1 September 2017
EMA/CHMP/581740/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 4 September 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

4 September 2017, 9.00 – 12.30, room 2E

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. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available.

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 4 September 2017 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of 4 September 2017 meeting will be adopted at the September 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

Final minutes for SWP virtual meeting held on 23 May 2017 (EMA/CHMP/SWP/335567/2017)

Action: For information

Final minutes for SWP virtual meeting held on 28 June 2017 (EMA/CHMP/SWP/415510/2017)

Action: For information

CMDh Question to SWP on acceptability of statement on potential residues of latex in the PI of products packed in containers with synthetic rubber stopper

Action: For adoption

Draft programme for SWP workshop on non-animal approaches in support of medicinal product development to be held 5 October 2017 at EMA

Action: For information

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh

Q/As on needle safety systems

Presentation by Keith Pugh

Action: For adoption

Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials (EMA/CHMP/QWP/545525/2017)

Action: For adoption

- Overview of comments received (EMA/CHMP/QWP/546045/2017)

  Action: For information

Nomination of new alternate member to the QWP - Kristofer Olofsson (SE)

- CV
- Current membership list

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: Kaisa Immonen

Report from a workshop on personalised medicines held by EMA on 14 March 2017 (EMA/185440/2017)

Action: For information

Draft Agenda AMR workshop - 19 Sept (EMA/765134/2016)

Action: For information

Draft agenda PCWP-HCPWP - 20 Sept (EMA/370525/2017)

Action: For information

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

Area of expertise of co-opted member

The mandate of Jan Mueller-Berghaus (expertise in Quality and safety of biological medicinal products, including biotechnology derived medicines, cell therapies and gene therapies) will expire on 13 November 2017. The needed area of expertise should be confirmed.

Action: For discussion

CHMP/CAT joint membership

The Advanced Therapies Regulation ((EC) 1394/2007) requires that 5 members or co-opted members of the Committee for Medicinal Products for Human Use (CHMP) together with an alternate, either proposed by the Member state of the member or identified by the co-opted member, are appointed by the CHMP to the Committee for Advanced Therapies (CAT). The Member States, who are not represented through the members appointed by the CHMP, nominate then one member and alternate to the CAT.

Action: For discussion

2.1.8. International Council on Harmonisation (ICH)

ICH Guideline Q11 Q&A on "Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)"

Action: For adoption

ICH Guideline E11(R1) draft Guideline on "Clinical Investigation of Medicinal Products in the Pediatric Population"

Action: For adoption

ICH Guideline E18 Guideline on Genomic Sampling and Management of Genomic Data

Action: For adoption

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, Co-Chair: Susanne Brendler-Schwaab

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)

Chair: Gérard Moulin

No items

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Martina Weise

Draft agenda of BMWP face to face meeting to be held on 20-21 September 2017 (EMA/527610/2017)

Action: For information

Draft agenda of Interested parties meeting with BMWP to be held on 21 September 2017 (EMA/397389/2017 and EMA/465298/2017)

Action: For information

Draft Minutes of BMWP virtual meeting held on 31 May 2017 (EMA/348708/2017)

Action: For information

Draft Minutes of BMWP virtual meeting held on 03 July 2017 (EMA/530736/2017)

Action: For information

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from face-to-face meeting held 12-14 June 2017 (EMA/CHMP/BWP/379325/2017)

Action: For information

Draft agenda for BWP face-to-face meeting to be held 2-4 October 2017 (EMA/CHMP/BWP/505217/2017)

Action: For information

Revised Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials (EMA/CHMP/BWP/534898/2008 rev. 1)

Action: For adoption

- Overview of comments (EMA/CHMP/BWP/563769/2017)

  Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Final Minutes of VWP face to face meeting held on 23-24 May 2017 (EMA/333084/2017)

Action: For information

Draft minutes of the VWP TC of 25 August 2017

Action: For information

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Agenda of BPWP face to face meeting held on 29-30 June 2017 (EMA/CHMP/BPWP/359534/2017)

Action: For information

Draft minutes of BPWP face to face meeting held on 29-30 June 2017 (EMA/CHMP/BPWP/414553/2017)

Action: For information

Agenda and draft minutes of the Blood cluster meeting held on 13 July 2017

Action: For information

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

No items

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus

Action: For adoption

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich/Greg Markey

Call for nomination of a new Vice-Chair to the CNSWP following the end of first mandate in October 2017

Nominations should be sent by **06 October 2017**.

Candidates should submit a brief résumé in support of their candidature. Election is going to take place at the October 2017 CHMP Plenary meeting.

Action: For information

Call for nomination of a new CNSWP core member following resignation of Dag Nilsson

Nominations should be sent by **06 October 2017**.

Action: For information

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

Call for nomination of a new Chair to the IDWP following the current Chair's resignation.

Action: For information

2.3.4. Oncology Working Party (ONCWP)

Chair: Pierre Demolis/Paolo Foggi

Draft agenda of ONCWP face to face meeting to be held on 18 September 2017

Action: For information

Draft minutes of ONCWP virtual meeting held on 11 July 2017 (EMA/441641/2017)

Action: For information

Draft minutes of ONCWP virtual meeting held on 14 June 2017 (EMA/380195/2017)

Action: For information

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

CMDh question to the Pharmacokinetics Working Party (PKWP) - Oral solutions - with or without water (EMA/CHMP/364793/2017)

Rapporteur: Sotiris Michaleas

Action: For adoption

Invitation to PKWP Chair Jan Welink to attend the 12th Workshop on Recent Issues in Bioanalysis as a speaker in April 2018 in Philadelphia, PA, USA

- Invitation

Action: For adoption

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Minutes of BSWP face to face meeting held on 27-28 March 2017 (EMA/205708/2017)

Action: For information

Minutes of BSWP face to face meeting held on 06-07 July 2017 (EMA/432665/2017)

Action: For information

Workshop on “draft reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development (EMA/CHMP/138502/2017)” to be held on 3-4 May 2018.
The main focus of the multidisciplinary workshop will be the discussion of comments received during the public consultation and stakeholders are hence encouraged to provide comments or suggest topics early on (ideally by the end of November 2017) which will help shape the format and content of the workshop. Stakeholders wishing to participate can express their interest

Action: For information

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)

No items

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

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

No items

3.2. Meeting organisation / templates

3.2.1. Multinational Assessment Team (MNAT) concept – broadening the concept to the post-authorisation phase

As outlined during the June 2017 Plenary meeting, the multinational team concept has been extended to post-authorisation procedures (extension of indications and line extensions) as of 1st of September 2017 onwards.

Multinational teams involved in the assessment of an initial MAA are reminded to inform EMA whether or not they wish to continue with the multinational team concept post-authorisation.

Further information can be found on the EMA website and in the published Guidance document.

Action: For information

3.3. Pharmacovigilance

No items