



European Federation of Pharmaceutical  
Industries and Associations



National Centre for the Replacement, Refinement  
and Reduction of Animals in Research

## Important step taken to reduce animals used in specific safety test for new medicines

Thousands of rodents per year are no longer being used in a particular test needed to develop new medicines. This outcome follows an extensive review by 18 pharmaceutical companies and the NC3Rs(1) with the support of EFPIA(2). The review, published in Regulatory Toxicology and Pharmacology(3), shows that this particular toxicity test, which can cause substantial effects to animals, is now redundant. In fact, the review has already led to more than a 70% reduction in animal use in acute toxicity tests by the companies involved, and there clearly is even greater potential for reducing animal use for this test worldwide.

Toxicity testing of new medicines for humans and animals accounts for 4% of all animal use in Europe, which means just under half a million rats and mice are used for this purpose each year(4). The estimated reduction of 15,000 in animal use following this review equates to around 3.5% of the rats and mice used in testing new human or veterinary medicines or dentistry products.

Given recent changes in the process for developing medicines, the review's authors questioned the need for a particular animal test that has been required in the safety testing of new medicines. The evidence they gathered showed that the information obtained had little or no value in assessing the risk to humans. The review focussed on the single dose acute toxicity test, which is usually conducted prior to the first clinical trial in humans. It is traditionally required to identify the dose of a medicine that causes major toxic effects.

The leader of the review, Dr Sally Robinson AstraZeneca, said: "Appropriate safety testing with animals is a worldwide regulatory requirement, providing protection to the public and providing doctors with important information on how to administer new medicines. Before new medicines are administered to humans, their safety is evaluated by screening for potentially harmful effects. This screening is mostly done using animals since these currently provide the best prediction of what might happen in people.

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## 2/ IMPORTANT STEP TAKEN TO REDUCE ANIMALS USED IN SAFETY TEST FOR MEDICINES

“In light of our desire to replace, refine and reduce animal use wherever possible, we were keen to examine whether there was a better way to conduct this type of test. We continuously shared and reviewed information between 2003 and 2007, which provided the evidence to reduce animal use by demonstrating that this acute toxicity test is no longer needed before a new medicine is tested in humans. While we recognize that this reduction represents a small proportion of the total, it is an important step in the right direction.”

Dr Kathryn Chapman, co-ordinator of the project, NC3Rs said: “The next step has to be changing the regulations that require this test to be carried out and the NC3Rs and the companies are working hard to achieve this with worldwide regulatory bodies.

“This novel approach shows that significant progress can be made by going back to first principles and examining the need for a particular test, rather than trying to replace the test with non-animal methods. It also highlights that impressive results can be achieved when companies share appropriate data in a focused way and the NC3Rs has adopted a similar approach in other areas of animal use.”

Brian Ager, Director General of EFPIA, said: “These findings have been considered as part of a revision of the international guidelines on toxicity testing which is currently underway, and the companies involved have already achieved significant reductions in animal use. We hope that the regulators, who have been involved throughout the project, will accept the evidence and no longer require this test prior to testing in man.”

### **NOTES FOR EDITORS:**

1. NC3Rs is the National Centre for the Replacement, Refinement and Reduction of Animals in Research - an independent, scientific organisation which finds innovative solutions to:
  - Replace animals in research with non-animal alternatives
  - Reduce the number of animals used in experiments
  - Refine scientific procedures and animal husbandry to minimise suffering

The Centre funds high-quality research, organises workshops and symposia to disseminate and advance the 3Rs, and develops information resources and guidelines. It is an independent organisation, set up by the Government in 2004, and reporting to the Science Minister and stakeholders through the publication of an annual report. More information can be found here: [www.nc3rs.org.uk](http://www.nc3rs.org.uk)

### 3/ IMPORTANT STEP TAKEN TO REDUCE ANIMALS USED IN SAFETY TEST FOR MEDICINES

2. EFPIA is the European Federation of Pharmaceutical Industries and Associations and represents the research-based pharmaceutical industry operating in Europe. Through its direct membership of 32 national pharmaceutical industry associations and 44 leading pharmaceutical companies, EFPIA is the voice on the European scene of about 2100 companies committed to researching, developing and bringing to patients new medicines that improve health and quality of life around the world.  
[www.efpia.eu](http://www.efpia.eu)
3. The paper is entitled 'A European pharmaceutical company initiative challenging the regulatory requirement for acute toxicity studies in pharmaceutical drug development' and is published online today. Regulatory Toxicology and Pharmacology can be found online at  
[www.sciencedirect.com/science/journal/02732300](http://www.sciencedirect.com/science/journal/02732300)
4. Fifth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union {COM (2007) 675 final}

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