13 September 2019
EMA/CHMP/447252/2019 Corr. 1[1]
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[2] minutes for the meeting on 15 April 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

15 April 2019, 09:30-12:30, room 0-F

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 the minutes is considered commercially confidential or sensitive and therefore not disclosed.

Of note, the minutes are a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes 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] Correction to section 2.1.6.
[2] 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

The CHMP ORGAM agenda for 15 April 2019 meeting was adopted.

1.3. Adoption of the minutes

CHMP Orgam Minutes of April 2019 meeting will be adopted at the April 2019 CHMP plenary.

2. Working Parties, Committees, SAGs and Drafting Groups

2.1. General

2.1.1. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan

No topics

2.1.2. Quality Working Party (QWP)

Chair(s): Keith Pugh/Blanka Hirschlerova

No topics

2.1.3. Scientific Advice Working Party (SAWP)

Co-Vice-Chairs: Peter Mol/Kolbeinn Gudmundsson

No topics

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

Co-chair: Kaisa Immonen

Call for nomination of one CHMP representative (and alternate) to the PCWP.

EMA Human Scientific Committees are invited to nominate representatives for the period covering June 2019 to May 2022. The current CHMP representatives in PCWP are Prieto Yerro and Harald Enzmann.

Proposals for nomination should be sent **by 15 May 2019**.

The first meeting under the new 3-year mandate is scheduled on 5 June 2019 (2-4pm CET) and will be a joint PCWP-HCPWP meeting.

The CHMP noted the call for nomination.

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

Co-chair: Gonzalo Calvo

Presented by EMA

Call for nomination of one CHMP representative (and alternate) to the HCPWP (can be the same person as for PCWP)

EMA Human Scientific Committees are invited to nominate representatives for the period covering June 2019 to May 2022. The current CHMP representative in HCPWP is Fatima Ventura.

Proposals for nomination should be sent **by 15 May 2019**.

The first meeting under the new 3-year mandate is scheduled on 5 June 2019 (2-4pm CET) and will be a joint PCWP-HCPWP meeting.

The CHMP noted the call for nomination.

2.1.6. Geriatric Expert Group (GEG)

No topics

2.1.7. Committees

No topics

2.1.8. International Council on Harmonisation (ICH)

- ICH MC Interim meeting update (presentation by EMA)

  Action: For information

  The CHMP was informed on the topics proposed for decision at the June 2019 ICH meeting in Amsterdam.

  In the context its training activities, ICH is looking for consultants to be contracted by ICH to become ICH Training Associates and assist ICH in addressing training needs for their Regulatory and Industry members and observers. CHMP members were asked, through their respective NCAs, to convey the message to any accredited training organisation/institution that would meet the criteria highlighted in the topic presentation. The deadline to apply as ICH Training Associates is 5th May. Subsequent calls will be issued at a later date.

- Draft ICH E8 (R1) step 2b – guideline on Revision on General Considerations for Clinical Trials (Presentation by A. Kirisits and EMA)

  Action: For adoption (5 months public consultation)

  ICH E8 was modernised to:

- Incorporate the most current concepts achieving fit-for-purpose data quality as one of the essential considerations for all clinical trials;
- Identify a basic set of critical-to-quality factors that can be adapted to different types of trials to support the meaningfulness and reliability of trial results and to protect human subjects;
- Address a broader range of trial designs and data sources (e.g. basket trials, umbrella trials, adaptive designs, prospective RCTs, observational studies… and data sources – eCRFs, EHRs, registries, RWE …)

The revision of ICH E8 will be followed by the renovation of ICH E6.
The CHMP adopted the draft guideline. The document will be now published for a 5-months public consultation period.

- ICH E19 – draft guideline on Optimisation of Safety Data Collection (Presentation by P. Mol)

Action: For information

The critical aspects of the guideline were highlighted. Regulators are invited to give input to the guideline (which is still under public consultation) until 29 September 2019.

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 topics

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

Chair: Nienke Rodenhuis

No topics

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

Chair: Gérard Moulin

No topics

2.1.12. Modelling and Simulation Working Party (MSWP)

Chair: Kristin Karlsson/Flora Musuamba Tshinanu

No topics

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair(s): Elena Wolff-Holz/Niklas Ekman

No topics

2.2.2. Biologicals Working Party (BWP)

Chair(s): Sol Ruiz/Nanna Aaby Kruse

- Final minutes of the BWP plenary meeting held on 21-23 January 2019
- Final minutes of the BWP plenary meeting held on 18-20 February 2019
- Draft agenda of the BWP plenary meeting to be held on 15-16 April 2019

  Action: For information

  The CHMP noted the documents.
- Nomination of an alternate for PT

  Action: For adoption

  The CHMP agreed on the nomination of Ângelo da Silva as the alternate member for PT.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell

No topics

2.2.4. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr

- Proposal for drafting a reflection paper on the clinical requirements for Tissue factor pathway inhibitor (TFPI) products indicated for Haemophilia

  Action: For discussion

  BPWP proposed to start an internal guidance on the clinical development of novel haemophilia products (such as TFPI) and as soon as possible (BCP permitting) make it an external guideline with BPWP drafting group with involvement of SAWP, CHMP and PDCO members.

  CHMP noted the ongoing scientific discussions in this space. It was agreed to start working on an internal document summarising the issue with BPWP, SAWP and CHMP members.
- Nomination of an additional expert for NL

  Action: For adoption

The CHMP agreed on the nomination of Marijke Van Den Berg as an additional expert to BPWP.

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair(s): Krishna Prasad/Markus Paulmichl

No topics

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair(s): Kristina Dunder/Alar Irs

No topics

2.3.2. Central Nervous System Working Party (CNSWP)

Chair(s): Karl Broich/André Elferink

No topics

2.3.3. Infectious Diseases Working Party (IDWP)

Chair(s): Maria Jesus Fernandez Cortizo

No topics

2.3.4. Oncology Working Party (ONCWP)

Chair(s): Pierre Demolis/Paolo Foggi

Nomination of two new core members following Bertil Jonsson's (SE) and Sinan Bardakci Sarac's (DK) resignations as members.

Nominations received:

Action: For information

The CHMP noted the candidates. The nomination was postponed to the May ORGAM.

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair(s): Jan Welink/Henrike Potthast

- PKWP Q&A for CMDh request on PK characteristics of iron products – acceptable bridging/bioequivalence data

  The Q&A had been adopted in March but the wording was slightly reviewed after the March meeting for clarification purpose. The document is presented for re-adoption.

  Rapporteur: Janet Mifsud

  Action: For adoption

The CHMP adopted the revised Q&A.

- Guideline on equivalence studies for the demonstration of therapeutic equivalence for locally applied, locally acting products in the gastrointestinal tract (CPMP/EWP/239/95 Rev. 1, Corr.1*)

  Corrigendum: On page 4, section 3, EC regulations No 1084/2003 and No 1085/2003 have been replaced with regulation (EC) No 1234/2008.

  Action: for information

  The CHMP noted the corrigendum.

- Etonogestrel and ethinylestradiol vaginal delivery system 0.12mg/0.015mg/day product-specific bioequivalence guidance (EMA/CHMP/97470/2019)

  Draft for 3 month public consultation

  Action: for adoption

  PKWP's recommendation is that the bioequivalence should be demonstrated for 28 days. The CHMP adopted the guidance for a 6-month public consultation.

- Call for nomination for two new PKWP members:

  The following expertise areas need to be filled as a result of the departure of Eva Gil-Berglund (SE). These should be special expertise areas in addition to general PK and/or biopharmaceutics:

  - PBPK modelling
  - Drug-Drug interactions

  Nominations received:

  Action: For adoption

  The CHMP nominated Elin Lindhagen as a PKWP member replacing Eva Gil-Berglund.

- Nomination of an additional assessor

  Action: For adoption

  The CHMP agreed on the nomination by the Swedish NCA of Erika Fredriksson as additional assessor to PKWP.

2.3.6. Biostatistics Working Party (BSWP)

Chair(s): Anja Schiel/Jörg Zinserling

No topics

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair(s): Jan Mueller-Berghaus/Romaldas Mačiulaitis

No topics

2.3.8. Scientific Advisory Groups (SAGs)

No topics

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No topics

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No topics

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

No topics

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

No topics

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF Meeting

Action: For adoption

The CHMP agreed on the meeting.

ITF Meeting

Action: For adoption

The CHMP agreed on the meeting.

ITF Meeting

Action: For adoption

The CHMP agreed on the meeting.

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Aranzazu Sancho-Lopez

No topics

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

3.1.1. Creation of a group on the use, misuse and abuse of opioids

Presented by EMA

Action: For information

EMA informed the CHMP of the intention to set up a group on the use, misuse and abuse of opioids to begin working on monitoring and preparedness with the aim of preventing a dependence crisis in EU. EMA, its committees and CMDh will collaborate with relevant European bodies and institutions involved in public health activities. International liaisons will be established.
CHMP members who are interested to join the group can express their interest via email.
Experience with Regulation (EC) No 847/2000 - assessment of similarity vis-à-vis orphans

Presented by EMA

Action: For discussion

EMA presented an overview of the experience gained with the assessment of similarity and derogation by the CHMP since the introduction of the Orphan legislation. EMA proposed the nomination of one or more CHMP sponsors to look at the findings and proposals.
Sol Ruiz volunteered as CHMP sponsor.

The CHMP agreed with EMA going ahead with the assessor's training on similarity assessment scheduled in May 2019.
A CHMP speaker is requested to present concrete case studies at the training.

EMA will inform the rapporteurs of the cases that will be used as examples during the training so that they have the opportunity to comment.

The formation of a dedicated group will be discussed at the May ORGAM

3.2. CHMP organisation / templates

3.2.1. Continuous improvement of CHMP work - Feedback and actions from consultation of CHMP members on CHMP organisation

Presented by Harald Enzmann

Action: For information

The chair presented the remaining topic for improvement identified during his one-to-one TCs with CHMP members: transparency.

3.2.2. Remuneration of multinational teams for post-authorisation activities

Presented by Fátima Ventura

Action: For information

3.2.3. Proposal to go paperless for oral explanations at CHMP

Presented by CHMP Secretariat

Action: For information

The CHMP secretariat proposed to go paperless for oral explanations at CHMP. Several committees have already stopped requesting printed presentations from companies.

The CHMP agreed to give it a try provided presentations are available before the OE starts. The secretariat will provide help as needed.

3.2.4. Initiative for an earlier assessment of Annex II

Presented by EMA

Action: For information

The CHMP was informed of the EMA initiative for an earlier assessment of information on conditions, obligations and RMMs to be included in Annex II of the product information. Guidance will be given to applicants in the revised QRD template to help them presenting a draft Annex II at the start of the procedure and an implementation plan will also be available. This will help to assess Annex II as part of the MAA evaluation and optimise the timelines for discussions on post-approval commitments.

3.2.5. Call for nomination for one CHMP co-opted member

Presented by EMA: CHMP Secretariat

Agreed area of expertise: expertise in biostatistics, principally on clinical trial methodology, and at least basic knowledge of the EU regulatory framework

Nominations to be sent **by 15 April 2019 end of business**.

The election will take place during the April 2019 CHMP plenary meeting.

Action: For information

The CHMP were reminded about the ongoing call for nomination and encouraged to submit proposals until CHMP week. The deadline was thus extended to 26 April 2019 end of business.

3.2.6. CHMP meeting in April 2020

Presented by EMA: CHMP Secretariat

Committee meeting dates 2019-2021 (EMA/391620/2016)

Action: For information

The CHMP was informed that in 2020, the CHMP April meeting will take place from 28 to 30 April. This is very likely to be a full 3-day meeting to compensate for its shortened duration.

3.2.7. CHMP Strategic Review and Learning Meeting (SRLM) – 7-8 May 2019, Budapest

Update on the HTA session at the SRLM in Budapest: Exchange with HTA bodies and Payers on the identification of the patient population in the SmPC and underlying assessment reports

Presented by EMA

Action: For information

The CHMP was updated on the plans regarding the HTA session that is aiming at promoting a dialogue between HTA, payers and CHMP on labelling and assessment reports.

3.2.8. Procedures involving SmPC section 4.2 changes for discussion at CHMP

Presented by Paula van Hennik

Action: For discussion

4. Any Other Business

No topics

5. List of participants

CHMP Chair:

Harald Enzmann

CHMP members:

Bruno Sepodes (Vice-Chair)

Agnes Gyurasics

Alexandre Moreau

Andrea Laslop

Bjorg Bolstad

Constantinos Markopoulos

Ewa Balkowiec Iskra

Frantisek Drafi

Jayne Crowe

Johann Lodewijk Hillege

Kristina Dunder

Maria Concepcion Prieto Yerro

Outi Mäki-Ikola

Sinan B. Sarac

CHMP alternate members:

Christophe Focke

Dana Gabriela Marin

Fátima Ventura

Janet Koenig

Milena Stain

Nithyanandan Nagercoil

Paula Boudewina van Hennik

Selma Arapovic Dzakula

Tuomo Lapveteläinen

Experts:

Andreas Kirisits

Henrike Potthast

Jan Welink

Keith Pugh

Kristina Bech Jensen

Milena Peraita Ezcurra

Peter Mol

Pierre Demolis

Sabine Mayrhofer

The meeting was run with support from the relevant EMA staff