



The use of animals in discovering *medicines*

The Association of the British Pharmaceutical Industry welcomes the report of the House of Lords Select Committee on animal research. The report should help clarify the need for animal research, the reasons why this research is conducted and the way the research is overseen in the UK. It also gives constructive suggestions about the way forward.

The Committee deliberated on this issue for over a year, hearing evidence from a wide range of individuals and organisations with diverse interests and expertise and with views from across the full spectrum. The ABPI supports the key findings of the report that:

- **It is morally acceptable for human beings to use other animals, but it is morally wrong to cause them unnecessary or avoidable suffering.**
- **There is at present a continued need for animal experiments.**
- **Toxicological testing in animals is at present essential for medical practice and the protection of consumers and the environment.**
- **The UK needs to strive for not the tightest regulation, but for the best regulation.**
- **There is scope for the scientific community to give greater priority to the 3Rs (reduction, refinement and replacement).**

- **The availability of good quality up to date information on animal experiments is necessary if the issue is to be discussed productively.**

THE 3 RS (REPLACEMENT, REDUCTION AND REFINEMENT)

The Committee accepts the need for animal research but believes the scientific community could do more to facilitate the development and use of alternative methods. It recommends that Government take a leading role in the search for alternatives. In particular, it recommends that a 'centre for the 3Rs should be set up, consisting of a small administrative hub which co-ordinates research units embedded in existing centres of scientific excellence'.

The pharmaceutical industry works at the forefront of technology and is committed to the use and development of new methods that replace or reduce the number of animals needed in medicines research. Industry already spends some £300 million on such alternatives every year.

In addition, industry researchers working with these new methods collaborate closely with colleagues in academia and share the results of their work through national and international conferences and relevant publications. A well thought out co-ordinating 'Centre for the 3Rs' systematically bringing together those working in a wide variety of disciplines could, however, be of great assistance.

The ABPI therefore supports a hub approach that concentrates on the dissemination of information and spreading best practice. The ABPI believes that specific research projects should be funded through existing successful models such as the Government's LINK Scheme developed to fund collaborative research between industry and universities.

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THE HOME OFFICE AND THE CONTROL OF ANIMAL RESEARCH

The Committee recognises that the implementation of the Animals (Scientific Procedures) Act 1986, the legislation that controls animal research in the UK, has become unnecessarily bureaucratic. The Committee also concludes that applications to conduct research are excessively detailed and the approval process too protracted.

Under the Animals (Scientific Procedures) Act, every single research project must be conducted under a Project Licence, approved in advance by a specialised Home Office Inspectorate. These licences are extremely complex – in the pharmaceutical industry, applications sometimes run to hundreds of pages. The licence applications take an inordinately long time to prepare and the Home Office then needs about 35 working days to process them. Once research projects are underway, licences often need to be returned to the Home Office to incorporate amendments. Such amendments are usually minor and do not impact on animal welfare but add to delays in research.

The Committee shares these concerns and recommends that **urgent consideration be given by the Home Office to the simplification of project licences, with the aim of reducing the length of a typical licence to 10 pages. The Committee also recognises that the preliminary review of proposed research projects, done at local level through a mandatory Home Office approved Ethical Review Process (ERP), could be utilised more effectively. In particular, the Committee recommends that the Home Office should delegate authority to the ERP to allow it to approve minor amendments to project licences.**

Both of these recommendations would be an enormous help. The industry does not wish to see any changes that would have a negative impact on animal welfare but believes that bureaucracy that brings no welfare benefit should be rooted out.

Simplifying the minutely detailed project licence would also have a direct bearing on the Committee's recommendation on the availability of information to the public.

AVAILABILITY OF INFORMATION

The report recommends that **Section 24 of the 1986 Act (the 'confidentiality clause') should be repealed. Specific justification should then be made for each class of information that needs to be kept confidential in each licence application.**

The pharmaceutical industry supports the need to explain to the public why and how animals are used in the development of medicines.

Clearly, however, details that put researchers and their research organisation at risk of violence and intimidation should not be made available. Equally, commercial confidentiality needs to be safeguarded if the UK is to remain a centre for medicines research.

Because of the extensive detail in the project licence as it is currently set up, information that could endanger individuals or be commercially sensitive is interwoven throughout the application document. Such a level of disclosure to Government (unmatched anywhere else in the world) was predicated on the principle of confidentiality. It is not feasible to extract all such sensitive information from the existing project licence. The industry had therefore suggested to the Committee that a system of Home Office approved lay summaries be published.

However, alongside the suggestion to repeal Section 24, the Committee recommends that project licences be made much simpler. If this were to be accepted and implemented, extracting the agreed commercially sensitive information, or points that could identify researchers, would become a feasible option. The ABPI would therefore suggest that the content of the project licence and confidentiality be considered together.

CONCLUSION

The ABPI welcomes the House of Lords Select Committee report on the use of animals in scientific procedures, acknowledging as it does that this research has contributed greatly to scientific advances in human medicine and animal health. It also acknowledges the major advances that have been made in the development of alternative methods.

All new medicines are, of necessity, developed with the help of information from animal studies. Yet the latest Home Office statistics show a further drop in the number of animals used in the UK, now the lowest figure in 45 years. This is a real achievement, particularly at a time when whole new areas of medical research are being investigated. The pharmaceutical industry fully accepts its responsibility and is committed to strive to replace animals in medicines research and to ensure that the animals in its care are looked after properly and spared all unnecessary distress.

Animal studies have a key role in medical research to understand, prevent, treat and cure disease. Such research has enabled the UK based pharmaceutical industry to earn a world class reputation for developing innovative medicines that have saved and improved the quality of life of millions of people.