

# The vaccines against tetanus and later injected



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The pharmaceutical industry conducts approximately one-third of the animal research in the UK. This research examines the development of new medicines and vaccines, improved diagnosis of toxicity testing. The development of medicine grew significantly over time leading more use of animal models in research. Animals are tested on their general physiological response to a medicine such as changes in blood pressure. This method requires a large number of animals, unproductive and complex leading to the development of computer technology, improved facilities and new techniques. The discovery of a new medicine demands a complex range of different methodologies and stages before the launching of a new product. Data from animal testing are important to researchers when determining whether a medicine is safe for humans.

Before a medicine is tested on humans, rodents are commonly tested first to ensure that it has an acceptable balance of safety and efficacy. Newly vaccines also require animal testing to ensure safety and potency. Table 1: Overview of the process of discovery and development of medicines. In the early stages of the discovery process, stage 1 and 2 involves target identification of receptors for active molecules and the relation of identification of possible medicines respectively. The number of animals used in both stages is small. Cloned human receptors are more preferred compared to animal tissues as they are more selective. The importance of a drug target is commonly examined on GM mice to determine the effect of deleting genes responsible for the synthesis of proteins such as receptors. The genetic modification applied affects the welfare of these animals.

In stages 3 and 4, 60-80% of animals are used. General research and testing such as administering a medicine and measuring concentration level in blood, as well as, in particular areas of research, specific animal models of disease are needed. It is not necessary for an animal to share all properties of humans to be an effective model, however, the model and relevant aspects of the disease being studied have to be similar. Mice are usually used to determine the importance of a gene as a target or, once the importance is known, it will be used as a specific animal model of a disease. At this stage, drug disposition and pharmacogenetics models are also used in a more limited way. Both testings of adjuvants and vaccine modification involve the use of animals by sampling their blood and tissue to measure their immune response.

For example, mice or guinea pigs are given vaccines against tetanus and later injected with tetanus toxin. If the vaccine works, the toxin will cause no effect to the animal. In the past, many more tests are conducted because the animals showed symptoms of the disease, which can be severe and lead to death. Once a candidate medicine has been selected, toxicity tests are conducted on animals, completing the pre-clinical phase.

The increased knowledge gained in the earlier stages means potential medicines are better characterised and is able to predict a safety and initial dose of medicine to be used in humans by the extrapolations made from animal and non-animal data. The final outcome of this stage is a drug successfully turning into a commercial product. In stages 6-8 the new medicines are tested on humans. This test is divided into four phases, Phase I-IV. In purpose of Phase I is to determine the behaviour of active ingredient

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in humans and the suitability to be developed into a medicine. Additional animal studies are undergoing if a medicine is intended to be given to pregnant women prior to Phase II studies.

The process of producing a new medicine is lengthy and complex and requires a wide range of information before proceeding on to the next stage. Animal testing plays an important role in determining safety and efficacy. In the UK, Medicines and Healthcare products Regulatory Agency (MHRA) monitors medicines on the market meet the required standards of safety, quality and effectiveness.

The Committee on Safety of Medicines (CSM) and MHRA will take appropriate actions if attaining evidence of a medicine suggest risk to patients to protect the health of them by withdrawing the medicine from use. Toxicity testing is carried out to evaluate the degree of toxicity of substances to humans, animals or the environment, to investigate the mechanism of toxic chemicals or the development of new or improved tests for specific types of chemically induced effects. Chemicals are assessed for their potential to cause irritation and other developmental complications. Toxicity tests are used to categorise chemicals to assign appropriate labels where necessary. Animal testing helps in predicting the likely effects of chemical exposure on human health.