Our ref: DE00000905720

Dear Ms Minns and Ms Irving,

Thank you for your recent correspondence to Vince Cable, Dan Poulter and George Freeman about the use of animals to predict human responses. As this is a health-related matter, your email to Vince Cable has been forwarded to the Department of Health and I have been asked to reply to all the emails.

The Government has made a commitment to reduce the numbers of animals in scientific research, and an inter-ministerial group has been set up to oversee this.

The Government report 'Working to reduce the use of animals in research: delivery plan' was published in February 2014, and can be found on the GOV.UK website at www.gov.uk by searching for the name of the report. This document highlights the work the Medicines and Healthcare products Regulatory Agency is conducting with the National Centre for the Replacement, Reduction and Refinement of Animals in Research (NC3Rs) on ways to reduce unnecessary animal use.

The Government's position is clear on minimising the use of animal testing, and on encouraging the development of other in vitro methods in place of animal testing. The NC3Rs was established in May 2004, and brings together stakeholders in the areas of academia, industry, government and animal welfare to exchange information and ideas, and to use research findings to benefit both animals and science. The Centre makes an annual report to the Minister for Universities and Science on its activities, and more information on the activities of the NC3Rs is available on its website at www.nc3rs.org.uk.

Animal experiments are constantly being evaluated and refined. There is an extensive list of guidelines on how best to conduct the range of toxicology studies to support the development of a new medicine. There are also various groups carrying out research into animal testing of new medicines. The Safety Working Party of the European Committee for Medicinal Products for Human Use collaborates with scientists in America and Japan through the International Congress on Harmonisation to establish global standardised methods for the testing of pharmaceutical products.

Animal research still plays an important role in providing vital safety information for potential new medicines. However, as scientists continually push the frontiers of science to their limits, new testing methods have to be developed. It is worth remembering that, as a result of findings from animal studies, a large number of potential new drugs never get as far as being tested in humans. Furthermore, some aspects of the toxicological assessment of new medicines cannot be adequately assessed in humans, and animal data will be the only kind available. The assessment of carcinogenic potential and of effects on reproduction in particular relies on the results of animal studies, for both ethical and practical reasons.

Sound science is used at all stages of research into health and disease, and in the development of new medical treatments. Animal research and testing is a small but vital part of this effort, and is essential for understanding physical and disease processes for the non-clinical development of new medicines, and for detecting unforeseen toxic effects. Approximately 99 per cent of new drugs are eliminated during testing, most during early research phases, but this is a necessary part of the process of demonstrating efficacy as well as safety. It is worth noting that, thanks to this testing, only a very small number of medicines, estimated at less than one per cent, are subsequently withdrawn as a result of serious side effects.

Most studies investigating the value of animal studies in drug development have methodological shortcomings, and datasets are often limited in size or scope. It is therefore challenging to make an unbiased and comprehensive analysis of whether animal studies are of value in predicting short- and long-term clinical safety. However, animal studies are not designed to identify rare adverse reactions that appear after market approval. Although the number of animals used in non-clinical studies is relatively small, by the time a new medicine reaches the marketing authorisation stage it will have been tested in more humans in clinical trials than animals in toxicity studies. The animal studies are designed to find important side effects that are likely to occur in humans. Even with animal models where predictive values are less than what is desired by researchers, animal testing serves to lower the risk of bringing potential new drugs into clinical trials. They may, for example, detect effects not caused by the intended pharmacology of the new medicine (so called 'off-target' effects). Lowering the risk of administering an unsafe drug or unsafe levels of a drug to humans is the main reason for testing drugs in multiple mammalian species. An analysis of the peer-reviewed literature and the documents available from regulatory agencies on biotechnology-derived medicines directed towards cellular targets has shown good concordance with human pharmacodynamics.

The Predictive Toxicology project, which is partly funded by the EU, concluded that the current standard of toxicology testing was acceptable and demonstrated 'a significant value of non-clinical safety assessment in predicting adverse drug reactions in humans'.

Finally, it is important to remember that without the judicious use of animal studies we would have no modern drugs. Without animal testing it is highly likely that a large number of potentially dangerous new medicines would be tested in healthy volunteers and patients in clinical trials. The Government believes that this would be quite unacceptable.

I hope this reply is helpful.

Yours sincerely,

Malcolm Jones
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