17 November 2016
EMA/CHMP/738830/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes of the meeting on 28 October 2016

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.

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 November 2016 meeting was adopted.

1.3. Adoption of the minutes

CHMP Orgam Minutes of November 2016 meeting were adopted at the November 2016 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

Final minutes of SWP meeting held by teleconference on 23 August 2016 (EMA/CHMP/SWP/567801/2016)

Action: For information

The CHMP noted the minutes.

Final minutes of SWP meeting held by teleconference on 20 September 2016 (EMA/CHMP/SWP/626792/2016)

Action: For information

The CHMP noted the minutes.

Reflection paper providing an overview of the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs (EMA/CHMP/738830/2016)

Action: For adoption for 6-month public consultation

The CHMP adopted the reflection paper for 6-month public consultation.

The reflection paper has been developed as a follow up to the draft guideline and provides an overview of the main animal tests required for the regulatory testing of human medicinal products and opportunities for further improvement in the application of 3Rs.

A parallel document has been developed in relation to veterinary medicinal products and was adopted by CVMP for a 6 month public consultation ending in October 2016

(EMA/CHMP/CVMP/JEG-3Rs/164002/2016). The human reflection paper has been reviewed by QWP, SWP, BWP, VWP, Biosimilars WP & the CAT.

SWP Work plan 2017 (EMA/CHMP/SWP/615357/2016)

Action: For adoption

The CHMP adopted the SWP Work Plan 2017 with minor amendments regarding timelines for ICH activities and on interaction with other stakeholders.

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Q&As on quality requirements for orally inhaled products (EMA/CHMP/738830/2016)

Action: For adoption

The CHMP adopted the Q&As on quality requirements for orally inhaled products, which consists of 4 questions.

Q&As on Improving the understanding of NORs, PARs, DSp and normal variability of process parameters (EMA/CHMP/738830/2016)

Action: For adoption

The CHMP adopted the Q&As on Improving the understanding of Normal Operating Ranges (NORs), Proven Acceptable Ranges (PARs), Design Space (DSp) and normal variability of process parameters, which consists of 5 questions.

Concept paper on developing a guideline on Quality requirements of medicinal products containing a device component for delivery or use of the medicinal product (EMA/CHMP/QWP/BWP/661488/2016)

Action: For adoption for 3 months public consultation

The CHMP adopted the concept paper for 3 months public consultation. There is a need for development of a guideline on dossier requirements for medical devices that are supplied along with medicinal products where a device is necessary for administration or localisation (site-specific delivery) of the medicinal product.

Corrigendum: 'Guideline on process validation for finished products -information and data to be provided in regulatory submissions' – change to the definition for "on line" measurement

- Letter from EDQM to QWP (EXT/672737/2016)

Action: For information

The CHMP noted the corrigendum and the letter from EDQM to QWP.

- Guideline on process validation for finished products -information and data to be provided in regulatory submissions (CLEAN & TC) (EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev1.1)
- Letter to EDQM (EMA/CHMP/CVMP/QWP/823395/2015)

Action: For adoption

The CHMP adopted the revised guideline and noted the reply letter to EDQM.

2.1.3. Scientific Advice Working Party (SAWP)

Chair: Robert Hemmings

Scientific guidance on Post-Authorisation Efficacy Study (PAES) (EMA/PDCO/CAT/CMDh/PRAC/CHMP/261500/2015)

Action: For adoption

- Overview of comments from public consultation (EMA/147348/2016)

Action: For information

Any comments regarding the document will be discussed during the November Plenary. In case of no comments, the Scientific guidance on Post-Authorisation Efficacy Study will be considered adopted.

Call for interest for nomination of a replacement SAWP member and his alternate following retirement of Dr Jens Ersbøll. The required area of expertise is *oncology*.

Nominations should be sent by 7th December 2016.

Candidates shall submit a letter of candidacy and a CV (for both member and alternate position) in support of their candidature as per the SAWP Mandate requirements [see Article 2(10)]

Action: For information

The CHMP noted the information.

Call for nominations for election of the Chair of SAWP

Nominations should be sent by 7th December 2016.

Candidates shall submit a brief résumé in support of their candidature

Action: For information

The CHMP noted the information.

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

Co-chair: David Haerry

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

Committee for Advanced Therapies (CAT): Draft Minutes of the October 2016 meeting (EMA/CAT/665136/2016)

Action: For information

The CHMP noted the minutes.

Pharmacovigilance Risk Assessment Committee (PRAC): Call for nomination of a CHMP representative to the ENCePP Steering Group.

Nominations should be sent by 30th November 2016.

Action: For information

The CHMP noted the information.

Area of expertise of CHMP Co-opted Member

Action: For discussion

The mandate of Robert J. Hemmings as Co-opted member of the CHMP expires in February 2017. His area of expertise is Medical statistics (clinical trial methodology /epidemiology).

The CHMP noted the information.

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 (JEG 3Rs)

Chair: Sonja Beken/ Ellen-Margrethe Vestergaard

Please see under SWP

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)

No items

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

Final agenda of BMWP meeting held face-to-face on 18 October 2016 (EMA/819159/2016)

Action: For information

The CHMP noted the agenda.

2.2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse/Ilona Reischl

Nomination of Marcos Timón as a new Spanish representative at BWP

- Current membership list

Action: For adoption

The CHMP appointed Marcos Timón as a new Spanish representative at BWP.

Assessor Training on viral safety evaluation of biotechnological medicinal products to be held on 02 December 2016

Action: For information

The CHMP noted the information.

Final BWP Minutes 5-7 Sep 2016

Action: For information

The CHMP noted the minutes.

Draft BWP December Agenda 5-7 Dec 2016

Action: For information

The CHMP noted the agenda.

BWP report: Formaldehyde used in the production of vaccines

Action: For adoption

The CHMP adopted the BWP report. This is related to deletion of warning statements regarding formaldehyde residuals in vaccine SmPCs.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell

Draft agenda of VWP meeting to be held face-to-face on 22-23 November 2016 (EMA/649282/2016)

Action: For information

The CHMP noted the agenda.

2.2.4. Blood Products Working Party (BPWP)

Chair: Anneliese Hilger

Draft agenda of the 16-17th November face-to-face meeting

Action: For adoption

The CHMP noted the agenda.

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad

No items

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Paediatric Addendum on the CHMP Guideline on clinical investigation of medicinal products for the treatment of acute heart failure (EMA/CHMP/707532/2013)

Action: For adoption

- Overview of comments received

Action: For information

The CHMP adopted the Paediatric Addendum and noted the overview of external comments received during the public consultation. This is an addendum to the adult guideline on clinical investigation of medicinal products for the treatment of acute heart failure and it outlines the paediatric medicine clinical development with specific guidance on design and conduct of studies in children of all ages (from birth to less than 18 years of age) when developing products for acute heart failure. Aspects relating to surgical treatment such as correction of congenital defects and mechanical support that are an integral part of treatment of heart failure in the paediatric population are beyond the scope of this guideline.

Guideline on clinical investigation of medicinal products for prevention of venous thromboembolism (VTE) in non-surgical patients (formerly CPMP/EWP/6235/04 Rev.1) (EMA/CHMP/41252/2015)

Action: For adoption

- Overview of comments received

Action: For information

The CHMP adopted the guideline and noted the overview of comments. The aim of this guideline is to provide guidance to industry when performing trials to develop medicinal products in the prevention of venous thromboembolism in non-surgical patients. The revised guideline does not deal with the development of medicinal products for prevention of long-term sequelae of VTE, such as post-thrombotic syndrome or chronic thromboembolic pulmonary hypertension.

Report on the outcome of the "FDA diabetes measures beyond hemoglobin A1c workshop" (EMA/CHMP/662796/2016)

Action: For information

The CHMP noted the report.

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

Concept paper on the need for revision of the guideline on clinical investigation of medicinal products in the treatment of depression (EMA/CHMP/183826/2016)

Action: For adoption for 3 months public consultation.

The CHMP adopted the concept paper for 3 months public consultation. The current guideline needs revision covering the latest developments with regard to requirements for clinical trials in partial and non-responders with Major Depressive Disorder and options of targeting new functional domains. In addition, it may include requirements to increase depression clinical trials efficiency.

Nomination of Darius Matusevicius (SE) as an observer to CNSWP

- Current membership list

Action: For adoption

The CHMP nominated Darius Matusevicius (SE) as an observer to CNSWP.

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

No items

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink

Question from CMDh to PKWP: BCS-classification of paracetamol

Action: For adoption

The CHMP agreed to send question to PKWP.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Thomas Lang

Nomination of new core member following resignation of David Jonathan Wright

- Current membership list

Action: For adoption

The appointment of new core member was postponed to November Plenary.

Final minutes of BSWP meeting held face-to-face on 12 July 2016 (EMA/482201/2016)

Action: For information

The CHMP noted the minutes.

Extension of a call for nominations for a new chairperson in light of resignation of David Jonathan Wright

Nominations should be sent by 30 November 2016
Candidates shall submit a brief résumé in support of their candidature.
Election is to take place at the December 2016 CHMP Plenary meeting.

Action: For information

The CHMP noted the information.

Nomination of Julia Saperia (UK) as an observer to BSWP

- Current membership list

Action: For adoption

The CHMP nominated Julia Saperia (UK) as an observer to BSWP.

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

Draft minutes of the F2F meeting held on 15-16 September 2016 (EMA/621110/2016)

Action: For information

The CHMP noted the minutes.

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

Guideline on core SmPC and Package Leaflet for nanocolloidal technetium (99mTc) albumin

Action: For adoption

Postponed

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

Action: For adoption for 4 months public consultation

The CHMP adopted the guideline for 4 months public consultation. The guideline describes the information to be included in the Summary of Products Characteristics (SmPC) and package leaflet for sodium iodide (131I) therapy capsule.

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

No items

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. Update on the NCA Dashboard

Scope: Presentation on the use of the NCA Dashboard

Action: For information

The CHMP noted the information.

3.1.2. Pilot Project on a model for a pre-marketing risk-based model for product testing

Comments should be provided by 31st October 2016

Action: For information

The CHMP noted the information on pilot project and noted the extended deadline for comments by 4 November 2016. HPRA will evaluate and incorporate comments on the Final Documents, to be presented to the HMA (1st meeting 2017).

3.2. Meeting organisation / templates

No items

3.3. Pharmacovigilance

No items

4. Any Other Business

No items

5. List of participants

CHMP Chairman

Tomas Salmonson

CHMP Members

Agnes Gyurasics

Andrea Laslop

Bjorg Bolstad (replacing Karsten Bruins Slot)

Jan Mueller-Berghaus

Jean-Louis Robert

Katarina Vučić

Kristina Dunder

Outi Mäki-Ikola

Pierre Demolis

CHMP Alternate Members

Dana Gabriela Marin

Melinda Sobor

Nithyanandan Nagercoil

Paula Boudewina van Hennik

Experts

Anabel Cortés Blanco

Anna Niwinska

Gabriele Schlosser-Weber

Jan Willem van der Laan

Krishna Prasad

Mette Madsen

Meeting was run with support from the relevant EMA staff