06 November 2019
EMA/CHMP/421790/2020
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes for the meeting on 4 November 2019

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

4 November 2019, 09:30–12:30, room 0-D

Disclaimers

Some of the information contained in this document is considered commercially confidential or sensitive and therefore not disclosed.

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

Note on access to documents

Some documents mentioned in the agenda/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

The CHMP ORGAM agenda for 4th November 2019 meeting was adopted.

1.3. Adoption of the minutes

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

2. Regulatory and organisational matters

2.1. Regulatory Issues / new legislation

2.1.1. EMA recommendation on the procedural aspects and dossier requirements for the consultation of the EMA by a notified body on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device or active implantable medical device (EMA/CHMP/696201/2017 1 rev .1)

This revision takes into account the changes introduced by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, and introduces updates to references to other EMA guidance documents.

Action: For adoption

The CHMP noted the changes and adopted the revised document.

2.2. CHMP organisation / templates

2.2.1. Changes to PRAC and CHMP involvement in type II variations

Following a proposal presented to CHMP in May 2018 and an agreement reached with nominated CHMP and PRAC members in September 2018, a proposal is presented to CHMP for endorsement in relation to PRAC and CHMP involvement in type II variations, as follows:

- PRAC to lead the assessment of variations submitted in follow-up to PSURs and signals
- PRAC to lead the assessment of variations including non-interventional PASS results
- PRAC- and CHMP-led variations not be accepted to be grouped, unless exceptionally interlinked

Action: For adoption

The scope of the proposal for adoption also covers variations falling under the first and second bullet points with an impact on the product information (PI). The CHMP adopted the proposed changes noting that an active communication will have to be established between

PRAC rapporteurs and CHMP rapporteurs/CHMP for a successful implementation of the proposal.

2.2.2. Type II variations discussed at the CHMP plenary

Following a topic presented at the May 2019 CHMP ORGAM, based on an analysis made by MEB on variations affecting section 4.2 of the SmPC, a proposal is presented to CHMP for endorsement, as follows:

- variations involving posology changes of the medicinal product will be included by the EMA in the CHMP agenda by default
- variations leading to a switch of a conditional MA to a full/standard MA will also be included by default in the CHMP agenda

Action: For adoption

The CHMP adopted the proposal.

2.2.3. Follow up on Strategic Review and Learning Meeting (SRLM) held on 21-23 October in Helsinki, Finland

Draft action plan agreed at the SRLM.

Action: For discussion

The action plan resulting from the discussions held at the SRLM in Helsinki was presented, as well as a set of recommendations to assessors/rapporteurs.

CHMP members were asked to send comments on the presented documents by 29th November 2019.

3. Harmonisation and consistency groups

3.1. International Council on Harmonisation (ICH)

No topic

3.2. Guideline Consistency Group (GCG)

Chair(s): Aranzazu Sancho-Lopez

No topic

4. Non therapeutic-area-specific working parties

4.1. Biologics Working Party (BWP)

Chair(s): Sol Ruiz/Nanna Aaby Kruse

4.1.1. Agenda(s) and minutes

- Final minutes for BWP meeting held face-to-face on 9-11 September 2019
- Draft agenda for BWP meeting to be held face-to-face on 4-6 November 2019

Action: For information

The CHMP noted the agenda and minutes.

4.2. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan/Susanne Brendler-Schwaab

No topic

4.3. Biosimilar Medicinal Product Working Party (BMWP)

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

No topic

4.4. Biostatistics Working Party (BSWP)

Chair(s): Anja Schiel/Jörg Zinserling

No topic

4.5. Modelling and Simulation Working Party (MSWP)

Chair(s): Kristin Karlsson/Flora Musuamba Tshinanu

4.5.1. Agenda(s) and minutes

- ToD for MSWP meeting 22 October 2019
- Minutes from MSWP meeting 22 October 2019

Action: For information

The CHMP noted the table of decisions and minutes.

4.6. Pharmacogenomics Working Party (PGWP)

Chair(s): Markus Paulmichl

No topic

4.7. Pharmacokinetics Working Party (PKWP)

Chair(s): Henrike Potthast

4.7.1. Call for nomination for the election of PKWP Chair in November 2019

Jan Welink's second 3-year term expired in September 2019. Nominations should be sent together with a CV and a brief motivation letter by 4th November 2019.

Election of PKWP chair will take place at the November Plenary.

Nominations received.

Action: For information

The CHMP noted the nomination(s) received.

4.7.2. PKWP response to CMDh question on lozenges

PKWP response on to what extent active ingredients should be released in order to allow a conclusion of comparable local exposure for lozenges.

Action: For adoption

The CHMP adopted the proposed PKWP response to CMDh and agreed to the publication of a Question & Answer on the topic. The rapporteur will take the lead.

4.7.3. In vitro requirements for the waiver of bioequivalence demonstration for azacitidine 25 mg/mL powder for suspension for injection

PKWP position

Action: For discussion

The topic was discussed in conjunction with topic 7.1.1: QWP response to CMDh question on assessment of the pharmaceutical development and finished product specifications for azacitidine powder for suspension for injection generics.

The topic will be further discussed by PKWP and QWP.

5. Therapeutic-area-specific working parties and SAGs

5.1. Blood Products Working Party (BPWP)

Chair(s): Jacqueline Kerr/Karri Penttilä

5.1.1. Agenda(s) and minutes

- Final agenda 29th October 2019

Action: For information

The CHMP noted the agenda.

5.2. Central Nervous System Working Party (CNSWP)

Chair(s): André Elferink

No topic

5.3. Cardiovascular Working Party (CVSWP)

Chair(s): Kristina Dunder/Alar Irs

No topic

5.4. Infectious Diseases Working Party (IDWP)

Chair(s): Maria Jesus Fernandez Cortizo

No topic

5.5. Oncology Working Party (ONCWP)

Chair(s): Sinan B. Sarac/Paolo Foggi

No topic

5.6. Rheumatology/Immunology Working Party (RIWP)

Chair(s): Romaldas Mačiulaitis

5.6.1. Guideline on clinical investigation of medicinal products for the treatment of gout (EMA/CHMP/774470/2018)

Final guideline for publication

Action: For adoption

The CHMP adopted the final guideline for publication.

5.7. Vaccines Working Party (VWP)

Chair(s): Mair Powell

No topic

5.8. Scientific Advisory Groups (SAGs)

No topic

6. Drafting groups

6.1. Excipients Drafting Group

No topic

6.2. Gastroenterology Drafting Group (GDG)

Chair: Mark Ainsworth

No topic

6.3. Geriatric Expert Group (GEG)

No topic

6.4. Radiopharmaceuticals Drafting Group (RadDG)

Chair: Anabel Cortes Blanco

No topic

6.5. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No topic

7. Joint groups and collaboration with other committees

7.1. Quality Working Party (QWP)

Chair(s): Keith Pugh/Blanka Hirschlerova

7.1.1. QWP response to CMDh question

QWP response to CMDh question on assessment of the pharmaceutical development and finished product specifications for azacitidine powder for suspension for injection generics

Action: For adoption

See the discussion under 4.7.3.

7.2. Patients and Consumers Working Party (PCWP)

Co-chair: Kaisa Immonen Co-chair: Juan Garcia Burgos (EMA)

No topic

7.3. Healthcare Professionals Working Party (HCPWP)

Co-chair: Gonzalo Calvo Co-chair: Juan Garcia Burgos (EMA)

No topic

7.4. 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(s): Ellen-Margrethe Vestergaard/Susanne Brendler-Schwaab

No topic

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

Chair: Nienke Rodenhuis

No topic

7.6. Collaboration with other committees

No topic

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair(s): Anja Schiel

8.1.1. Appointment of CHMP peer review for SA

Action: For information

The CHMP noted the list.

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 27th November 2019

Action: For adoption

The meeting was adopted.

8.2.2. ITF meeting

Meeting date: 12th November 2019

Action: For adoption

The meeting was adopted.

9. Any Other Business

9.1. Update of EMA pre-authorisation guidance

Presented by EMA

Action: For discussion

CHMP noted the proposed change to the pre-authorisation guidance.

9.2. Experience with Regulation (EC) No 847/2000 – assessment of similarity vis-à-vis orphans

Presented by EMA

Action: For information

The CHMP noted the report.

9.3. Draft Good Pharmacovigilance Practice guideline on Product- or Population-Specific Considerations III: Pregnant and breastfeeding women

The draft GVP guideline was adopted following the October PRAC ORGAM TC and we aim to publish it for public consultation before Christmas.

Action: For adoption

CHMP comments, if any, should be sent until Friday 8 November 2019 noon. In the absence of comments by the deadline, the document proposed will be considered adopted by the CHMP.

The CHMP noted the deadline for comments.

9.4. Workshop on the role of registries in the monitoring of cancer therapies based on genetic and molecular features, 29th November 2019

A one-day multi-stakeholders workshop on the role of registries in the monitoring of cancer therapies based on genetic and molecular features will take place on the 29th November 2019 at the EMA temporary premises in Amsterdam.

Action: For information

The CHMP noted the workshop.

10. List of Participants

CHMP Chair:

Harald Enzmann

CHMP members:

Bruno Sepodes (Vice-Chair)

Alexandre Moreau

Bjørg Bolstad

Christian Gartner

Ewa Balkowiec Iskra

Francisek Drafi

Jan Mueller-Berghaus

Jayne Crowe

Johann Lodewijk Hillege

Margareta Bego

Maria Concepcion Prieto Yerro

Martine Trauffler

Natalja Karpova

Nithyanandan Nagercoil

Outi Mäki-Ikola

Sinan B. Sarac

CHMP alternate members:

Agnes Gyurasics

Christophe Focke

Dana Gabriela Marin

Fátima Ventura

Janet Koenig

Milena Stain

Paula van Hennik

Selma Arapovic Dzakula

Tomáš Radiměřský

Experts:

Elisabeth Johanne Rook

Eva Schlosser

Henrike Potthast

Kim Notenboom

Mette Toftegaard Madsen

Milena Peraita Ezcurra

Sabine Mayrhofer

The meeting was run with support from the relevant EMA staff