10 July 2017
EMA/CHMP/439826/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 10 July 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

10 July 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.

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1.1. Welcome and declarations of interest of members, alternates and experts

1.2. Adoption of agenda

CHMP ORGAM agenda for 10 July 2017 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of 10 July 2017 meeting will be adopted at the July 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

Concept paper on the development of a reflection paper on the non-clinical evaluation of radiopharmaceuticals (EMA/CHMP/SWP/545959/2016)

Action: For adoption for 3-month public consultation

Revised SWP Work plan 2017 (EMA/CHMP/SWP/615357/2016 Rev. 01)

Action: For adoption

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Call for nomination of Vice-Chair

CHMP Members, and QWP Members and Alternates are eligible for the position of QWP Vice Chairperson. Eligible experts, who wish to apply for the Vice Chairperson position are requested to submit a brief resume in support of their candidature together with a brief resume, highlighting the expertise.

Nominations should be sent to the EMA **by 13 July 2017.**

The Vice Chair will be elected by CHMP at the July meeting.

Action: For information

Minutes from QWP CT January – June 2017

January (EMA/13259/2017); February (EMA/88667/2017); March (EMA/160002/2017); April (EMA/220423/2017); May (EMA/279850/2017); June (EMA/350856/2017)

Action: For information

Joint GMP/GDP IWG & QWP letters to MAHs and Industry organisations regarding qualification of active substance manufacturers as required by Article 46 of Directive 2001/83 (as amended) and Article 50 of Directive 2001/82 (as amended)

Action: For adoption

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

Minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting (EMA/182189/2017)

Action: For information

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

Co-chair: Gonzalo Calvo

See also 2.1.4.

2.1.6. Geriatric Expert Group (GEG)

Chair: Niccolo Marchionni

2.1.7. Committees

CHMP 2017 Work Plan: mid-year update

Action: For information

2.1.8. International Council on Harmonisation (ICH)

ICH guideline E2B (R3) - questions and answers, step 5 (EMA/CHMP/ICH/3943/2003)

Action: For adoption

ICH guideline M7(R1) on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk, step 5 (EMA/CHMP/ICH/83812/2013)

Action: For adoption for 6 months public consultation

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 (J3RsWG)

Chair: Ellen-Margrethe Vestergaard, Co-Chair: Susanne Brendler-Schwaab

Nomination of J3RsWG members by working parties and election of co-opted members by core-members. Election of Chairperson and Vice chairperson by J3RsWG members consisting of core-members and co-opted members for a 3-year mandate

Action: For adoption

Background information: J3RsWG's mandate (EMA/CHMP/CVMP/JEG-3Rs/442724/2012); CV of co-opted member R. Woodland (EMA/273340/2017), K. Cussler (EMA/273339/2017), E.-M. Vestergaard (EMA/273338/2017), S. Beken (EMA/273341/2017)

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

Call for nomination of a new member following retirement of Ann Johnsson (SE)

Nominations should be sent **by 01 September 2017**.
Candidates should submit a brief résumé in support of their candidature. Nomination is going to take place at the September 2017 CHMP Plenary meeting. Candidates can also express an interest to become Vice-Chair of BMWP as election of Vice Chair is also scheduled at the September 2017 CHMP Plenary meeting.

Action: For information

Nomination of Teresa Bazantova (CZ) and Kirstine Moll Harboe (DK) as observers to BMWP

- Current membership list

Action: For adoption

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from face-to-face meeting held 10-11 May 2017
(EMA/CHMP/BWP/294715/2017)

Action: For information

Draft agenda for BWP face-to-face meeting to be held 4-6 September 2017
(EMA/CHMP/BWP/405311/2017)

Action: For information

Guideline on Influenza Vaccines – Quality Module

(EMA/CHMP/BWP/310834/2012)

Action: For adoption

Concept paper on the revision of the Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells (EMA/CAT/424191/2017)
Rapporteur: M. Timon

Action: For adoption

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Presentation of the revised guideline on clinical investigation of recombinant and human plasma-derived factor VIII products (EMA/CHMP/BPWP/392490/2017)

Revised guideline (EMA/CHMP/BPWP/392489/2017)

Core SmPC (EMA/CHMP/BPWP/392488/2017)

Action: For discussion

Revised Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) and related core SmPC

Action: For discussion

Final BPWP Agenda 29-30 June 2017

Action: For information

Draft BPWP Minutes 29-30 June 2017

Action: For information

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Concept paper on predictive biomarker-based assay development in the context of drug development and lifecycle (EMA/CHMP/240411/2017)

Rapporteur: Joerg Engelbergs / Shirley Hopper

Action: For adoption for 3 months public consultation

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Guideline on clinical investigation of medicinal products for the treatment of chronic heart failure (EMA/CHMP/760545/2016)

Rapporteur: Giuseppe Rosano, Pieter de Graeff

Action: For adoption

- Overview of comments

Action: For information

Guideline on clinical investigation of new medicinal products for the treatment of acute coronary syndrome (CPMP/EWP/570/98) (EMA/CHMP/760125/2016)

Rapporteur: Amany El Gazayerly, Joseph Emmerich

Action: For adoption

- Overview of comments

Action: For information

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

Draft minutes of the F2F meeting on 17 March 2017 (EMA/CHMP/187515/2017)

Action: For information

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address the clinical development of new agents to treat pulmonary disease due to Mycobacterium tuberculosis

Rapporteur: Mair Powell

Action: For adoption

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

Nomination of Marcela Vostarkova (CZ) as an observer to ONCWP

- Current membership list

Action: For adoption

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

CMDh Question to PKWP - BE studies for oral solutions – Administration with or without water (EMA/CHMP/364793/2017): PKWP response

Rapporteur: Sotiris Michaleas

Action: For adoption

Product-specific bioequivalence guidelines:

1. Ibuprofen 200 - 800 mg oral use, immediate release formulations product-specific bioequivalence guidance (EMA/CHMP/356876/2017)

   Rapporteur: Susan Cole

2. Dimethyl fumarate gastro-resistant capsules 120 mg and 240 mg product-specific bioequivalence guidance (EMA/CHMP/421315/2017)

   Rapporteur: Henrike Potthast

3. Tadalafil film-coated tablets 2.5 mg, 5 mg, 10 mg and 20 mg product-specific bioequivalence guidance (EMA/CHMP/315234/2014)

   Rapporteur: Alfredo Garcia-Arieta

4. Prasugrel film-coated tablets 5 and 10 mg product-specific bioequivalence guidance (EMA/CHMP/158772/2016)

   Rapporteur: Christina Thygesen Eltorp

Action: For adoption for 3 months public consultation

Draft minutes of the F2F meeting on 25-26 April 2017 (EMA/271894/2017)

Action: For information

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Nomination of Ann-Kristin Leuchs (DE) as an observer to BSWP

- Current membership list

Action: For adoption

Minutes of BSWP virtual meeting held on 13 June 2017 (EMA/325842/2017)

Action: For information

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

2.3.8. Scientific Advisory Groups (SAGs)

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Elmer Schabel

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

Guideline on core SmPC and Package Leaflet for (68Ge-68Ga) generator (EMA/313282/2017)

Action: For adoption

- Overview of comments 'Guideline on core SmPC and Package Leaflet for (68Ge68Ga)' (EMA/313283/2017)

Action: For information

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

Annex to the Guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'

Action: For adoption

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF Briefing Meeting

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. EU-US Mutual Recognition Agreement on GMP Inspections

Draft Q&As on impact of EU-USA Mutual Recognition Agreement on marketing authorisation applications and relevant variations

Presentation on MRA

Action: For information

3.1.2. Change to CHMP Rapporteur and Co-Rapporteur AR due date in first phase of initial MAA

CHMP Rapporteurs' Assessment Reports in the first phase of MAA are due on D80 of the procedure which is a Saturday. The ARs are often circulated on Monday (D82) and this contributes to a reporting of an arterially high number of delayed ARs. It is proposed (based on an HMA proposal endorsed by EMA management) to formally move the CHMP Rapporteurs' ARs to D82 (Monday).

Action: For adoption

3.2. Meeting organisation / templates

3.2.1. Pilot phase for abolition of signatures for divergent positions for referral procedures

The proposal is to start new process from September onwards.

Action: For information

3.2.2. Update to the CHMP templates on initial Marketing Authorisation

Update to the Rapporteurs' D80 AR overview guidance document to add guidance specific to biosimilars (including a revised Benefit/Risk balance section). When adopted, the changes will be implemented in all relevant templates on initial MA.

Action: For discussion and adoption

3.3. Pharmacovigilance

3.3.1. Re-examination of Art.31 Referral on Gadolinium containing contrast agents: Briefing CHMP on PRAC recommendations

Action: For discussion