3 October 2016
EMA/CHMP/620067/2016 Rev.1
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 3 October 2016

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

3 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 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 October 2016 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes for October 2016 meeting will be adopted at the October 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

No items

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Minutes of QWP Core team held by Adobe connect on 13 July 2016 (EMA/460554/2016) and 7 September 2016 (EMA/577712/2016)

Action: For information

Final agendas of QWP meeting and joint GMDP IWG/ QWP meeting held face-to-face on 19 - 21 September 2016

Action: For information

Final meeting minutes of QWP meeting held face-to-face on 31 May – 2 June 2016

Action: For information

Organisation of Break-out-Session on 'Co-processed excipients' (Dec QWP meeting) with the Excipients Performance WP (EDQM)

Action: For information

Nomination of Diana van Riet (NL QWP member) as speaker at 'PQRI/USP Workshop on Implementation Status of ICH Q3D Elemental Impurity Requirements - Analytical and Risk Assessment Challenges'

Action: For adoption

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: 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

Final CAT's ToD of the meeting held on 8 – 9 September 2016

Action: For information

CHMP Chairman Tomas Salmonson representing CHMP in pre-ICDRA and ICDRA conference in Cape-Town South-Africa, 27 November - 02 December 2016

Action: For adoption

Election of CHMP Vice-chair

The election of the CHMP Vice-chair will take place on 12 October 2016 during the CHMP Plenary.

Candidates should declare their interest by circulating a letter, indicating their intention to stand, together with a motivation for so doing, by **17.00 hours UK time, October 7th 2016**.

Action: For 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

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: Martina Weise (acting)

Draft Agenda of BMWP meeting to be held face-to-face on 18-19 October 2016

Action: For information

Call for nomination of a new core member following resignation of Christian Schneider (UK)

Action: For adoption

Nominations received

• Current membership list

Election of BMWP chair

The election of the chair has been put on hold during September in order to first appoint the 10th member. The chair election will take place at the October Plenary. Any additional nominations to already those submitted should be sent to until 5 October 2016.

2.2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse, Ilona Reischl

Draft agenda for BWP face-to-face meeting to be held on 3-5 October 2016 (EMA/CHMP/BWP/518729/2016)

Action: For information

Final minutes from face-to-face meeting held on 11-13 July 2016

(EMA/CHMP/BWP/485124/2016)

Action: For information

CHMP position statement on quality and safety assessment for the Plasma Master File (PMF) certification with regards to donor deferral criteria for risk behaviour (EMA/CHMP/434217/2016);

PLUS Letter

Action: For discussion

Comments should be sent by **24 October 2016**

Agenda for assessor training on biosimilars to be held 17-18 November 2016

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: TBA

VWP/IDWP Concept paper on preparation of a guideline on the evaluation of medicinal products indicated for the treatment and prophylaxis of respiratory syncytial virus (RSV) infection (EMA/CHMP/360458/2016)

Action: For adoption and release for 3 months public consultation

Overview of comments received on 'Draft guideline on influenza vaccines: non-clinical and clinical module' (EMA/CHMP/VWP/457259/2014)

Action: For information

Election of VWP chairperson

The election of the VWP chair person will take place at the October CHMP Plenary.

Action: For information

2.2.4. Blood Products Working Party (BPWP)

Chair: Anneliese Hilger

No items

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Draft agenda – of the face to face meeting to be held on 17-18 October 2016 (EMA/536975/2016)

Action: For information

Programme of the EMA expert meeting on the *Good Pharmacogenomic Practices* draft guideline: comments from the public consultation and impact of ICH 18 *Genomic Sampling and Data Management* (EMA/420311/2016)

Action: For information

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

No items

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 product for the treatment of migraine (EMA/179671/2016)

Action: For adoption

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/ Maria Jesus Fernandez Cortizo

Draft agenda of IDWP meeting to be held face-to-face on 24-25 November 2016

Action: For information

Final minutes of IDWP meeting held face-to-face on 18-19 April 2016 (EMA/301460/2016)

Action: For information

2.3.4. Oncology Working Party

Chair: Pierre Demolis

Nomination of new additional assessor (observer)

Action: For adoption

• Current membership list

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

No items

2.3.6. Biostatistics Working Party (BSWP)

Chair: Thomas Lang (acting)

Final minutes of BSWP meeting held by teleconference on 14 June 2016 (EMA/412999/2016)

Action: For information

Draft agenda of BSWP meeting to be held face-to-face on 29-30 September 2016 (EMA/502792/2016)

Call for nomination of a new core member following resignation of David Jonathan Wright (UK)

Action: For information

Expertise sought: professionally qualified senior assessor within the European regulatory network, with relevant expertise in the field of biostatistics.

Nominations should be sent by **15 October 2016**.

Election is going to take place at the November 2016 CHMP Plenary meeting.

Nomination of new observers

Action: For adoption

• Current membership list

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

Draft minutes of the TC held on 12 May 2016 (EMA/336973/2016)

Action: For information

Election of RIWP chair person

Nominations, along with a short statement in support of candidature, should be sent by **Friday 7 October 2016**.

Action: For information

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

Respiratory Drafting Group letter to CHMP and PDCO - Request for advice on how to address issues related to therapeutic equivalence for orally inhaled products for children

Action: For discussion

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

Guideline on core SmPC and Package Leaflet for nanocolloidal technetium (^{99m}Tc) albumin

Action: For adoption

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

Action: For adoption and release for 4 months public consultation

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

Agenda of the 4th TC on the IPRF Nano Working Group

Action: For information

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

No items

3.2. Meeting organisation / templates

No items

3.3. Pharmacovigilance

No items

4. Any Other Business

No items