Improve early access to data from catastrophic clinical trials: A statement on behalf of the British Pharmacological Society

In 2006, in London, six young men almost died in a private clinic after receiving an immunomodulatory drug, TGN1412, which caused severe inflammatory reactions in a first-in-man study. Earlier this month, in France, at least five men were injured (one of whom subsequently died) in a private clinic after being given an FAAH inhibitor in its first study with multiple-dosing. Thankfully, such devastating outcomes to clinical trials are extremely rare events.

Current EU regulations state that data from early human experiments are commercially sensitive and, therefore, may be kept outside the public domain. However, in this circumstance, we believe that patient safety should outrank commercial sensitivity. A better understanding amongst the scientific community of the nature of the drug, and the way in which it was dosed, would be helpful, even at this early stage, in preventing further harm to volunteers in other clinical trials, which may require adaptation or even discontinuation based on this knowledge. An early release of data from the manufacturer is crucial.

The aircraft industry has an outstanding safety record, based on sharing information about accidents and near-misses and, if necessary, grounding planes until the problem is understood and resolved. We believe a similar approach is necessary in the field of clinical research on new medicines.

As experts in the field of drug discovery and development, drug safety assessment and early clinical trials, pharmacologists can contribute to diagnosing the causes of – and preventing future instances of – serious adverse reactions. We recommend release of the study design and protocol, the full Investigation Medicinal Product Dossier (IMPD) and the batch release data for such studies, at the earliest possible stage. This level of transparency is critical to maximise patient safety in the future and should outweigh considerations of commercial confidentiality.

We believe these essential improvements complement the UK Pharmaceutical Industry's continued focus on patient safety in clinical trials, and would be in line with Sir Gordon Duff's report from 2006 in response to the TGN412 clinical trial – in particular the report's third recommendation that "developers of medicines, research funding bodies and regulatory authorities should expedite the collection of information from unpublished pre-clinical studies relevant to the safety of human exposure…In the interests of safety, we believe that the ultimate goal should be an open access database…".

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