



Ms Sue Hayman MP
Shadow Secretary of State for Environment, Food and Rural Affairs
House of Commons
London
SW1A 0AA

14 May 2018

Dear Ms Hayman,

RE: BioIndustry Association (BIA) and the Association of the British Pharmaceutical Industry (ABPI) response to Labour's draft Animal Welfare Plan

We are writing to you to comment on Labour's proposals for animal research in its Animal Welfare Plan. As the UK's leading representative bodies of the life science industry, our members are at the forefront of developing cutting edge medicines and technologies to tackle the greatest health challenges in the UK. Their work and the health and societal benefits resulting from it would not be possible without animal research.

We are proud that the UK has one of the highest standards of animal research in the world and welcome this opportunity to work with the Labour Party to help develop its policies on the issue.

Animal research helps scientists better understand the underlying biology of diseases and develop new treatments to improve people's lives. Research using animals has led to many advances in the treatment of debilitating and life-threatening diseases. Blood transfusion, the use of anaesthetics, and kidney dialysis would almost certainly not be possible today without research using animals. HIV medication and high blood pressure treatments would also not be possible without animal research. Furthermore, animal research will be key in developing cures to currently incurable diseases such as Alzheimer's, Parkinson's, and type 1 diabetes. When discussing animal research, it is also important to note that testing cosmetic products on animals or marketing cosmetic products that have been tested on animals has been banned in the UK since 1988 and the EU since 2013 (1).

We have addressed a number of the specific policy proposals in your consultation document which we hope you will find useful.

Labour proposal: Contribute to the development and validation of non-animal research methods and technologies and encourage research in the field.

The BioIndustry Association (BIA) and the Association of the British Pharmaceutical Industry (ABPI) are fully supportive of the 3Rs – the reduction, refinement, and replacement of animals used in research. Therefore it's encouraging to see that between 2015 and 2016 there was a 5% decrease in the number of procedures performed in the UK (2). Sound scientific evidence is critical to the

development of non-animal methods, and the policies on which their adoption would depend. We would therefore welcome any increase in funding towards research that hastens development of such evidence.

The National Centre for the 3Rs (NC3Rs) is the main funder of 3Rs research in the UK. Since its launch in 2004, the NC3Rs has invested over £56 million into 3Rs research. The NC3Rs has an annual budget of around £10 million, the majority of which comes from government-funded research councils. Other funders, such as the pharmaceutical industry, provide support by funding specific programmes for 3Rs research. For example, the ABPI has a long-standing collaboration with the NC3Rs which has delivered substantial improvements in the 3Rs through regulatory changes and opportunities to minimise the use of non-human primates. This collaboration, funded by ABPI members, currently provides financial support for a Programme Manager whose role is to initiate and drive specific 3Rs programmes relating to the use of animals in drug discovery and development. One such recent project that has stemmed from this collaboration aims to investigate the necessity of testing new drugs in two animal species.

We would welcome an increase in funding towards the 3Rs, which would be best directed via the NC3Rs so that funds can be invested through a coherent and integrated approach.

Labour proposal: Commit to ending within an achievable timeframe, the permitting of ‘severe’ suffering as defined in UK legislation.

As per UK legislation, all regulated procedures carried out on animals must be assigned a severity category to allow the harm-benefit analysis of the project to be carried out. Severe procedures are defined as procedures that are likely to cause severe pain, suffering or distress, long-lasting moderate pain, suffering or distress or severe impairment of the wellbeing or general condition of the animals. It is important to note that UK legislation currently prohibits any animal research where pain and suffering cannot be ameliorated through anaesthetics and analgesics.

Severe animal experiments are never undertaken lightly. The Home Office is responsible for carrying out the formal ethical evaluation and authorisation of projects. This is complemented by Animal Welfare and Ethical Review Bodies (AWERBs), which further assess ethical aspects of severe experiments.

We fully support efforts to reduce, replace, and refine animal experiments to minimise and eliminate severe suffering, where possible. Despite the percentage of experiments defined as severe being small (only 3.9% of all procedures were defined as severe in 2016 (2)), industry is committed to refining the remaining severe models and identifying and validating possible non-animal alternatives in a timely manner to avoid or further reduce animal suffering. We recognise the need for these efforts to be science-led and to bring together stakeholders to ensure maximum impact.

The limited number of severe experiments only take place in medical research into specific conditions which are defined as severe due to the nature of the disease, for example, arthritis and the associated arthritic pain. This research is essential for understanding the mechanisms behind the pain and to help with the development of effective new treatments. Committing to a timeframe beyond which such research would be prohibited could curtail key research projects, possibly as they near fruition, particularly if no alternatives or more refined techniques have been developed.

Labour proposal: Commit to a stringent review of defined areas in regulatory testing, with the aim of identifying and eliminating avoidable tests.

The NC3Rs has led several successful projects identifying and eliminating avoidable tests. For example, the NC3Rs led a data-sharing initiative involving 18 companies from across Europe to show that single dose acute toxicity tests were no longer relevant, with the result that these tests are no longer required as the information can be obtained from other studies (3). This led to a change in international regulatory guidelines and a significant saving in animals used. A similar current review is underway investigating the regulatory requirement for testing in two species of mammals before new medicines are tested on humans in clinical trials (4). We would welcome an increase in funding for the NC3Rs to encourage further research in this area.

There would be great value in expanding the current work done by the Home office and its contractors in advocating the acceptance of novel non-animal alternatives, to foreign governments.

Labour proposal: Commit to a ban on the export of animals for use in research unless with specific consent from the Home Office where there would otherwise be greater welfare detriment.

A collaborative approach to scientific research is key for the UK to maintain a leading role in the global science and innovation community. These collaborations often require the sharing of resources, for example certain experimental animal strains, to confirm the robustness of the scientific data gathered. An export ban such as the one proposed could therefore disrupt ongoing and upcoming collaborative international projects thereby impacting the UK's life science ecosystem and medical progress.

This ban may also impact animal suffering in a negative manner. For example, animals may be imported from further afield in poorer travelling conditions, which would increase animal suffering rather than decrease it. For the ban to be meaningful, the Home Office would have to consider many variables with regards to animal welfare. We support efforts towards improving the experience of laboratory animals transported abroad through working with suppliers, transport companies and customs officials to ensure that the animals have the shortest and least stressful journey possible.

Labour proposal: Make animal testing project licenses open and transparent. This would be undertaken in such a way as to ensure addresses and names of individuals were not exposed.

The Concordat on Openness is a set of commitments for UK-based life science organisations to enhance their transparency and openness on their animal research (5). The Concordat was launched by Understanding Animal Research in 2014 and currently has 119 signatories, including the ABPI and BIA. As signatories to the Concordat, we are committed to increasing transparency around animal research.

Under current UK and EU legislation, a project summary in non-technical language must be submitted to the Home Office as part of the project license application. These summaries are then published every year by the Home Office. This is a requirement of the current EU legislation (EU Directive 2010/63) and aims to help keep the public informed of ongoing animal research. Labour is right to ensure addresses and names of individuals are not exposed. Many people in our sector working in animal research experienced significant personal threats of violence and intimidation in

the 1990s and early 2000s. The Labour government of 1997-2010 was right to take proactive action to protect the identities of researchers and prevent illegal and violent behaviour of animal rights extremists (6). Despite improvements in security, there is still a risk to the safety of individuals involved in this important area of life sciences research. It is also important to ensure transparency does not compromise commercial information.

About us

BIA is the trade association for innovative bioscience companies in the UK. The majority of our members are SMEs, and other members include more established bioscience companies, large pharmaceutical companies, academic research and philanthropic organisations, and service providers to the UK bioscience sector. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

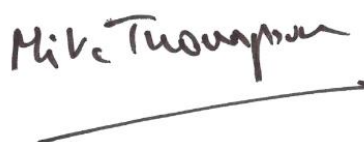
The Association of the British Pharmaceutical Industry (ABPI) represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK. We represent companies who supply more than 80 per cent of all branded medicines used by the NHS and who are researching and developing the majority of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases. Globally our industry is researching and developing more than 7,000 new medicines (7).

We do hope our comments above are useful as Labour develops its proposals further and would welcome a meeting with you or your office to discuss the proposals in more detail. To organise a meeting, or if you require further information, please contact Eric Johnsson at the BIA ejohnsson@bioindustry.org or Harriet Adams at the ABPI at hadams@abpi.org.uk.

Yours sincerely,



Steve Bates OBE
CEO, BIA



Mike Thompson
CEO, ABPI

References

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6. See, e.g.: Tony Blair. Time to act against animal rights protesters [Internet]. The Telegraph. 2006 May 14 [cited 2018 May 11]. Available from: <https://www.telegraph.co.uk/news/uknews/1518328/Tony-Blair-Time-to-act-against-animal-rights-protesters.html>
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