27 November 2017
EMA/606018/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] Minutes of the meeting on 4 September 2017

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. 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 4 September 2017 meeting

The CHMP adopted the ORGAM agenda with amendments.

1.3. Adoption of the minutes

CHMP Orgam Minutes of 4 September 2017 meeting were adopted at the September 2017 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 virtual meeting held on 23 May 2017 (EMA/CHMP/SWP/335567/2017)

Action: For information

The CHMP noted the final minutes.

Final minutes for SWP virtual meeting held on 28 June 2017 (EMA/CHMP/SWP/415510/2017)

Action: For information

The CHMP noted the final minutes.

CMDh Question to SWP on acceptability of statement on potential residues of latex in the PI of products packed in containers with synthetic rubber stopper

Action: For adoption

The CHMP agreed to send the CMDh question to SWP.

Draft programme for SWP workshop on non-animal approaches in support of medicinal product development to be held 5 October 2017 at EMA

Action: For information

The CHMP noted the draft programme for SWP workshop.

2.1.2. Quality Working Party (QWP)

Chair: Keith Pugh

Q/As on needle safety systems

Presentation by Keith Pugh

Action: For adoption

Keith Pugh presented the document. The Q&A document has 6 questions on needle safety systems. The questions have been prepared in response to queries often received by medicines regulatory agencies regarding the regulatory requirements for needle safety of medicinal products. It is aimed at a wide audience such as national competent authorities, healthcare professionals, hospital governors and hospital management, pharmaceutical companies, medical devices manufacturers, patient organisations, or medical professionals' societies.

The CHMP adopted the document.

Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials (EMA/CHMP/QWP/545525/2017)

Action: For adoption

- Overview of comments received (EMA/CHMP/QWP/546045/2017)

  Action: For information

The CHMP noted the overview of comments. The CHMP adopted the guideline. The guideline addresses the documentation on the chemical and pharmaceutical quality of IMPs and Auxiliary Medicinal Products containing chemically defined drug substances, synthetic peptides, synthetic oligonucleotides, herbal substances, herbal preparations and chemically defined radio- active/radio-labelled substances to be submitted to the competent authority for approval prior to beginning a clinical trial in humans. It includes the requirements for IMPs and Auxiliary Medicinal Products to be tested in phase I, phase II, phase III and phase IV studies as well as the requirements for modified and unmodified comparator products and IMPs to be tested in generic bioequivalence studies.

Nomination of new alternate member to the QWP - Kristofer Olofsson (SE)

- CV
- Current membership list

Action: For adoption

The CHMP appointed new alternate member to the QWP - Kristofer Olofsson (SE).

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

Report from a workshop on personalised medicines held by EMA on 14 March 2017" (EMA/185440/2017)

Action: For information

The CHMP noted the report.

Draft Agenda AMR workshop - 19 Sept (EMA/765134/2016)

Action: For information

The CHMP noted the draft agenda.

Draft agenda PCWP-HCPWP - 20 Sept (EMA/370525/2017)

Action: For information

The CHMP noted the draft agenda.

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

Co-chair: Gonzalo Calvo

See 2.1.4.

2.1.6. Geriatric Expert Group (GEG)

Chair: Niccolo Marchionni

No items

2.1.7. Committees

Area of expertise of co-opted member

The mandate of Jan Mueller-Berghaus (expertise in Quality and safety of biological medicinal products, including biotechnology derived medicines, cell therapies and gene therapies) will expire on 13 November 2017. The needed area of expertise should be confirmed.

Action: For discussion

The CHMP noted the information. The election will take place during CHMP November meeting. During September or October Plenary area should be agreed, the call for

nominations will be organised and deadline to submit nominations will be in October/November.

CHMP/CAT joint membership

The Advanced Therapies Regulation ((EC) 1394/2007) requires that 5 members or co-opted members of the Committee for Medicinal Products for Human Use (CHMP) together with an alternate, either proposed by the Member state of the member or identified by the co-opted member, are appointed by the CHMP to the Committee for Advanced Therapies (CAT). The Member States, who are not represented through the members appointed by the CHMP, nominate then one member and alternate to the CAT.

Action: For discussion

The CHMP noted the information. The current mandates expire 17 December 2017. 4 current mandates out of 5 confirmed the willingness to continue with the joint membership.

2.1.8. International Council on Harmonisation (ICH)

ICH Guideline Q11 Q&A on "Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)"

Action: For adoption

The CHMP adopted the document.

ICH Guideline E11(R1) draft Guideline on "Clinical Investigation of Medicinal Products in the Pediatric Population"

Action: For adoption

The CHMP adopted the document.

ICH Guideline E18 Guideline on Genomic Sampling and Management of Genomic Data

Action: For adoption

The CHMP adopted the document.

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

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Martina Weise

Draft agenda of BMWP face to face meeting to be held on 20-21 September 2017 (EMA/527610/2017)

Action: For information

The CHMP noted the draft agenda.

Draft agenda of Interested parties meeting with BMWP to be held on 21 September 2017 (EMA/397389/2017 and EMA/465298/2017)

Action: For information

The CHMP noted the draft agenda.

Draft Minutes of BMWP virtual meeting held on 31 May 2017 (EMA/348708/2017)

Action: For information

The CHMP noted the draft minutes.

Draft Minutes of BMWP virtual meeting held on 03 July 2017 (EMA/530736/2017)

Action: For information

The CHMP noted the draft minutes.

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from face-to-face meeting held 12-14 June 2017 (EMA/CHMP/BWP/379325/2017)

Action: For information

The CHMP noted the final minutes.

Draft agenda for BWP face-to-face meeting to be held 2-4 October 2017 (EMA/CHMP/BWP/505217/2017)

Action: For information

The CHMP noted the draft agenda.

Revised Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials (EMA/CHMP/BWP/534898/2008 rev. 1)

Action: For adoption

- Overview of comments (EMA/CHMP/BWP/563769/2017)

  Action: For information

The CHMP noted the overview of comments. The CHMP adopted the revised guideline. The guideline addresses the specific documentation requirements on the biological, chemical and pharmaceutical quality of IMPs containing biological / biotechnology derived substances. Moreover, this guideline lists, as regards documentation on the biological, chemical and pharmaceutical quality of the IMP, examples of modifications which are typically considered as 'substantial'.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

Final Minutes of VWP face to face meeting held on 23-24 May 2017 (EMA/333084/2017)

Action: For information

The CHMP noted the final minutes.

Draft minutes of the VWP TC of 25 August 2017

Action: For information

The CHMP noted the draft minutes.

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Agenda of BPWP face to face meeting held on 29-30 June 2017 (EMA/CHMP/BPWP/359534/2017)

Action: For information

The CHMP noted the agenda.

Draft minutes of BPWP face to face meeting held on 29-30 June 2017 (EMA/CHMP/BPWP/414553/2017)

Action: For information

The CHMP noted the draft minutes.

Agenda and draft minutes of the Blood cluster meeting held on 13 July 2017

- Agenda (EMA/400487/2017)
- Draft minutes

Action: For information

The CHMP noted the agenda and draft minutes.

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: Pieter de Graeff/Kristina Dunder

Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus (CPMP/EWP/1080/00 Rev. 2)

Action: For adoption for 6-months public consultation

The CHMP noted the update of the guideline and revision of safety (especially cardiovascular safety) section.

Post-meeting note: Further comments were received from CHMP after the meeting, therefore adoption remains to be confirmed.

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich/Greg Markey

Call for nomination of a new Vice-Chair to the CNSWP following the end of first mandate in October 2017

Nominations should be sent by **06 October 2017**.

Candidates should submit a brief résumé in support of their candidature. Election is going to take place at the October 2017 CHMP Plenary meeting.

Action: For information

The CHMP noted the call.

Call for nomination of a new CNSWP core member following resignation of Dag Nilsson

Nominations should be sent by **06 October 2017**.

Action: For information

The CHMP noted the call.

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

Call for nomination of a new Chair to the IDWP following the current Chair's resignation.

Action: For information

The CHMP noted the call. Candidates should submit a brief résumé in support of their candidature.

2.3.4. Oncology Working Party (ONCWP)

Chair: Pierre Demolis/Paolo Foggi

Draft agenda of ONCWP face to face meeting to be held on 18 September 2017

Action: For information

The CHMP noted the draft agenda.

Draft minutes of ONCWP virtual meeting held on 11 July 2017 (EMA/441641/2017)

Action: For information

The CHMP noted the draft minutes.

Draft minutes of ONCWP virtual meeting held on 14 June 2017 (EMA/380195/2017)

Action: For information

The CHMP noted the draft minutes.

Guideline on the evaluation of anticancer medicinal products in man (EMA/CHMP/205/95 Rev.5)

Action: For discussion

The CHMP was updated on the guideline. The purpose of the 5th revision of the main guideline is to address current changes in the therapeutic landscape that affect the requirements with regard to collection and reporting of safety data in order to inform the benefit-risk evaluation, including a need for more differentiated and detailed safety data presentation. Since cancer medicines may be approved for different stages of cancer, the side effects may carry different burden to patients. Therefore, the guideline addresses among other topics safety of medicines in adjuvant and palliative care setting. Further discussions will be held during the plenary. The guideline is meant for final adoption and publication.

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

CMDh question to the Pharmacokinetics Working Party (PKWP) - Oral solutions - with or without water (EMA/CHMP/364793/2017), response from PKWP

Rapporteur: Sotiris Michaleas

Action: For adoption

Sotiris Michaelas presented the response to the CMDh question. The CHMP agreed to the response and it will be sent back to CMDh.

Invitation to PKWP Chair Jan Welink to attend the 12th Workshop on Recent Issues in Bioanalysis as a speaker in April 2018 in Philadelphia, PA, USA

- Invitation

Action: For adoption

The CHMP agreed to the request. The costs of the meeting will be covered by the organisers.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Minutes of BSWP face to face meeting held on 27-28 March 2017 (EMA/205708/2017)

Action: For information

The CHMP noted the minutes.

Minutes of BSWP face to face meeting held on 06-07 July 2017 (EMA/432665/2017)

Action: For information

The CHMP noted the minutes.

Workshop on "draft reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development (EMA/CHMP/138502/2017)" to be held on 3-4 May 2018.

The main focus of the multidisciplinary workshop will be the discussion of comments received during the public consultation and stakeholders are hence encouraged to provide comments or suggest topics early on (ideally by the end of November 2017) which will help shape the format and content of the workshop. Stakeholders wishing to participate can express their interest

The output of the 1.5-day workshop will have a direct impact in the finalisation of the reflection paper.

The workshop will be advertised on the EMA external news webpage mid-September (see attached news text).

Action: For information

The CHMP noted the information.

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

No items

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

No items

2.3.10. Additional agenda points

No items

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

No items

3.2. Meeting organisation / templates

3.2.1. Multinational Assessment Team (MNAT) concept – broadening the concept to the post-authorisation phase

As outlined during the June 2017 Plenary meeting, the multinational team concept has been extended to post-authorisation procedures (extension of indications and line extensions) as of 1st of September 2017 onwards.

Multinational teams involved in the assessment of an initial MAA are reminded to inform EMA whether or not they wish to continue with the multinational team concept post-authorisation.

Further information can be found on the EMA website and in the published Guidance document.

Action: For information

The CHMP noted the information.

3.3. Pharmacovigilance

No items

4. List of participants

CHMP Chairman:

Tomas Salmonson

CHMP members:

Agnes Gyurasics

Alexandre Moreau

Andrea Laslop

Christophe Focke

Concepcion Prieto Yerro

Daniela Melchiorri

Emilia Mavrokordatou

Ewa Balkowiec Iskra

Jan Mueller-Berghaus

Jean-Louis Robert

Johann Lodewijk Hillege

Katarina Vučić

Kristina Dunder

Outi Mäki-Ikola

Robert James Hemmings

Simona Badoi

Svein Rune Andersen

CHMP alternate members:

Bjorg Bolstad

Dana Gabriela Marin

Fátima Ventura

Hanne Lomholt Larsen

Martina Weise

Nithyanandan Nagercoil

Selma Arapovic Dzakula

Experts:

Jan Willem van der Laan

Keith Pugh

Maria Escudero Galindo

Patricia Diaz Ramos

Trine Jensen

The meeting was run with support from the relevant EMA staff