13 February 2017
EMA/CHMP/105294/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 13 February 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

13 February 2017, 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. 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 CxMP <meeting highlights> <meeting reports> once the procedures are finalised and start of referrals will also be available.

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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1.2. Adoption of agenda

CHMP ORGAM agenda for February 2017 meeting

2. Working Parties, Committees, SAGs and Drafting Groups

2.1. General

2.1.1. Safety Working Party (SWP)

Chair: Jan Willem Van der Laan

Draft agenda for WP/DG meeting to be held face-to-face on 14-15 February 2017 (EMEA/CHMP/SWP/85402/2017)

Action: For information

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Final Minutes of the 81st QWP face-to-face meeting held on 29 November – 1 December 2016 (EMA/CHMP/CVMP/QWP/797355/2016)

Action: For information

Draft Q/As on information on capsule shells and their components to be stated in the SmPC for dry powder inhalers (EMA/CHMP/QWP/83866/2017)

Action: For adoption

Draft Concept paper on revision of the guideline on the pharmaceutical quality of inhalation and nasal products (EMA/CHMP/QWP/83432/2017)

Action: For adoption for 3-month consultation

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

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

Co-chair: Gonzalo Calvo

2.1.6. Geriatric Expert Group (GEG)

Chair: Niccolo Marchionni

2.1.7. Committees

CHMP Draft Work plan 2017 (EMA/CHMP/67982/2017)

Action: For adoption

2.1.8. International Council on Harmonisation (ICH)

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

Overview of comments (EMA/CHMP/CVMP/JEG-3Rs/25975/2015) received on the guideline on regulatory acceptance of 3R (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012)

Action: For information

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

Minutes of BMWP meeting held by Adobe connect on 16 November 2016

Action: For information

Minutes of BMWP meeting held by Adobe connect on 10 January 2017

Action: For information

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse/Ilona Reischl

Nomination Maeve Lally as new member to BWP in replacement to Una Moore

Action: For adoption

Draft agenda for BWP face-to-face meeting to be held 13-15 February 2017 (EMA/CHMP/BWP/870331/2016)

Action: For information

Final minutes from face-to-face meeting held 5-7 December 2016 (EMA/CHMP/105294/2017)

Action: For information

Letter to CHMP - Further Revision of the European Pharmacopoeia monograph on Human plasma (pooled and treated for virus inactivation)

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/vacant

Call for nomination for Vice-chair of the Vaccines Working Party following resignation of Daniel Brasseur

Nominations, along with a short statement in support of candidature, should be sent by 31 March 2017. Election of vice-chair during April CHMP meeting

Action: For information

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017. VWP secretariat's proposal: Daniel Brasseur's involvement in VWP as additional expert

Action: For discussion

Participation of VWP Chair Mair Powell as CHMP representative in EMA-PMDA-FDA antimicrobial drug development meeting 26-27 April 2017 in Vienna, Austria

Action: For adoption

2.2.4. Blood Products Working Party (BPWP)

Chair: Anneliese Hilger

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

Draft agenda of BPWP meeting to be held on 17 February 2017

Action: For information

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017. Two additional experts will be proposed

Action: For discussion

Nomination of two new additional experts: Sir Munir Pirmohamed (UK) and Wilko Weichert (DE) to PGWP

Action: For discussion

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

Call for nomination of CVSWP core member following resignation of Karsten Bruins Slot

Nominations should be sent by 13th March 2017

Action: For information

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

Minutes of ONCWP meeting held by Adobe connect on 07 December 2016

Action: For information

Concept paper on a proposal to replace the reflection paper on the regulatory guidance for the use of health – related quality of life (HRQL) measures in the evaluation of medicinal products with a new PRO guideline

Action: For adoption for public consultation

Overview of GCG comments

Action: For information

Concept paper on the need to revise Condition – Specific guidance, Appendix 4 to the guideline on the evaluation of anticancer medicinal products in man on MRD as an endpoint in clinical studies in MM (EMA/102314/2017)

Action: For adoption for 3-months public consultation

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Nomination of new Swedish additional expert Anita Andersson to the PKWP

Action: For adoption

Product specific bio equivalence guidance, 5th batch final

- Abiraterone tablets 250 mg product-specific bioequivalence guidance (EMA/CHMP/474712/2016)
- Exenatide powder and solvent for prolonged-release suspension for injection 2 mg, and powder and solvent for prolonged-release suspension for injection in pre-filled pen 2 mg product-specific bioequivalence guidance (EMA/CHMP/474782/2016)
- Paliperidone palmitate depot suspension for injection 25 mg, 50 mg, 75 mg, 100 mg and 150 mg product-specific bioequivalence guidance (EMA/CHMP/474825/2016)
- Vandetanib film-coated tablets 100 mg and 300 mg product-specific bioequivalence guidance (EMA/CHMP/474883/2016)
- Vemurafenib film-coated tablets 240 mg product-specific bioequivalence guidance (EMA/CHMP/476248/2016)

Action: For adoption

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Minutes of BSWP meeting held by Adobe connect on 06 December 2016

Action: For information

Minutes of BSWP meeting held by Adobe connect on 16 November 2016

Action: For information

Minutes of BSWP meeting held by Adobe connect on 17 January 2017

Action: For information

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

2.3.8. Scientific Advisory Groups (SAGs)

The revised mandate and rules of procedure for SAGs and ad hoc expert groups

Action: For adoption

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Elmer Schabel

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

Concept paper on revision of the guideline on the requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of asthma and chronic obstructive pulmonary disease (COPD) in adults and for the treatment of asthma in children and adolescents (EMA/CHMP/267194/2016)

Action: For adoption for 3 month public consultation

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

Review of the composition of drafting groups and temporary working parties in view of goals to be achieved in 2017

Action: For discussion

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

Call for nomination of additional experts to contribute to revision of following excipients

- Dextrans (clinical)
- Maltose and sucrose (non-clinical + clinical)
- Maltodextrin (oral) (non-clinical + clinical)
- Polyethylene glycols and macrogols (non-clinical + clinical)
- Xylitol and maltitol (non-clinical + clinical)

Nominations should be sent

Action: For information

Minutes of ExcpDG meeting held face-to-face on 8-9 November 2016

Action: For information

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF briefing meeting Meeting date: 27 February 2017

Action: For discussion and agreement

ITF briefing meeting Meeting date: 13 March 2017

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. ATMP guideline on safety and efficacy follow-up and risk management (EMA/CHMP/65416/2016)

Action: For discussion

3.1.2. SmPC Advisory Group 2016 activity report

Action: For information

3.2. Meeting organisation / templates

3.2.1. CHMP Plenary and ORGAM meeting dates

CHMP Plenary meeting dates 2019-2021 (EMA/391620/2016)

Action: For adoption

CHMP ORGAM meeting dates 2019-2021 (EMA/CHMP/69637/2017)

Action: For adoption

3.3. Pharmacovigilance

3.3.1. Topic

4. Any Other Business

EU Network Regulatory Awareness Sessions for 2017

Action: For information