

#### CAT workplan 2015-2016

Presentation to the CAT Interested Parties (11 Dec 2014)

Presented by: P Celis

**CAT** secretariat



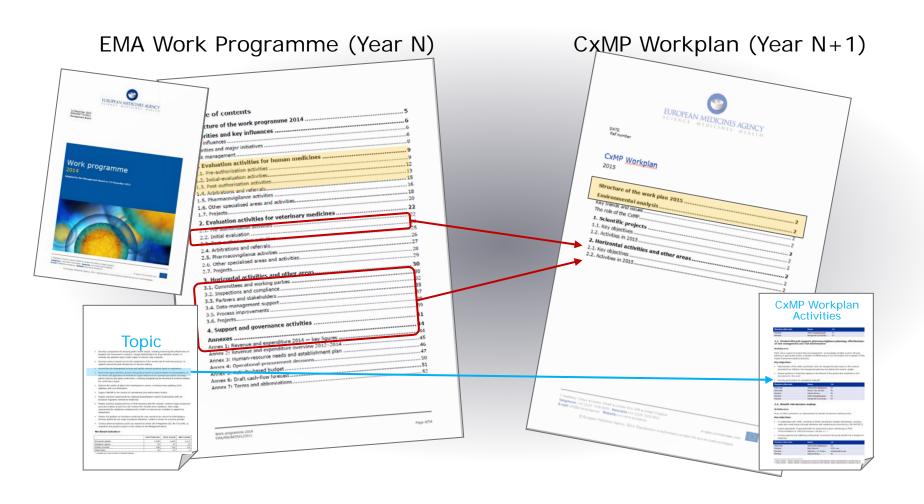


## Commitee workplans

What is new & common to all Committees?

- Align the Committee Work plans more closely to the EMA Work programme / EMA Roadmap
- Align to available resources
- Increase consistency of WP between different committees
- Core business and guidelines are not to be included in the CAT workplan
- Implementation plan to track progress







# CAT workplan 2015-2016

- Identify topics from the 2010-2015 CAT Workprogramme that will be taken forward to 2015-2016
- Align those proposals to the EMA Workprogramme
- CAT discussions June October 2014
- CAT adopted its workplan 2015-2016 in November 2014



## What is planned for 2015 (1)

- To set up a 2/3 hour webinar-training session for staff from NCAs / NCA innovation offices involved in classification questions for ATMPs. The aim of this training is to increase harmonisation of the classification outcomes throughout the EU.
- To develop and hold an assessor training for the evaluation of applications for marketing authorisation and certification of ATMPs.
  - Topic of training to be defined (e.g. RBA)
  - Training to the held in beginning of 2016



# What is planned for 2015 (2)

- 3. Understand trends in R&D of ATMPs via the analysis of EudraCT for the years 2010 to 2014. Compare the results with outcome of the EudraCT analysis for 2004-2010. Analyse and compare the profile of ATMP developers and the ATMPs under development with that in non-EU regions/countries (e.g. USA, Canada).
- 4. Provide assistance to ATMP developers via the organisation of a scientific workshop in collaboration with a scientific society.



#### Additional activities of CAT

- Guidance development, e.g. on requirements for clinical trials with ATMPs, Q&A's (e.g. on RBA), ...
- Support to EC on scientific issues related to the revision of ATMP Regulation (tbc)
- Development of CAT priorities for 2016-2020
  - Might no longer be in the format of a CAT Work Programme, but rather included in the EMA multi-annual Work programme