



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 December 2017
EMA/828521/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP) ORGAM¹ minutes of the meeting on 4 December 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

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 ongoing 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 was adopted.

1.3. Adoption of the minutes

CHMP Orgam Minutes of 4 December 2017 meeting were 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

The CHMP noted the information. Members were invited to answer the questionnaire. The members' answers should be submitted through SWP, therefore answers should be sent to SWP. NCAs can also submit answers directly to EC.

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

Action: For adoption

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh

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

Action: For adoption

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

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

The document and template has been updated and will be published on EMA website. The CHMP adopted the guidance and the template.

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

The CHMP noted the minutes.

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

Action: For information

The CHMP noted the report.

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

Action: For information

The CHMP noted the draft agenda.

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

Action: For information

The CHMP noted the agenda.

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

The CHMP agreed to the new chairperson for the GEG - Katarina Vučić.

Nomination of new core member

Action: For adoption

The CHMP appointed a new core member Elina Rönnemaa.

Nomination of new additional ad-hoc expert

Action: For adoption

Post-meeting note: the nomination should be postponed as proposed by respective CHMP member.

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

The CHMP noted the draft minutes. Comments should be provided by the end of CHMP December Plenary (by 14th December). In case of no comments, the minutes will be considered adopted.

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

The CHMP noted the proposed area of expertise.

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

Action: For adoption

The CHMP appointed Pieter Kiely and Doreen Fagan from Ireland as members to SmPC Advisory Group.

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

The CHMP adopted the recommendation. The document will be published on 3Rs website.

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

The chair of BMWP presented the work plan. The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

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

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

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

Action: For information

The CHMP noted the minutes.

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

Action: For information

The CHMP noted the draft agenda.

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

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

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

The CHMP noted the agenda.

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

Action: For information

The CHMP noted the draft minutes.

Draft agenda Blood cluster meeting 4 December 2017

Action: For information

The CHMP noted the draft agenda.

BPWP Work Plan 2018

Action: For adoption

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

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

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

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

The CHMP noted the call.

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. Nominations should be sent t by **12th February 2018**.

Action: For information

The CHMP noted the call.

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

Action: For information

The CHMP noted IDWP member who volunteered.

IDWP Work plan 2018

Action: For adoption

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

Nomination of a new additional assessor

Action: For adoption

The CHMP nominated Elma O'Reilly as new additional assessor.

Nomination of a new observer

Action: For adoption

The CHMP nominated Didier Meulendijks as observer.

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

Action: For information

The CHMP noted the draft minutes.

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

The CHMP adopted the guidance for 3 months public consultation.

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

Action: For adoption

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

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

The CHMP noted the reflection paper. Further discussions during the plenary are expected.

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

Action: For adoption

The CHMP agreed to send PRAC request to PKWP.

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

The CHMP noted the call.

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

Action: For information

The CHMP noted the comments.

BSWP – Work plan 2018

Action: For adoption

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

Post-meeting note: RIWP work plan was tabled in MMD at the time ORGAM meeting, and it should be presented during the December Plenary.

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

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

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

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

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

Action: For information

The CHMP noted the final minutes.

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

Nomination of observer to RadDG

- CV
- Motivation letter

Action: For adoption

The CHMP nominated Christof Krummeich as observer to RadDG.

Nomination of observer to RadDG

- CV
- Motivation letter

Action: For adoption

The CHMP nominated Joao Correia as observer to RadDG.

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

The CHMP noted the minutes.

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

The CHMP noted the work plan. In case there are no comments received, the work plan will be considered as adopted during the December Plenary.

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

The CHMP agreed to the meeting.

ITF Briefing Meeting

Meeting date: 19 December 2017

Action: For discussion and agreement

The CHMP agreed to the meeting.

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

The CHMP noted that the user manual needs slight updates, however generally CHMP agreed to the document. The main question was how to distinguish between committee or EMA representation and participation in personal capacity. It was explained that the invitation should mention, whether committee official representation or EMA

representation is invited. If a committee member participates in a personal capacity, this should be clear from the invitation and in any further documentation of the conference/meeting.

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

The CHMP appointed following CHMP members as joint CHMP/CAT members: Romaldas Mačiulaitis, Sol Ruiz, Bruno Sepodes, John Borg and Jan Mueller-Berghaus. Mandates will be valid from December 2017 until December 2020. The proposal will also be presented at CAT for nomination of alternates for the CHMP co-opted members.

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

The CHMP noted the GCP Inspection Programme 2018-2019. There were questions to be answered, therefore the adoption is postponed and further discussions will be held during the Plenary.

5. List of participants

CHMP Vice-Chair:

Harald Enzmann

CHMP members:

Agnes Gyurasics

Alexandre Moreau

Andrea Laslop

Christophe Focke

Concepcion Prieto Yerro

Katarina Vučić

Outi Mäki-Ikola

Robert James Hemmings

Sinan B. Sarac

CHMP alternate members:

Bjorg Bolstad

Dana Gabriela Marin

Fátima Ventura

Natalja Karpova

Nithyanandan Nagercoil

Paula Boudewina van Hennik

Peter Kiely

Selma Arapovic Dzakula

Experts:

Anne Hasle Buur

Elena Wolff-Holz

Valerie Lescrainier

The meeting was run with support from the relevant EMA staff