



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 January 2020  
EMA/CHMP/654738/2019  
Inspections, Human Medicines Pharmacovigilance and Committees Division

## Committee for medicinal products for human use (CHMP) ORGAM<sup>1</sup> Minutes for the meeting on 2 December 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

2 December 2019, 09:30 – 12:30, room 0E

### 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).

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<sup>1</sup> 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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## 1. Agenda and Minutes

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

### 1.2. Adoption of agenda

The CHMP ORGAM agenda for 2<sup>nd</sup> December 2019 meeting was adopted with the addition of topic 9.4.

### 1.3. Adoption of the minutes

CHMP ORGAM Minutes of December 2019 meeting will be adopted at the December 2019 CHMP plenary.

## 2. Regulatory and organisational matters

### 2.1. Regulatory Issues / new legislation

#### 2.1.1. New medical devices Regulation (EU) 2017/745

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- EMA procedural guidance for consultation to the European Medicines Agency by a notified body on substance-based medical devices

**Action:** For adoption

Participants were informed that the EMA procedural guidance was put on.

- EMA workshop on implementation of Article 117 of the medical devices regulation which introduces changes for medicinal products with an integral medical device

**Action:** For information

The CHMP was informed that a workshop is scheduled in March 2020 to address concerns expressed from various stakeholders on the potential impact of Article 117 on new and existing marketing authorisations and to allow for an interactive discussion between Regulators, EC, Notified Bodies and Industry to facilitate the implementation of the new requirements ahead of 26th May 2020.

### 2.2. CHMP organisation / templates

#### 2.2.1. CHMP Workplan 2020

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- Draft Workplan 2020

**Action:** For discussion

The draft work plan was presented. CHMP members and topic leaders were invited to comment on the draft by Wednesday 4<sup>th</sup> December 2019. The draft was discussed by EMA on 29 November 2019, the input received will be circulated for CHMP consideration.

### 3. Harmonisation and consistency groups

#### 3.1. International Council on Harmonisation (ICH)

No topics

#### 3.2. Guideline Consistency Group (GCG)

No topics

#### 3.3. Summary of product characteristics Advisory Group

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

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- Final minutes for BWP meeting held face-to-face on 7-9 October 2019
- Draft agenda for BWP meeting to be held face-to-face on 2-4 December 2019

**Action:** For information

The CHMP noted the agenda and minutes.

##### 4.1.2. Call for nomination for the election of the BWP chair

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Sol Ruiz second term will expire in February 2020. Nominations have to be sent together with a CV and a brief motivation letter by 19<sup>th</sup> February 2020.

**Action:** For information

The CHMP noted the call for nomination.

[*Post-meeting note:* Chairs already in charge when the new rules of procedure were adopted were considered serving their first term **under the new rules of procedure** and were allowed to compete for a second and last 3-year term.]

##### 4.1.3. CMDh questions to BWP

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- Questions on DCP application for medicinal product

**Action:** For adoption

The topic was postponed to the plenary meeting.

## 4.2. Safety Working Party (SWP)

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

### 4.2.1. Agenda(s) and minutes

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- Final minutes for SWP meeting held by teleconference on 16 September 2019

**Action:** For information

The CHMP noted the minutes.

## 4.3. Biosimilar Medicinal Product Working Party (BMWP)

No topics

## 4.4. Biostatistics Working Party (BSWP)

Chair(s): Anja Schiel/Jörg Zinserling

### 4.4.1. Changes in BSWP Composition

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- Call of interest for a new member

Sought expertise: professionally qualified senior assessor within the European regulatory network, with relevant expertise in the field of biostatistics. Additional preferred criteria are SAWP membership, in order to support BSWP-SAWP interaction, and representing another European country to those of current members (see list). CVs to be sent by 20 January 2020.

**Action:** For information

The CHMP noted the call of interest.

- Nomination of a new additional assessor

The Spanish Agency (AEMPS) has nominated an additional assessor to the BSWP.

**Action:** For adoption

The nomination of Borja García López-Rey as an additional assessor to the BSWP was endorsed.

## 4.5. Modelling and Simulation Working Party (MSWP)

Chair(s): Kristin Karlsson/Flora Musuamba Tshinanu

### 4.5.1. Changes in MSWP Composition

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- Nomination of new additional assessors

The Norwegian Medicines Agency (NOMA) has nominated additional assessors to the MSWP.

**Action:** For adoption

The nomination of Dr. Elisabet Størset and Dr. Erlend Johannessen Egeland as additional assessors to the MSWP was endorsed.

#### **4.6. Pharmacogenomics Working Party (PGWP)**

Chair(s): Markus Paulmichl

No topics

#### **4.7. Pharmacokinetics Working Party (PKWP)**

Chair(s): Henrike Potthast

##### **4.7.1. Product-specific guidelines**

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###### **Final product-specific guidelines (batch 10)**

- Overview of comments received on 'Alectinib hard capsule 150 mg product-specific bioequivalence guidance'.

**Action:** For information

The CHMP noted the overview of comments.

### **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**

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- Question from BPWP to BWP

**Action:** For adoption

The CHMP adopted the question from BPWP to BWP.

#### **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)**

Chair(s): Maria Jesus Fernandez Cortizo

#### 5.4.1. Nomination for the election of the EU regulatory (IDWP member) representative in HIV Forum for HIV PreP activities

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Nominations should be sent by 6 December 2019.

For background information see:

<https://forumresearch.org/hiv-forum/226-hiv-forum-overview/1605-hiv-forum-overview>

**Action:** For information

The CHMP noted the call for nomination.

[*Post-meeting note:* one nomination was received for Regine Lehnert (BfArM)]

### 5.5. Oncology Working Party (ONCWP)

Chair(s): Sinan B. Sarac/Paolo Foggi

#### 5.5.1. Agenda(s) and minutes

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- Final minutes for the ONCWP Adobe meeting held on 22<sup>nd</sup> October 2019

**Action:** For information

The CHMP noted the minutes.

### 5.6. Rheumatology/Immunology Working Party (RIWP)

No topics

### 5.7. Vaccines Working Party (VWP)

No topics

### 5.8. Scientific Advisory Groups (SAGs)

No topic.

## 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. QWP response to CMDh question on azacitidine powder for suspension for injection generics**

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QWP response to CMDh question on assessment of the pharmaceutical development and finished product specifications for azacitidine powder for suspension for injection generics

**Action:** For adoption

The QWP-PKWP consolidated response to the CMDh question on azacytidine generics was presented to CHMP. The CHMP adopted the response for circulation to CMDh.

#### **7.2. 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: Gonzalo Calvo Co-chair: Juan Garcia Burgos (EMA)

##### **7.2.1. Agenda(s) and minutes**

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- Meeting Summary PCWP Plenary Meeting 24 Sep 2019
- Meeting Summary HCPWP Plenary Meeting 24 Sep 2019
- Meeting Summary PCWP/HCPWP Joint Meeting 25 Sep 2019
- Agenda for the Annual PCWP/HCPWP meeting with all eligible organisations, 20 November 2019

**Action:** For information

The CHMP noted the agendas and minutes.

#### **7.3. 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

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

No topics

#### **7.5. Collaboration with other committees**

##### **7.5.1. CHMP-PRAC cooperation group**

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Call for volunteers

**Action:** For information

The call for volunteers will be repeated in the CHMP plenary meeting.

### **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**

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**Action:** For information

The CHMP noted the list.

##### **8.1.2. SAWP composition re-examination – March 2020**

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**Action:** For information

The CHMP was informed that the SAWP was launching a re-examination of its composition one year after the chairperson has been elected, as foreseen in their rules of procedure. A call for nominations will be issued in December 2019 based on expertise. The candidates' capacity to function as a SAWP co-ordinator and their commitment for attendance will also be considered. The new SAWP composition will be presented to CHMP in March 2020 for adoption.

#### **8.2. Innovation Task Force**

No new meeting was reported. It was decided to leave the meetings already adopted in the agenda until they take place.

### **9. Any Other Business**

#### **9.1. Direct healthcare professional communication (DHPC) – proposal for publication on the EMA website**

**Action:** For information

EMA outlined its proposal to start publishing DHPCs on the EMA website. This will serve as a central repository for DHPCs and the webpage will also have links to national competent authorities' websites where disseminated versions in national language would be found. Implementation is foreseen as of January 2020.

## **9.2. Report from steering group on opioids**

**Action:** For information

EMA informed the CHMP that a steering group on opioids had been set up, in agreement with CHMP, CMDh and PRAC Chairs. The Steering group first TC will take place on 2 December 2019. The group will report regularly from their activities to CHMP.

## **9.3. EU NTC proposal for training on pharmacoepidemiology**

**Action:** For information

The CHMP welcomed the initiative. EMA will circulate a detailed Table of Contents and requests for comments and expression of interest in being involved in the curriculum development.

## **9.4. Update on nitrosamines in metformin products**

**Action:** For information

The CHMP noted the update.

# **10. List of Participants**

### **CHMP Chair:**

Harald Enzmann

### **CHMP members:**

Bruno Sepodes (Vice-Chair)

Andrea Laslop

Björg Bolstad

Blanka Hirschlerova

Christian Gartner

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Kristina Dunder

Margareta Bego

Maria Concepcion Prieto Yerro

Martine Trauffler

Melinda Sobor

Natalja Karpova

Nithyanandan Nagercoil

Simona Badoi

Sinan B. Sarac

**CHMP alternate members:**

Agnes Gyurasics

Christophe Focke

Dana Gabriela Marin

Fátima Ventura

Janet Koenig

Mark Ainsworth

Milena Stain

Nevenka Trsinar Brodt

Tomas Radimersky

Tuomo Lapveteläinen

**Experts:**

Anne Hasle Buur

Eva Schlosser

Henrike Potthast

Hilke Zander

Jörg Engelbergs

Keith Pugh

Maria Victoria Tudanca Pacios

Sabine Mayrhofer

Susanne Müller-Egert

The meeting was run with support from the relevant EMA staff