CAT Workshop 12 January 2012 – Questions from Participants

Questions on Session 2: Focus group 'better system to navigate ATMP guidance documents'

1. *There is a good system already.*
2. A good idea, but will need to cover the applicability and extent of relevance of more general guidelines, and how these relate to the specific requirements for ATMPs.
3. Is there a plan to also develop a flow-chart for Somatic Cell and Tissue engineered therapies?
4. In Somatic Cell Therapies: 1. More clarity to proceed towards phase III and marketing authorization. 2. Clarity on allogeneic and autologous therapy 3. Difference between therapy, treatment and CBMP
5. Guidance on autologous somatic cell therapeutics: Is CAT required for autologous therapies to be used in (a) clinical trials (b) 'transplant' procedures undertaken by surgeons
6. How does one decide on the appropriate testing strategy to be used for an ATMP? Guidance documents seem to provide conflicting advice for a cellular therapy as opposed to a viral vector.
7. Could you begin with a glossary?
8. Is it possible to simplify the number and type of documents needed for one lot of ATMP?
9. Can a system be set up with an entry point and a step-by-step procedure to guide to the point where interaction is needed?
10. Harmonisation of submission in Europe
11. Clarification on opportunities to interact directly with CAT Alignment of CAT and CHMP in guidance and decisions
12. Possibility of an online tool hosted by EMA? More publicity on 'Focus Groups' and option to join?
13. *The current Eudralex document library is considerably more user friendly than previous incarnations. No question to ask here*.