14 December 2017
EMA/CHMP/413341/2017

Work plan for the Oncology Working Party (ONCWP) for 2018

Chairperson: Pierre Demolis

Status of the work plan: December 2017 – Adopted

The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

1. Meetings scheduled for 2018

Meetings are planned for the following dates:

- January (virtual meeting*)
- February (virtual meeting)
- March (virtual meeting)
- April (virtual meeting)
- April 2018 – face to face meeting
- May (virtual meeting)
- June (virtual meeting)
- July (virtual meeting)
- September (virtual meeting)
- September 2018– face to face meeting
- October (virtual meeting)
- November (virtual meeting)

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- December (virtual meeting)

*Virtual meetings are to be followed by the international Oncology Cluster TCs – dates to be agreed with FDA

The above mentioned dates may be modified as needed. Additional virtual meetings may be organised ad-hoc to respond to time-sensitive requests on products and to progress guidelines, as required.

2. Guidelines

2.1. New EU Guidelines

Action: Lead

The use of minimal residual disease as an endpoint in clinical trials in multiple myeloma

Target date Draft to be released for public consultation Q1 2018

Final to be published Q4 2018

Comments To be included in the Annex 4 (Disease specific guidance) to the Note for Guidance on the Evaluation of anticancer medicinal products in man CHMP/205/95

2.2. EU Guidelines under revision

Action: Lead

Note for Guidance on the Evaluation of anticancer medicinal products in man, CHMP/205/95 Rev. 5

Target date Draft Revision 6 of the guidance to be released for public consultation Q3 2018

Comments Comments received during the public consultation for rev.5 trigger further updates. Revisions will focus on New clinical endpoints; Biomarkers; Interim Analysis and data maturation; Estimands in Oncology. BSWP position on "Methods on treatment cross-over for time-to-event endpoints in oncology clinical trials"; Integration of information on paediatric requirements.

Revision of the addendum to the guideline on evaluation of anticancer medicinal products in man - paediatric oncology, CPMP/EWP/569/02 Rev. 2

Target date Draft addendum to be released by Q3 2018 – in line with revision 6.

Comments Update of the paediatric guidance in oncology was foreseen during Rev.4 of the Note for Guidance on the evaluation of anticancer medicinal products in man CHMP/205/95.

2.3. ICH Guidelines

ICH S9 Q&A: Nonclinical Evaluation for Anticancer Pharmaceuticals— Questions and Answers

Target date Step 4 planned for Q1 2018

Comments Ongoing drafting work to address public comments received. ONCWP to review the updated document.

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

- Contribution to the scientific advice and protocol assistance provided by the SAWP upon request of SAWP.
- Recommendation to the CAT on data submitted to the Agency for scientific evaluation of the clinical data of an ATMP (Art. 18 of Regulation (EC) 1394/2007).
- Contribution to the Innovation Task Force.
- Contribution to paediatric investigation plans (PIP) upon request of PDCO.

3.2. Evaluation and supervision activities

- Contribution/recommendation to CHMP marketing authorisation or post-authorisation evaluation procedures upon request of CHMP.
- Input on non-centralised products (NAPs) evaluation/referral procedures upon request of the CMDh.
- Contribution to referral discussions upon request from CHMP/PRAC.
- Input into discussion of pharmacovigilance issues upon request from CHMP/PRAC.

4. Input in European activities

4.1. Training for the network and knowledge building

Assessors' training; On line training on the assessment of survival – in collaboration with the BSWP.

5. Input in International activities (beyond ICH guidelines)

5.1. Activities with other regulators

International Oncology cluster Monthly teleconferences and joint activities with FDA, HC, PMDA, TGA, Swissmedic.

6. Contribution to dialogue and engagement with stakeholders and external parties

6.1. Workshops

- EMA- EORTC meeting on Health related Quality of life – date tbc (estimated March 2018)

  Workshop planned with the EORTC in Q4 2017. The EORTC having recognised the need for more agility of using QoL and PROs in clinical research, has transformed its 'core questionnaire', the EORTC QLQ-C30 into computer-adaptive testing (CAT). Another approach allowing more dynamic assessment is the use an item library to supplement the standardized ('static') instruments. The purpose of the workshop is to discuss optimal validation approaches of the new QoL instruments with the various stakeholders.

- ONCWP workshop in Single Arm trials – date to be confirmed (estimated April 2018)

  This is a follow up to the EMA / ESMO Rare cancers initiative in 2015 and Single arm trials workshop in 2016 –A workshop is being planned with the aim to provide guidance.

In addition to the actions identified above, the working party can be involved in any other activities foreseen in its mandate:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/08/WC500095453.pdf