28 October 2016
EMA/CHMP/679213/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 28 October 2016

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

28 October 2016, 09.30 – 12.30 (UK time), 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 CxMP 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 November 2016 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes for November 2016 meeting will be 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 / Sonja Beken,

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

Action: For information

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

Action: For information

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/679213/2016)

Action: For adoption for 6-month public consultation

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

Action: For adoption

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Q&As on quality requirements for orally inhaled products (EMA/CHMP/679213/2016)

Action: For adoption

Q&As on Improving the understanding of NORs, PARs, DSp and normal variability of process parameters (EMA/CHMP/679213/2016)

Action: For adoption

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

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

- 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

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

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

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

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

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

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).

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

No items

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

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

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

Action: For information

Final BWP Minutes 5-7 Sep 2016

Action: For information

Draft BWP December Agenda 5-7 Dec 2016

Action: For information

BWP report: Formaldehyde used in the production of vaccines

Action: For adoption

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

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

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

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

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

Action: For information

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

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

- Current membership list

Action: For adoption

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

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

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

Action: For information

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

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

- Current membership list

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

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

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

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

Action: For adoption for 4 months public consultation

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

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

3.2. Meeting organisation / templates

No items

3.3. Pharmacovigilance

No items

4. Any Other Business

No items