



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 May 2019  
EMA/CHMP/445958/2019  
Inspections, Human Medicines Pharmacovigilance and Committees Division

## Committee for medicinal products for human use (CHMP) DRAFT ORGAM<sup>1</sup> minutes for the meeting on 20 May 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

20 May 2019, 09:30 – 12:30 CET, room 1B

### 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 the minutes is considered commercially confidential or sensitive and therefore not disclosed.

Of note, the minutes are a working document primarily designed for CHMP members and the work the Committee undertakes.

### Note on access to documents

Some documents mentioned in these 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 ongoing 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.

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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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 the 20 May 2019 meeting was adopted.

### 1.3. Adoption of the minutes

CHMP Orgam Minutes of May 2019 meeting will be adopted at the May 2019 CHMP plenary.

## 2. Working Parties, Committees, SAGs and Drafting Groups

### 2.1. General

#### 2.1.1. Safety Working Party (SWP)

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Chair(s): Jan Willem Van der Laan

No topics

#### 2.1.2. Quality Working Party (QWP)

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Chair(s): Keith Pugh/Blanka Hirschlerova

Draft QWP/BWP guideline on the quality requirements for drug device combinations

Rapporteur: Abigail Moran (UK); Co-Rapporteur: Nick Lee (IE);

**Action:** For adoption for 3-month public consultation

The draft guideline that had already been adopted by BWP, QWP and CAT, was presented to the CHMP. A few editorial comments were made during the meeting. CHMP members were asked to send any other comments they may have to the rapporteur, co-rapporteur and EMA before the May CHMP plenary meeting. If no substantial comments are received, the draft guideline will be considered adopted and released for a 3-month public consultation.

#### 2.1.3. Scientific Advice Working Party (SAWP)

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Chair: Anja Schiel

No topics

#### 2.1.4. European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)

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Co-chair: Kaisa Immonen

Call for nomination of one CHMP representative (and alternate) to the PCWP for a 3-year term covering June 2019 to May 2022

**Action:** For adoption

The CHMP nominated Maria Conception Prieto Yerro as CHMP representative in PCWP and Fátima Ventura as her alternate.

Note: the first meeting under the new 3-year mandate is scheduled on 5 June 2019 (2-4pm CET) and will be a joint PCWP-HCPWP meeting.

#### 2.1.5. [European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations \(HCPWP\)](#)

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Co-chair: Gonzalo Calvo

Call for nomination of one CHMP representative (and alternate) to the HCPWP for a 3-year term covering June 2019 to May 2022

**Action:** For adoption

The CHMP nominated Fátima Ventura as CHMP representative in HCPWP and Maria Conception Prieto Yerro as her alternate.

Note: the first meeting under the new 3-year mandate is scheduled on 5 June 2019 (2-4pm CET) and will be a joint PCWP-HCPWP meeting.

#### 2.1.6. [Geriatric Expert Group \(GEG\)](#)

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No topics

#### 2.1.7. [Committees](#)

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- PDCO - Revised "Concept paper on the need for revision of the guideline on the investigation of medicinal products in the term and preterm neonate following public consultation" (EMA/CHMP/445958/2019)

**Action:** For adoption

The revised concept paper was presented to the CHMP. CHMP members were asked to send any comments they may have to EMA before the May CHMP plenary meeting. If no substantial comments are received, the revised concept paper will be considered adopted.

#### 2.1.8. [International Council on Harmonisation \(ICH\)](#)

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No topics

#### 2.1.9. [Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs \(replacement, reduction and refinement\) in the regulatory testing of medicinal products \(J3RsWG\)](#)

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Chair: Ellen-Margrethe Vestergaard, CoChair: Susanne Brendler-Schwaab

No topics

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

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Chair: Nienke Rodenhuis

No topics

#### 2.1.11. Joint CVMP-CHMP antimicrobial advice ad hoc expert group (AMEG)

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Chair: Gérard Moulin

No topics

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

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Chair: Kristin Karlsson/Flora Musuamba Tshinanu

- Agenda for MSWP meeting 16 May 2019

**Action:** For information

The CHMP noted the agenda.

- Minutes from MSWP meeting 11 April 2019

**Action:** For information

The CHMP noted the minutes.

## 2.2. Biologicals

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

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Chair(s): Elena Wolff-Holz/Niklas Ekman

No topics

#### 2.2.2. Biologicals Working Party (BWP)

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Chair(s): Sol Ruiz/Nanna Aaby Kruse

- Nomination of Mr Grzegorz Kontny as the new BWP Polish member

**Action:** For information

The CHMP noted the nomination of Mr Grzegorz Kontny as the new Polish member in BWP.

#### 2.2.3. Vaccines Working Party (VWP)

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Chair(s): Mair Powell/Svein Rune Andersen

No topics

#### 2.2.4. Blood Products Working Party (BPWP)

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Chair(s): Jacqueline Kerr

- Final minutes of the Blood cluster held in December for the BPWP

**Action:** For information

The CHMP noted the minutes.

- Nomination of a new alternate:

**Action:** For adoption

- Marissa Opelt (AT) – replacing Lisa Rosner

The CHMP endorsed the nomination of Marisa Opelt as the new Austrian alternate.

- Call for nomination for the election of BPWP Vice-Chair in June 2019

Karri Penttilä's first 3-year term will expire in June 2019. An election will be organised during the June CHMP plenary meeting. Nominations have to be sent together with a CV and a brief motivation letter by 18 June 2019.

**Action:** For information

The CHMP noted the call of interest.

#### 2.2.5. Pharmacogenomics Working Party (PGWP)

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Chair(s): Krishna Prasad/Markus Paulmichl

No topics

### 2.3. Therapeutics

#### 2.3.1. Cardiovascular Working Party (CVSWP)

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Chair(s): Kristina Dunder/Alar Irs

No topics

#### 2.3.2. Central Nervous System Working Party (CNSWP)

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Chair(s): Karl Broich/André Elferink

No topics

#### 2.3.3. Infectious Diseases Working Party (IDWP)

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Chair(s): Maria Jesus Fernandez Cortizo

No topics

#### 2.3.4. Oncology Working Party (ONCWP)

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Chair(s): Pierre Demolis/Paolo Foggi

- Nomination of two new core members following Bertil Jonsson's (SE) and Sinan Bardakci Sarac's (DK) resignations as members.

**Action:** For adoption

The CHMP nominated Sigrid Klaar (SE) and Olga Kholmanskikh (BE) as ONCWP members.

- Final minutes for ONCWP meeting held by Adobe on 19 March 2019

**Action:** For information

The CHMP noted the minutes.

- Pierre Demolis (ONCWP Chair) to represent EMA at the Multi Stakeholder Meeting on bureaucracy in clinical research, June 27 2019, The Hague, NL

**Action:** For adoption

The CHMP agreed to the ONCWP Chair to represent EMA at the Multi Stakeholder Meeting on bureaucracy in clinical research.

- Pierre Demolis (ONCWP Chair) to represent ONCWP at the CDDF multi-stakeholder workshop on Involving patients in Oncology Drug development, June 18-19 2019, Amsterdam, NL

**Action:** For adoption

The CHMP agreed to the ONCWP Chair to represent the ONCWP at the CDDF multi-stakeholder workshop on Involving patients in Oncology Drug development.

### 2.3.5. Pharmacokinetics Working Party (PKWP)

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Chair(s): Jan Welink/Henrike Potthast

- Jan Welink (PKWP Chair) to represent EMA at AAPS workshop on ICH draft guideline on Bioanalytical Method Validation (ICH M10) June 10-12, 2019 in Silver Spring, MD

**Action:** For adoption

The CHMP agreed to the PKWP Chair to represent EMA at the AAPS workshop on ICH draft guideline on Bioanalytical Method Validation.

- PKWP response to CHMP question regarding: dose recommendations for oncology products and acceptance criteria

**Action:** For discussion

At the CHMP December 2018 ORGAM, in the discussion of two product specific bioequivalence guidelines, CHMP raised the question whether 20% dose reduction for adverse events might impact on acceptance criteria for generics.

Submitted dossiers/ARs were searched for relevant data. PKWP findings were presented to CHMP. The CHMP agreed that further discussions were needed not just involving PKWP.

### 2.3.6. Biostatistics Working Party (BSWP)

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Chair(s): Anja Schiel/Jörg Zinserling

No topics

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

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Chair(s): Jan Mueller-Berghaus/Romaldas Mačiulaitis

No topics

### 2.3.8. Scientific Advisory Groups (SAGs)

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No topics

### 2.3.9. Drafting Groups (DGs)

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#### **2.3.9.1. Gastroenterology Drafting Group (GDG)**

Chair: Mark Ainsworth

No topics

#### **2.3.9.2. Respiratory Drafting Group (RDG)**

Chair: Karolina Törneke

RDG advice to PDCO on a PIP submission

**Action:** For adoption

The RDG advice was presented to the CHMP. CHMP members were asked to send any comments they may have to EMA before the May CHMP plenary meeting. If no substantial comments are received, the RDG advice to PDCO will be considered adopted.

#### **2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)**

Chair: Anabel Cortes

No topics

#### **2.3.9.4. Excipients Drafting Group**

Chair: Dominique Masset

No topics

### 2.3.10. Additional agenda points

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#### **2.3.10.1. Innovation Task Force**

- Expansion of ITF for discussion



**Action:** For discussion

The CHMP agreed on the proposal.

- ITF briefing meeting

**Action:** For adoption

The CHMP agreed on the proposed meeting.

- ITF briefing meeting

**Action:** For adoption

The CHMP agreed on the proposed meeting.

### **2.3.10.2. Guideline Consistency Group (GCG)**

Chair: Aranzazu Sancho-Lopez

No topics

## **3. Organisational, regulatory and methodological matters**

### **3.1. Regulatory Issues / new legislation**

#### **3.1.1. Article 58 and the WHO-EMA collaborative registration procedure**

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**Action:** For information

The CHMP noted the presentation.

### **3.2. CHMP organisation / templates**

#### **3.2.1. Call for nomination for one CHMP co-opted member**

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Presented by CHMP Secretariat

Agreed area of expertise: expertise in biostatistics, principally on clinical trial methodology, and at least basic knowledge of the EU regulatory framework

Nominations to be sent **by 22 May 2019 end of business.**

**Action:** For information

The CHMP noted the extension of the call.

#### **3.2.2. Update from the CHMP development group**

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**Action:** For discussion

CHMP members were informed about the progress of the CHMP development group.

### 3.2.3. ORGAM agenda template

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Presented by CHMP secretariat

**Action:** For information

The CHMP was informed that a new template will be used for the ORGAM agenda as of June 2019.

## 4. Any Other Business

- Update on the current Ebola outbreak in Democratic Republic of Congo

**Action:** For information

CHMP members were updated on the Ebola outbreak in DRC.

- International Pharmaceutical Regulators Programme (IPRP, formerly IPRF)

**Action:** For information

The International Pharmaceutical Regulators Programme (IPRP) is reviewing membership of all its 8 working groups. This is taking place ahead of the next IPRP Management Committee meeting on 1-2 June 2019.

The list of nominees will be presented to CHMP for information, once completed.

The mandates and terms of reference of each working group can be found on the IPRP website here: <http://www.iprp.global/working-groups>.

## 5. List of participants

### **CHMP Chair:**

Harald Enzmann

### **CHMP members:**

Bruno Sepodes (Vice-Chair)

Agnes Gyurasics

Blanka Hirschlerova

Constantinos Markopoulos

Ewa Balkowiec Iskra

Greg Markey

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Kristina Dunder

Maria Concepcion Prieto Yerro

Outi Mäki-Ikola

### **CHMP alternate members:**

Christophe Focke

Fátima Ventura

Janet Koenig

Milena Stain

Nithyanandan Nagercoil

Selma Arapovic Dzakula

### **Experts:**

Abigail Moran

Alfredo García-Arieta

Anita Andersson

Keith Pugh

Milena Peraita Ezcurra

Pierre Demolis

Sabine Mayrhofer

Valerie Lescrainier

A representative of the European Commission attended the meeting.

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