agenda(s) and minutes

- Final minutes for BWP meeting held face-to-face on 4-6 November 2019
- Draft agenda for BWP meeting to be held face-to-face on 20-22 January 2020

Action: For information

The CHMP noted the agenda and minutes.

4.1.2. Change(s) to BWP composition

Nomination of a new member for Portugal

Action: For adoption

The CHMP endorsed the nomination of Ângelo Ferreira da Silva as BWP member for Portugal.

4.2. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan/Susanne Brendler-Schwaab

4.2.1. Agendas and minutes

- Final minutes for SWP meeting held by teleconference on 11 November 2019

Action: For information

The CHMP noted the minutes**.**

4.2.2. Response from SWP to CMDh regarding Genotoxicity and Contraception

- Final SWP response to CMDh regarding Genotoxicity and Contraception

Action: For adoption

The CHMP adopted the response from SWP to CMDh with a recommendation to get input from the PRAC and the Clinical Trials Facilitation Group to be included in the final response document.

4.2.3. Change(S) to SWP composition

Nomination of a new Swedish alternate member

Action: For adoption

The CHMP endorsed the nomination of Henrik Alm as SWP alternate for Sweden.

4.3. Biosimilar Medicinal Product Working Party (BMWP)

No topics

4.4. Biostatistics Working Party (BSWP)

No topics

4.5. Modelling and Simulation Working Party (MSWP)

No topics

4.6. Pharmacogenomics Working Party (PGWP)

No topics

4.7. Pharmacokinetics Working Party (PKWP)

No topics

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

5.1.1. BPWP request for BWP input regarding a query on heparins

Draft response for discussion and agreement

- BWP input
- BPWP draft response to the external query received

Action: For adoption

The CHMP adopted the proposed response.

5.1.2. Agendas and minutes

Draft minutes Blood cluster TC held on 11th October 2019

Action: For information

The CHMP noted the minutes.

5.2. Central Nervous System Working Party (CNSWP)

No topics

5.3. Cardiovascular Working Party (CVSWP)

No topics

5.4. Infectious Diseases Working Party (IDWP)

No topics

5.5. Oncology Working Party (ONCWP)

No topics

5.6. Rheumatology/Immunology Working Party (RIWP)

No topics

5.7. Vaccines Working Party (VWP)

No topics

5.8. Scientific Advisory Groups (SAGs)

No topics

6. Drafting groups

6.1. Excipients Drafting Group

No topics

6.2. Gastroenterology Drafting Group (GDG)

No topics

6.3. Geriatric Expert Group (GEG)

No topics

6.4. Radiopharmaceuticals Drafting Group (RadDG)

No topics

6.5. Respiratory Drafting Group (RDG)

No topics

7. Joint groups and collaboration with other committees

7.1. Quality Working Party (QWP)

Chair(s): Keith Pugh/Blanka Hirschlerova

7.1.1. Agendas and minutes

Minutes December 2019 QWP Core Team

Action: For information

The CHMP noted the minutes.

7.2. Patients and Consumers Working Party (PCWP)

No topics

7.3. Healthcare Professionals Working Party (HCPWP)

No topics

7.4. 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

7.5. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

No topics

7.6. Collaboration with other committees

7.6.1. Correspondence with European Commission on assessment of orphan medicinal products and proposal for fostering collaboration between CHMP and COMP

Correspondence with European Commission on the scientific assessment of the orphan medicinal products by the COMP and the CHMP is included for information. In this regard, EMA has prepared a corresponding proposal for fostering the scientific collaboration between CHMP and COMP.

Action: For discussion

The CHMP welcomed the proposals but noted that a pragmatic approach should be taken regarding the common participation to meetings. The importance of using the right terminology in the right context was highlighted. There was a suggestion to add a reference to the legislation concerned, for more clarity.

CHMP members were invited to provide comments on the proposals in writing to by 20th February.

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair(s): Anja Schiel

8.1.1. Appointment of CHMP peer review for SA

Action: For information

The CHMP noted the list.

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 04 February 2020

Action: For adoption

The CHMP adopted the meeting.

8.2.1. ITF meeting

Meeting date: 19 February 2020

Action: For adoption

The CHMP adopted the meeting.

9. Any Other Business

9.1. Nitrosamines Art 5(3) - Involvement of Industry as part of the procedure

Action: For discussion

The intention is to organise a short face to face meeting with Industry, the rapporteurs, EMA and CMDh/CHMP members willing to participate in the discussion on nitrosamines, before the ad-hoc expert group meeting takes place. The questions to Industry will be adopted at the January CHMP plenary meeting.

CHMP members who are interested in participating in the meeting with Industry were invited to look at the questions to Industry (once available) and to contact the topic rapporteur.

10. List of Participants

CHMP Chair:

Harald Enzmann

CHMP members:

Andrea Laslop

Bjørg Bolstad

Blanka Hirschlerova

Christian Gartner

Ewa Balkowiec Iskra

Frantisek Drafi

Jayne Crowe

Johann Lodewijk Hillege

John Joseph Borg

Konstantinos Markopoulos

Margareta Bego

Martina Weise

Martine Trauffler

Melinda Sobor

Nithyanandan Nagercoil

Outi Mäki-Ikola

Sinan B. Sarac

CHMP alternate members:

Agnes Gyurasics

Christophe Focke

Dana Gabriela Marin

Fátima Ventura

Mark Ainsworth

Milena Stain

Nevenka Trsinar Brodt

Selma Arapovic Dzakula

Experts:

Anja Schiel

Keith Pugh

Maria Victoria Tudanca Pacios

Mette Tranholm

Sabine Mayrhofer

Sofia Bosdotter Enroth

Susanne Brendler-Schwaab

A representative of the EC attended the meeting.

The meeting was run with support from the relevant EMA staff.