TGN 1412 Clinical Trial – Release of Information

This pack contains information made available under the terms of the Freedom of Information Act. It consists of several documents from the TGN 1412 healthy volunteer clinical trial, recently associated with a number of severe adverse reactions. Such documentation is submitted to the MHRA in confidence and would not normally be for publication. But in the MHRA's view, given the events of this trial, there is a public interest in disclosure of the information that outweighs the public interest in maintaining confidentiality in this case.

The documents are the Protocol, the Investigator Brochure, the Investigational Medicinal Product Dossier and the Assessment report.

Protocol: This document sets out the design of the clinical trial, the type of trial subject to include and exclude, how the drug is to be given, the procedures to be carried, how the trial is to be evaluated and all other information essential to the conduct of the trial. One of the main purposes of this document is to ensure that all patients are treated in an identical way in all sites that the trial is conducted in (which may be in different hospitals, even different countries).

Investigator brochure: This document provides information to the investigators participating in a trial on all relevant aspects of the drugs development to date, including results from other clinical and non-clinical trials, where relevant. This information is regularly updated during the development of the drug by the development company, typically annually, to ensure that all the current information available on the drug is available to the investigators.

Investigational Medicinal Product Dossier: This document is normally compiled by the company developing a new drug. It is made up of three sections, the Clinical section containing data from human trials, the Pre-clinical section containing data on laboratory and animal testing and the Pharmaceutical section containing data on the manufacturing and testing of the product. Each section contains summaries of all of the relevant data collected to date and forms the basis for the assessment of the Clinical Trial Authorisation application by the MHRA assessors.

Assessment Report: This report is compiled from the three separate assessments carried out on the data by medical, toxicological and pharmaceutical assessors in the Clinical Trials Unit of the MHRA.

The EU Clinical Trials Directive 2001/20/EC and the UK Regulations 2004/1031 require that any one wishing to conduct a clinical trial of a medicine in humans must obtain a Clinical Trial Authorisation (CTA) approval from the Licensing Authority (in the UK, the MHRA) and a positive opinion from a recognised Ethics Committee.

The CTA application form, a standard form across all EU Member States, must be accompanied by sufficient supporting data from previous clinical, pre-clinical and pharmaceutical development work to support the proposed trial defined in the protocol. These data are submitted in the documents listed above and allow MHRA assessors to form an opinion on the safety of the proposed trial. In some cases more information may be requested or modifications required and occasionally the application may be rejected because information is lacking or the science behind the trial is not sound.

Not all information held by the MHRA has been released, and some information contained in the documents has been withheld under Sections 38, 40 and 43 of the Act. These relate, for instance, to the details of the manufacturing process for the product, where there is a legitimate interest in maintaining confidentiality and where there is no relevance to the adverse events that occurred with the trial. In this context the MHRA considers that the public interest in disclosure is not outweighed by the public interest in maintaining this confidence.

MHRA
5 April 2006