



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 November 2018
EMA/CHMP/693788/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP) ORGAM¹ agenda for the meeting on 08 October 2018

Chair: Harald Enzmann

08 October 2018, time 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).

¹ 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 08 October 2018 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of October 2018 meeting will be adopted at the October 2018 CHMP plenary.

2. Working Parties, Committees, SAGs and Drafting Groups

2.1. General

2.1.1. Safety Working Party (SWP)

Chair: Jan Willem Van der Laan

Draft agenda for SWP meeting to be held face-to-face on 9-10 October 2018 (EMA/CHMP/SWP/621583/2018)

Action: For information

Final minutes for SWP meeting held by teleconference on 25 June 2018 (EMA/CHMP/SWP/431212/2018)

Action: For information

Final minutes for SWP meeting held by teleconference on 21 August 2018 (EMA/CHMP/SWP/567686/2018)

Action: For information

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Guideline of quality and equivalence of topical products (EMA/678311/2018)

Presented by Sean Jones

Action: For adoption for public consultation

Q&As on Quality data requirements to demonstrate suitability of multidose containers for preservative free eye drops (EMA/CHMP/QWP/677572/2018)

Presented by Blanka Hirschlerova

Action: For adoption

Guideline on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials (EMA/685812/2018)

Presented by Blanka Hirschlerova

Action: For adoption

QWP responses to CMDh questions on latex in synthetic rubber stoppers (EMA/CHMP/CVMP/QWP/660995/2018)

Presented by Blanka Hirschlerova

Action: For adoption

Guideline on Active Substance Master File Procedure – corrections to the GL

Presented by Blanka Hirschlerova

Action: For adoption

2.1.3. Scientific Advice Working Party (SAWP)

Chair: Robert Hemmings

Call for nomination of new SAWP delegates

Action: For agreement

The following expertise areas will need to be filled:

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

2.1.4. European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)

Co-chair: Kaisa Immonen

No items

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

Co-chair: Gonzalo Calvo

No items

2.1.6. Geriatric Expert Group (GEG)

Chair: Katarina Vučić

No items

2.1.7. Committees

Area of expertise for CHMP Co-opted member

CHMP should start discussion on area of expertise in light of the expiry of the mandate of co-opted member Koenraad Norga on 24 January 2019

Action: For discussion

Paediatric Committee (PDCO): Final reflection paper on the use of extrapolation in the development of medicines for paediatrics

CHMP: Rob Hemmings,

Action: For discussion

2.1.8. International Council on Harmonisation (ICH)

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)

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

No items

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

Chair: Nienke Rodenhuis

No items

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

Chair: Gérard Moulin

No items

2.1.12. Modelling and Simulation Working Party (MSWP)

Chair: Kristin Karlsson/Flora Musuamba Tshinanu

Nomination of additional expert to MSWP

Presented by Kristin Karlsson

Action: For adoption

Paediatric modelling Q&A (EMA/168474/2018) – 3 questions:

- Presentation of PK Results/Predictions for dose selection in children
- Fixed or estimated values for allometric scaling exponents in paediatric PK models
- Ontogeny/organ maturation in paediatric models

Presented by Kristin Karlsson

Action: For adoption

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Niklas Ekman

No items

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from July face-to-face meeting held 16-18 July 2018
(EMA/CHMP/BWP/494863/2018)

Action: For information

Draft agenda for BWP face-to-face meeting to be held 8-10 October 2018
(EMA/CHMP/BWP/566496/2018)

Action: For information

Questions and answers on Bovine Spongiform Encephalopathies (BSE) and vaccines
(EMA/CHMP/BWP/192228/2017)

Action: For adoption

- Overview of comments received on 'Questions and Answers on Bovine Spongiform Encephalopathies (BSE) and vaccines'
(EMA/CHMP/BWP/637549/2018)

Action: For information

Questions and answers on the Haemagglutination Inhibition (HI) test for qualification of influenza vaccine (inactivated) seed preparations (EMA/CHMP/BWP/426390/2017)

Action: For adoption

- Overview of comments received on “Questions and answers on the Haemagglutination Inhibition (HI) test for qualification of influenza vaccine (inactivated) seed preparations” (EMA/CHMP/BWP/652969/2018)

Action: For information

Guideline on quality aspects included in the product information for vaccines for human use (EMA/CHMP/BWP/133540/2017)

Action: For adoption

- Overview of comments received on 'Guideline on quality aspects included in the product information for vaccines for human use' (EMA/CHMP/BWP/668918/2018)

Action: For information

Revision of the CHMP position statement on Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products (EMA/CHMP/BWP/303353/2010 Rev 1)

Action: For adoption for public consultation (Presentation by Sol Ruiz)

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Final joint guideline with IDWP on the clinical evaluation of medicinal products indicated for the prophylaxis or treatment of respiratory syncytial virus (RSV) disease.

Action: For adoption

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

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

Action: For adoption

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)

Chair: Krishna Prasad/Markus Paulmichl

No items

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder/Alar Irs

Paediatric addendum to CHMP guidelines on the clinical investigations of medicinal products for the prevention and treatment of thromboembolic disease (EMA/CHMP/763438/2017)

Action: For adoption for public consultation

Concept Paper on the revision of the Guideline on clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease (CPMP/EWP/714/98 rev.1) (EMA/CHMP/78339/2018)

Action: For adoption for public consultation

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich/André Elferink

No items

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

No items

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

Nomination of new additional assessor

Action: For adoption

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

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

Rapporteur: Alfredo Garcia-Arieta

Action: For adoption

- Overview of comments received on 'Guideline on equivalence studies for the demonstration of therapeutic equivalence for products that are locally applied, locally acting in the gastrointestinal tract (EMA/CPMP/EWP/239/95 Rev.1)

Action: For information

Draft minutes for the F2F meeting on 17-18 April 2018 (EMA/247464/2018)

Action: For information

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

No items

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus/Romaldas Mačiulaitis

Draft Agenda for the teleconference meeting on 21 September 2018
(EMA/CHMP/658682/2018)

Action: For information

Draft Minutes for the teleconference meeting on 11 July 2018 (EMA/481994/2018)

Action: For information

2.3.8. Scientific Advisory Groups (SAGs)

No items

2.3.9. Drafting Groups (DGs)

No items

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No items

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

Call for nomination of a new Chair

Action: For information

Nominations should be sent

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

2.3.10.1. *Innovation Task Force*

ITF Briefing Meeting: Meeting date: 10 October 2018.

Action: For discussion and agreement

ITF Briefing Meeting: Meeting date: 10 October 2018.

Action: For discussion and agreement

Minutes of ITF Briefing meeting held on 28th June 2018

Action: For information

Minutes of ITF Briefing meeting held on 2nd July 2018

Action: For information

ITF Briefing meeting report from the meeting held on 4th September 2018

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/Jean Louis Robert

No items