27 March 2018
EMA/106932/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

# Committee for medicinal products for human use (CHMP)

## ORGAM[1] minutes for the meeting on 12 February 2018

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

**Disclaimers**

Some of the information contained in the minutes is considered commercially confidential or sensitive and therefore not disclosed. Of note, this document 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 minutes 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

# Table of contents

# 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 February 2018 meeting was adopted.

## 1.3. Adoption of the minutes

CHMP Orgam Minutes of 12 February 2018 meeting will be adopted at the February 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 13-14 February 2018 (EMA/CHMP/SWP/40675/2018)

**Action**: For information

The CHMP noted the draft agenda.

Final minutes for SWP meeting held face-to-face on 3-4 October 2017 (EMA/CHMP/SWP/667387/2017)

**Action**: For information

The CHMP noted the minutes.

Final minutes for SWP meeting held by teleconference on 21 November 2017 (EMA/CHMP/SWP/773822/2017)

**Action**: For information

The CHMP noted the minutes.

SWP response to CMDh Question - Acceptability of statement on potential residues of latex in the Product information of products packed in containers with synthetic rubber stopper (EMA/CHMP/SWP/652246/2017)

Presentation by Jan Willem Van der Laan

**Action**: For adoption

The SWP response was presented. SWP's view on the potential risk for allergic reactions is that, should there be residues of naturally-derived rubber in relevant quantity this could potentially cause allergic reactions. However non-clinical studies are considered of very little relevance to define a threshold for generation of allergic reactions in humans.

The CHMP agreed to re-discuss the response during the February Plenary.

PRAC questions to SWP regarding prenatal exposure to paracetamol and impact on the urogenital apparatus or impact on neurodevelopment (EMA/89520/2018)

**Action**: For adoption

- Signal assessment report about prenatal exposure to paracetamol and impact on the urogenital apparatus or impact on neurodevelopment (EMA/PRAC/45065/2018)

  **Action:** For information

The PRAC questions to SWP were presented. The CHMP noted the signal assessment report and adopted the questions to SWP.

### 2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Co-processed excipients – Letter to EDQM (EMA/CHMP/CVMP/64280/2018)

**Action**: For adoption

The letter was presented by Keith Pugh**.** The letter is the formal QWP comments to the draft monograph on Co-processed excipients. The CHMP adopted the letter.

Nomination of new UK member and alternate:

**Action**: For adoption

The CHMP appointed a new UK member Sean Jones and alternate member Abigail Moran.

CMDh Question to QWP on Paclitaxel Hetero (PT/H/1256/001/DC) (EMA/CMDh/64913/2018)

**Action**: For adoption

The CHMP adopted the CMDh questions to QWP.

### 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

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

Work plan for the Geriatric Expert Group (GEG) for 2018 (EMA/633939/2017)

**Action:** For adoption

The work plan was presented by Katarina Vučić. GVP guideline (led by PRAC) is anticipated and CHMP AR pilot on 10 products will be continued and finalised in 2018. It was agreed that concept paper on multi-morbidity will be developed by GEG in Q4 2018-2019.

The CHMP adopted the work plan.

### 2.1.7. Committees

CHMP 2018 Work Plan (EMA/CHMP/55038/2018)

**Action**: For adoption

The CHMP noted the updated work plan based on comments received after January plenary. The topic Documenting medicines evaluation was placed back as separate topic into work plan. However some more contributors from EMA side should be identified. Further discussions will be held at the February Plenary.

Call for nomination of 5$^{th}$ co-opted member at the Committee on Herbal Medicinal Products HMPC

Agreed area of expertise: Clinical pharmacology (widened scope to clinical assessment/trials in general). Either general or focused on the most common areas herbal medicinal products are used.

**Action**: For information

The CHMP noted the call.

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

Nomination of experts to contribute to guidelines:

- Gabriele Schwarz (DE) – ICH E19 EWG (Guideline in development on Optimisation of Safety Data Collection) – Deputy Topic Lead
- Peter Theunissen (NL) – ICH S5(R3) EWG (Guideline on reproductive toxicology: detection of toxicity to reproduction for human pharmaceuticals) - Deputy Topic Lead - Temporary replacement for Louise Lauritsen (DK)
- Kristina Dunder (SE) – ICH E17 IWG (Guideline on General principles for planning and design of Multi-Regional Clinical Trials) - Topic Lead
- Armin Koch (DE) – ICH E17 IWG (Guideline on General principles for planning and design of Multi-Regional Clinical Trials) - Deputy Topic Lead

**Action:** For adoption

The CHMP nominated experts to contribute to guidelines.

### 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

JEG3Rs (J3RsWG) Annual Report 2017 (EMA/CHMP/CVMP/3Rs/502136/2017)

**Action:** For adoption

The report was presented. The CHMP adopted the annual report, which will also be published.

### 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

Overview of comments received on 'Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues' (EMEA/CHMP/BMWP/42832/2005 Rev. 1), (EMA/772616/2013)

**Action:** For information

The CHMP noted the overview of comments.

### 2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from December face-to-face meeting held 4-6 December 2017 (EMA/CHMP/BWP/810336/2017)

**Action:** For information

The CHMP noted the minutes.

Draft agenda for BWP face-to-face meeting to be held 12-14 March 2018 (EMA/CHMP/BWP/27089/2018)

**Action:** For information

The CHMP noted the draft agenda.

### 2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Nomination of additional assessor (observer) to VWP

**Action:** For adoption

Follow-up item from January

Postponed to February Plenary.

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

Chair: Jacqueline Kerr

Final Minutes of the BPWP 16-17th November 2017 (EMA/CHMP/BPWP/759445/2017)

**Action:** For information

The CHMP noted the minutes.

Agenda and time schedule of the F2F meeting 8-9th February 2018 (EMA/CHMP/BPWP/13936/2018)

**Action:** For information

The CHMP noted the draft agenda and time-schedule.

TC with FDA 5th February 2018 (EMA/CHMP/BPWP/48972/2018)

**Action:** For information

The CHMP noted the TC with FDA.

TC with FDA to discuss the treatment of direct or indirect factor Xa(FXa) inhibitor when reversal of anticoagulation is needed (13th February 2018; date TBC)

**Action:** For information

The CHMP noted the TC with FDA.

### 2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Guideline on good pharmacogenomic practice (EMA/CHMP/268544/2016)

Rapporteur: Krishna Prasad

**Action:** For adoption

The guideline was presented by Krishna Prasad. The guideline provides guidance on methods of evaluation of genetic variations related to pharmacokinetics and response, where this could affect efficacy and/or safety. The guidance primarily focusses on the analysis of genomic germline DNA and does not discuss somatic DNA and genomic biomarkers for cancer treatment, RNA variations, proteomics or metabolomics, which are outside the scope of this document, however some principles might apply.

It was agreed to adopt the guideline at the February Plenary so that there is some time to reflect. In case no comments are received by Monday 19th February 2018, the guideline will be considered adopted.

## 2.3. Therapeutics

### 2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder

Final agenda for CVSWP meeting held by teleconference on 7 February 2018 (EMA/29049/2018)

**Action**: For information

The CHMP noted the agenda.

Final minutes for CVSWP meeting held face-to-face on 22 November 2017 (EMA/775601/2017)

**Action**: For information

The CHMP noted the minutes.

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

Chair: Karl Broich/André Elferink

Guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease and other dementias (CPMP/EWP/553/95 Rev.2)

**Action:** For adoption

Follow-up item from January Plenary

Postponed to February Plenary due to comments received.

Nomination of an additional expert to the CNSWP

**Action:** For adoption

The CHMP nominated Sylvie Benchetrit as additional expert to CNSWP for the Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders, CPMP/EWP/566/1998 Rev. 2.

### 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

Minutes of ONCWP TC on 06th December 2017 (EMA/811786/2017)

**Action:** For information

The CHMP noted the minutes.

### 2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

Ibuprofen 200 - 800 mg oral use immediate release formulations product-specific bioequivalence guidance (EMA/CHMP/356876/2017)

Rapporteur: Susan Cole

**Action:** For adoption

- Overview of comments received on 'Ibuprofen 200 – 800 mg oral use, immediate release formulations product-specific bioequivalence guidance' (EMA/CHMP/730723/2017)

  **Action:** For information

The guidance was presented and main changes since last month were highlighted. The CHMP noted the overview of comments. It was agreed to have further discussions in the margins of February Plenary and possibly adopt the guidance at the February Plenary.

## 2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

Nomination of new additional assessor

**Action:** For adoption

The CHMP adopted the additional assessor Aldana Rosso (Danish Medicines Agency).

## 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

No items

### *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

#### *2.3.10.1. Innovation Task Force*

No items

#### *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

### 3.1.1. Topic

No items

## 3.2. Meeting organisation / templates

### 3.2.1. Discussion on additional assessors (so called observers) to working parties and drafting groups

CHMP: Tomas Salmonson

**Action:** For discussion

Follow-up item from January Plenary

EMA presented the current situation with additional assessors (so called observers) and composition of working parties. There are pros and cons to limiting the number of additional assessors per working party and figures do not provide a compelling argument in favour of limitation.

It was agreed to consult the working parties' chairs about their experience and question was sent to working parties' chairs: *Considering the current number of members and additional assessors in your working party / drafting group, did you experience any negative impact of the group size on its work, or would you have any concerns regarding the effect of a possibly expanded size on the group and/or its functioning?*

Responses should be sent by Friday 9 February COB.
The discussion will resume at CHMP plenary next week.

## 4. List of participants

**CHMP Chair:**

Tomas Salmonson

**CHMP members:**

Andrea Laslop

Concepcion Prieto Yerro

Ewa Balkowiec Iskra

Greg Markey

Harald Enzmann

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Katarina Vučić

Kristina Dunder

Outi Mäki-Ikola

Svein Rune Andersen

**CHMP alternate members:**

Dana Gabriela Marin

Fátima Ventura

Milena Stain

Nithyanandan Nagercoil

**Experts:**

Anna Niwinska

Anne Hasle Buur

Jan Willem van der Laan

Keith Pugh

Krishna Prasad

Valerie Lescrainier

The meeting was run with support from the relevant EMA staff