



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

5 November 2018  
EMA/CHMP/777011/2018  
Inspections, Human Medicines Pharmacovigilance and Committees Division

## Committee for medicinal products for human use (CHMP) ORGAM<sup>1</sup> agenda for the meeting on 5 November 2018

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

5 November 2018, 09:30–12:30, 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.

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 05 November 2018 meeting

### 1.3. Adoption of the minutes

CHMP Orgam Minutes of 05 November 2018 meeting will be adopted at the November 2018 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

Draft Guideline on the environmental risk assessment of medicinal products for human use (EMA/CHMP/SWP/4447/00 Rev. 1)

**Action:** For adoption for 7-month public consultation

Draft Guideline on the non-clinical requirements for radiopharmaceuticals (EMA/CHMP/SWP/686140/2018)

**Action:** For adoption for 7-month public consultation

Draft Reflection paper on the qualification of non-genotoxic impurities (EMA/CHMP/SWP/545588/2017)

**Action:** For adoption for 10-month public consultation

SWP response to CMDh Question concerning “Diethanolamine” and “coconut oil diethanolamine condensate” as excipients (EMA/CHMP/SWP/636821/2018)

**Action:** For adoption

Final minutes for the SWP meeting held by teleconference on 18 September 2018 (EMA/CHMP/SWP/639112/2018)

**Action:** For information

### 2.1.2. Quality Working Party (QWP)

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Chair: Keith Pugh/Blanka Hirschlerova

Nomination of new alternate member

**Action:** For adoption

Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container (EMA/CHMP/CVMP/QWP/850374/2015)

**Action:** For adoption

- Overview of comments received (EMA/CHMP/CVMP/QWP/366428/2018)  
**Action:** For information

Letter to EDQM from QWP

**Action:** For adoption

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

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Chair: Robert Hemmings

Call for nomination of new SAWP delegates

**Action:** For information

The following expertise areas will need to be filled with four new delegates:

- Statistics, Novel methodologies
- Cardiology, Diabetes
- Central Nervous System, Geriatrics
- Pharmacokinetics, Modelling & Simulation
- Oncology

Nominations should be submitted in writing by **9<sup>th</sup> November 2018**. The appointment of the new SAWP members will take place at the CHMP Plenary November 2018 meeting.

### 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

Agenda for the PCWP meeting of 25 September 2018 (EMA/610994/2018)

**Action:** For information

Agenda for the Joint PCWP/HCPWP meeting of 25 September 2018 (EMA/610994/2018)

**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

Agenda for the HCPWP meeting of 26 September 2018 (EMA/610994/2018)

**Action:** For information

See 2.1.4

#### 2.1.6. Geriatric Expert Group (GEG)

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Chair: Katarina Vučić

No items

#### 2.1.7. Committees

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Area of expertise for CHMP Co-opted member

In light of the expiry of the mandate of co-opted member Koenraad Norga on 24 January 2019 the CHMP should discuss and agree on the required area of expertise at the November CHMP Plenary.

The area of expertise of Koenraad Norga is Pharmacology.

**Action:** For discussion

CHMP 2019 Work Plan, draft

**Action:** For discussion

Overview of comments on 'Guideline on Clinical Development of Fixed Combination Medicinal Products'

To be presented by Peter Mol, the lead author from the ad hoc drafting group

**Action:** For information

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

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No items

#### 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 items

#### 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 items

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

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Chair: Gérard Moulin

No items

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

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Chair: Kristin Karlsson/Flora Musuamba Tshinanu

No items

## 2.2. Biologicals

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

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Chair: Elena Wolff-Holz/Niklas Ekman

No items

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

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Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from September face-to-face meeting held 10-12 September 2018  
(EMA/CHMP/BWP/618392/2018)

**Action:** For information

Draft agenda for BWP face-to-face meeting to be held 5-7 November 2018  
(EMA/CHMP/BWP/635558/2018)

**Action:** For information

Update on Workshop with stakeholders on support to quality development in early access approaches (i.e. PRIME, Breakthrough Therapies) – 26 November 2018

- Workshop agenda (EMA/188075/2018)
- Presentation

**Action:** For discussion

### 2.2.3. Vaccines Working Party (VWP)

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Chair: Mair Powell/Svein Rune Andersen

No items

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

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Chair: Jacqueline Kerr

Nomination of new core member

- CV
- Current membership list

**Action:** For adoption

Guideline on clinical investigation of recombinant and human plasma-derived factor IX products (EMA/CHMP/BPWP/144552/2009 rev. 2)

**Action:** For adoption for public consultation

Guideline on core SmPC for human plasma derived and recombinant coagulation factor IX products (EMA/CHMP/BPWP/1625/1999 rev. 3)

**Action:** For adoption

### 2.2.5. Pharmacogenomics Working Party (PGWP)

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Chair: Krishna Prasad/Markus Paulmichl

No items

## 2.3. Therapeutics

### 2.3.1. Cardiovascular Working Party (CVSWP)

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Chair: Kristina Dunder/Alar Irs

No items

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

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Chair: Karl Broich/André Elferink

No items

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

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Chair: Maria Jesus Fernandez Cortizo

No items

#### 2.3.4. Oncology Working Party

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Chair: Pierre Demolis/Paolo Foggi

Final minutes of the ONCWP meeting held by Adobe on 12 September 2018  
(EMA/619778/2018)

**Action:** For information

Final minutes of the ONCWP meeting held F2F 20-21 September 2018 (EMA652244/2018)

**Action:** For information

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

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Chair: Jan Welink/Henrike Potthast

Q&A - Ferric citrate coordination complex 1g film-coated tablets - product specific  
equivalence guidance (EMA/CHMP/246806/2018)

Rapporteur: Sotiris Michaleas

**Action:** For adoption

Final minutes of the PKWP meeting held by Adobe on 15 June 2018 (EMA/418256/2018)

**Action:** For information

#### 2.3.6. Biostatistics Working Party (BSWP)

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Chair: Anja Schiel/Jörg Zinserling

No items

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

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Chair: Jan Mueller-Berghaus/Romaldas Mačiulaitis

Call for nomination of a new core member

**Action:** For information

Nominations should be sent by **30 November 2018**

#### 2.3.8. Scientific Advisory Groups (SAGs)

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No items



### 2.3.9. Drafting Groups (DGs)

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

Chair: Mark Ainsworth

Draft reflection paper on regulatory requirements for the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH)

Rapporteur: Elmer Schabel

**Action:** For adoption for 9-month public consultation

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

Chair: Karolina Törneke

No items

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

Chair: Anabel Cortes

No items

#### 2.3.9.4. *Excipients Drafting Group*

Chair: Dominique Masset

No items

### 2.3.10. Additional agenda points

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#### 2.3.10.1. *Innovation Task Force*

ITF Briefing Meeting

Meeting date: 4th December 2018

**Action:** For discussion and agreement

ITF Briefing Meeting

Meeting date: 27 November 2018

**Action:** For discussion and agreement

Minutes of ITF meeting

**Action:** For information

Minutes of ITF meeting

**Action:** For information

Minutes of ITF meeting

**Action:** For information

Minutes of ITF

**Action:** For information

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

Chair: Aranzazu Sancho-Lopez

No items

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

Chair: Harald Enzmann

No items