



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 June 2017  
EMA/CHMP/371261/2017  
Inspections, Human Medicines Pharmacovigilance and Committees Division

## Committee for medicinal products for human use (CHMP) ORGAM<sup>1</sup> agenda for the meeting on 12<sup>th</sup> June 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

12 June 2017, 09:30 – 12.30 UK time, room 2D

### 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. Additional details on some of these procedures will be published in the CxMP <meeting highlights> <meeting reports> once the procedures are finalised and start of referrals will also be available.

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 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 12 June 2017 meeting

### 1.3. Adoption of the minutes

CHMP Orgam Minutes of 12 June 2017 meeting will be adopted at the June 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: Jan Willem Van der Laan

Final minutes for SWP virtual meeting held on 24 April 2017  
(EMA/CHMP/SWP/263253/2017)

**Action:** For information

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

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Chair: Jean-Louis Robert

QWP Response to CMDh Questions on similarity of bortezomib versus ixazomib  
(EMA/CHMP/QWP354858/2017)

**Action:** For adoption

Q/As on Normal Operating Ranges (NORs) and Proven Acceptable Ranges (PARs)  
(EMA/CHMP/CVMP/QWP/354895)

**Action:** For information

Reflection paper on the dissolution specification for generic solid oral immediate release products with systemic action (EMA/257304/2017)

**Action:** For adoption

- Overview of comments (EMA/257305/2017)

**Action:** For information

Final minutes for QWP face-to face meeting held on 31st January – 2nd February  
(EMA/CHMP/CVMP/QWP/66148/2017)

**Action:** For information

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

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Chair: Robert Hemmings

SAWP Strategic Review and Learning Meeting, Malta 26 – 28 April 2017: feedback from the meeting to CHMP

Presentation by Robert Hemmings

**Action:** For information

### 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

Draft Agenda of the PCWP/HCPWP joint meeting – 27/28 June (EMA/213892/2017)

**Action:** For information

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

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Co-chair: Gonzalo Calvo

Draft Agenda of the PCWP/HCPWP joint meeting

**Action:** For information

### 2.1.6. Geriatric Expert Group (GEG)

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Chair: Niccolo Marchionni

### 2.1.7. Committees

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

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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 (JEG 3Rs)

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Chair: Sonja Beken/ Ellen-Margrethe Vestergaard

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

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

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Chair: Gérard Moulin

## 2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

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Chair: Elena Wolff-Holz/Martina Weise

Minutes of BMWP virtual meeting held on 26 April 2017 (EMA/286058/2017)

**Action:** For information

Revised Minutes of BMWP face to-face meeting held on 08-09 March 2017 (EMA/CHMP/BMWP/169267/2017)

**Action:** For information

Call for nomination of a new Vice-Chairperson following end of 2nd mandate in July 2017

Nominations should be sent by 31 July 2017.

Candidates should submit a brief résumé in support of their candidature. Election is going to take place at the September 2017 CHMP Plenary meeting.

**Action:** For information

2.2.2. Biologicals Working Party (BWP)

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Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from face-to-face meeting held 10-11 April 2017 (EMA/CHMP/BWP/241529/2017)

**Action:** For information

Draft agenda for BWP face-to-face meeting to be held 10-12 July 2017 (EMA/CHMP/BWP/332522/2017)

**Action:** For information

Nomination of new member Helerin Margus (EE) to BWP

**Action:** For adoption

- CV
- Current membership list

### 2.2.3. Vaccines Working Party (VWP)

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Chair: Mair Powell/Svein Rune Andersen

Nomination of Annette Lommel (PEI) as an observer to VWP

**Action:** For adoption

Draft Agenda of VWP face-to-face meeting held on 23-24 May 2017 (EMA/237022/2017)

**Action:** For information

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

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Chair: Jacqueline Kerr

Nomination of new member from Sweden in the BPWP Sofia Bosdotter Enroth to replace current member Eva Macri

**Action:** For adoption

### 2.2.5. Pharmacogenomics Working Party (PGWP)

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Chair: Krishna Prasad/Markus Paulmichl

Draft agenda for the TC meeting on Ethylmorphine to be held on 8 June 2017 (EMA/342953/2017)

**Action:** For information

Pharmacogenomics drafting group on Addendum to the guideline on the Use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products on terminology in pharmacogenomics

Draft agenda for the TC meetings on 30 May 2017 (EMA/341732/2017)

**Action:** For information

Concept paper on an Addendum on terms and concepts of pharmacogenomic features related to metabolism to the Guideline on the use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products (EMA/CHMP/37646/2009)

Rapporteurs: Marc Maliepaard, Adrian Llerena

**Action:** For adoption for 3 months public consultation

## 2.3. Therapeutics

### 2.3.1. Cardiovascular Working Party (CVSWP)

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Chair: Pieter de Graeff/Kristina Dunder

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

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Chair: Karl Broich

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

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Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

Call for nomination of a Vice-Chairperson following end of 1<sup>st</sup> mandate in July 2017

Nominations should be sent by 1<sup>st</sup> September 2017.

Candidates should submit a brief résumé in support of their candidature. Election is going to take place at the September 2017 CHMP Plenary meeting.

**Action:** For information

### 2.3.4. Oncology Working Party

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Chair: Pierre Demolis/Paolo Foggi

### 2.3.5. Pharmacokinetics Working Party (PKWP)

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Chair: Jan Welink/Alfredo Garcia-Arieta

Response to CMDh Question to PKWP on BE studies for oral solution - Administration with or without water (EMA/CHMP/364793/2017)

Rapporteur: Sotiris Michaleas,

**Action:** For adoption

Product specific bioequivalence guidance: Batch 6, final:

- Crizotinib hard capsules 200 mg and 250 mg product-specific bioequivalence guidance (EMA/CHMP/805479/2016)

Rapporteur: Ridha Belaiba

- Elvitegravir 85 mg & 150 mg film-coated tablets product-specific bioequivalence guidance (EMA/CHMP/805507/2016)

Rapporteur: Susan Cole

- Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil film-coated tablets 150 mg/150 mg/200 mg/245 mg product-specific bioequivalence guidance (EMA/CHMP/805518/2016)

Rapporteur: Susan Cole

- Emtricitabine/rilpivirine/tenofovir disoproxil, film-coated tablets, 200 mg/25 mg/245 mg product-specific bioequivalence guidance (EMA/CHMP/805532/2016)

Rapporteur: Carolien Versantvoort

- Vortioxetine hydrobromide, 5 mg, 10 mg, 15 mg, and 20 mg immediate release tablets, vortioxetine lactate, oral drops solution 20 mg / ml product-specific bioequivalence guidance (EMA/CHMP/474974/2016)

Rapporteur: Henrike Potthast

**Action:** For adoption

Product specific bioequivalence guidance: Batch 7, draft:

- Dolutegravir, film-coated tablets, 10 mg, 25 mg, 50 mg, product specific bioequivalence guidance

Rapporteur: Eva Berglund/Malin Filler

- Dronedarone, film-coated tablets, 400 mg product-specific bioequivalence guidance

Rapporteur: Carolien Versantvoort

- Paracetamol oral use, immediate release formulations, product-specific bioequivalence guidance

Rapporteur: Jan Welink

- Rilpivirine 25mg, product-specific bioequivalence guidance

Rapporteur: Carolien Versantvoort

**Action:** For adoption for 3 months public consultation

Nomination of Gro Dahlseng Håkonsen (NO) as an observer to PKWP

**Action:** For adoption

### 2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang



Minutes of BSWP virtual meeting held on 11 April 2017 (EMA/242120/2017)

**Action:** For information

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

Chair: Jan Mueller-Berghaus

### 2.3.8. Scientific Advisory Groups (SAGs)

### 2.3.9. Drafting Groups (DGs)

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

Chair: Elmer Schabel

Final minutes for GDG F2F meeting held on 22 March 2017 (EMA/215695/2017)

**Action:** For information

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

Chair: Karolina Törneke

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

Chair: Anabel Cortes

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

Chair: Dominique Masset

### 2.3.10. Additional agenda points

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

ITF Briefing Meeting

Meeting date: 29 June 2017

**Action:** For discussion and agreement

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

Chair: Barbara van Zwieten-Boot

### **2.3.10.3. IPRF Nano Working Group**

Chair: Harald Enzmann/Jean Louis Robert

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

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

### **3.2. Meeting organisation / templates**

#### **3.2.1. Update to the CHMP templates**

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Updates to the CHMP templates:

- 1) CHMP and Rapporteurs' joint assessment report template on assessment of similarity;
- 2) Annex 1 - ASMF assessment report template;
- 3) (Co)-Rapp JAR of the grounds for re-examination template.

**Action:** For adoption