27 November 2017
EMA/720087/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 30 October 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

30 October 2017, 09:30-12:30, 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. 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.

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

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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

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

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

Action: For adoption

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

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

- CV Birger Scholz

Action: For adoption

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

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

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

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

- Nomination Letter Ivana Tasevska
- CV – Ivana Tasevska

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

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

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

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

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

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

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

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

Action: For information

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

Action: For adoption

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

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

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

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

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

Action: For adoption

PKWP response to CMDh question on bioequivalence study requirements for generic applications for agomelatine co-crystals

Action: For adoption

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

Action: For information

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

No items

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

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

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

2.3.9.3. Radiopharmaceuticals Drafting Group (RadDG)

Chair: Anabel Cortes

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

Action: For adoption

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

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

ITF Briefing Meeting

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

ITF Briefing Meeting

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

ITF Briefing Meeting

Meeting date: 14th December 2017
Action: For discussion and agreement

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.

3.3. Pharmacovigilance

No items

4. Any Other Business

No items