Use of animals in pharmaceutical research

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The pharmaceutical industry is committed to the 3Rs principle of replacement, reduction and refinement for use of animals in research. Animals are only used in pharmaceutical research when there is no available alternative.

The current status of the science does not allow full replacement of animals in the discovery and development of new medicines and vaccines.

Animals used in pharmaceutical research in the UK are treated and cared for to the highest welfare standards in compliance with the Animals (Scientific Procedures) Act of 1986.

The pharmaceutical industry is actively developing potential alternatives that can be used in place of animals and phasing in alternative methods wherever possible.

Why are animals used in pharmaceutical research?

- Animals are only used in pharmaceutical research when there is no alternative available.
- Animals are used during early discovery research to understand biology and disease so that a medicine can be developed. Animal studies are then performed to ensure the medicine is safe and effective.
- Pharmaceutical companies must strictly adhere to rigorous international and UK regulatory requirements for the development of a new medicine. Medicines regulators globally, including the UK's Medicines and Healthcare products Regulatory Agency (MHRA), usually require animal studies to provide essential safety data about a potential new medicine before it is tested in humans. Testing the safety of a medicine in animals, prior to testing in humans, is currently the best method available and significantly reduces the risk of serious adverse reactions occurring in humans during clinical trials.

What are 'alternative methods'?

- 'Alternative methods', also known as 'new-approach methodologies' or 'non-animal methods' (NAMs) are approaches that can address important scientific questions without the use of animals.
- Alternative methods include *in vitro* tests, for example organ-on-a-chip, or virtual methods such as computational modelling.

How are alternative methods used in medicines development?

- Where available, alternative methods are used in all stages of medicines development from early research to safety testing. Alternative methods must be qualified (proven to work) and accepted by the regulator in order to generate safety testing data to replace the data from animal studies.
- Pharmaceutical companies use alternative methods to generate data prior to animal studies. The alternative method is used to build confidence in the medicine being developed, thereby reducing the number of animal studies that need to be performed.
- The pharmaceutical industry invests significantly into the development of alternative methods.

Why are animals used in medicines development if there are alternative methods?

- Animal research in the UK is regulated by the Home Office under the Animals (Scientific Procedures) Act of 1986. Under this legislation, the use of animals in research is prohibited if there is a non-animal method available that could be used instead. Therefore, animals can only be used in research where there are no alternative methods available.
- The pharmaceutical industry is committed to the principles of replacement, reduction and refinement (3Rs). Through these principles, the pharmaceutical industry aims to minimise the number of animals used in research by replacing them with alternatives wherever possible. Where there are no alternatives available and animals must be used in research, as few animals as possible will be used and the research will be performed in a way that minimises pain or suffering.

Why is full replacement of animals in pharmaceutical research not possible right now?

- The pharmaceutical industry is committed to phasing in alternative methods wherever possible and accelerating the development of further alternative methods. However, the current status of the science does not allow full replacement of animals in the discovery and development of new medicines and vaccines.
- It is scientifically challenging to develop an alternative method that exactly replicates the complex biological processes that occur in a living animal or human. Alternative methods do not yet have the necessary biological complexity to fully replicate what would happen in an animal or human and therefore, cannot be used in isolation to model human disease or determine whether a medicine is safe and effective.

- Regulators are responsible for authorising human clinical trials. To provide authorisation, and allow a medicine to be tested in humans, regulators will review data provided by pharmaceutical companies to demonstrate that a potential medicine is safe. Regulators usually require data generated from animal studies to have confidence that a potential medicine is safe for humans. For alternative methods to fully replace the use of animals in pharmaceutical research, regulators would need to accept data generated from alternative methods.
- Pharmaceutical companies research a broad range of diseases to develop medicines for many conditions. Different disease areas would require different models for research. For example, scientists need a model of the brain to research neurodegenerative diseases and a model of the lung to research respiratory diseases. Full replacement of animals in pharmaceutical research will only be possible when alternative methods are available to research all disease areas.

What would be the consequences of banning the use of animals in pharmaceutical research in the UK?

- **Increase the risk of serious adverse reactions occurring in humans during clinical trials.** Animal studies generate data that provides confidence that a medicine is safe before it is tested in humans during clinical trials. Without animal studies, scientists would be unable to generate essential safety data, which would reduce confidence in a medicine being safe for humans and increase the risk of serious adverse reactions.
- **Delays in development of safe and effective medicines for patients**
  - It would significantly delay medical research. For conditions where there are no alternative methods available, life-changing research is dependent on the use of animals to further understand the cause of the condition and identify potential targets for new medicines.
  - For conditions where there are no alternative methods available, it would not be possible to generate data showing that a medicine in development is safe for humans. Without this data, regulators would not grant approval for the medicine to be tested in humans, a vital step to the medicines potentially becoming available for humans.
- **Deter inward industry R&D investment in the UK.** The pharmaceutical industry is the largest investor in UK R&D, investing £9 billion in in 2022,[1] delivering £17.6 billion in economic value,[2] and providing 126,000 highly skilled jobs across the country.[3] If animal studies were banned, some pharmaceutical companies would have to relocate their animal studies (and supporting teams and infrastructure) to alternative locations around the world, often with lower animal welfare standards than in the UK. This would result in a significant loss of jobs in the research sector and impact the UK economy, while not reducing the total numbers of animals used for research globally.
- **Delays in development of safe and effective veterinary medicines for animals.** Many pharmaceutical companies develop veterinary medicines for animals. If pharmaceutical companies were unable to use animals in research, they would be unable to research animal diseases to understand the cause and develop a medicine.

References

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