5 June 2018
EMA/CHMP/324079/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] agenda for the meeting on 22 May 2018

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

22 May 2018, 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. Agenda and Minutes

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

1.2. Adoption of agenda

CHMP ORGAM agenda for 22 May 2018 meeting

1.3. Adoption of the minutes

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

Nomination of Bill Vestergaard as temporary Danish SWP member until Q2/Q3 2019 replacing Louise Lauritsen

Action: For adoption

CMDh Question to SWP on “diethanolamine” and “coconut oil diethanolamine condensate” as excipients (EMA/CMDh/270149/2018)

- Background note (EMA/CMDh/270137/2018)

Action: For adoption

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Nomination of a new alternate member to the QWP

- Nomination Letter Kevin Gauci (MT)
- E-CV – Kevin Gauci (MT)

Action: For adoption

2.1.3. Scientific Advice Working Party (SAWP)

Chair: Robert Hemmings

CMDh questions to SAWP on multi-stakeholder scientific advice for OTC products (EMA/CMDh/296507/2018)

Action: For adoption

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

No items

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, Co-Chair: 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

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Niklas Ekman

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from March face-to-face meeting held 12-14 March 2018 (EMA/CHMP/BWP/164017/2018)

Action: For information

Draft agenda for BWP face-to-face meeting to be held 18-20 June 2018 (EMA/CHMP/BWP/261425/2018)

Action: For information

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Nomination of additional assessor to VWP

Action: For adoption

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

BPWP final response on signal of lupus like syndrome for immunoglobulins to PRAC

Action: For adoption

Nomination of Spanish member to BPWP (to replace Nuria Prieto): Antonio Gómez-Outes
Action: For adoption

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Programme of EMA multi-stakeholder workshop on predictive biomarker-based assay development in the context of drug development and lifecycle (EMA/136048/2018): Scheduled on 18 June 2018, meeting room 3A

Action: For information

Draft minutes for the F2F meeting on 16-17 October 2017 (EMA/CHMP/269258/2018)

Action: For information

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Kristina Dunder/Alar Irs

Nomination of additional assessor to CVSWP

- CV and DoI
- Nomination email

Action: For adoption

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich/André Elferink

Nomination of a new core member to CNSWP

Action: For adoption

Draft minutes for the Adobe meeting on 6 December 2017 (EMA/813560/2017)

Action: For information

Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders (CHMP/EWP/566/98 Rev.3)

Rapporteur: Andre Elferink

Action: For adoption for 6 months public consultation

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Maria Jesus Fernandez Cortizo

Concept paper on preparation of a revised guideline on the evaluation of medicinal products indicated for treatment of bacterial infections (EMA/CHMP/75653/2018)

Presented by Mair Powell

Action: For adoption for 3 months public consultation

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

No items

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

Draft minutes of the Adobe meeting on 19 December 2017 (EMA/844924/2017)

Action: For information

Product-specific bioequivalence guidelines:

- Prasugrel hydrochloride film-coated tablets 5 mg and 10 mg product-specific bioequivalence guidance (EMA/CHMP/158772/2016/Rev.1) (batch 2)
  Rapporteur: Christina Thygesen
- Dabigatran etexilate hard capsules 75 mg, 110 mg and 150 mg product-specific bioequivalence guidance (EMA/CHMP/805498/2016) (batch 6)
  Rapporteur: Christina Thygesen
- Dimethyl fumarate gastro-resistant capsules 120 mg and 240 mg product-specific bioequivalence guidance (EMA/CHMP/421315/2017) (batch 7)
  Rapporteur: Henrike Potthast
- Ibuprofen 200 - 800 mg oral use, immediate release formulations product-specific bioequivalence guidance (EMA/CHMP/356876/2017) (batch 7)
  Rapporteur: Susan Cole
- Paliperidone prolonged-release tablet 1.5 mg, 3 mg, 6 mg, 9 mg and 12 mg product-specific bioequivalence guidance (EMA/CHMP/154812/2016) revision 1 (batch 4)
  Rapporteur: Eva Berglund/ Malin Filler
- Pegylated liposomal doxorubicin hydrochloride 2 mg/ml product-specific bioequivalence guidance (batch 8)
  Rapporteur: Henrike Potthast

Action: For adoption

Product-specific bioequivalence guidelines, batch 9:

- Aliskiren film-coated tablet 150 mg and 300 mg product-specific bioequivalence guidance (EMA/CHMP/205608/2018)
  Rapporteur: Janet Mifsud
- Apixaban film-coated tablets 2.5 and 5 mg product-specific bioequivalence guidance (EMA/CHMP/205609/2018)
  Rapporteur: Carolien Versantvoort
- Gefitinib film-coated tablet 250 mg product-specific bioequivalence guidance (EMA/CHMP/210963/2018)

Rapporteur: Eva Berglund/ Malin Filler

- Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance (EMA/CHMP/257298/2018)
  Rapporteur: Eva Berglund/ Malin Filler
- Octreotide acetate depot powder and solvent for suspension for injection 10 mg, 20 mg or 30 mg product-specific bioequivalence guidance (EMA/CHMP/291571/2018)
  Rapporteur: Susan Cole

Action: For adoption for public consultation

PKWP response to CMDh request for clarification on paliperidone PR tablets PSBGL (EMA/CHMP/277265/2018)

Action: For adoption

Rapporteur: Eva Gil-Berglund/Malin Filler

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

No items

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

Draft Minutes for the plenary meeting on 08-09 March 2017 (EMA/180675/2017)

Action: For information

Call for nomination of a new core member to RIWP

One new member is envisaged, for the development of a “Concept paper on development strategies for allergen products intended for allergies with low prevalence” experts with regulatory and/or clinical expertise for this topic are sought.

Please send the nominations to the Agency by **22nd June 2018**.

Action: For information

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

Draft minutes for the teleconference meeting on 2 February 2018 (EMA/70884/2018)

Action: For information

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

Final minutes for the F2F meeting on 12-13 October 2017 (EMA/680179/2017)

Action: For information

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

Draft agenda for face-to-face meeting on 12-13 June 2018

Action: For information

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

No items

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

3.1.1. PRAC and CHMP involvement in type II variations

Action: For discussion

A proposal for an initiative is brought to the PRAC to create a working group of PRAC and CHMP members. The purpose of the group is to clarify the two committees' involvement in type II variations, in order to address issues encountered in the experience to date, most notably the lack of PRAC involvement in PRAC-requested variations (e.g. following signals,

PSURs, other PRAC recommendations) or in the assessment of NI PASS results with implications for the PI.

Nomination of PRAC and CHMP representatives for the initiative.

3.2. Meeting organisation / templates

No items

3.3. Pharmacovigilance

No items

4. Any Other Business

4.1.1. Analysis of the outcome of the 2016-2017 GCP inspection programme

Action: For information