1 December 2017
EMA/800758/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda of the meeting on 4 December 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

4 December 2017, 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 4 December 2017 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of 4 December 2017 meeting will be adopted at the December 2017 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

EC consultation on Pharmaceuticals in the environment

The **public consultation** on pharmaceuticals in the environment was launched. The deadline for responses is **21 February 2018**.
https://ec.europa.eu/info/consultations/public-consultation-pharmaceuticals-environment_en

The targeted stakeholder consultation is available via:
https://ec.europa.eu/eusurvey/runner/PharmaInEnvTargetedConsultation2017

The deadline is **21 January 2018**.

We would welcome your input to the targeted consultation in particular, but also to the public consultation if you wish.

Action: For information

Work plan for the Safety Working Party (SWP) for 2018 (EMA/CHMP/SWP/420217/2017)

Action: For adoption

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh

QWP Work Plan 2018 - DRAFT (EMA/CHMP/CVMP/QWP/504882/2017)

Action: For adoption

Guidance document on the content of the <Co->Rapporteur day <60*><80> critical assessment report (EMA/CHMP/CVMP/QWP/793631/2017)

Template: <Co->Rapporteur day <60*><80> critical assessment report (EMA/CHMP/CVMP/QWP/793632/2017)

Action: For adoption

2.1.3. Scientific Advice Working Party (SAWP)

Chair: Robert Hemmings

No items

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

Co-chair: Kaisa Immonen

Minutes of the PCWP/HCPWP joint meeting held on 20 Sep 2017 (EMA/626905/2017)

Action: For information

Report of the Information session on antimicrobial resistance held on 19 Sep 2017

Action: For information

Draft Agenda - Training session for patients, consumers and healthcare professionals interested in EMA activities (21 Nov) - (EMA/662990/2017)

Action: For information

Agenda of the PCWP meeting with all eligible organisations (22 Nov) (EMA/663268/2017)

Action: For information

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

Co-chair: Gonzalo Calvo

See under 2.1.4.

2.1.6. Geriatric Expert Group (GEG)

Chair: Niccolo Marchionni

Nomination of new chairperson to the GEG

Action: For adoption

Nomination of new core member

Action: For adoption

Nomination of new additional expert

Action: For adoption

2.1.7. Committees

Draft Minutes from Joint CHMP-PRAC Strategic Review and Learning meeting in Tallinn, Estonia 16-18, October under EU Estonian Presidency

Action: For adoption

Area of expertise for the 5th CHMP co-opted member to replace Jean-Louis Robert (current expertise: Quality (non-biologicals))

The discussion and agreement on the area of expertise is planned for the December 2017 Plenary. Proposals should be sent by **11 December 2017**

Action: For information

SmPC Advisory Group: Nomination of CHMP representative(s) in the SmPC AG following resignation of CHMP member Patrick Salmon

Action: For adoption

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, CoChair: Susanne Brendler-Schwaab

Recommendation to marketing authorisation holders, highlighting recent measures in the veterinary field to promote replacement, reduction, and refinement (3Rs) measures described in the European Pharmacopoeia (EMA/CHMP/CVMP/3Rs/614768/2017)

- Background note CHMP - New EMA statement extraneous agents and cell substrates (EMA/793669/2017)

Action: For adoption

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

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Niklas Ekman

BMWP Work Plan 2018

Action: For adoption

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Work plan for the Biologics Working Party (BWP) for 2018 (EMA/CHMP/BWP/400117/2017)

Action: For adoption

Final minutes from face-to-face meeting held 2-4 October 2017 (EMA/CHMP/BWP/660687/2017)

Action: For information

Draft agenda for BWP face-to-face meeting to be held 15-17 January 2018 (EMA/CHMP/BWP/743327/2017)

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Work plan for the Vaccines Working Party (VWP) for 2018 (EMA/CHMP/VWP/515395/2017)

Action: For adoption

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Agenda of the BPWP face to face meeting held on 16-17 November 2017

Action: For information

Draft minutes of the face to face meeting held on 16-17 November 2017

Action: For information

Draft agenda Blood cluster meeting 4 December 2017

Action: For information

BPWP Work Plan 2018

Action: For adoption

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Work plan for the Pharmacogenomics Working Party (PGWP) for 2018 (EMA/CHMP/370931/2017)

Action: For adoption

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

. Call for nomination for CVSWP Chair.

Nominations should be sent by **7th December 2017.** Election will take place during the December Plenary.

Action: For information

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

Call for nomination for IDWP Vice-Chair. Applications should be sent to the Agency to the IDWP Secretariat IDWPSecretariat@ema.europa.eu by **12th February 2018.**

Action: For information

EMA/AMEG advice: IDWP member, has volunteered for this project

Action: For information

IDWP Work plan 2018

Action: For adoption

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

Nomination of a new additional assessor:

Action: For adoption

Nomination of a new observer:

Action: For adoption

Draft minutes for the virtual meeting on 15 November 2017 (EMA/760810/2017)

Action: For information

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

Product-specific bioequivalence guidance – 8th Batch:

- Cholic acid capsules 50 mg and 250:
- Posaconazole gastro-resistant tablet 100 mg;
- Ledipasvir/sofosbuvir film-coated tablet 90 mg/400 mg;

- Vismodegib tablet 150 mg
- Agomelatine co-crystals citric acid

Action: For adoption for 3 months public consultation

Work plan for the Pharmacokinetics Working Party (PKWP) for 2018 (EMA/CHMP/365756/2017)

Action: For adoption

Reflection paper on investigation of pharmacokinetics and pharmacodynamics in the obese population

Rapporteurs: Ridha Belaiba, Carolien Versantvoort, Eva Gil Berglund and Susan Cole

Action: For adoption for 6 months public consultation

PRAC request to PKWP on a signal on Norvir, Kaletra and a possible interaction with levothyroxine

Action: For adoption

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Call for nominations for BSWP Vice-Chair

Nominations should be sent to the by **15th January 2018**. Elections will take place at the January CHMP Plenary meeting.

Action: For information

Consolidated comments on the FDA guidance on Statistical Approaches to Evaluate Analytical Similarity

Action: For information

BSWP – Work plan 2018

Action: For adoption

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

No items

2.3.8. Scientific Advisory Groups (SAGs)

No items

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Elmer Schabel

Work Plan for the Gastroenterology Drafting Group (GDG) for 2018 (EMA/CHMP/350919/2017)

Action: For adoption

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

Work plan for the Respiratory Drafting Group (RDG) for 2018 (EMA/CHMP/383892/2017)

Action: For adoption

Final minutes from face-to-face meeting held 11-12 October 2017

Action: For information

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

Nomination of observer to RadDG

- CV
- Motivation letter

Action: For adoption

Nomination of observer to RadDG

- CV
- Motivation letter

Action: For adoption

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

Minutes of the ExcpDG face-to-face meeting held on 9-10 October 2017 (EMA/695162/2017)

Action: For information

Work plan for the CHMP Excipients Drafting Group (ExcpDG) for the revision of the EC guideline 'Excipients in the labelling and package leaflet of medicinal products for human use' for 2018 (EMA/CHMP/672198/2017)

Action: For adoption

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF Briefing Meeting

Meeting date: 15 December 2017

Action: For discussion and agreement

ITF Briefing Meeting

Meeting date: 19 December 2017

Action: For discussion and agreement

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Barbara van Zwieten-Boot

No items

2.3.10.3. IPRF Nano Working Group

Chair: Harald Enzmann/Jean Louis Robert

No items

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

No items

3.2. Meeting organisation / templates

3.2.1. User manual – CxMP/WP/SAG members and experts representing CxMP or EMA at external meetings

Action: For discussion

3.2.2. CHMP/CAT joint membership

The Advanced Therapies Regulation ((EC) 1394/2007) requires that 5 members or co-opted members of the Committee for Medicinal Products for Human Use (CHMP) together with an alternate, either proposed by the Member state of the member or identified by the co-opted member, are appointed by the CHMP to the Committee for Advanced Therapies (CAT). The Member States, who are not represented through the members appointed by the CHMP, nominate then one member and alternate to the CAT.

Action: For adoption

3.3. Pharmacovigilance

No items

4. Any Other Business

4.1. Good Clinical Practice Inspectors Working Group

GCP Inspection Programme 2018-2019

Action: For adoption