

Man, Animal and Science

September 15, 2011

Summary, Programme and Discussants

Indian National Science Academy

New Delhi-110002

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Background of the meeting

Smt. Rukmini Devi Arundale Member of Rajya Sabha (1952-56) was instrumental for catalyzing the legislation for the Prevention of Cruelty to Animal Act 1960. This act dealt only with Cruelty to domestic and captured animals and did not deal with the animal use in experimentation. An Animal Welfare Board was set up in 1962. The Act of 1960 was amended in 1982 to prevent the infliction of unnecessary pain and suffering on animals. In 1996 the Animal Welfare Board Constituted a 'Committee for the Purpose of Control and Supervision of Experiments on Animals' (CPCSEA) and framed the Rules and Regulations for implementation of the Act. Rules and Regulations of this act were amended in 1998 and 2001. These, however, did not provide any guidelines for the humane care of laboratory animals. During 1980s there was a sudden upsurge of anti-vivisectionist/animal welfare movement in India and many other countries which prompted a reappraisal of conditions of animal houses by scientists themselves resulting in laying down of guidelines for providing ideal conditions for housing, nutrition, health and humane care of experimental animals. In the year 1992, INSA took an initiative of its own and appointed an Expert Committee which for the first time in the country prepared the guidelines for care and use of animals in research institutions in the country. In 1998, Govt. of India through a Gazette notification, modified the Rules and Regulation of the Act. INSA scrutinized the new guidelines with help of an Expert Committee and modified as well as updated INSA guidelines framed in 1992 and submitted its recommendation to the Govt. of India in 1999. At the initiative of the

Prime Minister's Office and detailed discussions with the CPCSEA, modifications in the Rules and Regulation were finalized for the Gazette Notifications. The CPCSEA was reconstituted in 2000 which arbitrarily modified these Rules in September 2000, and further amended these in February 2001. INSA published its updated guidelines in 2000. Finally as a result of mutual consultation and understanding, CPCSEA published 'Guidelines for Care of Animals' in 2002. Many institutions in India started following guidelines of CPCSEA and the quality of animal experimentation improved in the country. About 1500-1700 institutions got registered with CPCSEA. Many others smaller institutions however, failed to register.

In 2011, Ministry of Environment and Forest posted a proposed draft of 'Animal Welfare Act 2011' on a website and invited comments/views from interested persons. This new Act was designed to replace the existing "Prevention of Cruelty to Animal Act". No reason was provided justifying the new Act and the need for replacement of existing guidelines framed in 2002. Bio-medical scientists expressed concerns about the various clauses of the proposed draft Act. INSA set up a study group for scrutiny of the draft document and found many clauses which are highly detrimental to the teaching, training and promotion of bio-medical research in the country needing animal experimentation. It was obvious that the draft Act needed revision before it is put up to the Parliament. INSA communicated the views of the Committee reflecting the concerns of the Scientific Community to the Minister of Environment and Forest. No formal response has been received from the ministry by the Academy but it is understood that the views expressed by the INSA and other Scientific agencies have been taken into consideration and concern of the Scientists have been addressed to modify the Act put on the website. INSA has always held that usage of animals in bio-medical research, testing and teaching though essential and

unavoidable, should be governed by strict laws as per the best international practices and standards to ensure humane treatment of animals.

To understand the entire issue in a more holistic manner, a brain storming meeting on 'Man, Animal & Science' was organized by the INSA on 15th of September, 2011. Speakers and discussants were invited from animal lover's groups, Regulatory Agencies in the country and the major scientific institutions, like NCLAS (NIN, Hyderabad), CDRI and IITR (Lucknow), IISc (Bangalore), NCCS (Pune), ICMR, AIIMS, NII, Medical Colleges, private sector drug laboratories like Ranbaxy and Vins-Bioproducts, Animal Welfare Organization Like PETA, Blue Cross and Federation of Animal Welfare Board, Drug Controller of India, CPCSEA and Legal as well as reputed media person. A copy of the programme attached gives the list of speakers and discussants who participated (**Annexure 1**).

Summary of the day long deliberations

Welcome Address by the President INSA, Dr. Krishan Lal, Address by Professor P.N. Tandon (President, National Brain Research Centre) and Dr. S. Chinny Krishna (Co-Founder of Blue Cross and Vice Chairman AWBI) set the tone of the meeting. Dr. Krishan Lal pointed out some of the vagueness in the new Act, like the definition of an animal itself and the drastic punishment proposed without any rationale. While Prof. Tandon conveyed the scientific point of view, and INSA's role in preparing guidelines for Animal Experimentation, Dr. Chinny Krishna conveyed the apprehension of animal welfare activists and pointed out the fault lines, particularly with

regard to the functioning of smaller animal facilities which have failed to register with CPCSEA till now.

Need for animals in biomedical research, testing, and teaching

Experimental animals are used for bio-medical research, drug development and toxicological testing of new products including bio-engineered foods, and for teaching biology and imparting surgical skills.

Most of the drugs used in the country have been developed abroad but are manufactured in the country after the patent period is over. There is an urgent need for India to develop new drugs, especially for diseases which are not major health problems in developed countries. This has become particularly important after the imposition of product patent in addition to process patent. Development of a molecule into a drug takes 10-15 years and is a very costly affair which needs finances to the tune of around 800 million dollars including adherence to and maintenance of world class animal experimental facilities for drug testing. Around 40% drugs fail at the level of toxicity test. Each drug has to subscribe to the mandatory requirement of Drug & Cosmetics Act 1945 and strictly pass through schedule Y of the Act which mandates animal experiments to confirm to safety, therapeutic efficacy and adverse effects prior to entering in the phase – III of human trials. Thus for drug development research, animal experimentation is unavoidable. However, it is the duty and responsibility of the scientists to ensure humane care of animals, prior to, during and after the experiments.

Medical education, training and research are most important part of health care system of a country and India is committed to provide world class health care system at affordable cost. Animals are used for acquisition of knowledge, develop understanding of the basic functioning of physiology,

causes, process, mechanism of diseases and methods to prevent them. The entire process of demonstration and hands-on-training helps medical and veterinary and students and research trainees to handle animals in much better way. However, it is now internationally accepted that use of animals for teaching and demonstration in undergraduate courses should be stopped and computerized models used for the purpose. Both the Medical Council of India and Pharmacy Council of India have given directives to this effect. The Medical Council of India (MCI) stated in 2009 that medical schools may replace live animals in classroom experiments with sophisticated non-animal training methods such as computer-aided technology (Medical Council of India, New Delhi, Amendment Notification of 8th July, 2009 to the Minimal Standard,)

(<http://www.mciindia.org/meetings/EC/2003/ECMN%2013.3.03.pdf>>.,

http://www.mciindia.org/helpdesk/how_to_start/STANDARD%20FOR%2050.pdf).

Many of the most renowned institutions of higher education around the world—including Yale, Harvard, and Stanford—no longer use animals in student practice (Physicians Committee for Responsible Medicine, "Medical School Curricula with No Live Animal Laboratories," May 1, 2008 < <http://www.pcrm.org/research/edtraining/meded/medical-schools-with-live-animal-laboratories> >). JIPMER, Pondichery, has developed an EX-PHARM Blank CD, specially prepared as 100 percent replacement of animals used in undergraduate courses in Medicine, Pharmacology and Veterinary Science. This can be a very useful tool to replace the use of laboratory animals for teaching, provided the colleges have the necessary computer facilities. In the present day and age of computer learning, and inducting computer use for teaching should not pose a problem.

-ICMR has also developed ethical guidelines for medical and educational institutes. (http://icmr.nic.in/ethical_guidelines.pdf)

It was observed during discussions that large number of institutions particularly the educational ones are not registered with CPCSEA. It has to be made mandatory. All the concerned science agencies have to work together for enforcement of prescribed guidelines. It was pointed out that out of large numbers of animals used for experimentation only 7% are used for the purpose of teaching of Life Sciences and Health Sciences. Training courses to generate human resource to manage animal facilities and assist with animal experimentation are urgently required. Training programmes for researchers who use experimental animals are also necessary. Without such training no researchers should be allowed to touch laboratory animals. Institutions should ensure such training. Simultaneously scientists need to work on alternative protocols, e.g. In-SILICO (computer simulation), In-vitro (including use of cell lines), so that need for experimentation on whole animal is minimized.

Legislation to ensure and oversee ethical use of experimental animals

Animal Welfare Legislation has been enacted to check unnecessary pain, and sufferings to animals. 4 R principles, i.e. Reduction of number of animals used, Refinement of Techniques for reduction of pain and suffering and Replacement of animal non-animal models and the Rehabilitation should be the basic ethical frame work for animal experimentations. CPCSEA guidelines for Laboratory Animal Experimentation adhere to these principles besides providing guidelines for animal house, infrastructure, training and periodically monitor the functioning of Institutional Ethics Committees. Institutional Animal Ethical Committees should be bestowed with the responsibility of supervising the ethical issues related to animal care and experimentation. It should be left to the Ethics Committee of Research

Institutes/Laboratories to grant license/permission regarding animal experimentation, as is the case with clinical research on human subjects. Maintenance and management of the animal houses is a costly affair, depending upon size, requirement and type of animals. Provision should be made for establishment and running of standard animal facilities in every institution conducting animal experimentation. Institutional committees should have as their members, research scientists of repute, members of Animal Welfare Board (CPCSEA) and a legal expert. In a large country like India, it is not possible for a Central Regulatory Agency to evaluate and provide speedy clearance for experiment needed for larger animals. Hence, institutional body with representation of researchers, members of Animal Welfare Board, CPCSEA representative and a legal expert should be bestowed with the power to evaluate and approve the animal experimentations. This will ensure efficiency and speed in clearing applications. Institutions are expected to introduce more transparent system of research programmes and functioning of the Ethics Committees and Animal House facility. Periodical inspection and consultation between research laboratories and regulatory agency will help to develop better understanding of each other's views. Animal house should function according to the prescribed guidelines and managed by trained personnel, preferably a veterinarian who is trained in care of small as well as large laboratory animals. Ethics Committee of the institute should supervise its functioning.

Problems with the Animal welfare Act 2011

The current draft of Animal Welfare Act 2011 does not provide the reasons or evidence for revision of Act. The draft also appears to empower regulators to ban animal experimentation in research and teaching and is

too vague. Even the definition of "Animal" is vague. Punitive measures provided in the Act are too harsh and do not match the gravity of the offense and other section of IPC. Expecting scientists/institutions to pay such large fines is not practical. The best approach would be to take in house corrective and effective measures for the breach of any protocol. Legal provisions in the new Act definitely require a thorough examination and scrutiny. As long as drug Control Statutorily requires animal testing, any absolute ban on animal testing will be a contradiction. Chapter V of the proposed bill requires Legal Vetting because it must clearly define the animals that are subject to control of the regulatory body. The offences created by the Statute are 1. Experimentation without permission and 2. Breach of protocol of the experiment. While experimentation without permission could be penalized to stop repetition, breach of protocol does not require punishments at all as any breach of protocol will be counterproductive of the experimentation itself as recognized in USA. Importing ideas of pecuniary damage is irrelevant to this field. Legislative policy should be based on evidence and hence the matter requires a study by a parliamentary committee before the amendment is passed.

Use of Validated alternatives

Interaction of health scientists, biomedical scientists, drug development agencies and animal lovers, with media reflected that if the country is committed to provide first rate health care, it needs expert doctors and researchers and for that use of animals in teaching and experimentation is unavoidable at the present stage. Until appropriate validated alternatives are available, the already available alternative methods such as In-Vitro and, In-Silico, methods should be used contextually, at least for preliminary screening. Also, the Regulatory

Authorities should permit adoption of validated alternative methods of Regulatory Testing since Current Regulatory Requirement is a mandatory for the scientists and drug companies to use animals.

While the draft animal welfare act is more sympathetic to animals than to human beings, medical experts and researchers have moral responsibility to take care of animals in pre, during and post period of experimentation. Every scientific organization has to allocate resources for development of alternatives to the use of animals in teaching, testing and research. The prescribed ethical standards should be followed strictly. All scope of using alternatives should be exhausted before using animals for experimentations.

Need for separate guidelines for different categories of animals

In India, as elsewhere, animals are used for a variety of purposes. Hence, it is desirable to have separate guidelines for the welfare of wild animals, domestic (pet) animals in the houses, stray animals on roads, scientific animals farms in veterinary colleges, slaughter houses in cities, towns and villages, circus and zoo animals and experimental animals used for teaching and toxicological testing and biomedical research. Invertebrates used in zoology departments should be excluded from inspection and licensing protocols. This idea is not new as many countries have enacted separate guidelines/laws for different uses, after thoughtful considerations. Awareness and education of all stake holders and policy makers is essenti

