16 July 2018
EMA/CHMP/492328/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 16 July 2018

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

16 July 2018, 09:00–12:30, 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 16 July 2018 meeting

1.3. Adoption of the minutes

CHMP Orgam Minutes of July 2018 meeting will be adopted at the July 2018 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

Call for nomination of a new SWP chairperson following the end of mandate of Jan Willem van der Laan in October 2018.

Nominations should be sent by **12th October 2018**

Interested candidates should send a cover letter and CV to the CHMP secretariat ahead of the deadline.

Action: For information

Final minutes for SWP meeting held by teleconference on 20 March 2018 (EMA/CHMP/SWP/180320/2018)

Action: For information

Final minutes for SWP meeting held by teleconference on 24 April 2018 (EMA/CHMP/SWP/265928/2018)

Action: For information

Final minutes for SWP meeting held by teleconference on 29 May 2018 (EMA/CHMP/SWP/366427/2018)

Action: For information

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Nomination of new core members to the QWP

• Abigail Moran (UK) – replacing Sean Jones

- Nomination Letter
- E-CV

• Maria Vassiliou (CY) – replacing Katerina Savvidou

- Nomination Letter
- E-CV

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: Katarina Vučić

No items

2.1.7. Committees

HMPC and QWP: Guideline on quality of herbal medicinal products /traditional herbal medicinal products, DRAFT Revision 3 (EMA/CPMP/QWP/2819/00 Rev. 3)

Action: For adoption for 3 months public consultation

HMPC and QWP: Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products /traditional herbal medicinal products, DRAFT Revision 3 (EMA/CPMP/QWP/2820/00 Rev. 3)

Action: For adoption for 3 months public consultation

SmPC Advisory Group: Proposal for the development of an eLearning product information review curriculum

Action: For discussion

Follow-up from June CHMP Plenary meeting

PDCO: Concept paper on the need for revision of the guideline on the investigation of medicinal products in the term and preterm neonate (EMA/PDCO/362462/2016)

Action: For adoption for public consultation

2.1.8. International Council on Harmonisation (ICH)

No items

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

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

2.1.12. Modelling and Simulation Working Party (MSWP)

Chair (acting): Kristin Karlsson/ Flora Musuamba Tshinanu

No items

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Niklas Ekman

Guideline on similar biological medicinal products containing recombinant granulocyte-colony stimulating factor (rG-CSF)(EMA/483392/2018 Rev 1)

Action: For adoption

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from May face-to-face meeting held 22-23 May 2018 (EMA/CHMP/BWP/327614/2018)

Action: For information

Draft agenda for BWP face-to-face meeting to be held 10-12 September 2018 (EMA/CHMP/BWP/450681/2018)

Action: For information

Industry/regulators BWP/QWP Workshop on quality support to early access approaches (PRIME), which is being planned to take place on 26 Nov 2018 at the EMA (in London).

The aim of this workshop is to discuss with industry quality challenges during development of PRIME designated products due to shortened timelines and to identify scientific and regulatory approaches which could facilitate preparation of robust quality data packages at the time of submission of the MAA.

This workshop is intended to cover all product classes (Chemical/biological/ATMP), in line with the PRIME-designated products, and it is also planned to involve SMEs and Big Pharma.

The workshop is being organised by an organising committee consisting of BWP, QWP, IWG experts and QoM colleagues. Five FDA colleagues representing chemical molecules, Biologicals and ATMPs have joined the organising committee and will also participate in the workshop.

The organising committee has prepared a first draft agenda (tabled), which has been endorsed by BWP, QWP and IWG, and would like to receive CHMP-ORGAM's agreement on this draft agenda in order to share it with industry stakeholders with the aim to invite case study proposals to be included under the respective scientific topics on the agenda.

Action: Draft agenda for agreement

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Kristin Karlsson

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products (EMA/CHMP/BPWP/144533/2009 rev. 2)

Action: For adoption

Core SmPC for human plasma derived and recombinant coagulation factor VIII products (EMA/CHMP/BPWP/1619/1999 rev. 2)

Action: For adoption

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: Kristina Dunder/Alar Irs

No items

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich/André Elferink

Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders Rev. 3 (EMA/CHMP/264942/2017)

Action: For adoption for 6-months public consultation

Rapporteur André Elferink via TC

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

No items

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

Guideline on the use of minimal residual disease as a clinical endpoint in multiple myeloma studies (EMA/CHMP/183565/2018)

Action: For adoption for 3 month public consultation

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

Product-specific bioequivalence guidelines, batch 8 (final guidelines):

- Agomelatine oral tablet 25 mg product-specific bioequivalence guidance, EMA/CHMP/800802/2017
- Cholic acid capsules 50 mg and 250 mg product-specific bioequivalence guidance, EMA/CHMP/800759/2017
- Posaconazole gastro-resistant tablet 100 mg product-specific bioequivalence guidance, EMA/CHMP/800785/2017
- Ledipasvir/sofosbuvir film-coated tablet 90 mg/400 mg product-specific bioequivalence guidance, EMA/CHMP/800789/2017
- Vismodegib hard capsule 150 mg product-specific bioequivalence guidance, EMA/CHMP/800794/2017

Action: For adoption

PKWP response to CMDh request on referral procedure vaginal ring

PKWP rapporteur: Sotiris Michaleas

Chair Jan Welink and Co-Chair Henrike Potthast will join

Action: For adoption

Jan Welink (Chair) representing CHMP at the 13th WRIB conference in New Orleans, LA, USA in April 1-5, 2019.

Action: For adoption

Final minutes of the PKWP F2F meeting held 17-18 April 2018 (EMA/247464/2018)

Action: For information

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

Creation of multidisciplinary drafting group for finalisation of "draft reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development" (EMA/CHMP/138502/2017) after public consultation

BSWP is seeking CHMP endorsement for the creation of a multi-disciplinary drafting group with members of BWP, BMWP, BSWP and QWP to finalise the draft reflection paper by the end of 2018.

Notes: The European Medicines Agency has published a reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development (EMA/CHMP/138502/2017), for a 1-year public consultation until 31 March 2018.

In total, 15 stakeholders provided extensive general and specific comments on the draft reflection paper comprising over 900 individual comments.

Further to the external consultation, the Agency held a multi-disciplinary scientific workshop with stakeholders from industry associations and international regulatory agencies on the

3rd and 4th of May 2018 to discuss comments received during the public consultation phase.

The organisation committee of the workshop - consisting of members of the BSWP, BMWP, BMWP, QWP - suggests that the finalisation of the reflection paper which touches upon quality, manufacturing, statistics, and methodology areas should be a shared responsibility between the respective working parties. BWP, BMWP, BSWP and QWP endorsed this proposal and will nominate a total of up to 10 working party members for the drafting group.

A finalisation of the reflection paper by the end of 2018 is envisaged with monthly and additional ad-hoc TCs planned as needed.

Action: For adoption

BSWP statement on Mahalonobis Distance (Original request from CMDh – input from PKWP and QWP) (EMA/810713/2017)

Action: For adoption

Nomination of new core member to BSWP

Following the resignation of one of the core members, BSWP opens a call for nomination of new core member.

Action: For adoption

Questions and Answers on Data Monitoring Committee issues (EMA/479382/2018)

The aim of this question-and-answer document is to supplement the CHMP Data Monitoring Committee Guideline (EMEA/CHMP/EWP/5872/03) by providing clarification on the role and necessity for a Data Monitoring Committee (DMC) in different phases of drug development and throughout the product lifecycle as well as with regard to the responsibilities for implementing DMC decisions.

Action: For adoption for 1-year public consultation

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

Final minutes for RIWP meeting held by teleconference on 15 May 2018 (EMA/294067/2018)

Action: For information

CMDh questions to RIWP and PKWP on Classification as Narrow Therapeutic Index (NTI) drug and advice on requirements for bioequivalence studies – colchicine (EMA/CMDh/455656/2018)

Action: For adoption

Concept paper on the need to develop a reflection paper on development of medicinal products to prevent and treat acute kidney injury (EMA/CHMP/171100/2018)

Action: For re-adoption for public consultation

This is a correction to add "reflection of ICH E9 addendum on estimands".

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 Answorth

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

Final minutes from June face-to-face meeting held 12-13 June 2018 (EMA/430398/2018)

Action: For information

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF Briefing Meeting

Meeting date: 5th September 2018

Action: For discussion and agreement

Minutes from the meeting held on 25th June 2018

Action: For information

Minutes from the meeting held on 14th March 2018.

Action: For information

Minutes from the meeting held on 16th March 2018.

Action: For information

Minutes from the meeting held on 20th March 2018.

Action: For information

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Barbara van Zwieten-Boot

Call for interest for a new Guideline Consistency Group Chair.

All GCG/CHMP/SAWP Members are eligible for the position of GCG Chairperson. Those who wish to apply for the Chairperson position are requested to submit a brief letter in support of their candidature together with a brief CV, highlighting the expertise.

Applications should be sent **by 17th July 2018**. Elections will take place at the July 2018 CHMP Plenary.

Action: For information

2.3.10.3. IPRF Nano Working Group

Chair: Harald Enzmann/Jean Louis Robert

No items

3. Organisational, regulatory and methodological matters

3.1. Meeting organisation / templates

3.1.1. Final Rapporteur Assessment Report templates for Initial MAA and Generics applications

Follow-up from 22 March 2018 presentation and request for CHMP comments

Final track-changes documents following implementation of CHMP and PRAC members comments

Action: For information

4. Any Other Business

4.1. Community Interests - Referral under Article 31 of Directive 2001/83/EC

4.1.1. Valsartan-containing medicinal products - EMEA/H/A-31/1471

MAHs: various

Rapporteur: TBC, Co-Rapporteur: TBC,

Scope: Start of procedure, list of questions, timetable, appointment of Rapporteurs

Action: For adoption

Referral notification from EC