



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 April 2019  
EMA/CHMP/447251/2019  
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 15 April 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 April 2019, 09:30-12:30, room 0-F

### 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. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Of note, this agenda is a working document primarily designed for CHMP 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 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 15 April 2019 meeting

### 1.3. Adoption of the minutes

CHMP Orgam Minutes of April 2019 meeting will be adopted at the April 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

No topics

#### 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.

EMA Human Scientific Committees are invited to nominate representatives for the period covering June 2019 to May 2022. The current CHMP representatives in PCWP are Prieto Yerro and Harald Enzmann.

Proposals for nomination should be sent **by 15 May 2019**.

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

Presented by EMA

Call for nomination of one CHMP representative (and alternate) to the HCPWP (can be the same person as for PCWP)

EMA Human Scientific Committees are invited to nominate representatives for the period covering June 2019 to May 2022. The current CHMP representative in HCPWP is Fatima Ventura.

Proposals for nomination should be sent **by 15 May 2019**.

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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No topics

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

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- ICH MC Interim meeting update (presentation by EMA)  
**Action:** For information
- Draft ICH E8 (R1) step 2b – guideline on Revision on General Considerations for Clinical Trials (Presentation by A. Kirisits and EMA)  
**Action:** For adoption (5 months public consultation)
- ICH E19 – draft guideline on Optimisation of Safety Data Collection (Presentation by P. Mol)  
**Action:** For information

#### 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

No topics

## 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

- Final minutes of the BWP plenary meeting held on 21-23 January 2019
- Final minutes of the BWP plenary meeting held on 18-20 February 2019
- Draft agenda of the BWP plenary meeting to be held on 15-16 April 2019

**Action:** For information

- Nomination of an alternate for PT

**Action:** For adoption

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

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Chair: Mair Powell

No topics

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

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Chair(s): Jacqueline Kerr

- Proposal for drafting a reflection paper on the clinical requirements for Tissue factor pathway inhibitor (TFPI) products indicated for Haemophilia

**Action:** For discussion

- Nomination of an additional expert for NL

**Action:** For adoption

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

Chair(s): Krishna Prasad/Markus Paulmichl

No topics

### **2.3. Therapeutics**

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

Chair(s): Kristina Dunder/Alar Irs

No topics

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

Chair(s): Karl Broich/André Elferink

No topics

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

Chair(s): Maria Jesus Fernandez Cortizo

No topics

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

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 information

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

Chair(s): Jan Welink/Henrike Potthast

- PKWP Q&A for CMDh request on PK characteristics of iron products – acceptable bridging/bioequivalence data

The Q&A had been adopted in March but the wording was slightly reviewed after the March meeting for clarification purpose. The document is presented for re-adoption.

Rapporteur: Janet Mifsud

**Action:** For adoption

- Guideline on equivalence studies for the demonstration of therapeutic equivalence for locally applied, locally acting products in the gastrointestinal tract (CPMP/EWP/239/95 Rev. 1, Corr.1\*)

Corrigendum: On page 4, section 3 EC regulations No 1084/2003 and No 1085/2003 have been replaced with Regulation (EC) No 1234/2008.

**Action:** for information

- Etonogestrel and ethinylestradiol vaginal delivery system 0.12mg/0.015mg/day product-specific bioequivalence guidance (EMA/CHMP/97470/2019)

Draft for 3 month public consultation

**Action:** for adoption

- Call for nomination for two new PKWP members:

The following expertise areas need to be filled as a result of the departure of Eva Gil-Berglund (SE). These should be special expertise areas in addition to general PK and/or biopharmaceutics:

- PBPK modelling
- Drug-Drug interactions

Nominations received:

**Action:** For adoption

- Nomination of an additional assessor

**Action:** For adoption

### 2.3.6. Biostatistics Working Party (BSWP)

Chair(s): Anja Schiel/Jörg Zinserling

No topics

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

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

No topics

### 2.3.8. Scientific Advisory Groups (SAGs)

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

No topics

#### **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**

##### **ITF Meeting**

**Action:** For adoption

##### **ITF Meeting**

**Action:** For adoption

##### **ITF Meeting**

**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. Creation of a group on the use, misuse and abuse of opioids

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Presented by EMA

**Action:** For information

#### 3.1.2. Experience with Regulation (EC) No 847/2000 - assessment of similarity vis-à-vis orphans

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Presented by EMA

**Action:** For discussion

### 3.2. CHMP organisation / templates

#### 3.2.1. Continuous improvement of CHMP work - Feedback and actions from consultation of CHMP members on CHMP organisation

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Presented by Harald Enzmann

**Action:** For information

#### 3.2.2. Remuneration of multinational teams for post-authorisation activities

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Presented by Fátima Ventura

**Action:** For information

#### 3.2.3. Proposal to go paperless for oral explanations at CHMP

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Presented by CHMP Secretariat

**Action:** For information

#### 3.2.4. Initiative for an earlier assessment of Annex II

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Presented by EMA

**Action:** For information

#### 3.2.5. Call for nomination for one CHMP co-opted member

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Presented by EMA: 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 15 April 2019 end of business.**

The election will take place during the April 2019 CHMP plenary meeting.

**Action:** For information

### 3.2.6. CHMP meeting in April 2020

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Presented by EMA: CHMP Secretariat

Committee meeting dates 2019-2021 (EMA/391620/2016)

**Action:** For information

### 3.2.7. CHMP Strategic Review and Learning Meeting (SRLM) – 7-8 May 2019, Budapest

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Update on the HTA session at the SRLM in Budapest: Exchange with HTA bodies and Payers on the identification of the patient population in the SmPC and underlying assessment reports

Presented by EMA

**Action:** For information

### 3.2.8. Procedures involving SmPC section 4.2 changes for discussion at CHMP

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Presented by Paula van Hennik

**Action:** For discussion

## 4. Any Other Business

No topics