2. Feedback on communication meetings

Roland Dieterle summarised the status of communication meetings with regulatory authorities and overview of feedback. Actions regarding the reports are captured below.

[No comments on slides. It appears regulatory feedback was better than expected. Were any test results not disclosed to regulators?]
Tests have been conducted since late 1989s, exploring initially research studies and later potential formulations. We did not include everything we have ever done as this was not appropriate. We moved testing from CTL to MPI in 2006. We did not disclose the last formulations done at CTL because they were not relevant to the communication. However, we disclosed all of the new data on formulations that was done at MPI-none was withheld.

3. First discussion on future formulation testing strategies

A brainstorming session was held to explore the possible scenarios and questions that may arise as the new formulation strategy develops. This will form the basis of preparation work for the next meeting. The potential scenarios fell into three areas:

3.1: Establishing the toxicity of new formulations as required for regulatory submission and for classification and labelling

- Should we use the standard rat tests for simplicity and as others do?
  - With the extensive database available, what insights can be gained of rat and dog testing

[Why is C57Bl6J strain of mouse not used for formulation studies but is used for PD-related studies? The rat is used in some PD studies.]
The C57Bl6J mouse is of relevance only to the acute model being used to investigate effects on the substantia nigra. This model is used widely by academics to study MPTP.

Normally in regulatory studies for new formulations acute oral toxicity studies are done in the rat. For the purpose of comparing INTRON and non-INTRON formulations of paraquat, a vomiting species (ie the dog) was considered to be more appropriate.

- What other options do we have to assess the oral toxicity of paraquat formulations for regulatory purposes?

[What is purpose of pursuing other options? Is there dissatisfaction with existing oral toxicity tests?]

The purpose of considering other options is that the rat is the normal regulatory requirement, and is used by us and other applicants, ie we will do the oral toxicity tests in the rat regardless (the dog would be supplementary). Using the dog model to explore

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