Home Office

Baroness Williams of Trafford
Minister of State for
Countering Extremism

2 Marsham Street
London SW1P 4DF
www.gov.uk/home-office

Iain Stewart MP
House of Commons
London
SW1A 0AA

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Dear Iain,

Thank you for your email of 22 October to the Department for Environment, Food and Rural Affairs on behalf of several of your constituents regarding EDM 175 on animal research. Your email has been passed to the Home Office and I am replying as the Minister responsible for the regulation of the use of animals in science. I am sorry for the delay in responding to your email.

The use of animals in research continues to play a vital part in our understanding of how biological systems work and supports the development of new medicines and medical technologies, for both humans and animals. The use of animals in research is carefully regulated and the use of animals in such testing is strictly limited to that necessary to achieve the scientific benefits. Under UK law no animal testing may be conducted if there is a non-animal alternative available. Without this basic research we would limit our ability to make scientific discoveries which eventually lead to new targets for drug discovery and development and the pipeline of new medicines.

Non-animal technologies (sometimes referred to as new approach methodologies (NAMs) or human relevant methodologies) do not use animals in research; instead they use “in silico” methods (such as computer modelling) and “in vitro” methods (tests outside of living organisms – for example in test tubes). These methodologies have the potential to reduce the reliance on the use of animals, improve the efficiency of drug research and development and to deliver safer, cheaper, and more effective medicines to patients. However, at this current point in time, the availability of non-animal alternatives does not allow us to transition away from the use of animals in science and testing in order to achieve the delivery of benefits.

Such benefits include the early information obtained on potential efficacy and safety of potential new medicines. Although there are always effects in humans that cannot be accurately predicted in animals, animal studies are successfully used to characterise toxic effects of potential medicines with respect to the target organs which may be affected and to understand how such effects vary with the dose of the substance administered.

Additional information can be obtained about whether toxic effects seen can be reversed. This information allows for the identification of factors which can be monitored to assess adverse effects from potential new medicines in their first clinical trials and also to establish the first dose which can safely be given in these studies. This is a critical part of protecting the safety of the participants (often healthy volunteers) in these studies.

Understanding the difference between the levels of the drug which are likely to be effective in humans and the levels of the drug likely to cause side effects is also a critical output from animal studies and can be part of the decision making as to whether to progress the development of a potential new medicine or not. Thus, animal testing is not considered in a stand-alone context but part of an integrated set of evidence from a variety of sources including from non-animal testing. Very few drugs that enter human clinical trials prove to pose an unacceptable risk to humans due to the use of this evidence derived from animal testing. There are many reasons why drugs that are assessed as potentially effective and safe in animals do not progress to market, including commercial reasons and this does not minimise the important contribution to drug development and human safety of animal testing of potential new medicines.

Under ASPA, dogs (together with cats, horses, and non-human primates) are specially protected species. This means that greater oversight is required of establishments holding these species and of projects using these species. As with any project approved under ASPA, all projects proposing to use dogs for research must be for a purpose which is permissible as stated in ASPA. Potential benefits from this research must be likely to be achieved and maximised otherwise no authorisation will be permitted.

Most dogs used for research purposes are for the safety testing of potential new medicines. This is based on internationally set requirements which require testing of potential new medicines in non-rodent mammals (usually dogs or macaque monkeys) to protect human health. However, it is legal to use dogs in other research provided the project meets the requirements of ASPA and has a positive harm benefit assessment.

No dogs are authorised for use within the UK if the scientific objective can be achieved without using animals or by using animals of less sentience. As with all projects approved under ASPA all projects proposing to use dogs in research must justify why any animals need to be used, why dogs in particular need to be used, and why the specific number of dogs and exact procedures are required. Project licences will only be granted by the Animals in Science Regulation Unit (ASRU) when all of these are adequately justified.

Dogs are a species often used in research because of their genetic similarity to humans which means they suffer from similar diseases to humans such as diabetes, epilepsies, and cancers. The dog genome has been sequenced and mutations mapped and therefore dogs are used in basic research which required such knowledge, such as research on muscular dystrophy where there is a known mutation in dogs.

Research using dogs has been instrumental in the development of more than 95 percent of all new chemical medicines approved for use in the EU in the last 20 years. This has included medications for use in treatments for cancer, heart disease, diabetes, and specific genetic disorders.

All establishments licensed to breed or supply animals, or to carry out regulated procedures on animals under ASPA in Great Britain are subject to the full requirements of the Animals (Scientific Procedures) Act. This provides for a regulatory regimen of activities that protects animals in science including systems and thematic audits by the Home Office to ensure compliance with the terms of their licences, the Code of Practice and with ASPA.

Both announced and unannounced site visits are undertaken within a risk-based framework to assure compliance and inspect the welfare, health, and environment of animals at any establishment. The Home Office takes any allegations regarding potential non-compliance with ASPA, the Code of Practice or individual licence conditions very seriously.

MBR Acres was granted an establishment licence in October 2017. Since then ASRU has conducted ten on-site inspections, five of which were unannounced. All aspects assessed on each inspection were compliant with the Animal (Scientific Procedures) Act, licence conditions (for the establishment, projects and individuals), and the Code of Practice for the housing and care of animals bred, supplied or used for scientific purposes.

However, whilst recognising the benefits that are derived from the use of animals in science (including dogs), the Government actively supports and funds the development and dissemination of techniques that replace, reduce, and refine the use of animals in research (the 3Rs). This is achieved primarily through funding for the National Centre for the 3Rs (NC3Rs), which works nationally and internationally to drive the uptake of 3Rs technologies and ensure that advances in the 3Rs are reflected in policy, practice, and regulations on animal research.

Since the NC3Rs was launched it has committed £100 million through its research, innovation, and early career awards to provide new 3Rs approaches for scientists in academia and industry to use. This includes almost £27 million in contracts through its CRACK IT Challenges innovation scheme to UK and EU-based institutions, mainly focusing on new approaches for the safety assessment of pharmaceuticals and chemicals that reduce the use of animals.

In 2015, the NC3Rs published the non-animal technologies roadmap for the UK. The roadmap sets a vision and strategy to accelerate the translation of technologies emerging from research into tests for assessing the safety and efficacy of chemicals (including medicines and drugs) without the use of animals.

This Government believes, in line with the current scientific position, that there is a need to continue to use animals in some areas of research where there are no non-animal alternatives, to protect human and animal health and the environment. We believe robust regulation exists in the UK to protect animals in science and we continue to fund and support the uptake of non-animal alternatives. Therefore, we have no current plans to hold a review into the use of animals in science.

Thank you again for taking the time to write. I hope you will find this information useful in responding to your constituents.

Baroness Williams of Trafford