14 February 2018
EMA/48249/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] Minutes of the meeting on 15 January 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 this agenda is considered commercially confidential or sensitive and therefore not disclosed. Of note, this agenda is a working document primarily designed for CxMP 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 15 January 2018 meeting was adopted

1.3. Adoption of the minutes

CHMP Orgam Minutes of 15 January 2018 were adopted at the January 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 meeting held by teleconference on 21 August 2017 (EMA/CHMP/SWP/548672/2017)

Action: For information

The CHMP noted the minutes.

Final minutes for SWP meeting held by teleconference on 19 September 2017 (EMA/CHMP/SWP/622352/2017)

Action: For information

The CHMP noted the minutes.

EC consultation on Pharmaceuticals in the environment

The SWP is responding on behalf of the CHMP to the targeted stakeholder consultation

Action: For adoption (if no extension to deadline is given)

The SWP response to the EU Survey was presented by Laila Sortvik-Nilssen. The CHMP noted the documents. It was agreed to ask for extension of deadline, which allows re-discussion at the January Plenary. Please send any comments by 19th January.

Nomination of Maria Grazia Evandri as new Italian SWP member replacing Annarita Meneguz.

Action: For adoption

The CHMP appointed Maria Grazia Evandri as new Italian SWP member replacing Annarita Meneguz.

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh/Blanka Hirschlerova

Teicoplanin – Letter to EDQM (EMA/CHMP/CVMP/848192/2017)

Action: For adoption

The letter was presented by Keith Pugh.

The CHMP adopted the letter.

85th Joint CHMP/CVMP Quality Working Party (QWP) Face-to-Face meeting on 28 - 30 November 2017: Table of Actions & Decisions (EMA/CHMP/CVMP/QWP/782647/2017)

Action: For information

The CHMP noted the Table of Actions and Decisions.

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

Meeting Summary PCWP meeting with all eligible organisations – 22 November 2017 (EMA/48249/2018)

Action: For information

The CHMP noted the meeting summary.

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

Reflection paper on physical frailty: instruments for baseline characterisation of older populations in clinical trials (EMA/CHMP/778709/2015)

Action: For discussion

The reflection paper was presented by Katarina Vučić. The scope of this is to describe the recommended instruments to be applied for the baseline characterisation of physical frailty of patients aged 65 years and older enrolled in a clinical trial or other clinical investigation (e.g. registry). These instruments are proposed to supplement age, as delineated in ICH E7, as a demographic characterisation factor in order to support a better understanding of the benefit-risk of a medicine in the older population.

Multimorbidity was also included in the draft Points to consider on frailty. A complementary "Reflection paper on multimorbity: instruments for baseline characterisation of older populations in clinical trials" is proposed to be developed.

The CHMP noted the reflection paper.

In case no comments received the reflection paper will be considered as adopted at the January CHMP Plenary meeting.

2.1.7. Committees

Call for nominations of co-opted member: The CHMP agreed during its December meeting on the following area of expertise: quality of non-biologicals and pharmacokinetics expertise. Nominations should be sent by **February 14th 2018**, end of business.

The election will take place during the February CHMP meeting.

Action: For information

The CHMP noted the call.

CHMP Work Plan 2018

The work plan is meant for adoption at the January 2018 CHMP Plenary meeting. Please send any final comments

Action: For information

The CHMP noted the reminder.

Final Minutes from Joint CHMP-PRAC Strategic Review and Learning meeting in Tallinn, Estonia 16-18, October under EU Estonian Presidency

Action: For adoption

The CHMP adopted the final minutes. Some of the follow-up actions were included into CHMP Work Plan and should be completed during 2018.

ATMPs guideline on S&E follow-up and risk management (EMA/CHMP/65416/2016) – CAT and PRAC

Action: For adoption

The guideline was presented. Main points for the update were Risk Minimisation measures, efficacy and safety follow-up studies, management and reporting of adverse reactions and PSURs and compliance monitoring. The CHMP noted the update. The guideline and especially the registries aspect is also meant to help the Workshop on CAR-T cells taking place on 9th February 2018.

The guideline is intended for further review, discussion and adoption next week at the January CHMP Plenary meeting.

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

JEG3Rs (J3RsWG) Annual Report 2017 (EMA/CHMP/CVMP/3Rs/502136/2017)

Action: For information

The CHMP noted the annual report.

Executive Summary (EMA/CHMP/CVMP/3Rs/820238/2017)

Action: For information

The CHMP noted the executive summary.

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

No items

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from November face-to-face meeting held 30-31 October 2017 (EMA/CHMP/BWP/725110/2017)

Action: For information

The CHMP noted the final minutes.

Draft agenda for BWP face-to-face meeting to be held 12-14 February 2018 (EMA/CHMP/BWP/822457/2017)

Action: For information

The CHMP noted the draft agenda.

Question and Answer Document on the Haemagglutination Inhibition (HI) test for qualification of influenza vaccine (inactivated) seed preparations (EMA/CHMP/BWP/426390/2017)

Action: For adoption for 6 months public consultation

The document was presented. The CHMP adopted the Question and Answer Document for 6 months public consultation.

Guideline on quality aspects included in the product information for vaccines for human use (EMA/CHMP/BWP/133540/2017)

Action: For adoption for 6 months public consultation

The document was presented. The CHMP adopted the guideline for 6 months public consultation.

Questions and answers on Bovine Spongiform Encephalopathies (BSE) and vaccines (EMA/CHMP/BWP/192228/2017)

Action: For adoption for 6 months public consultation

The document was presented. The CHMP adopted the document for 6 months public consultation.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Nomination of additional assessor (observer) to VWP

Action: For adoption

The CHMP postponed the nomination in order to clarify the number of additional assessors (observers) needed. Further discussions will be held at the January CHMP Plenary meeting.

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

No items

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

Call for nomination of Vice-Chair

CHMP Members, and CVS Members and Alternates are eligible for the position of CVS 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 **by 15 February 2018.**

The election is envisaged to take place at the February 2018 plenary meeting.

Action: For information

The CHMP noted the information.

Draft agenda for the Face to Face meeting on 22 November 2017 (EMA/709461/2017)

Action: For information

The CHMP noted the draft agenda.

Draft minutes for the Face to Face meeting on 22 November 2017 (EMA/775601/2017)

Action: For information

The CHMP noted the draft agenda.

Draft Table of Decisions (ToD) 22 November 2017 (EMA/775941/2017)

Action: For information

The CHMP noted the draft agenda.

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

Patient-reported outcome (PRO) analyses in the EPAR and SmPC of oncology medicines

To share with CHMP the on-going initiative from ONCWP on the development of high level principles on how and when to report PRO data in assessment report and SmPC.

Action: For information

The presentation was given. PRO analyses are often included in pivotal clinical trials in oncology as secondary or exploratory endpoints with (positive) claims, however PRO claims in SmPC are often based on weak data (e.g., poorly justified instrument selection, a large proportion of missing data not appropriately accounted for). Furthermore, there are currently no agreed approach on the structure and level of details in reporting PRO data in EPAR and SmPCs (inconsistent reporting of PRO data in EPARs or SmPCs).

As a result the ONCWP has started working on high level principles on how and when to include PROs in AR and SmPC (section 5.1). The other ongoing initiative is a joint EORTC – EMA meeting on Quality of life on 23rd March 2018, which is also a good opportunity to raise awareness on the topic.

The CHMP noted the information and was supportive to the initiative.

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Henrike Potthast

Product-specific bioequivalence guidelines:

1. Dolutegravir film-coated tablets 10 mg, 25 mg and 50 mg product-specific bioequivalence guidance (EMA/CHMP/356874/2017)

   Rapporteur: Eva Gil Berglund/Malin Filler

2. Dronedarone film-coated tablets 400 mg product-specific bioequivalence guidance (EMA/CHMP/356875/2017)

   Rapporteur: Carolien Versantvoort

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

   Rapporteur: Susan Cole

4. Paracetamol oral use immediate release formulations product-specific bioequivalence guidance (EMA/CHMP/356877/2017)

   Rapporteur: Jan Welink

5. 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

6. Rilpivirine film-coated tablets 25 mg product-specific bioequivalence guidance

   Rapporteur: Carolien Versantvoort

Action: For adoption

The guidelines were presented. The CHMP adopted the guidelines. The only comment was made on ibuprofen guideline, which should be revised.

CHMP request on biosimilarity to Pharmacokinetics Working Party (PKWP) (EMA/CHMP/230419/2017)

Rapporteur: Eva Gil Berglund/Anita Andersson

Action: For information

The CHMP request was presented by Anita Andersson. The CHMP discussed the acceptance range. Further discussions will be held at the January CHMP Plenary meeting.

Reflection paper on investigation of pharmacokinetics and pharmacodynamics in the obese population

Rapporteurs: Ridha Belaiba, Carolien Versantvoort, Eva Gil Berglund and Susan Cole

Action: For adoption for 6 months public consultation

The reflection paper was presented. The reflection paper was adopted for 6 months public consultation.

PRAC request - Signal on Norvir, Kaletra and possible interaction with levothyroxine

Rapporteur: Eva Gil Berglund

Action: For adoption

The PRAC request was presented by Eva Gil Berglund. The CHMP adopted the response from PKWP. The response will be sent back to PRAC.

Draft minutes for the PKWP face-to-face meeting on 25-26 October 2017

Action: For information

The CHMP noted the draft minutes.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Nomination of additional assessors (observers) to BSWP

Action: For adoption

The nominations were postponed and they will be considered as part of discussions on the composition of the BSWP, to be held in the margins of the January CHMP plenary.

Analysis of Individual Patient Data for evaluation and surveillance of medicinal products

Action: For discussion

Outcome of the BSWP reflection was presented. Opportunities for access and use of IPD in evaluation were presented. The CHMP supported the views expressed in the BSWP position paper. It was proposed to create a small group composed by EMA and CHMP, tasked to drive this initiative forward with a gap analysis that will look into specific aspects (e.g.,

legal, IT, resources). The relevant experts in the Committees and the network will be consulted.

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

No items

2.3.8. Scientific Advisory Groups (SAGs)

No items

2.3.9. Drafting Groups (DGs)

No items

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Elmer Schabel

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

2018 Work Plan

Action: For adoption

The CHMP adopted the work plan.

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

Amendments to the Work plan for the CHMP Excipients Drafting Group (ExcpDG) for the revision of the EC guideline 'Excipients in the labelling and package leaflet of medicinal products for human use' for 2018 (EMA/CHMP/672198/2017 rev. 1)
Action: For adoption

The CHMP adopted the amended work plan for the revision of the EC guideline.

Draft agenda for the ExcpDG TC to be held on 18 January 2018 (EMA/14429/2018)

Action: For information

The CHMP noted the draft agenda.

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF Briefing Meeting

Meeting date: 16th March 2018
Action: For discussion and agreement

The CHMP agreed to the ITF meeting.

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. Similarity assessment for fixed-dose combination products vs. mono-component

Action: For discussion and agreement

The presentation was given.

The CHMP noted the problem and agreed to the proposal.

3.2. Meeting organisation / templates

3.2.1. EPAR publication process

The proposal is to table EPARs “for information” (instead of tabling “for adoption”) in order to streamline the publication process and increase adherence to publication timelines.

Action: For information

The proposal to table “for information” the EPAR for CHMP adoption helps saving 2 weeks in the process and would help increasing adherence to the publication timelines. The change would come into force in March 2018.

The CHMP agreed to the proposal.

4. List of participants

CHMP Chair:

Tomas Salmonson

CHMP members:

Agnes Gyurasics

Alexandre Moreau

Andrea Laslop

Christophe Focke

Harald Enzmann

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Katarina Vučić

Kristina Dunder

Ondřej Slanař

Outi Mäki-Ikola

Robert James Hemmings

Sinan B. Sarac

Svein Rune Andersen

CHMP alternate members:

Fátima Ventura

Milena Stain

Nithyanandan Nagercoil

Experts:

Anita Andersson

Jan Willem van der Laan

Keith Pugh

Laila Sortvik Nilssen

Mette Tranholm

Patricia Diaz Ramos

Valerie Lescrainier

Elina Rönnemaa

A representative from the European Commission attended the meeting

The meeting was run with support from the relevant EMA staff