27 November 2017
EMA/CHMP/734503/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

# Committee for medicinal products for human use (CHMP)

## ORGAM[1] minutes of the meeting on 30 October 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 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 30 October 2017 meeting

The CHMP adopted the agenda.

## 1.3. Adoption of the minutes

CHMP Orgam Minutes of 30 October 2017 meeting will be adopted at the November 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

SWP Answers to CHMP List of Questions on Estragole (EMA/CHMP/SWP/620432/2017)

**Action**: For adoption

The CHMP noted the SWP answers. Further discussions will be held at the November Plenary. The Committee discussed the question 4 more extensively.

Reply regarding EMA workshop on non-animal approaches (EMA/CHMP/SWP/696860/2017)

**Action**: For adoption

The CHMP adopted the reply regarding EMA workshop on non-animal approaches. There will be a closed workshop organized with only a limited number of speakers. Participants with this specific expertise were contacted to contribute to the workshop. Invited participants are from EU pharmaceutical industry associations, research organisations, academia and regulators.

SWP response to CMDh Question on 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)

**Action**: For adoption

The CHMP adopted the SWP response. It was proposed that the question should be referred to QWP or Excipients Drafting Group in order to better understand the exact quantities of natural latex residues that could be present in butyl rubber stopper and to PRAC

Further discussions will be held in the margins of CHMP during November Plenary.

Nomination of Birger Scholz (MPA) as drafting group member for ERA guideline replacing Per Garberg (MPA)

- CV Birger Scholz

**Action:** For adoption

The CHMP appointed Birger Scholz (MPA) as drafting group member for ERA guideline replacing Per Garberg (MPA).

Risk-assessment meeting on seven new psychoactive substances: AB-CHMINACA, ADB-CHMINACA, 5F-MDMB-PINACA, CUMYL-4CN-BINACA, 4F-iBF, THF-F and carfentanil, 7-8 November 2017, EMCDDA, Lisbon

- Nomination of Leon van Aerts as EMA representative

**Action:** For information

The CHMP noted the attendance of Leon van Aerts as EMA representative at the risk assessment meeting.

### 2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh

Questions and Answers on in-use shelf life (EMA/CHMP/CVMP/QWP/696703/2017)

**Action**: For adoption

The CHMP adopted the Questions and Answers on in-use shelf life.

84th Joint CHMP/CVMP Quality Working Party (QWP) face-to-face meeting on 27 – 29 September 2017: Table of decisions

- ToD – 84th QWP

**Action**: For information

The CHMP noted the table of decisions.

Nomination of new alternate member to the QWP – Ivana Tasevska (CZ)

- Nomination Letter Ivana Tasevska
- CV – Ivana Tasevska

**Action:** For adoption

The CHMP appointed Ivana Tasevska (CZ) as new alternate member to the 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: Niccolo Marchionni

No items

### 2.1.7. Committees

SmPC Advisory Group: Call for expression of interest for CHMP representative(s) in the SmPC AG following resignation of CHMP member Patrick Salmon.

Please send nominations by 30th November 2017.

**Action**: For information

The CHMP noted the call.

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

Nomination of Mair Powell and Svein-Rune Andersen to represent CHMP in preliminary discussions on Vaccines to be held at the ICH biannual meeting to be held in Geneva, Switzerland on 11-16th November

**Action:** For adoption

The CHMP agreed to the participation of Mair Powell and Svein-Rune Andersen to represent CHMP in preliminary discussions on Vaccines to be held at the ICH biannual meeting to be held in Geneva, Switzerland on 11-16th November.

### 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

EPAA Partners Forum on Toxicokinetics & Read Across; November 21, 2017 Brussels

- Nomination of Leon van Aerts (SWP) as EMA expert

**Action:** For information

The CHMP noted the participation of Leon van Aerts (SWP) as EMA expert at EPAA Partners Forum.

EPAA Annual Conference on "Building synergies across sectors to accelerate the development and acceptance of alternative approaches for safety assessment": 22 November 2017, Brussels

- Nomination of Susanne Brendler-Schwaab (J3RsWG vice-chair) to represent EMA

**Action:** For information

The CHMP noted the participation of Susanne Brendler-Schwaab (J3RsWG vice-chair) representing EMA at EPAA Annual Conference.

Guidance for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs (EMA/CHMP/CVMP/3Rs/94436/2014)

**Action:** For adoption

- Background note
- Overview of comments

  **Action**: For information

The CHMP noted the overview of comments. The CHMP adopted the guidance. The guidance aims to facilitate transfer and acceptance of the new methods validated in such trials with a view to implementing 3Rs for testing in a product specific context in laboratories originally involved in the collaborative trial or in new laboratories. It is applicable to both human and veterinary medicines for quality control of medicinal products where animals have been traditionally used. It aims to facilitate transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs, for testing in a product specific context.

The guidance should be helpful in supporting regulatory applications for variations to existing marketing authorisations as well as new applications. The guidance has been developed from work initiated by JEG3Rs and principally the BWP and IWP and finalised by J3RsWG.

### 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/Martina Weise

No items

### 2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from face-to-face meeting held 4-6 September 2017 (EMA/CHMP/BWP/590649/2017)

**Action:** For information

The CHMP noted the final minutes.

Draft agenda for BWP face-to-face meeting to be held 4-6 December 2017 (EMA/CHMP/BWP/669751/2017)

**Action:** For information

The CHMP noted the draft agenda.

BWP-QWP Joint Guidance for assessors for the Overviews - Quality Part (EMA/CHMP/CVMP/QWP/641461/2017)

**Action**: For adoption

The guidance was presented. The CHMP adopted the guidance. Both working parties, QWP and BWP, have already agreed to it.

### 2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

No items

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

Chair: Jacqueline Kerr

No items

### 2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Draft minutes for the F2F meeting on 27-28 March 2017 (EMA/208906/2017)

**Action:** For information

The CHMP noted the draft minutes.

## 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

**Action:** For information

The CHMP noted the call.

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

Chair: Karl Broich/André Elferink

Draft minutes for the Adobe meeting on 12 June 2017 (EMA/372411/2017)

**Action:** For information

The CHMP noted the draft minutes.

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

Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

No items

### 2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

No items

### 2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

PKWP response to CMDh question on bioequivalence studies programme for multiple strengths product

**Action:** For adoption

The CHMP adopted the response.

PKWP response to CMDh question on bioequivalence studies for an oral solution of a BCS class II drug – Aripiprazole

**Action:** For adoption

The CHMP adopted the response.

PKWP response to CMDh question on bioequivalence study requirements for generic applications for agomelatine co-crystals (EMA/CHMP/703965/2017)

**Action:** For adoption

The CHMP adopted the response.

Draft minutes for the Adobe meeting on 20 June 2017 (EMA/398416/2017)

**Action:** For information

The CHMP noted the draft minutes.

### 2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Call for nominations for BSWP Vice Chair:

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

Action: For information

The CHMP noted the call. The call will also be highlighted at the November Plenary.

### 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: Mark Ainsworth

Draft minutes for the F2F meeting held on 28 June 2017 (EMA/414657/2017)

**Action:** For information

The CHMP noted the draft minutes.

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

Chair: Karolina Törneke

Draft minutes for the F2F meeting on 23-24 March 2017 (EMA/202283/2017)

**Action:** For information

The CHMP noted the draft minutes.

Call for nomination for new core member. Eligible experts, who wish to apply for the member position are requested to submit a brief letter in support of their candidature together with a brief CV, highlighting their expertise.

Nominations should be sent by 31st October 2017.

**Action:** For information

The CHMP was reminded the call. No nominations were received so far and it was agreed to extend the deadline until 7th November 2017.

#### 2.3.9.3. Radiopharmaceuticals Drafting Group (RadDG)

Chair: Anabel Cortes

Guideline on core SmPC and Package Leaflet for sodium iodide (131I) therapy capsule (EMA/630248/2017)

**Action:** For adoption

The CHMP noted the guideline. CHMP was ready to adopt the guideline, but the question was whether the guideline had been sent to the ONCWP for their information. The CHMP will come back to the guideline during the CHMP November Plenary.

Nomination of two new core members: Rad DG members have requested that one of the new core members would have expertise in clinical and another member would have expertise in quality aspects of radiopharmaceuticals.

**Action:** For adoption

The CHMP noted the nominations received. Appointment of two new core members will take place during the November Plenary.

#### 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: 6th November 2017
**Action:** For discussion and agreement

The CHMP agreed to the meeting.

ITF Briefing Meeting

Meeting date: 7th November 2017
**Action:** For discussion and agreement

The CHMP agreed to the meeting.

ITF Briefing Meeting

Meeting date: 1st December 2017
**Action:** For discussion and agreement

The CHMP agreed to the meeting.

ITF Briefing Meeting

Meeting date: 14th 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 information

The user manual describes the process for allowing a scientific committee (CxMP), working party (WP) or scientific advisory group (SAG) chair, member, alternate or expert to participate in an external meeting or conference representing the CxMP or the European Medicines Agency (EMA or Agency) in an official capacity, where the participation is fully or partially reimbursed by the Agency or by the organiser of the meeting or conference.

The CHMP noted the user manual, however further discussion is needed. In case of comments, please send them. The question, which was discussed, was regarding the representatives of EMA or CHMP – how to distinguish between those representations, as well as regarding participation in a personal capacity – where some participation on behalf of CHMP could be beneficial. It was agreed that further clarification is expected.

## 3.3. Pharmacovigilance

No items

# 4. Any Other Business

No items

# 5. List of participants

**CHMP Chairman:**

Tomas Salmonson

**CHMP members:**

Andrea Laslop

Concepcion Prieto Yerro

Eleftheria Nikolaidi

Ewa Balkowiec Iskra

Harald Enzmann

Jayne Crowe

Johann Lodewijk Hillege

Kristina Dunder

Outi Mäki-Ikola

Svein Rune Andersen

**CHMP alternate members:**

Christophe Focke

Dana Gabriela Marin

Fátima Ventura

Hanne Lomholt Larsen

Natalja Karpova

Nithyanandan Nagercoil

Milena Stain

**Co-opted members**

Robert James Hemmings

**Experts:**

Jan Willem van der Laan

Anabel Cortés Blanco

Jan Welink

Carolien Versantvoort

Janet Mifsud

Anna Niwinska

Keith Pugh

Theis Moeslund Jensen

The meeting was run with support from the relevant EMA staff