CAT Workshop 12 January 2012 – Questions from Participants

Questions on Session 3: Focus group 'Incentives for Academia, hospitals and charities developing ATMPs'

ACADEMIA-RELATED

1. How can Academia afford an EU ATMP registration?
2. How to make best use of hospital exemptions/Specials in early clinical studies
3. How can the Hospital Exemption Art 28(2) be delineated better with regard to the Specials clause, with regard to small-scale clinical trials and with regard to "Compassionate use"?
4. Need of GMP requirements for early exploratory clinical trials. Adaptability of current GMP requirements to ATMP in particular to cell therapy
5. What support is available for academics wishing to conduct trial in two as opposed to three or more Member States?
6. Academic institutions are graded according to their research activities. Could similar efforts be made to champion hospitals achieving translational targets? Perhaps an award scheme - whereby units/depts./institutions can be nominated as opposed to a grading of all, which would be easier to administrate. Can you place emphasis on awarding a team or department as it is definitely a team effort to achieve translation:
7. How can the ATMP certification be made accessible to academic institutions?
8. How can data sharing be encouraged towards advancement of clinical translation?
9. What is the EMA and CAT position on substantiating Master Files
10. Is harmonisation of IMPD and CTD dossiers for ATMPS foreseen in the CAT-workplan?
11. How can industry collaborate with Academia & charities?
12. Will you fund training courses on regulatory compliance?

SME-RELATED

13. Product development is a commercial activity.
14. Are there also incentives for SMEs?
15. Why are SME excluded from discussions of incentives with this group? Many hospitals and charities have GREATER resources than an SME. Why can't SMEs be treated equally with academia, hospitals and charities when developing ATMPs?
16. Should there be a special treatment for different interest groups? Should we not have an adjustment towards common standards of doing clinical investigations?
17. Is there any funding mechanism available for foreign private companies?
18. Is such a mechanism in place for academics to develop ATMPs? How much development work can realistically be carried out whilst "in shelter"?

MAA-RELATED

19. The number of companies taking up the free non-clinical data certification service appears to be very low with many SMEs choosing to seek clinical

trial authorisation from the NCAs without it. Does the committee see this as a risk for SMEs, given that the next time the committee will see the data is at MAA level when issues with the non-clinical data are more difficult to resolve?

20. How can CAT help with the advancement through to a successful MAA?