



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 June 2019  
EMA/CHMP/447861/2019  
Inspections, Human Medicines Pharmacovigilance and Committees Division

## Committee for medicinal products for human use (CHMP) Final ORGAM<sup>1</sup> agenda for the meeting on 17 June 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

17 June 2019, 09:30–12:30, 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 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

CHMP ORGAM agenda for 17 June 2019 meeting

### 1.3. Adoption of the minutes

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

## 2. Regulatory and organisational matters

### 2.1. Regulatory Issues / new legislation

No topic

### 2.2. CHMP organisation / templates

#### 2.2.1. Appointment of joint CHMP/PDCO members

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Proposed joint CHMP-PDCO membership

**Action:** For adoption

#### 2.2.2. Handling of competing interests

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**Action:** For information

## 3. Harmonisation and consistency groups

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

No topic

### 3.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No topic

## 4. Non therapeutic-area-specific working parties

### 4.1. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

#### 4.1.1. BWP response to CMDh questions on leeches

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**Action:** For adoption

#### 4.1.2. Final BWP Minutes - 15-16 April 2019

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**Action:** For information

#### 4.1.3. Draft BWP Agenda - 17-19 June 2019

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**Action:** For information

### 4.2. Safety Working Party (SWP)

Chair: Jan Willem Van der Laan

#### 4.2.1. Final SWP Minutes 25 Feb 2019

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**Action:** For information

#### 4.2.2. EMA speaker nomination to the 50th Annual Environmental Mutagenesis and Genomics Society (EMGS)

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Proposal

**Action:** For adoption

#### 4.2.3. Publication of SWP summary report on temporary interim limits for NMBA, DIPNA and EIPNA impurities in sartan blood pressure medicines

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**Action:** For information

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

Chair: Elena Wolff-Holz/Niklas Ekman

No topic

### 4.4. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

#### 4.4.1. Nomination of an additional assessor to the BSWP

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Mats Økvist has been nominated by Norwegian medicines Agency (NoMA) as an additional assessor to the BSWP

**Action:** For adoption

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

Chair: Kristin Karlsson/Flora Musuamba Tshinanu

No topic

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

Chair: Krishna Prasad/Markus Paulmichl

No topic

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

Chair: Jan Welink/Henrike Potthast

##### 4.7.1. Question from CMDh to PKWP on acenocumarol generics and need for chiral measures

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**Action:** For adoption

##### 4.7.2. PKWP response to CMDh question on Biowaiver for oral solutions with the "same concentration"

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**Action:** For adoption

##### 4.7.3. Question from CMDh to PKWP Bioequivalence for orally inhaled products containing beclomethasone dipropionate (BDP)

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**Action:** For adoption

## 5. Therapeutic-area-specific working parties and SAGs

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

Chair: Jacqueline Kerr

##### 5.1.1. Election of BPWP Vice-Chair at June 2019 CHMP plenary

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Nominations received

**Action:** For information

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

Chair: Karl Broich/André Elferink

No topic

## 5.3. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder/Alar Irs

No topic

## 5.4. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

No topic

## 5.5. Oncology Working Party (ONCWP)

Chair: Pierre Demolis/Paolo Foggi

### 5.5.1. Nomination of additional assessors to the ONCWP

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- Liisa Pylkkänen has been nominated by the Finnish medicines Agency (Fimea) as an additional assessor to the ONCWP
- Lucia Lopez-Anglada Fernandez has been nominated by the Spanish medicines Agency (AEMPS) as an additional assessor to the ONCWP
- João de Oliveira Baptista Geraldes Freire has been nominated by the Portuguese medicines Agency (INFARMED) as an additional assessor to the ONCWP

**Action:** For adoption

### 5.5.2. Guideline on MRD as an endpoint in clinical trials in Multiple Myeloma

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Possible need for a consultation with the SAG Oncology

**Action:** For discussion

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

Chair: Jan Mueller-Berghaus/Romaldas Mačiulaitis

No topic

## 5.7. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

No topic

## **5.8. Scientific Advisory Groups (SAGs)**

No topic

## **6. Drafting groups**

### **6.1. Excipients Drafting Group**

Chair: Dominique Masset

No topic

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

Chair: Mark Ainsworth

No topic

### **6.3. Geriatric Expert Group (GEG)**

Chair: Katarina Vučić


No topic

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

Chair: Anabel Cortes Blanco

No topic

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

Chair:  Karolina Törneke

No topic

## **7. Joint groups and collaboration with other committees**

### **7.1. Quality Working Party (QWP)**

Chair: Keith Pugh/Blanka Hirschlerova

No topic

### **7.2. Patients and Consumers Working Party (PCWP)**

Co-chair: Kaisa Immonen

No topic

### **7.3. Healthcare Professionals Working Party (HCPWP)**

Co-chair: Gonzalo Calvo



No topic

#### **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)**

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

No topic

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

Chair: Nienke Rodenhuis

No topic

#### **7.6. Committees**

No topic

### **8. Product development support**

#### **8.1. Scientific Advice Working Party (SAWP)**

Chair: Anja Schiel

##### **8.1.1. Appointment of CHMP peer reviewer for SA**

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**Action:** For discussion

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

##### **8.2.1. ITF Meeting**

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Meeting date: 17<sup>th</sup> June

**Action:** For adoption

##### **8.2.2. ITF Meeting**

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Meeting date: 3<sup>rd</sup> July

**Action:** For adoption

##### **8.2.3. ITF Meeting**

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Meeting date: 15<sup>th</sup> July

**Action:** For adoption

#### 8.2.4. ITF Meeting

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Meeting date: 25<sup>th</sup> September

**Action:** For adoption

## 9. Any Other Business

### 9.1. EMA Public engagement department: methodologies for consulting with patients and consumers

### 9.2. Study update

Presentation

**Action:** For information