

# animal research for human



## medicines

### SUMMARY

- Turning a scientific theory into a new medicine now takes, on average, 12 years. During that time, computer models of new molecules will be studied, thousands of variations will be investigated in the test-tube and a small number will go on to be studied in animals. Then, if doctors and scientists are confident they can do so without undue risks, the potential new medicine will be studied in people.
- Animal research is essential to help scientists evaluate the safety and effectiveness of new medicines. This is because most of those effects of a new medicine which are not yet predictable by using computer models or test-tube research can be seen in well designed and conducted animal studies.
- The biological similarities between ourselves and other animals are enormous. Animal research therefore provides essential guidance enabling researchers to bridge the gap between the test-tube and the patient. There are, of course, species differences between ourselves and other animals but compared to the similarities, the differences are minor and can usually be taken into account.
- Animal research is not a cheap option and is conducted under strict UK legislative controls.

### UNEXPECTED EFFECTS

Even after years of intensive study, and a comprehensive evaluation of all the data by both the originating company and the Government's licensing authority, medicines sometimes cause unexpected side-effects in general use. Those who campaign against animal research frequently cite such side-effects as an argument against animal testing but this is to misunderstand the careful step-by-step nature of the research process.

No-one expects animal studies to provide all the necessary information and final decisions are never made on the basis of animal tests alone. Rather, they enable researchers to move as close as possible to the human situation, before a new medicine is tested and used in people. All medicines approved since the introduction of the Medicines Act 1968, including ones later found to have unexpected effects, passed all the testing stages including non-animal, animal and human research.

No amount of testing can guarantee to find all possible side-effects for every person who may take a medicine. A reaction which occurs at a rate of 1 in 100,000 people or even at a higher rate of 1 in 10,000 for instance, may not be seen until very large numbers of people use the medicine.

### DO COMPUTERS HELP?

Computers have made research much more efficient and have therefore helped to reduce the number of animals needed. Computers have been particularly important in the design of potential new medicines, where existing knowledge is used to 'design in' features that could be helpful and 'design out' features likely to cause harm.

But however advanced technology has become, biological knowledge is still limited and computer modelling only makes theoretical molecules. This is a long way from testing a real medicine in the living body. As knowledge of our biology increases, so too will the contribution computers make to medicines research.

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## Scientific procedures involving animals

Mouse	61.8%	Fish	4.6%
Rat	21.3%	Other carnivore	0.2%
Other rodent	3.1%	Primate	0.2%
Rabbit	1.6%	Other mammal	2.4%
Cat	0.1%	Bird	4.0%
Dog	0.3%	Reptile/amphibian	0.6%
Total approximately 2.66 million procedures			
Approximately 6 per cent of the procedures were for non-medical safety testing			

(Based on Home Office figures for 1999)

## CAN CELL CULTURE BE USED MORE?

Cell culture work in the test-tube is used wherever possible and its usefulness will continue to increase as knowledge improves of how our cells work in the body. This is desirable not only for humane reasons but also because today's cell culture work is much cheaper and faster than the animal tests it replaced.

Cell cultures do not however, tell us about the range of effects (both helpful and harmful) which only occur when a medicine is in the complete living body, as opposed to in cells in isolation.

## HOW IS ANIMAL RESEARCH REGULATED?

The Animals (Scientific Procedures) Act 1986 aims to strike a balance between the needs of research and the welfare of laboratory animals.

The main requirements of the Animals (Scientific Procedures) Act 1986 are that:

- Only competent people can conduct the research;
- Research premises must have the staff and facilities to look after the animals properly before, during and after procedures;
- The likely benefits of the research must justify any possible distress to the animals.

The law also aims to ensure that studies are well designed so that as few animals as possible are needed and requires that non-animal alternatives are used wherever applicable. Where animals are needed, appropriate steps must be taken to ensure that any distress they may experience is kept to the minimum possible given the nature of the research. Proper veterinary care must be provided at all times.

Most laboratory animals experience little or only momentary pain but where more pain is likely, researchers must plan in advance how they will prevent or relieve it. If an animal is in severe distress which cannot be alleviated it must, by law, be humanely killed immediately regardless of whether the purpose of the research has been achieved.

Home Office approval of each research project must be granted before the work can begin and their inspectors regularly visit laboratories, often unannounced, to check that the Act's requirements are being followed.

## WILL THE NUMBER OF ANIMALS NEEDED BE REDUCED?

Researchers aim to use the smallest number of animals necessary in the development of new and improved medical treatments. Advances in biological knowledge and new technology have led to big reductions in the number of animals needed in many areas. Over the past 20 years, the total has fallen by nearly half.

However, this does not mean that there will automatically be reductions year after year in the number of procedures involving animals across the research spectrum. Some years show small increases because of new areas of research.

For example, with the help of transgenic animals, researchers are now able to study the genetic basis of illness in a way that has not been possible in the past. This work is bringing real hope for people living with many hitherto untreatable, or inadequately treated, conditions. In addition, new public health concerns, such as BSE, will arise from time to time and need to be investigated.

Furthermore, UK pharmaceutical companies that successfully develop new medicines may be able to increase their research programmes. This may make overall reductions more difficult to achieve. The pharmaceutical industry wants to reduce the use of animals in research but only insofar as this can be done without compromising human health.

## IS THE PHARMACEUTICAL INDUSTRY COMMITTED TO ANIMAL WELFARE?

The UK pharmaceutical industry fully recognises its responsibility to obey the spirit as well as the letter of the law. The ABPI believes that all organisations under whose auspices research is conducted must ensure that they create a culture which embodies the principles and encourages the day to day practice of good animal welfare. The UK pharmaceutical industry has a well deserved reputation for high standards of laboratory animal welfare.

The ABPI is also taking a major role in international discussions between the pharmaceutical industry of the US, the EU and Japan, along with their respective medicines regulatory authorities, to ensure that those tests demanded by Governments around the world are consistent so that duplication or unnecessary animal research is eliminated.