3 July 2018
EMA/CHMP/442690/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes of the meeting on 18 June 2018

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

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. 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 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 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] 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 18 June 2018 meeting was adopted.

1.3. Adoption of the minutes

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

Final minutes for SWP face-to-face meeting on 13-14 February 2018 (EMA/CHMP/SWP/101516/2018)

Action: For information

The CHMP noted the final minutes.

SWP report on anaesthetics and sedatives in young children and pregnant women (EMA/CHMP/SWP/172599/2018)

Action: For adoption

The SWP report was presented. The SWP conclusion related to SmPC sections 5.3 and 4.6. It was agreed to give some time to members to reflect and in case there are no comments the report is considered adopted next week at the June plenary meeting. The report will be sent to PRAC and CMDh.

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Minutes from QWP Core team from January to May 2018:

Minutes of January (EMA/6919/2018); Minutes of February (EMA/76839/2018); Minutes of March (EMA/140220/2018); Minutes of April (EMA/227324/2018); Minutes of May (EMA/270742/2018)

Action: For information

The CHMP noted the minutes.

Guideline on the quality of water for pharmaceutical use (EMA/CHMP/CVMP/QWP/383481/2018)

Action: For adoption for 6 months public consultation

The guideline is intended to provide guidance to the industry on the pharmaceutical use of different grades of water in the manufacture of active substances and medicinal products for human and veterinary use and should be considered for new marketing authorisation applications, as well as any relevant variation application to existing marketing authorisations.

The CHMP adopted the guideline for 6 months public consultation.

Nomination of new QWP Core Team member – Laivi Saaremäel (replacing Jean-Louis Robert)

Action: For adoption

The CHMP appointed QWP new Core Team member – Laivi Saaremäel.

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

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, CoChair: Susanne Brendler-Schwaab

Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken (EMA/CHMP/CVMP/3Rs/677407/2015)

Action: For adoption

- Background note for CHMP - J3RsWG - Review of EMA GLs considering 3Rs - report on actions taken (EMA/292206/2018)

  Action: For information

- Overview of comments received - JEG 3Rs - best practise (EMA/CHMP/CVMP/3Rs/731086/2016)

  Action: For information

In February 2014 CHMP and CVMP published a joint concept paper announcing a review and update of EMA guidelines to implement best practice with regard to 3Rs. The purpose of the review was not to reconsider established testing requirements but, rather, to ensure that EMA guidelines do not make reference to animal tests that are no longer considered appropriate. The CHMP and CVMP working parties involved in animal tests subsequently undertook a review of the relevant guidelines with a view to implement best practice towards the 3Rs. Following the public consultation each working party was requested to review the status, hence the significant time gap between the end of the public consultation and the presentation of the document for adoption. In addition, the working parties decided to make some updates to reflect the status of the guidelines in 2017/2018 to ensure stakeholders were in receipt of the most recent information once the document is published.

At their May meeting, CVMP discussed the “Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken” (EMA/CHMP/CVMP/3Rs/677407/2015) and overview of comments (EMA/CHMP/CVMP/3Rs/731086/2016), and minor amendments were introduced to the best practice document. CVMP is expected to adopt both documents at the June (19-21) CVMP meeting.

The CHMP noted the background note and overview of comments received. The CHMP adopted the document.

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): 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 non-clinical and clinical development of similar biological medicinal products containing recombinant erythropoietins (EMEA/CHMP/BMWP/301636/2008 Corr.*)

Action: For adoption

There was a technical update in the guideline to reflect current best practise with regard to implementation of 3Rs approaches and it is not intended as a full revision of this guideline (only section 4.1 is affected). These changes are considered to be minor and uncontroversial and consequently a consultation phase was considered unnecessary.

The CHMP adopted the guideline.

Guidance on similar medicinal products containing somatropin (EMEA/CHMP/BMWP/94528/2005)

Action: For adoption

There was a technical update in the guideline to reflect current best practise with regard to implementation of 3Rs approaches and it is not intended as a full revision of this guideline (only section 4.1 is affected). These changes are considered to be minor and uncontroversial and consequently a consultation phase was considered unnecessary.

The CHMP adopted the guideline.

2.2.2. Biologics Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from April face-to-face meeting held 16-18 April 2018 (EMA/CHMP/BWP/243354/2018)

Action: For information

The CHMP noted the final minutes.

Draft agenda for BWP face-to-face meeting to be held 16-18 July 2018 (EMA/CHMP/BWP/333696/2018)

Action: For information

The CHMP noted the draft agenda.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

No items

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

BPWP virtual meeting 14th June 2018: agenda (EMA/CHMP/BPWP/345658/2018) and timeschedule (EMA/CHMP/BPWP/395902/2018)

Action: For information

The CHMP noted the agenda and timeschedule for BPWP virtual meeting 14th June 2018.

Draft Agenda – EMA-FDA-HC Blood Cluster teleconference 14th June 2018 (EMA/374189/2018)

Action: For information

The CHMP noted the draft agenda.

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

Rapporteur: Jacqueline Kerr

Action: For adoption

Postponed to June Plenary

Haemophilia registries workshop: Final agenda (EMA/138425/2018) and presentations

Action: For information

The CHMP noted the final agenda and presentations from the Haemophilia registries workshop held on 8th June 2018.

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

No items

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

No items

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

Draft PKWP Q&A on Appendix I of the modified release guideline (EMA/CPMP/EWP/280/96 Corr1; clarification on sensitisation and irritation test for transdermal products) (EMA/CHMP/365909/2018)

Rapporteur: Henrike Potthast

Action: For adoption

The CHMP adopted the Question and Answer document.

CMDh question to PKWP/MSWP on Perlinring 0.015mg/0.12mg/ 24 hours Vaginal Delivery System - UK/H/6234/001/DC (EMA/CMDh/379205/2018):

- Background information (EMA/398716/2018)

Action: For information

Rapporteur: Sotiris Michaleas

Action: For adoption

The CHMP adopted the questions from CMDh.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Jörg Zinserling

Call for nomination of a new core member to BSWP

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

Please send the nominations to the Agency **by 10th July 2018**. Eligible experts, who wish to apply for the member position are requested to submit a brief letter in support of their candidature together with a brief CV, highlighting their expertise.

Action: For information

The CHMP noted the call.

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

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

The CHMP noted the call.

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)

Rapporteur: Romaldas Mačiulaitis

Action: For adoption for 3 months public consultation

The concept paper was presented by Romaldas Mačiulaitis. Regulatory and scientific experience in the field of acute kidney injury (AKI) from some of these activities provides the opportunity to summarise and consolidate agreed scientific advice in a guidance for development of medicinal products in various AKI settings.

The reflection paper intends to include discussion of and recommendations for the requirements for evaluation and development of medicinal products for the prevention and/or treatment of AKI and its long-term complications. Relevant topics for discussion include patient populations, endpoints, study methodology and study duration.

The CHMP agreed that BSWP should be involved.

The CHMP adopted the concept paper for 3 months public consultation.

2.3.8. Scientific Advisory Groups (SAGs)

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth,

To be presented by Mark Ainsworth and Peter Szitanyi (paediatric part)

Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis (CHMP/EWP/18463/2006) Rev.1

Action: For adoption

- Overview of comments received on ''Draft guideline on the development of new medicinal products for the treatment of Ulcerative Colitis' (EMA/CHMP/EWP/18463/2006 Rev. 1) EMA/CHMP/354664/2017

  Action: For information

Mark Ainsworth and Peter Szitanyi presented the 1st revision of the Guideline on the development of new medicinal products for the treatment of ulcerative colitis. The main aim of this 1st revision was to update the guidance on the design of studies in adult patients, especially on potential claims, primary and secondary endpoints and comparators. The scope of the revision also included to give further guidance with regards the possibility for extrapolation from adults, or the need to generate separate data in children and to give recommendations regarding the exploration of PK/PD in paediatric drug development. Possible targets of estimation that define treatment effects of interest in UC were also considered.

The CHMP noted the overview of comments and adopted the guideline.

Guideline on the development of new medicinal products for the treatment of Crohn's Disease (CPMP/EWP/2284/99) Rev. 2

Action: For adoption

- Overview of comments received on 'Draft guideline on the development of new medicinal products for the treatment of Crohn's Disease' (EMA/CPMP/EWP/2284/99 Rev. 2) EMA/CHMP/261409/2017

  Action: For information

Mark Ainsworth and Peter Szitanyi presented the 2nd revision of the Guideline on the development of new medicinal products for the treatment of Crohn's Disease. The main aim of the 2nd revision was to update the guidance on the design of studies in adult patients, especially on potential claims, primary and secondary endpoints, and comparators. The scope of the revision also include to give further guidance regarding the possibility for extrapolation from adults, or the need to generate separate data in children and to give

recommendations regarding the exploration of PK/PD in paediatric drug development. Possible targets of estimation that define treatment effects of interest in UC were also considered.

The CHMP noted the overview of comments and adopted the guideline.

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

No items

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF Briefing Meeting - Meeting date: 28th June 2018

Action: For discussion and agreement

Postponed to June plenary.

ITF Briefing Meeting - Meeting date: 19th July 2018

Action: For discussion and agreement

Postponed to June plenary.

ITF Briefing Meeting - Meeting date: 27th June or 2nd July 2018

Action: For discussion and agreement

Postponed to June plenary.

ITF Briefing Meeting - Meeting date: 25th June 2018

Action: For discussion and agreement

Postponed to June plenary.

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. Abolishment of physical signatures for divergent positions for centrally authorised products (CAPs)

The divergent position members will be approached to confirm the agreed final wording for the divergent position electronically.

Action: For information

The CHMP noted the information. It was agreed to extend the electronic process for divergent positions for CAP procedures from June CHMP Plenary onwards.

3.1.2. EMA Implementation plan of the new medical device and in vitro diagnostic regulation

Action: For information

Important changes introduced by the new regulations focussing on the impact for EMA/Medicines Competent Authorities were presented. CHMP sponsors were invited to contribute to the following new consultation procedures: Substance Based medical devices, Companion Diagnostics and Integral Drug Device Combinations. Interested members should send email **by 16 July 2018**. Further discussions and sponsors appointment will be made in July CHMP Plenary. Regular updates to CHMP on various workstreams have been planned.

The CHMP noted the information.

4. Any Other Business

4.1.2. Understanding the training needs of NCA assessors involved in the work of the CHMP: Priority needs and plans for training 2018 – 2020

Action: For discussion

Linked to the Network 2020 the objective is to reinforce the scientific and regulatory capacity and capability of the network: specifically identification of gaps in scientific and regulatory expertise based on current and future needs, and meeting these needs through corresponding training development offered through the EU Network Training Centre (EU NTC).

The CHMP was updated on the training opportunities being made available to the European Regulatory Network through the EU NTC and specifically on the EU NTC Learning

Management System. Committee members were asked to identify the training needs and priorities (for both CHMP members and assessors involved in the work of the CHMP for the coming year), taking into account the upcoming challenges in the context of Brexit and the EMA relocation. No specific priorities were identified – although the CHMP noted that discussion would now start on how the priorities identified through the recent HMA survey on training needs might now be addressed.

5. List of participants

CHMP Chair:

Tomas Salmonson

CHMP members:

Agnes Gyurasics

Daniela Melchiorri

Emilia Mavrokordatou

Harald Enzmann

Jayne Crowe

Johann Lodewijk Hillege

Katarina Vučić

Kristina Dunder

Outi Mäki-Ikola

Robert James Hemmings

Romaldas Mačiulaitis

Simona Badoi

Sinan B. Sarac

Svein Rune Andersen

CHMP alternate members:

Christophe Focke

Dana Gabriela Marin

Mark Ainsworth

Natalja Karpova

Nithyanandan Nagercoil

Experts:

Jan Welink

Jan Willem van der Laan

Christine Siezen

Henrike Potthast

Irene Diaz Ortiz

Keith Pugh

Maria Escudero Galindo

Mette Toftegaard Madsen

Milena Peraita Ezcurra

Patricia Diaz Ramos

Peter Szitanyi

Stefan Bonné

The meeting was run with support from the relevant EMA staff