

The Care and Ethical Use of Animals in Research

The Issue

Like all major research-based pharmaceutical companies, GlaxoSmithKline (GSK) is the focus of attention by animal welfare activists as well as animal rights extremists. Media coverage of their campaigns means that we are increasingly being asked to justify our policies and practices.

GSK's Position

- There is a real need for new medicines and vaccines and the benefits they can bring to society as a whole and to individual patients
- There can be no new medicines or vaccines without using animals for research and development; regulatory authorities world-wide require animal research to ensure the highest standards of medicinal product safety in man
- The animals GSK uses are usually bred specifically for research and are well cared for throughout their lives by qualified, trained staff
- Animals are only used where no alternative is available and GSK constantly strives to reduce the numbers used; unnecessary pain or suffering is scrupulously avoided
- Animal testing is not the cheap option
- GSK is committed to maintaining high standards of humane care and treatment for our animals
- GSK's Nutritional Healthcare products (Lucozade, Horlicks, Ribena) are not tested on animals

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 safe and effective vaccines, antibiotics, antiviral and anti-asthma drugs. Others have the quality of their lives improved significantly by GSK medicines which treat peptic ulcers or alleviate the symptoms of conditions such as arthritis or depression. None of the medicines which benefit society today would have been developed without the appropriate use of laboratory animals.

GSK's Approach

GSK acknowledges that use of animals for research purposes is a subject of enormous sensitivity that rightly commands a high level of public interest. It also acknowledges that it has a moral responsibility to ensure high standards in the humane treatment of laboratory animals. This policy defines GSK's principles and standards for the care and use of animals by the company or on behalf of the company.

1. Animal research is vital to the discovery of new life-saving medicines

Many serious diseases such as AIDS, cancer, malaria, TB and stroke are still both poorly understood and treated, and cause immense suffering and death. New and better therapies are desperately needed.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

GSK's aim is to discover and develop vaccines and medicines that will help alleviate the suffering caused by these and other diseases. This goal is 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 medicines before they are given to humans.

Regulatory authorities world-wide require that all new prescription medicines and vaccines must be subjected to extensive and prolonged safety testing in animals and in human clinical studies before they are approved for use by doctors. These requirements were developed to protect people from potentially dangerous products. Much research work can be done using non-animal methods, such as computer modelling and isolated cells and tissues, and GSK uses them wherever possible. However, these methods simply cannot reproduce the complexity of changing the course of a disease in a living creature. They cannot, for instance, tell the scientist if the candidate medicine will get to the right part of the body in the right concentration for the right amount of time to produce the desired effect, or if it will do so safely. Such questions can only be answered by carrying out well-designed tests in live animals. That is why national regulatory authorities require animal testing to fulfil the legal requirement for safe and efficacious medicines. It is not possible to obtain regulatory approval for new medicines without using animals.

GSK also markets and manufactures over-the-counter medicines that people can buy for self-treatment without a prescription. Information about the safety and efficacy of the ingredients used in these medicines is generally already available before they are offered 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's Nutritional Healthcare products, which include Lucozade, Horlicks and Ribena, are not tested on animals. Non-medicinal Consumer Healthcare products, like toothpastes or their ingredients, which are classed as cosmetics in some countries, are never tested on animals unless there is a specific demand for this from individual national governments or in the rare event that there is a clear scientific justification that the study is needed to support safety.

2. Code of Practice observed by GSK

GSK is committed to maintaining high standards for the humane care and treatment of all laboratory animals and it is the policy of GSK that all due measures are taken to prevent or minimise pain and distress before, during and after experimental procedures.

GSK's animal facilities and R&D programmes comply with all national laws, guidelines, codes of conduct and GSK's core principles for care and welfare for animals in research. The core principles are:

- Access to species appropriate food and water
- Access to species specific housing, including species appropriate temperature and humidity levels
- Access to humane care and a program of veterinary care
- Animal housing that minimizes the development of abnormal behaviours and allows for normal species specific behaviour,
- Adherence to principles of replacement, reduction and refinement in the design of in vivo studies
- Study design reviewed by institutional ethical review panel
- Commitment to minimizing pain and distress during in vivo studies
- Work performed by appropriately trained staff

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

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. In addition, the Company also has its own ethical Code of Practice that imposes higher standards and more stringent constraints on its scientific staff than the laws of individual countries governing animal research. Peer-review and Animal Care and Use Committees, comprising veterinarians, scientific staff, senior managers and technicians, meet regularly to review animal practices and animal-based research is allowed to begin only after approval of scientific proposals or protocols by these groups (and any external authorities where required). 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.

Ultimately the welfare of our animals depends on the individuals who handle them on a day-to-day basis. These people – veterinarians, scientists, technicians – care about the well-being of animals just as other people do. Many of them have chosen their work precisely because they love animals. Our policy on animal care and use states that failure to meet Company standards, maltreatment of animals or non-compliance with the laws governing animal studies is subject to disciplinary action up to and including dismissal. All staff involved in animal research are trained to standards which are approved by recognised professional bodies and which adhere to national guidelines. Animals are transported, housed and cared for by dedicated staff. All due measures are taken to prevent or minimise pain and distress during and after experimental procedures. The company supervises all staff appropriately and provides suitable facilities so that staff can carry out their duties responsibly and humanely. Qualified veterinarians are available at all times for advice and help in the care of animals and in the conduct of the research.

The vast majority of animals (over 98%) used by GSK are rodents (such as rats, mice, guinea pigs) and rabbits. The remaining 2% includes fish, ferrets, pigs, dogs, cats and primates. Animals used in Research and Development are specifically-bred for research with the exception of some fish and amphibians which we obtain from sustainable sources. Minimising the number of surplus animals we breed for research purposes is a priority. We have replaced the use of wild caught primates for polio vaccine production and testing and GSK would only use wild caught primates under exceptional circumstances and only with specific authorisations by national authorities.

When GSK engages other entities to breed animals, perform animal studies on its behalf or supply materials for use *in vivo* studies on GSK's behalf, GSK requires that such entities meet all applicable legal and regulatory requirements. This also applies to any organization to which GSK supplies animals. GSK further requires adherence by these entities to our core principles for animal care and welfare. The Company implements robust review processes to ensure that it is aware of, and monitors use of, animals in research which it sponsors via contractors and academic partners.

3. Reduction, Replacement and Refinement

GSK is committed to implementing the three R's - Reducing the number of animals used for research, Replacement by non-animals methods whenever possible and Refinement of the techniques used to eliminate or reduce suffering and improve animal welfare. In addition, GSK has added a fourth R - Respect to ensure that appropriate care is taken in the conduct of all our animal studies. The 3R's approach is not only ethical; it also makes good financial sense because animal testing is not a cheap option. Much preliminary research undertaken by GSK scientists on new prescription medicines is carried out on isolated tissues and cell cultures rather than animals. Not only is this more humane, it is also a more cost effective way to conduct research.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

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, with the least effect on individual 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 GSK has 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. The company shares our practices with other scientists and pursues the acceptance of validated alternatives with regulatory authorities.

The Company is also actively involved with external organisations that aim to reduce the need for animals: These include: FRAME (The Fund for the Replacement of Animals in Medical Experiments) and the National Centre for the 3Rs in the UK (NC3Rs), ECVAM (European Centre for the Validation of Alternative Methods), EPAA (European Partnership for Alternative Approaches to Animal Testing) and the European Cosmetics Companies' Trade Association's "Alternatives to Animal Testing" programme in Europe.

4. Engaging in public debate/communication

Animals could not be used in the discovery and development of new medicines without public acceptance that it is necessary, done humanely and benefits society. GSK therefore welcomes and encourages responsible dialogue about the need for animal research and the care and welfare of the animals used. Sharing their concerns about the welfare of laboratory 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, and the Scientists Center for Animal Welfare.

GSK publishes the results of its research in scientific journals that have world-wide readership and in a way that ensures the work is made available to other researchers. It supports publications that emphasise the 3R's approach. The company also provides data to the Centre for Medicine Research, which has established a database for sharing information from pharmaceutical companies around the world.

A comprehensive schools programme is in place to enable students and teachers to visit GSK's facilities to learn more about medicines research and to see the animals under our care. Our animal facilities are also open to all employees and other small groups do visit these facilities.

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 lifesaving medicines.

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. However, 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.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

GSK works closely with law enforcement agencies, government and the scientific community to ensure the safety of its personnel and increase security at our facilities. The company has implemented various initiatives to help employees reduce the risks to themselves and their families, and to provide support to those who are victimised by extremists.