

The Care, Welfare and Treatment of Animals

The Issue

Animal research can be a sensitive subject and a topic of debate for many people. At GSK we recognise this and seek to explain our position.

A key part of our mission is to discover and develop new treatments and vaccines that can help alleviate or avoid the ill health, pain and distress caused by diseases. Animal studies represent a small but vital part of our research efforts and at present it is not possible to eliminate animal studies from these discovery and development processes.

Our company-wide policy outlines the standards of care and the ethical treatment of animals used by or on behalf of GSK. The policy defines and drives the acceptable standards for our animal work.

GSK's Position

- There is a real need for new medicines and vaccines and the benefits these can bring to patients and society.
- Animal studies remain a small but vital part of our research. Such studies are the only method that can show the effects of a potential new treatment or intervention in a living body before it is used in humans.
- Regulatory authorities world-wide that approve medicines and vaccines for use in humans require safety studies in animals before they will approve the use of a compound in clinical trials or license a new medicine.
- Ultimately GSK would like to see the important benefits of research being achieved and applied to humans without the need for animals in research. We do not believe this can be achieved in the foreseeable future. Our goal is to use animals only when scientifically necessary, use as few as scientifically feasible and to minimise pain and distress.
- We are actively engaged in research to develop and validate experimental methods that can provide alternatives to the use of animals in research.
- GSK is committed to high standards of humane care and treatment for our animals.
- The animals we use are nearly all bred specifically for research and all animals are well cared for throughout their lives by qualified, trained staff. Exceptions to the purpose bred animals include some fish and amphibians, which we obtain from sustainable sources. We never use pets or strays.
- We only test non-medicinal products on animals where there is a specific legal or regulatory requirement to do so to make a health benefit claim.
- We will not carry out animal testing for products whose primary use is to improve the appearance of individuals (i.e. aesthetic or beautifying purposes).
- GSK has voluntarily decided to end the use of great apes (i.e. chimpanzees) in research. We no longer initiate or initiate funding of studies using great apes as part of our voluntary decision.

BACKGROUND

GSK is committed to improving the quality of human life by enabling people to do more, feel better and live longer. Millions of people across the world owe their lives to our success in discovering and developing effective vaccines, and medicines including antibiotics, antivirals and treatments for asthma. Others have the quality of their lives improved significantly by GSK medicines which treat or alleviate symptoms of epilepsy, migraine or osteoporosis. None of the medicines would have been developed without the appropriate studies on laboratory animals.

GSK's Approach

GSK recognises that the use of animals for research purposes is a subject of enormous sensitivity that rightly commands a high level of public interest. We also believe that we have a moral responsibility to ensure high standards in the humane treatment of laboratory animals.

We have our own company-wide policy that covers the standards of care and the ethical treatment of animals and sets out core principles. The policy defines and drives the acceptable standards for our animal work. All animal studies carried out by or on behalf of GSK must comply with these principles.

1. Animal research is vital to the discovery of new treatments

Many diseases that cause suffering or death - including HIV/AIDS, cancer, malaria, and Alzheimer's - are in need of new, more effective treatments. At GSK, our aim is to discover and develop vaccines and medicines that will help alleviate the suffering caused by these and other diseases. This goal would be unattainable if animals could not be used to understand disease mechanisms, discover novel ways to rectify them and evaluate the efficacy and safety of potential new treatments before they are given to humans.

Regulatory authorities world-wide require that all new prescription medicines and vaccines must be studied in animals before any studies can be commenced in humans and before the new treatments are approved for use in patients. These requirements were developed to help understand the risks and benefits of potential new medicines.

Much research work can be done using non-animal methods, such as computer modelling and isolated cells and tissues, and we use these wherever possible. However, these methods cannot always give the insight into how a potential medicine affects disease mechanisms or biological systems. So studies in animals are still a requirement: humans are biologically very similar to other mammals, with most of the same organs performing similar functions and controlled by comparable mechanisms, such as the circulatory and nervous system.

GSK manufactures and sells over-the-counter medicines that people can buy without a prescription. Information about the safety and efficacy of the medicinal ingredients used in these medicines is already available before they are made available for sale to consumers. Consequently our policy is not to test them on animals unless required to do so by regulatory authorities to substantiate safety. Even then, animal tests would only be undertaken following a comprehensive internal review procedure to ascertain that the product had proven therapeutic benefits and there were no alternatives to animal tests.

GSK also makes a wide range of non-medicinal products from nutritional drinks to vitamins. The definition of a non-medicinal product can vary between governments, as do the different regulatory testing requirements. Some countries may require animal testing to support safety or efficacy claims of non-medicinal products or ingredients. GSK does not carry out animal testing of non-medicinal products unless there is a specific legal or regulatory requirement to support a health benefit claim.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

We will not carry out animal testing for products designed primarily to improve the appearance of individuals (i.e. aesthetic or beautifying purposes). For products with both aesthetic and healthcare uses and/or those classified as cosmetics by regulators GSK will only test in animals when it is required by regulators and when the primary use and marketing claim relates to its healthcare benefits.

2. GSK Policies

We are committed to maintaining high standards for the humane care and ethical treatment of all laboratory animals. GSK's policy requires that scientists try to devise tests that do not require any animals at all, and if that is not possible, they try to obtain the information they need from the smallest number of animals, while minimising pain and distress.

Our animal facilities and research and development programmes comply with all national laws, guidelines, codes of conduct and our own core principles for care and welfare for animals in research. The core principles, as laid out in our GSK policy, mandate that, as a minimum, all animals in our care must have access to:

- food, water and housing that is appropriate to the animal species
- humane care and a programme of veterinary care

This policy also outlines requirements for study design and approval, including that studies must:

- follow the principles of the 3Rs of replacement, reduction and refinement in the design of animal studies
- be reviewed by an ethical review panel
- minimise any pain or distress to animals
- be performed by appropriately trained staff.

Staff involved in animal research are trained to standards that are approved by recognised professional bodies and that adhere to national guidelines. Qualified veterinarians are available at all times for advice and help in the care of animals and in the conduct of the research. All due measures are taken to prevent or minimise pain and distress before, during and after experimental procedures.

Failure to meet our company standards, the maltreatment of animals or non-compliance with the laws governing animal studies by staff can lead to disciplinary action up to and including dismissal.

When GSK engages other entities to breed animals, perform animal studies on its behalf or supply materials for use in *in vivo* studies on GSK's behalf, we require that such entities meet all applicable legal and regulatory requirements and ask that they adhere to our core principles for animal care and welfare. The Company implements review processes to ensure that it is aware of, and monitors the use of, animals in research which it sponsors via contractors and academic partners.

GSK's ethical policies and the regulatory framework within which we operate commit us to the 3Rs, which are recognised by the biomedical community as:

- replacing research using animals with other methods where possible
- reducing the number of animals used in a study whilst still providing information of a given amount and precision
- refining techniques to minimise pain and distress and improve the welfare of animals.

GSK is actively engaged in research to develop and validate experimental methods that can provide more and better alternatives to the use of animals in research. To this end we have instituted an Animal

Welfare Award to encourage and recognise individual efforts to develop alternative test methods and other practices to ensure we use only the optimal number of animals.

We are also involved with other organisations that aim to reduce the need for animal testing and promote animal welfare including, but not limited to:

- UK National Centre for the 3Rs
- European Centre for the Validation of Alternative Methods (ECVAM)
- European Partnership for Alternative Approaches to Animal Testing (EPAA)
- The US National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)
- The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)
- Center on Alternatives for Animal Testing (CAAT)
- Scientist Center for Animal Welfare (SCAW)
- Institute for Laboratory Animal Research (ILAR)

3. External Regulation

Animal research is highly regulated and all of GSK's facilities and programmes comply with the national laws, guidelines and codes of conduct for that country. Inspectors from many regulatory agencies, including the UK Home Office, the UK Department of Health, the US Department of Agriculture and the US Food and Drug Administration, pay unannounced visits to check that the projects and the animal care and use programmes meet all statutory requirements.

We involve people not affiliated with GSK in these activities and voluntarily undergo independent accreditation of animal care, for example by the Association for the Assessment and Accreditation for Laboratory Animal Care International (AAALAC-I).

4. Engaging in public debate and communication

Animals could not be used in the discovery and development of new treatments without public acceptance that it is necessary, conducted humanely and benefits society. Our policy therefore is to be open about animal research and we welcome and encourage responsible dialogue about the need for animal research and the care and welfare of the animals.

GSK engages with law-abiding organisations such as the Royal Society for the Prevention of Cruelty to Animals, the Universities Federation for Animal Welfare, the Scientists Centre for Animal Welfare, and the Welfare and the European Federation of Laboratory Animal Science.

We publish the results of our research in scientific journals that have world-wide readership and in a way that ensures the work is made available to other researchers, including through publications that emphasise the 3R's approach. The company also provides data to the Centre for Medicine Research, which shares information from pharmaceutical companies around the world. By doing so, we contribute to improve access to existing information and study results.

Our scientists visit schools to explain the role of animal studies in medical research, and our animal facilities are open to employees and other small groups to visits.

5. Safeguarding employees and premises

GSK believes that companies and scientists should be able to pursue legitimate research goals in accordance with the law without fear of harassment, intimidation or violence. This includes pharmaceutical companies conducting animal research to discover and develop new medicines.

GLOBAL
PUBLIC POLICY ISSUES
GlaxoSmithKline's Position

For many years' pharmaceutical and research industries have been the focus of protests by various animal protection groups. Animal research is a subject of enormous sensitivity which, understandably, provokes strong emotions. We believe there is a substantive difference between lawful protest against the company and aggressive, abusive and hostile demonstrations at private residences and the sending of vicious hate mail and hoax bombs to family homes to cause disruption and alarm. The company condemns organisations and extremists that terrorise people, destroy property and commit other acts of aggression under the banner of animal rights to prevent individuals and organisations from going about their legitimate business.

Revised March 2011