



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 September 2019  
EMA/CHMP/246396/2019 Corr. 1<sup>1</sup>  
Inspections, Human Medicines Pharmacovigilance and Committees Division

## Committee for medicinal products for human use (CHMP) ORGAM<sup>2</sup> agenda 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 this agenda is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this agenda is a working document primarily designed for CxMP members and the work the Committee undertakes.

### Note on access to documents

Some documents mentioned in the agenda 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> Correction to section 2.1.6.

<sup>2</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 20 May 2019 meeting

### 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

#### 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

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

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/447545/2019)

**Action:** For adoption

#### 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 (J 3RsWG)

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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

- Minutes from MSWP meeting 11 April 2019

**Action:** For information

## 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

### 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

- Nomination of a new alternate:

**Action:** For discussion

- Marissa Opelt (AT) – replacing Lisa Rosner

- 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

#### 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.

Nominations received:

**Action:** For adoption

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

**Action:** For information

- 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

- 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

### 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

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

**Action:** For discussion

### 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

#### 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

- ITF briefing meeting

Meeting date: 21<sup>st</sup> May

**Action:** For adoption

- ITF briefing meeting

Virtual Meeting date: 6<sup>th</sup> June

**Action:** For adoption

##### **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

### **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



### 3.2.2. Update from the CHMP development group

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**Action:** For discussion

### 3.2.3. ORGAM agenda template

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Presented by CHMP secretariat

**Action:** For information

## 4. Any Other Business

Update on the current Ebola outbreak in Democratic Republic of Congo

Presented by EMA

**Action:** For information