



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CAT workplan 2015-2016

Presentation to the CAT Interested Parties (11 Dec 2014)

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An agency of the European Union





Committee 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

CxMP Workplan (Year N+1)

[illegible]



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)

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.
2. 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 be 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