EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Advanced Therapies (CAT)

Report from CAT-Interested Parties Focus Groups (CAT-IPs FG) on non-clinical development of ATMPs

11th October 2012

Chair: Christian Schneider

Item	Agenda points/Summary of discussions
1.	**Tracking Progress** The participants revised the CAT-IPs Focus group action plan (version September 2012) and identified how to progress on the on activities proposed by the focus group and agreed by CAT in 2011 as follows:
a)	CAT, in cooperation with the Scientific Advice Working Party (SAWP), to explore generation of a document tracking the experience gained with scientific advice on non-clinical questions for ATMPs This document will provide CAT with an overview on the advice given, products types evaluated, proof of concept models recommended, toxicology models agreed and, where used, disease models. As a second phase it will be determined if common elements can be extrapolated and transformed into mock-up case studies to be shared with stakeholders. Current status: First phase (collection and analysis of SA): Completed. Second phase (extrapolation of common elements): Completed. Further actions identified: translate the common elements identified in a Questions and Answer Document.
b)	To ensure that assessors in the NCAs have a consistent approach for the evaluation/request of non-clinical studies CAT to include discussions on non-clinical development in ATMP assessors' training courses.

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	Current status: Already addressed in the programme of the ATMP Assessors' training (5th-6th April 2011). It will remain an on-going topic in future ATMP Assessors' training. No further actions identified.
c)	Risk-based approach: CAT Working Parties and other CAT members to work on scenarios with different types of risks to be potentially included in the upcoming guideline. Current status: Addressed via coordination between CAT and its WPs on the draft guidance on the risk-based approach. Completed. No further actions identified. CAT to identify areas of risk relevant to ATMPs (e.g. tumorigenicity, immunosuppression/immunomodulation, immunogenicity) to inform the discussions on the risk-based approach. Current status: Addressed via coordination between CAT and its WPs on the draft guidance on the risk-based approach. Completed. No further actions identified.
d)	To consider existing ISO standards used for medical devices to compare and gain experience on the risk-based approach used in the medical device field and see how certain elements can be used in the risk based approach used for ATMPs. Current status: Relevant ISO standards forwarded to CPWP and GTWP for their considerations. No further actions identified.
2.	**Collection of data on risks that have been already identified and possible scenarios to address these issues in non-clinical studies** Stakeholders to collect data on risks that have been already identified (e.g. tumorigenicity for embryonic stem cell products, insertional mutagenesis in gene therapy products) and on possible scenarios to address these issues in non-clinical studies, and to report back to CAT to inform the Committee's discussions. Current status: CAT Interested Parties representatives reported on the difficulty to collect data on identified risks from ATMP developers. They renewed their commitment to raise attention to this issue amongst stakeholders. Activity put on hold until collection of data by CAT Interested Parties will be completed.
3.	**Awareness sessions on significant innovative approaches in non-clinical**

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	development (e.g. emerging animal models, new labelling techniques in biodistribution). This could be achieved, for example, by presenting these findings to CAT as scientific lectures given by relevant researchers. Current status: 1st awareness session held on 11 Oct 2012 (see workshop report at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2012/11/event_detail_000684.jsp&mid=WC0b01ac058004d5c3). Further actions identified: Stakeholders to propose future awareness sessions on significant innovative approaches in non-clinical development.
4.	**Wrap up and conclusion** The summary of the discussions held and the proposed actions will be reported to CAT in November 2012 for endorsement. Stakeholders will be informed on the progress made on activity a) and c) above. It was agreed that the group had completed the vast majority of its activities and it will resume meetings if/when new activities will arise. The Chair thanked all participants for the fruitful discussions and closed the meeting.

LIST OF PARTICIPANTS	
Christian Schneider	CAT Chair
Egbert Flory	CAT member
Romaldas Maciulaitis	CAT member
Gopalan Narayanan	CAT member
Dariusz Śladowski	CAT member
Lucia D'Apote	CAT Secretariat
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