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In the UK, there is no explicit legal requirement to use animals for testing pharmaceuticals and chemicals. International guidelines do however include animal tests as the standard expectation. To use a non-animal method it must be formally validated and accepted as a "replacement". If no officially accepted non-animal method exists, the UK Home Office will automatically grant a licence for the animal testing to go ahead. In practice this means tests that use animals are ***functionally*** required by law even though there is ***no explicit*** legal requirement to use animals in this way. This is in direct conflict with Animals in Scientific Procedures Act (ASPA 1986, revised 2012) which states in section 2A:

"…the principle of replacement is the principle that, wherever possible, ***a scientifically satisfactory*** *method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure."*

Yet animal use per se has never been validated or approved and is certainly not scientifically satisfactory.

Since 2021 medicines are regulated independently under the Human Medicines Regulations 2012 which does not mandate animal testing specifically. The latest version - Schedule 8, states that the materials to accompany a UK marketing authorisation for new drugs must include:

"The results of the following in relation to the medicinal product and its constituent active substances -

(a) Pharmaceutical (physico-chemical, biological or microbiological) tests;
(b) Pre-clinical (toxicological and pharmacological) tests; and
(c) Clinical trials."

The UK is part of the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use, which publishes guidelines and standards for testing, e.g., Guidance M3(R2) on non-clinical safety studies. The latter lists all sorts of tests on animals for pharmacology and toxicity assessments. However, it also mentions that;

"This guidance should [..] reduce the use of animals in accordance with the 3R (reduce/refine/replace) principles [..]. Although not discussed in this guidance, consideration should be given to use of new in vitro alternative methods for safety evaluation. These methods, if validated and accepted by all ICH regulatory authorities, can be used to replace current standard methods."

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The ICH guidelines are an expectation to enable smoother trade between the participating countries of UK, EU, USA and Japan. They are *not a legal requirement.*

For basic research carried out in universities, scientists are generally free to use entirely non-animal approaches, yet animals use is still widespread.

ASPA 1986
https://www.legislation.gov.uk/ukpga/1986/14/contents

The Regulators are the Animals in Science Regulatory Unit (ASRU) which is part of the Home Office.