Animal work for the licensing of medicines – the facts

This fact sheet explains how animal work is used to test the safety of medicines before they are made available to the public.

It takes an average of 10 years from initial development for a medicine to become available to the public. Part of the development process involves pharmaceutical companies carrying out clinical trials in humans with the medicine before a licence can be issued to enable it to be marketed as a new medicine in the UK.

A clinical trial tests whether a medicine is safe and effective for human use. Before tests are run on humans, the law requires that animal studies are carried out to help establish the safety and effectiveness of a new medicine, and to understand its likely effects on people. If tests on animals reveal that the toxicity profile of a particular drug is not acceptable, then it does not progress to human clinical trials.

Animal research is carried out because, in most cases, the body system of mammals works similarly to the human body; therefore animal tests can predict how the human body will react to a new drug. Animal studies are successfully used to:

- identify potential target organs;
- detect toxic effects of a medicine;
- investigate relationships between the duration and extent of drug exposure inside the body;
- find out how to reverse any toxic effects; and
- provide the estimated safe starting dose for clinical trials in humans.

The process of using animals in the development of new drugs has been scientifically progressed for more than 40 years. While there are alternative methods being developed for testing of drugs, there is still no other laboratory method available that can completely replace animal testing of new medicines. Without animal testing, there is a significant risk that potentially dangerous medicines could be tested on healthy volunteers and patients at clinical trials, which could cause serious harm and damage to the human body.

This work is carried out by pharmaceutical companies as part of their development of a submission for authorisation to carry out a clinical trial. This submission is sent to the MHRA for consideration and review. The information we review includes the results of the animal tests carried out by the pharmaceutical company.

As the UK’s medicines regulator, the MHRA is committed to the government’s aim of minimising the use of animal testing and to encouraging the development of alternative tests. We actively support the National Centre for the Replacement, Reduction and Refinement of Animals in Research (NC3Rs). Our staff are active in a number of their projects and further information is available from their website at http://www.nc3rs.org.uk.