05 December 2016
EMA/CHMP/814177/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 05 December 2016

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

05 December 2016, 09.30 – 12.30 (UK time), room 2D

[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

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).

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 December 2016 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of December 2016 meeting will be adopted at the December 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

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

Action: For adoption

Final minutes from face-to-face meeting held 4-5 October 2016 (EMA/CHMP/SWP/662977/2016)

Action: For information

Jan Willem Van der Laan, representing EMA at the EC conference on "Non-Animal Approaches – The Way Forward" to be held in Brussels on 6-7 December 2016

Action: For information

- Presentation - Conference Brussels 5th version 28-11-2016 (EXT/800590/2016)

Action: For information

Question and Answers on Implementation of risk based prevention of cross contamination in production and 'Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities' (EMA/CHMP/SWP/169430/2012)

Action: For adoption for 3 months public consultation

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

2.1.3. Scientific Advice Working Party (SAWP)

Chair: Robert Hemmings

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

Co-chair: Kaisa Immonen

PCWP Work plan 2017 (EMA/540720/2016)

Action: For adoption

Report from the PCWP/HCPWP workshop on social media held on 19 September 2016 (EMA/625077/2016)

Action: For information

Agenda for the training session for patients and consumers interested in EMA activities on 29 November 2016 (EMA/636824/2016)

Action: For information

Agenda for the PCWP meeting with all eligible organisations on 30 November 2016 (EMA/668397/2016)

Action: For information

2.1.5. European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP)

Co-chair: Gonzalo Calvo

HCPWP Work plan 2017 (EMA/493549/2016)

Action: For adoption

Report from the PCWP/HCPWP workshop on social media held on 19 September 2016 (EMA/625077/2016)

Action: For information

2.1.6. Geriatric Expert Group (GEG)

Chair: Niccolo Marchionni

2.1.7. Committees

Committee for Advanced Therapies (CAT): Draft Minutes of the November 2016 meeting (EMA/CAT/707323/2016)

Action: For information

CHMP Draft Work plan 2017 (EMA/CHMP/474618/2016)

Action: For discussion

2.1.8. International Council on Harmonisation (ICH)

ICH guideline Q11 on development and manufacture of drug substances (chemical entities and biotechnological / biological entities) – questions and answers, step 2b ((EMEA/CHMP/ICH/809509/206)

Action: For adoption for 3 months public consultation

Q3C (R6): Impurities: guideline for residual solvents, step 5 (EMA/CHMP/ICH/82260/2006)

Action: For adoption

Guideline for good clinical practice E6(R2), step 5, Integrated Addendum (EMEA/CPMP/ICH/135/95)

Action: For adoption

Report on meeting in Osaka – November 2016

- ICH report (EMA/807597/2016)

Action: For discussion

- ICH report (presentation)

Action: For information

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)

Acting Chair: Ellen-Margrethe Vestergaard

Revised mandate, objectives and rules of procedure for the joint CVMP/CHMP working group on the application of the 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (J3RsWG) (EMA/CHMP/CVMP/JEG-3Rs/442724/2012)

- Background note (EMA/624150/2016)
- JEG 3Rs progress report 2011-2016 (EMA/CHMP/CVMP/JEG-3Rs/498328/2016)

Action: For adoption

JEG 3Rs Work plan 2017 (EMA/CHMP/CVMP/JEG-3Rs/647540/2016)

Action: For adoption

Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches EMA/CHMP/CVMP/JEG-3Rs/450091/2012

- Background note (EMA/756897/2016)

Action: For adoption

2.1.10. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

Chair: Nienke Rodenhuis

2.1.11. Joint CVMP-CHMP antimicrobial advice ad hoc expert group (AMEG)

Chair: Gérard Moulin

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Martina Weise

BMWP Work plan 2017 (EMA/627104/2016)

Action: For adoption

Final minutes of BMWP meeting held on 02 September 2016 (EMA/687226/2016)

Action: For information

Final minutes of BMWP meeting held on 18 October 2016 (EMA/690775/2016)

Action: For information

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse/Ilona Reischl

Draft agenda for BWP face-to-face meeting to be held 16-18 January 2017 (EMA/CHMP/BWP/754304/2016)

Action: For information

Final minutes from face-to-face meeting held 3-5 October 2016 (EMA/CHMP/BWP/661858/2016)

Action: For information

BWP Work Plan 2017 (EMA/CHMP/BWP/612761/2016)

Action: For adoption

Update on Triton X-100 and REACH Regulation

Action: For information

Alan Fauconnier to represent BWP at IABS conference (International Alliance for Biological Standardization) on deep sequencing to take place on 27-28 October 2017 at the US Pharmacopeia, Rockville, MD

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell

VWP Work plan 2017 (EMA/654970/2016)

Action: For adoption

Final agenda of VWP held on 22-23 November 2016 (EMA/649282/2016)

Action: For information

Final minutes of VWP held via teleconference on 17 June 2016 (EMA/427229/2016)

Action: For information

Nomination of Květoslava Mlčochová (CZ) as an observer to VWP

- Current membership list

Action: For adoption

2.2.4. Blood Products Working Party (BPWP)

Chair: Anneliese Hilger

BPWP Work plan 2017 (EMA/CHMP/BPWP/583702/2016)

Action: For adoption

Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) (EMA/CHMP/BPWP/94033/2007 rev. 3) and related core SmPC (EMA/CHMP/BPWP/94038/2007 Rev. 5)

Action: For adoption for 3-months public consultation

Final Minutes of BPWP face-to-face meeting held on 16-17 November 2016 (EMA/CHMP/BPWP/753658/2016)

Action: For information

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

PGWP Work plan 2017 (EMA/CHMP/389037/2016)

Action: For adoption

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Draft agenda of CVSWP meeting to be held face-to-face on 23 November 2016 (EMA/703661/2016)

Action: For information

CVSWP Work plan 2017 (EMA/CHMP/639699/2016)

Action: For adoption

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

Draft agenda of CNSWP meeting to be held face-to-face on 2 December 2016 (EMA/731153/2016)

Action: For information

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/ Maria Jesus Fernandez Cortizo

IDWP Work plan 2017 (EMA/662804/2016)

Action: For adoption

Final agenda for IDWP held on 24 November 2016 (EMA/644649/2016)

Action: For information

Nomination of Shiva Ramroop (UK) as an observer to IDWP (EMA/828382/2010)

- Current membership list

Action: For adoption

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

ONCWP Work plan 2017 (EMA/633841/2016)

Action: For adoption

Final agenda for ONCWP held on 17 November 2016 (EMA/740268/2016)

Action: For information

Final minutes of ONCWP held on 05 October 2016 (EMA/754341/2016)

Action: For information

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Jan Welink representing CHMP at the 11th WRIB conference in California 3-7 April 2017

Action: For information

Appointment of Gustav Ahlin (SE) as additional expert to the PKWP

Action: For adoption

PKWP Work plan 2017 (EMA/CHMP/643117/2016)

Action: For adoption

Q&A CHMP request to PKWP for clarification on demonstrating bioequivalence of low dose acetylsalicylic acid gastro-resistant formulations in fixed dose combinations with substitution indication (EMA/CHMP/754380/2016)

Action: For adoption

Q&A Question on requirements for bioequivalence studies under fasting and fed conditions (general) (EMA/CHMP/805455/2016)

Action: For discussion

Q & A PKWP clarification on Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**); Appendix II section on oral solutions

Action: For adoption

Product-specific bioequivalence guidance Batch 4 – Final guidance

- Everolimus tablets 0.25, 0.5, 0.75 and 1mg; 2.5, 5 and 4 10mg, dispersible tablets 0.1 and 0.25mg; 2, 3 and 5mg 5 product-specific bioequivalence guidance (EMA/CHMP/154772/2016)
- Pazopanib film-coated tablet 200mg and 400mg product-specific bioequivalence guidance (EMA/CHMP/154805/2016)
- Levodopa/Carbidopa/Entacapone film-coated tablet 4 200mg/50mg/200mg, 175mg/43.75mg/200mg, 5 150mg/37.5mg/200mg, 125mg/31.25mg/200mg, 6 100mg/25mg/200mg, 75mg/18.75mg/200mg and 7 50mg/12.5mg/200mg product-specific bioequivalence 8 guidance (EMA/CHMP/162889/2016)
- Fingolimod capsules 0.5mg product-specific bioequivalence guidance (EMA/CHMP/154812/2016)
- Paliperidone prolonged-release tablets 1.5mg, 3mg, 6mg, 9mg and 12mg product-specific bioequivalence guidance (EMA/CHMP/154812/2016)

Action: For adoption

Product-specific bioequivalence guidance Batch 6:

- Crizotinib hard capsules 200 and 250 mg product-specific bioequivalence guidance
- Dabigatran etexilate hard capsules 75 mg, 110 mg and 150 mg product-specific bioequivalence guidance
- Elvitegravir, 85 and 150 mg product-specific bioequivalence guidance
- Elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil, film-coated tablets, 150 mg/150 mg/200 mg/245 mg product-specific bioequivalence guidance
- Emtricitabine/rilpivirine/tenofovir disoproxil, film-coated tablets, 200 mg/25 mg/245 mg product-specific bioequivalence guidance (EMA/CHMP/805532/2016)
- Vortioxetine - hydrobromide, 5, 10, 15, and 20 mg immediate release tablets; vortioxetine lactate, oral drops solution 20 mg/ml product-specific bioequivalence guidance (EMA/CHMP/474974/2016)

Action: For adoption for 3 months public consultation

Draft agenda for PKWP meeting to be held by Adobe on 5 December 2016 (EMA/747053/2016)

Action: For information

Final programme of the EMA workshop on qualification and reporting of physiologically-based pharmacokinetic (PBPK) modelling and simulation (EMA/128306/2016) held on 21 November 2016 (EMA/128306/2016)

Action: For information

2.3.6. Biostatistics Working Party (BSWP)

Chair: Vacant/Thomas Lang

BSWP Work plan 2017 (EMA/626873/2016)

Action: For adoption

Final minutes of BSWP meeting held on 29-30 September 2016 (EMA/646364/2016)

Action: For information

Draft Agenda for BSWP meeting to be held on 06 December 2016 (EMA/792259/2016)

Action: For information

Guideline on multiplicity issues in clinical trials (EMA/CHMP/720718/2016)

Action: For adoption for 6-months public consultation

- Presentation on multiplicity issues in clinical trials (EMA/813056/2016)

Action: For information

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

RIWP Work plan 2017 (EMA/646364/2016)

Action: For adoption

2.3.8. Scientific Advisory Groups (SAGs)

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Elmer Schabel

Call for nomination of a new Chairperson following end of mandate in February 2017

Action: For information

Nominations to be sent by 31 January 2017

Candidates should submit a brief résumé in support of their candidature.

Gastroenterology Drafting Group Work plan 2017 (EMA/CHMP/653568/2016)

Action: For adoption

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

RDG Work plan 2017 (EMA/CHMP/571474/2016)

Action: For adoption

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

Core SmPC and PL for nanocolloidal technetium (99mTc) albumin (EMA/CHMP/337958/2016)

Action: For adoption

- Overview of consultation with OncWP and of comments received by EMA Paediatric team

Action: For information

Core SmPC and PL for iopamidol 300 (EMA/25459/2016)

Action: For adoption for 4-months public consultation

Core SmPC and PL for iopamidol 370 (EMA/25460/2016)

Action: For adoption for 4-months public consultation

Core SmPC and PL for fluorodopa (18F) (EMA/CHMP/337958/2016)

Action: For adoption

- Overview of comments received (EMA/CHMP/758629/2016)

Action: For information

RadDG Work plan 2017 (EMA/CHMP/633868/2016)

Action: For adoption

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

Excipients drafting group Work plan 2017 (EMA/CHMP/750448/2016)

Action: For adoption

Final minutes of the Excp DG held via teleconference on 28 September 2016 (EMA/655812/2016)

Action: For information

Information in the package leaflet for aspartame in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/134648/2015)

Action: For adoption

- Overview of comments received (EMA/CHMP/581993/2016)

Action: For information

Information in the package leaflet for fructose and sorbitol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/460886/2014)

Action: For adoption

- Overview of comments received (EMA/CHMP/581887/2016)

Action: For information

Information in the package leaflet for phosphates in eye drops in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/632775/2016)

Action: For adoption

Document prepared in reference to the 'Questions and answers on the use of phosphates in eye drops' (EMA/CHMP/753373/2012)

Information in the package leaflet for fragrance allergens in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/273718/2014)

Action: For adoption

- Overview of comments received (EMA/CHMP/579645/2016)

Action: For information

Questions and answers on propylene glycol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/704195/2013)

Action: For adoption

- Overview of comments received (EMA/CHMP/157147/2015)

Action: For information

- Background report (EMA/CHMP/334655/2013)

Action: For information

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF Briefing Meeting
Meeting date: 13 December 2016

Action: For discussion and agreement

ITF briefing meeting
Meeting date: 13 December 2016

Action: For discussion and agreement

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Barbara van Zwieten-Boot

2.3.10.3. IPRF Nano Working Group

Chair: Harald Enzmann/Jean Louis Robert

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

3.1.1. Update of the procedural documentation on Article 58 applications

Revision of the procedural guideline on Article 58 applications and related application forms

- Application forms (EMA/619738/2016), (EMA/619737/2016)
- Presentation (EMA/747762/2016)
- Pre and Post “Article 58” scientific opinions procedural advice for users (EMA/534107/2008)

Action: For discussion

3.1.2. Best practice guide on measures improving predictability of submissions and adherence to communicated submission deadlines (EMA/760652/2016)

Action: For discussion

3.1.3. ATMP guideline on safety and efficacy follow-up and risk management

Follow-up from April ORGAM meeting, where the CHMP agreed on the guideline revision

Action: For discussion

3.2. Meeting organisation / templates

3.3. Pharmacovigilance

4. Any Other Business