

PHARMACEUTICAL JURISPRUDENCE

PREVENTION OF CRUELTY TO ANIMALS ACT-1960

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Objectives of the act

The Prevention of Cruelty to Animals Act is an Act of the Parliament of India enacted in 1960 to prevent the infliction of unnecessary pain or suffering on animals and to amend the laws relating to the prevention of cruelty to animals.

The act prevent the infliction of unnecessary pain or suffering from animals. This act prevent the man from behaving cruelty towards animals.

Definitions

- (a) Animal:- means any living creature other than a human being.
- (b) Cruelty:- Roughly it means infliction of unnecessary pain or suffering.
- (c) Breeder :- Means a person including an institution which breeds animals for the purpose of transfer to the other authorized institution for performing experiments.
- (d) Establishment :- Means any individual, company, firms, cooperation, institutions other than schools upto higher secondary level, which performs experiment to animals.

(e) Experiment :- Means any program or project involving use of an animal for the acquisition of knowledge of a biological, physiological, ethological, physical and chemical nature and includes the use of animal in the production of reagents and products such as antigens and antibodies, routine diagnostics, testing activity and establishment of transgenic stocks, for the purpose of saving or prolonging or alleviating suffering or for combination any disease whether on human beings or animals.

(f) Owner :- It used with reference to an animal, includes not only the owner but also any other person for the time being in possession or custody of the animal, whether with or without the consent of the owner.

Committee for the Purpose of Control and Supervision on Experiments on Animals (CPCSEA) - Good Laboratory Practices (GLP) for animal facilities is intended to assure quality maintenance and safety of animals used in laboratory studies while conducting biomedical and behavioral research and testing of products. The goal of these Guidelines is to promote the humane care of animals used in biomedical and behavioral research and testing with the basic objective of providing specifications that will enhance animal wellbeing, quality in the pursuit of advancement of biological knowledge that is relevant to humans and animals.

Institutional Animal Ethics Committee (IAEC)

It houses an animal facility, well maintained according to CPCSEA guidelines to facilitate preclinical studies. All research proposals are carried out only after obtaining the approval of Institutional Animal Ethics Committee (IAEC).

IAEC was constituted in 2006 and registered with CPCSEA. It takes care of all aspects of animal care and research in accordance with CPCSEA guidelines.

Functions

The functions of the Institutional Animal Ethics Committee (IAEC) are as follows:

- To review and approve research proposals involving lab animals
- To provide suggestions for modification of the proposals wherever necessary
- To conduct periodic supervision of Institute's animal facility
- To ascertain ethical use of animals and protection of well being of animals during and after research

- When research activity is not found in accordance to CPCSEA guidelines to help adopt correct measures.
- To see that all those persons involved in animal care and research are adequately trained to handle the animals.
- To ensure that GLP guidelines are followed in animal facility to protect the researchers and all others involved in animal handling.

Composition of Institutional Animal Ethics Committee (IAEC):

1. A biological scientist
2. Two scientists from different biological disciplines preferably involved in animal experiments, out of two, one from the non-clinical discipline.
3. One veterinarian involved in the care of animals
4. A scientist in charge animal House
5. A scientist from outside the institute
6. One non-scientific socially aware person

7. One nominee of CPCSEA One specialist may be co-opted while reviewing special projects using hazardous agents such as radio-active substance and deadly micro - organisms. The Chairperson of the committee and member secretary shall be nominated by the institution from amongst the eight members. Members against serial no. 5, 6 & 7 will be nominated by CPCSEA with a provision of a link nominee for CPCSEA nominee.

Authority under which IAEC is constituted and duration:

- Five names against serial numbers 1- 4 will be sent from the institute to CPCSEA.
- The duration of IAEC will be for a period of 3 years.
- The IAEC will be reconstituted at the time of renewal of registration to CPCSEA.
- Changes can be made in deserving cases with the approval of CPCSEA, Membership duration and responsibilities:
 - The duration of membership will be 3 years (coinciding with renewal of registration).
 - The committee will be reconstituted at the time of renewal of registration and at least half of the members will be replaced.
 - A member can be replaced in the event of long-term non-availability (three consecutive meetings) or death.
 - Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
- Conflict of interest should be declared by members of IAEC.
- A member can tender resignation from the committee.

- (7) Five non-official persons actively engaged in the promotion of animal welfare, nominated by the Central Government.

Committee is authorised to make rules.

PERFORMANCE OF EXPERIMENTS :

- (1) Where experiments are performed, the head of that institution is responsible for fulfilment of the objects of the Act.

Where individuals perform the experiment, he should be qualified and perform the experiments on their full responsibility.

- (2) Every registered establishment before acquiring an animal or conducting any experiment on animal shall apply for the permission of the committee OR The Institutional Animals Ethics Committee alongwith the details. After scrutiny of the application, if satisfied, may grant permission.
- (3) Experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is,
- * Degree OR diploma holders in veterinary science OR
 - * Degree in medicine OR
 - * Laboratory Animal Science of a university or an institution recognised by the Government.
- (4) No establishment shall perform any experiment on animals unless it registered.
- (5) Experiments shall be performed with due care and humanity.
- (6) Animals intended for the performance of experiments are properly looked both before and after experiments.
- (7) An establishment shall not acquire any animal by sale OR otherwise except from registered breeder/ establishment.
- (8) Every establishment after acquisition of a animal shall not transfer such animal by sale or otherwise to any establishment/person.

- (9) Experiments involving operative procedure shall be performed under the influence of anaesthesia to prevent the animal feeling pain and it shall remain so throughout the experiment.

Anaesthesia shall be administered by a veterinary surgeon trained in methods of anaesthesia OR a scientist/technician so trained and shall remain present near the animal till completion of the experiment.

- (10) Animals which in the course of experiments under the influence of anaesthetic are so injured that their recovery would involve pain or suffering shall be destroyed humanely while still under the influence of anaesthesia.
- (11) When there is reason to believe that an animal is suffering abnormal or severe pain at any stage of a continuing experiment, it shall be painlessly destroyed at that stage without proceeding with the experiment.
- (12) The experiment shall not be performed for the purpose of attaining OR retaining manual skill **except** in **schools, colleges** and recognised training institutions.
- (13) Experiments shall not be performed by way of an illustration.
- (14) If possible use small Animal instead of large animal.
And if possible use models, films, etc. in place of Animals.
- (15) Experiments shall not be performed as a public demonstration.
- (16) The substance known as **Urari** or Curari or any such paralyson shall not be used or administered for the purpose of any experiment except in conjunction with anaesthetic of sufficient depth to produce loss of consciousness.
- (17) No experiment the result of which is already conclusively known shall be repeated without previous Justification.

- (18) There shall not be applied to the eye of an animal by way of experiment any chemical substance for the purpose of absorption through the conjunctival membrane or through the cornea calculated to only give pain.
- (19) Dogs held for experimental purposes shall not be debarked.
- (20) The record of experiment performed should be maintained as -
- * Kind of animal used.
 - * Health of Animal.
 - * Nature of experiment.
 - * Reasons necessitating the performance.
- (21) No establishment shall contract or undertake to perform contract research or experiments on contract basis on behalf of any other establishment or research or educational institution. This shall not apply to collaborative research between academic institutions.

15.4. BREEDING OF ANIMALS :

- (1) No establishment shall carry on the business of breeding of animals or trade of animals for the purpose of experiments unless it is registered.
- (2) Every breeder/establishment carrying on the business of breeding animals or trade of animals for the purpose of experiments shall, apply for registration within sixty days from the date of commencement of these rules and, stop breeding of animals if registration is subsequently refused to it by the committee.
- (3) The application for registration by breeder under sub rule (b) of rule-3 and an establishment under sub-rule (b) of rule-4 shall be made in the specified format to the Member-Secretary or any other officer authorised in this regard by the committee.
- (4) The member - secretary or the authorised officer of the committee may for deciding the issue of registration ask for information relating to -

- * Premises where experiment are to be conducted
 - * Animal housing facilities
 - * Details of breeding of animals and its trade
 - * Other infrastructure
 - * Availability of trained man power.
- (5) A breeder or the establishment on registration for the purpose of performing experiments on animals shall comply with conditions as may be specified, at the time of registration, by the Member Secretary of the Committee.
- (6) The animals shall be stocked by the breeder and the establishment in the following manner :-
- (a) Animal houses shall be located in a quiet atmosphere undisturbed by traffic and the premises kept tidy, hygienic and the animals protected from drought and extremes of weather.
 - (b) Animal cages for small animals and stables for large animals shall be such that animals can live in comfort and overcrowding is avoided.
 - (c) Where standards have been laid down by the Indian Standards Institution, the cages, the stable, as the case may be, shall conform to those standards.
 - (d) Animals attendants must be suitably trained and experienced in the duties allotted to them.
 - (e) Animals shall be looked after, before and after the experiments by a trained and experienced attendant.
 - (f) There shall be satisfactory arrangement for looking after the animals during off house and on holidays.
- (7) A breeder shall not transfer any animal by sale or otherwise to an establishment which is not registered.
- (8) No animal shall be imported by a breeder or an establishment which is available in the country.
- (9) A breeder/establishment shall comply with the directions given by the committee.

Stocking of animals.— The animals shall be stocked by the breeder and the establishment in the following manner:-

- (a) animal houses shall be located in a quiet atmosphere undisturbed by traffic, and the premises kept tidy, hygienic and the animals protected from drought and extremes of weather;
- b) animal cages for small animals and stables for large animals shall be such that animals can live in comfort and overcrowding is avoided;
- (c) where standards have been laid down by the Indian Standards Institution, the cages, the stable, as the case may be, shall conform to those standards;
- (d) animals attendants must be suitably trained and experienced in the duties allotted to them,
- (e) animals shall be looked after, before and after the experiments by a trained and experienced attendant;
- (f) there shall be satisfactory arrangement for looking after the animals during off hours and on holidays.

Transfer and acquisition of animals for experiment. –

- (a) A breeder shall not transfer any animal by sale or otherwise to an establishment which is not registered under these' rules.
- (b) An establishment shall not acquire any animal by sale or otherwise except from a registered breeder/establishment
- (c) Every establishment after acquisition of a animal or animals shall not transfer such animal or animals by sale or otherwise to any other establishment or person except to a registered breeder/establishment
- .(d) The animals used for experimentation in a production/ breed improvement programme may be given out by the breeder' institution for domestic use.
- (e) No animal shall be imported by a breeder or an establishment which is available in the country.
- (f) A breeder or establishment shall comply, with the directions given by the Committee for the purpose of controlling and supervising experiments on animals

Record keeping

The animal house should maintain the following records:

- Ø Animal house plans, which includes typical floor plan, all fixtures etc.
- Ø Animal house staff record-both technical and non -technical
- Ø Health record of staff/ animals
- Ø All standard operating procedures (SOPs) relevant to the animals
- Ø Breeding, stock, purchase and sales records
- Ø Minutes of institute Animals Ethics Committee Meetings
- Ø Records of experiments conducted with the number of animals used
- Ø Death Record
- Ø Clinical record of sick animals and Training record of staff involved in animal activities
- Ø Water analysis report

Offences and penalties :-

- Treating animals cruelly is punishable with fine NLT Rs. 10/- which may extend to Rs. 50/- on first conviction
- On subsequent conviction within three years of previous offence, it is punishable with fine NLT Rs. 25/- which may extend to Rs. 100/- or imprisonment of three months or with both.
- Performing operation like Phooka or any other operation to improve lactation which is injurious to the health of an animal is punishable with fine up to Rs. 1000/- or imprisonment up to 2 years or with both. Animal may be forfeited by the government.
- Contravention of any order of committee or breach of law imposed by committee is punishable with fine up to Rs. 200/-.

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