

# Animal welfare and the European Pharmaceutical industry

## Your questions answered



### Why are animals used for testing?

Tests on animals can provide much information – for instance they can help to advance scientific knowledge, understanding of diseases, and to investigate the development of new medicines. Non-animal alternative methods are used to gain this information whenever possible. However, while improved biological knowledge, technological advances, computer simulations and test tube methods allow significant reduction of the number of animals used, these methods are yet to fully replicate the complexity and reactions of a living organism.

### What is animal testing exactly?

Tests performed on animals help advance scientific research and medicines development. Animal research takes several forms.

**Basic or fundamental research** helps advance scientific knowledge about how animals and humans behave, develop and function biologically. In the EU, basic research accounts for approximately 48% of all animals used for research purposes and tends to be publicly funded with some private funding from industry and medical research charities.

**Targeted or applied research** helps scientific understanding of diseases leading to and including the development of new vaccines and medicines. This type of research is both publicly and privately funded and may also use findings obtained from basic research. Targeted research is the second largest area where animals are used. In the EU this accounts for approximately 18% of animals used for research purposes.

8% of animals are used in **toxicological or other product safety evaluation**, which are performed to test potential harm to animals, humans or the environment. Such research is required by European legislation and international guidelines. Of these, just over half of the animals are used for evaluating human (incl. dentistry) and veterinary medicines. The remainder are used to obtain quality and safety data from household and industrial chemicals, herbicides, fertilizers, and food additives. Quality and safety tests are usually funded by private organizations.

The remaining 26% of animals are used for the purposes of production and quality control, diagnosis of diseases, education and training or other purposes.



## What is animal testing exactly?

### Animal welfare view

Animal rights groups on the whole object to all animal testing and many advocate that the results of the testing are unreliable, and that all experiments could be replaced with non-animal testing methods.

Many argue that scientists automatically opt to use animals in trials rather than seeking out non-animal alternatives, and that this mindset needs to change.

They campaign to modernise parts of the legislation governing animal testing arguing that it is out dated. Science has never had to prove that animal testing works, yet there is a scientific and legal demand to prove that alternatives do work.

Animal rights groups want to see animals being regarded as sentient beings instead of tools for research.

There is also concern about the rise in use of animals in genetic manipulation and cloning.

### Research view

The pharmaceutical and scientific community focus on developing new medicines that are effective in humans, and that deliver the expected result with identified side effects before they get a licence to produce and go to market.

The scientific community argues that even though animal testing doesn't always deliver perfect results with 100% accuracy, it's still the only way to do invasive research to understand living systems and to provide the best possible assurance of the effects of new medicines.

### Legislative view

In the Lisbon treaty animals have been given rights as sentient beings, and it's now a legal requirement not to use animals where there's an alternative.

European and national legislation requires all medicines are tested using a combination of methods that require animals and others that have replaced animals before they can be tested in humans.

Some medicines and vaccines must be tested on animals for every batch. These tends to be medicines that are made of, or derived from a live product – such as botox, polio vaccine etc.

New legislation, Directive 2010/63, on the protection of animals took effect in member states on 1st January 2013.



## Are there any non-animal testing alternatives?

Yes, there are many non-animal methods approved and used today. Animals are replaced, either by methods that don't involve animals at all or by those that use only the cells or tissues of animals. Many replacement alternatives involve these *in vitro* ("in glass") techniques, where the studies are done with cells or tissues in culture. Other alternatives include *silico* methods replicating animals' reactions through a computer program.

These methods are very useful for studies on particular types of tissue and help considerably to limit the number of animals used. However they are still not able to simulate an entire organism with all its cells, tissues and systems working together.