

Editorial

CAN LARGE ANIMAL EXPERIMENTS BE TOTALLY REPLACED BY ALTERNATIVES ?

The number of experiments on large animals in India has become nonexistent over the last decade. The committee for purpose of Control and Supervision of Experiments on Animals (CPCSEA) had been set forth by the Government of India for the purpose of controlling and supervising experiments on animals. All institutions where animal research is conducted have to have a mandatory Institutional Animal Ethics Committee (IAEC) which critically examines the research proposals and monitors the conduct of experiments and ensures humane use of animals.

The constitution of IAEC has one veterinarian, one pharmacologist, a layman, two scientists, and essentially a nominee of CPCSEA. Presently the IAEC is entitled to consider only the applications for use of small animals, eg. rabbit, rodents, frogs, hamsters etc. For the use of large animals such as dog, cat, monkey etc., the permission for use is also to be obtained from the central office of CPCSEA located at Chennai. Thus, scientists have been facing various bottlenecks like delays in decisions, i.e. approval or otherwise, unwarranted paper work etc. Time is one of the most important factors in current cutting edge science. The multitier procedures of seeking approvals, especially in the biotech sector, have led the stakeholders resort to outsourcing preclinical testing to laboratories in other countries at exorbitant costs, draining substantial foreign exchange funds out of the country. For a developing country like India, this translates into a massive economic burden apart from nontangible costs. In the post genome era, where global competition cannot afford such delays in approvals, this amounts to huge financial losses. It is indeed ironical for a country like India, an emerging global hub for clinical research. We draw readers' attention to these issues, which seem as deadlocked as ever.

We do advocate the adoption and application of the Four Rs in using animals for research: reduction, refinement, replacement, and rehabilitation, for humane and ethical use of animals and make the earnest efforts to put into practice the elaborate guidelines set forth by Indian National Science Academy, a premier body for scientific research in India (1). However, it is a fallacy that animal experiments can be totally replaced by alternatives. There are disease conditions and indications like AIDS, malaria, tuberculosis, Hepatitis B & C, where use of non human primates appears essential. These

non-human primates are ideal models due to their phylogenetic, immunological, physiological, and neurological similarities with humans. We owe much of our existing knowledge about heart diseases, cancer, corneal transplants, and brain biology to monkeys and chimpanzees. Eradication of dreadful diseases like measles, mumps, polio, whooping cough is attributable to animal research. The unraveling of the genome would further lead to an increase in the number of drug candidates, which perhaps would need subsequent testing in higher non human primates. This would perhaps increase the need for large animal experimentation in biomedical research.

How then are scientists and scientific organizations to proceed? Researchers in India seek transparent and competent regulation, faster single window ethical clearances, adherence to strict time frames, easing approval and import procedures particularly for transgenic animals, framing standard operating procedures for the regulatory bodies, and most importantly

empowering institutional ethics committees for major decisions for the use of higher animals in biomedical research. This would accelerate the approval process as well help maintain secrecy of intellectual property rights of the protocols. In this era of world trade, based on patent regime, there is a strong need to synthesize new molecule entities, which may then be patented. There is an urgent need for liberalizing the import of animals for such instances. In a developing country like India, various country specific infectious diseases are prevalent, which are not seen in the developed nations. There is thus a greater need for strengthening the research resource in developing countries.

There is perhaps a need for a middle ground between two sides of the same coin, viz animal welfare and cutting edge scientific research, for the welfare of both humans as well as animals. The issue needs to be addressed quickly and logically by scientists, policy planners and regulators for the good of biomedical researchers particularly in India.

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REFERENCE

1. Guidelines for Care and Use of Animals in Scientific Research, Indian National Science Academy, Edition 2000.