



## **Issues of Animal Welfare Regulations on Pharmacy Education and Research in India**

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### **Authors' contributions**

*This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.*

### **Article Information**

DOI: 10.9734/JPRI/2021/v33i45A32732

#### Editor(s):

(1) Dr. V. Y. Atsu Barku, University of Cape Coast, Ghana.

#### Reviewers:

(1) Radhwan Nidal Al-Zidan, University of Mosul, Iraq.

(2) Andrés Joaquín Guarnizo Chávez, Universidad de Cuenca, Ecuador.

(3) Mingwan Zhang, University of Connecticut, USA.

Complete Peer review History: <https://www.sdiarticle4.com/review-history/73922>

**Review Article**

**Received 14 July 2021**  
**Accepted 24 September 2021**  
**Published 30 September 2021**

### **ABSTRACT**

Biomedical research is essential to the health and well-being of our society. Animal use for biomedical research has a long history and is routinely performed in new drug discovery and development processes. Animal experiments are an integral part of the curriculum for students in the life sciences, including pharmacy, to learn how to conduct animal experiments. These experiments may cause pain and distress to the animals. Laws and regulations have been enacted to make it illegal to cause undue pain or suffering to animals. These guidelines provide that due and full consideration should be given to alternative technologies not involving animal testing. Despite the movement to minimize animal use in research, pieces of evidence show that there has been a continuous increase in the worldwide use of laboratory animals over 10 years, from 115.2 animals to 192.1 million. The lack of suitable animal-alternative technologies and unavailability of required infrastructures are some of the reasons for animal use. As per directives of the University Grant Commission, the Pharmacy Council of India has decided to prohibit animal experimentation in pharmacy education. This adversely affected teaching and research activities in pharmacy institutions. As a result, the number of seats available for the postgraduate course (Master of Pharmacy) in Pharmacology is decreasing every year. In 2021, the highest number of seats are available for Pharmaceutics (9510, 35%) followed by that for the Pharmacology (4620, 17%). This article mainly focuses on the background of Indian legislation for animal experimentation and the impact of these regulations on animal experiments for pharmacy education and research in India.

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**Keywords:** *Animal experiments; CPCSEA; pharmacy education and research; the constitution of India; the prevention of cruelty to animals Act.*

## 1. INTRODUCTION

Animals have long been used in biomedical research. They were used by early Greek physician-scientists such as Aristotle and Erasistratus [1]. Various vertebrate animals have been used as models for the study of anatomy, physiology, pathology, and pharmacology. Rats were used from 1828 for scientific studies, and the use of animals for testing drugs became important in the twentieth century [2]. Animal studies became most important after the late 1950s due to the well-known Thalidomide tragedy. This tragedy demonstrated the severity of harm to humans if drugs are given to humans without prior testing on animals [3]. Animal research began in India in the 1860s, when Britain began introducing new medicines to the colony. The use of animals in biomedical research in the twentieth century resulted in significant advances in the treatment of a wide range of health problems. Animal experiments are basically used in the drug discovery and development process to demonstrate that a particular drug is suitable for testing in humans [4]. Potential drug candidates that are safe and effective are only approved by regulatory authorities for testing in humans.

These laboratory experiments may cause pain and distress to the animals similar to that of human beings [5]. Earth belongs to all the living creatures and they have an equal right to live on the earth like humans. Many countries, including India, have passed and enforced legislation to regulate animal use for experimentation to ensure animal welfare. This article outlines the background of Indian legislation for animal experimentation and the impact of these regulations on animal experiments performed for teaching and research purposes in Pharmacy institutions.

## 2. METHODOLOGY OF LITERATURE REVIEW

Various databases like PubMed, Springer, Google Scholar, ScienceDirect were explored to find relevant literatures that would act as an anchorage to this literature review. National portal of India was searched for Constitution of India and other animal welfare regulations. Databases of national statutory bodies such as CPCSEA, UGC, PCI were stirred to find out the

updated literatures and evaluate the present status quo of the theme. Key words such as animal experiments, animal alternatives, CPCSEA, IAEC, prevention of cruelty to animals were used.

## 3. CONSTITUTIONAL PROVISIONS FOR ANIMAL WELFARE

The constitution of India, 1950, contains some provisions for ensuring animal welfare (Fig 1). Articles 48, 48A, 51A (g), list II and III of the seventh schedule, eleventh schedule and twelfth schedule of the Indian constitution speak about animal care and welfare [6].

According to Article 48, the state must “*strive to organise animal husbandry on modern and scientific lines, and, in particular, take measures to preserve and improve breeds, and prohibit the slaughter of cows and calves in other milch and draught cattle.*” This constitutional provision is important from an animal welfare point of view as it directs the state to take steps to prevent the slaughter of animals.

The state has a responsibility under Article 48A to “*seek to protect and improve the environment, as well as to safeguard the country's forests and wild life.*” The Indian constitution imposes a responsibility on the state and people to protect the country's wildlife.

Articles 48 and 48A of the Constitution are directive principles of state policy. These are just guidelines that can not be enforced in a court of law. However, it lays down policies which are to be followed by the state at the time of discharging the powers to establish a welfare society.

The 42nd Amendment Act of 1976 added Article 51A to the constitution, which establishes a code of fundamental duties for citizens. “*Every citizen of India shall have the duty to protect and improve the natural environment, including forests, lakes, rivers, and wild life, and to have compassion for living creatures,*” according to Article 51A(g) of the Constitution.

The Indian constitution also provides for legislative competence of the union, state and local self-government. According to List III of the seventh schedule, both the union and state legislatures have legislative authority on the

subject of “prevention of cruelty to animals, protection of wild animals and birds, and prevention of the extension of infectious or contagious diseases or pests affecting persons, animals, or plants from one state to another.” List II of this seventh schedule gives legislative authority to states for “preservation, protection and improvement of stock and prevention of animal diseases; veterinary training and practice.” According to the constitution’s eleventh schedule of constitution, panchayats have the authority to pass laws regulating “animal husbandry, dairying, poultry, and fisheries.” Municipalities can take on certain responsibilities related to the “regulation of slaughterhouses and tanneries” under the twelfth schedule of the constitution. All these provisions indicate that the parliament, state legislatures, and local self-governments like panchayats and municipal corporations can take appropriate steps through making suitable regulations to ensure animal welfare.

The Apex court of India has also taken a positive view to protect animal welfare. It is held by the Supreme Court of India that, “the state and people of the country have a fundamental duty to protect and improve the environment, including forests, lakes, rivers, and wild life, as well as to respect living creatures” [7]. In a case, the petitioners argued that the Bombay Animal (Preservation of Gujrat Amendment) Act 1994, which prohibited the slaughter of cows and their progeny, was unconstitutional because it infringed on their right to carry on business under Article 19(1)(g) of the constitution [8]. It is held that, “the prohibition imposed by the Act on

pursuing the goals of the directive principles in Articles 48 and 51A is a reasonable restriction on petitioners’ fundamental rights to continue and therefore legal.” In a landmark case, the apex court extended the definition of life under Art 21 of the Constitution to include animal life, which means a life of dignity, worth and honour [9]. The court further held that, “animals, like humans, have a right not to be tortured and against the infliction of unnecessary pain or suffering.”

#### 4. LEGALITY OF EXPERIMENTS ON ANIMALS

The Indian parliament passed the Prevention of Cruelty to Animals Act 1960 (PCA Act) to prohibit the infliction of unnecessary pain or suffering on animals and to amend the legislation relating to the prevention of cruelty to animals [10]. Furthermore, in 1972, the parliament passed the Wildlife (Protection) Act, which ensures environmental and ecological security by protecting the country’s wild animals, birds, and plant species [11]. There are some other laws for preventing animal sacrifice, such as the Indian Penal Code, 1860, and the Drugs and Cosmetics Rules, 1945 [12-13].

According to Section 14 of the PCA Act, “nothing in the PCA Act makes it illegal to conduct experiments (including operations) on animals for the purpose of advancing physiological information or knowledge that would be useful for saving or prolonging life, alleviating suffering, or combating any disease, whether of human beings or animals or plants” [10].

Article 48 (Directive Principles of State Policy)	Article 48A (Directive Principles of State Policy)	Article 51A(g) (Fundamental Duties)	7 <sup>th</sup> , 11 <sup>th</sup> and 12 <sup>th</sup> Schedules
<ul style="list-style-type: none"> <li>• Organization of animal husbandry</li> <li>• Preservation and improvement of breeds</li> <li>• Prohibition of slaughter of cows and other milch and draught cattle</li> </ul>	<ul style="list-style-type: none"> <li>• Protection and improvement of the environment</li> <li>• Safeguarding the wildlife of the country</li> </ul>	<ul style="list-style-type: none"> <li>• Protection and improvement of the natural environment including wild life.</li> <li>• Having compassion for living creatures</li> </ul>	<ul style="list-style-type: none"> <li>• Law-making power to parliament, state legislatures and local self-governments for animal welfare</li> </ul>

Fig. 1. Constitutional provisions for animal welfare

The Drugs and Cosmetics Rules, 1945, Part XV(A) regulates the “*approval of institutions for conducting research on drugs/cosmetics and raw materials used in their manufacture on behalf of licensees for the manufacture of drugs/cosmetics for sale*” [13].

These provisions suggest that the legality of experiments on animals depends on the objectives of the intended experiments. Regulatory authorities approve institutions for carrying out such experiments for drugs/cosmetics and their raw materials if they comply with conditions mentioned in the Drugs and Cosmetics Rules, 1945.

### **5. COMMITTEE FOR PURPOSE OF CONTROL AND SUPERVISION OF EXPERIMENTS ON ANIMALS (CPCSEA)**

Section 15 of the PCA Act establishes the CPCSEA for the control of animal experiments. It provides that the central government may form a committee comprised of such a number of officials and non-official members for the purpose of controlling and supervising animal experiments [10]. The CPCSEA was formed for the first time in 1964 for the purpose of controlling, supervising, and preventing the use of animals in experiments [14].

According to Section 17(1) of the PCA Act, it is the responsibility of CPCSEA to “*take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them.*” The CPCSEA may make rules to achieve these objectives by notification in the Indian Gazette and subject to prior publication. Therefore, CPCSEA has rule making powers to prohibit the use of animals for various purposes, including teaching-learning activities. The rules made by the CPCSEA shall be designed to secure “*that experiments on animals are avoided wherever it is possible to do so; as for example; in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the like, may equally suffice*”, according to Section 17(2)(d) of the PCA Act. Animal experimentation should be avoided in educational institutes if other teaching devices are available and sufficient for the teaching activity. Section 17(2)(f) of the PCA Act also states that, “*experiments are not performed merely for the purpose of acquiring manual skill.*” All these sections of the PCA Acts are the

replacement principles of animal ethics, stating that animal experiments can not be performed to acquire manual skills and such experiments should be avoided if other equally effective teaching devices are available [10].

The PCA Act has given rule-making powers to CPCSEA to prohibit animal experiments and decide punishments to be applied for contravening provisions of the Act. According to Section 19 of the Act, “*if the CPCSEA is satisfied that its rules are not being followed, it may forbid a person or institution from conducting any such experiments for a specified period of time or indefinitely, or it may allow the person or institution to conduct such experiments subject to such special conditions as the Committee deems appropriate.*” According to Section 20 of the Act, “*anyone who violates a Committee order or breaches a condition imposed by the committee to prevent animal experimentation, such person shall be punishable with a fine of up to two hundred rupees, and if the violation or breach occurred in an institution, the person in charge of the institution shall be punishable with a fine of up to two hundred rupees*” [10].

### **6. BREEDING OF AND EXPERIMENTS ON ANIMALS (CONTROL AND SUPERVISION) RULES**

In exercising the rule-making power given under sections 17(1), 17(1A), and 17(2) of the PCA Act, the CPCSEA enacted the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998[15]. These rules were further amended in 2001 and 2006.

Rule 3 of this regulation provides that every establishment involved in the breeding of animals for trade and performing experiments on animals must be registered by CPCSEA. It is mandatory to constitute an Institutional Animal Ethics Committee (IAEC) at the time of registration, which is comprised of a group of people who have been nominated by CPCSEA for controlling and supervising animal experiments in the establishment (Fig 2). Furthermore, rule 8 states that any registered institution must obtain permission from the IAEC and, in the case of large animals, the CPCSEA before acquiring an animal or performing experiments on an animal. While granting permission, the IAEC or CPCSEA can impose conditions to ensure that animals do not suffer unnecessarily before, during, or after experiments [15].

According to rule 9(g), “experiments shall not be conducted for the sole purpose of attaining or retaining manual skill except in schools, colleges, and programmes duly scrutinised and permitted in registered establishments by the CPCSEA.” No experiment shall be repeated without prior justification under Rule 9(k) if the outcome is already conclusively known. Rules 9(g) and 9(k) provide the basis for prohibiting the use of animals for teaching purposes as they are mainly performed to acquire animal experimentation skills and these experiments yield already known results [15].

## 7. ALTERNATIVES TO ANIMAL EXPERIMENTATION

The Government of India published Guidelines on the Regulation of Scientific Experiments on Animals in 2007. This guideline outlines the CPCSEA's ethical guidelines for the use of animals in scientific experiments. It is also provided in the guidelines that due and full consideration should be given to alternatives not involving animal testing. Sound justification is needed if these alternatives are not used even though they are available [16]. The main alternatives available for animal experimentation are computer-based models, cell and tissue culture techniques, and the use of alternative organisms such as zebrafish, drosophila, prokaryotes, bacteria, etc. [17].

### 7.1 Computer Based Models

Computers are one of the major sources of knowledge which can help to understand various concepts related to biology. There are a variety

of computer software and simulation programs which can be useful for predicting the pharmacological and toxicological profiles of drug molecules. Computer Aided Drug Design (CADD) is a software program helpful for predicting drug-receptor interactions which are then confirmed by performing animal studies [18]. The most useful computer software is Structure Activity Relationship (SAR), which is used for prediction of biological activity of test drugs on the basis of chemical structures. The Quantitative Structure Activity Relationship (QSAR) is a mathematical description which relates the physicochemical properties of a test drug to their biological effects [19]. These softwares are basically very useful for prediction of drugs having carcinogenic or mutagenic potential [17, 20]. However, these software designs have certain disadvantages. The major limitation is the unavailability of structures for the majority of the drug targets. Furthermore, these docking softwares have the capability to produce results with an accuracy level of only 51-71% [21].

### 7.2 Cells and Tissue Culture

*In-vitro* studies are another commonly used alternative to animal models. It involves evaluation of drug activity using cell lines grown outside the living organism. The cells of various organs are collected from animals and are then grown on special media outside the body. These cell lines are used for preliminary screening of toxicity and efficacy studies of test drugs [22-23]. The main limitation of cell line studies is the unavailability of *in-vitro* cultures for most of the target organs [17].



Fig. 2. Origin and functions of institutional animal ethics committee

### 7.3 Alternative Organisms

Ethical issues related to the use of common laboratory animals are a motivation for the use of alternative organisms as an alternative to animal models. Many invertebrates, like Zebrafish, *Drosophila*, etc. are used for drug testing. *The Danio rerio*, commonly known as the Zebrafish, is a small freshwater fish. It can be easily used for evaluation of developmental studies [17,24]. *Drosophila melanogaster* is useful for study of molecular mechanisms of human diseases [25]. Nearly 75% of the genes of human diseases are believed to have a functional homolog in the fly like *Drosophila* [17, 26-27]. One of the most common disadvantages of these invertebrate models is their short life span and are limited to only some research studies. Also, direct translation of animal dose to human dose calculations is not available for these invertebrates [28].

Despite the movement to minimise animal use in research, evidences show that the use of animals in research is not declining [29]. There has been a continuous increase in the worldwide use of laboratory animals over a period of 10 years, from 115.2 animals used for procedural and non-procedural purposes to 192.1 million [30]. This includes about 80 million experiments on animals. In 2015, top ten animal testing countries in the world were China (20,496,670 (estimated)), Japan (15,033,305 (adjusted)), the United States (14,574,839 (adjusted)), Canada (3,570,352 (official)), Australia (3,248,483 (adjusted)), South Korea (3,110,998 (adjusted)), Brazil (2,179,621 (estimated)), the United Kingdom (2,586,942 (official)), Germany (2,044,894 (official)) and France (1,901,752 (official)). It is to be noted that the publicly accessible statistics are not available for many countries including India.

The lack of suitable animal-alternative technologies is the key reason for animal use. Furthermore, many research and educational institutes do not have the required facilities to perform studies using these animal alternatives.

### 8. REGULATION OF ANIMAL EXPERIMENTS BY PHARMACY COUNCIL OF INDIA

With reference to CPCSEA letters [31, 32], the Pharmacy Council of India (PCI) has communicated on 17.03.2011 and 09.06.2014 to all PCI approved institutions that pharmacy

institutions involved in breeding and experimentation should get registered with CPCSEA [33-34].

The University Grant Commission (UGC) of India is a statutory body of the government of India. The UGC is involved in coordination, determination and maintenance of standards of higher education in India. The UGC has published guidelines for the discontinuation of dissection and animal experimentation in Zoology/Life Sciences in a phased manner with the acquisition of appropriate replacement technology and the development of human resources for the same [35]. Later on, the UGC issued two semi-official letters to vice-chancellors of universities to ensure strict adherence to these UGC guidelines [36-37].

The Ministry of Environment and Forest, Government of India [38] and CPCSEA [39] have communicated to statutory bodies, including the Pharmacy Council of India, to direct all institutions to strictly follow UGC guidelines for discontinuation of dissection and animal experimentation in universities and colleges. It is directed to introduce alternatives to animal experimentation. In response to this, PCI instructed all PCI approved institutions to discontinue the use of animals for dissection and experimentation [40].

This circular created hurdles for many academic activities, such as regular practical sessions, projects and summer schools involving animal experiments. These activities were a basic part of the pharmacy curriculum, which provides necessary training to make students aware of common animal experimentation techniques. The PCI has implemented uniform rules and syllabus for undergraduate courses throughout the country. According to this syllabus, all animal experimental skills must be demonstrated by suitable animal-alternative technologies such as software and videos. However, many pharmacy institutions do not have necessary set up of these alternative technologies for animal experiments. Many teachers are not trained in the use of such alternatives. Furthermore, certain skills, such as animal handling, can be acquired effectively only by performing lab experiments. Alternatives such as software and videos provide only knowledge and, in the majority of cases, they fail to give practical skills to students. As a result of the ban on the use of animals for dissection and experimentation for the B. Pharm. course, students are losing their interest in animal experimentation and are not selecting this

area of pharmacy for higher studies and future career. These students, who may have otherwise pursued a career in animal experimentation, are now considering other options. As a result, the number of seats available for the postgraduate course (Master of Pharmacy) in Pharmacology is decreasing every year. As per PCI list-2021 of approved institutions for Master of Pharmacy course (41), the top five specializations in the number of seats are Pharmaceutics (9510, 35%), Pharmacology (4620, 17%), Pharmaceutical Analysis (3108, 11%), Pharmaceutical Quality Assurance (2956, 11%), and Pharmaceutical Chemistry (2944, 11%) (Fig 3). In the long run, this would cause many problems, such as a shortage of skilled personnel for animal experiments. Government funding agencies can support private or public organisations that innovate in animal-alternative technologies. These alternative approaches should be established as soon as possible, along with proper teacher training.

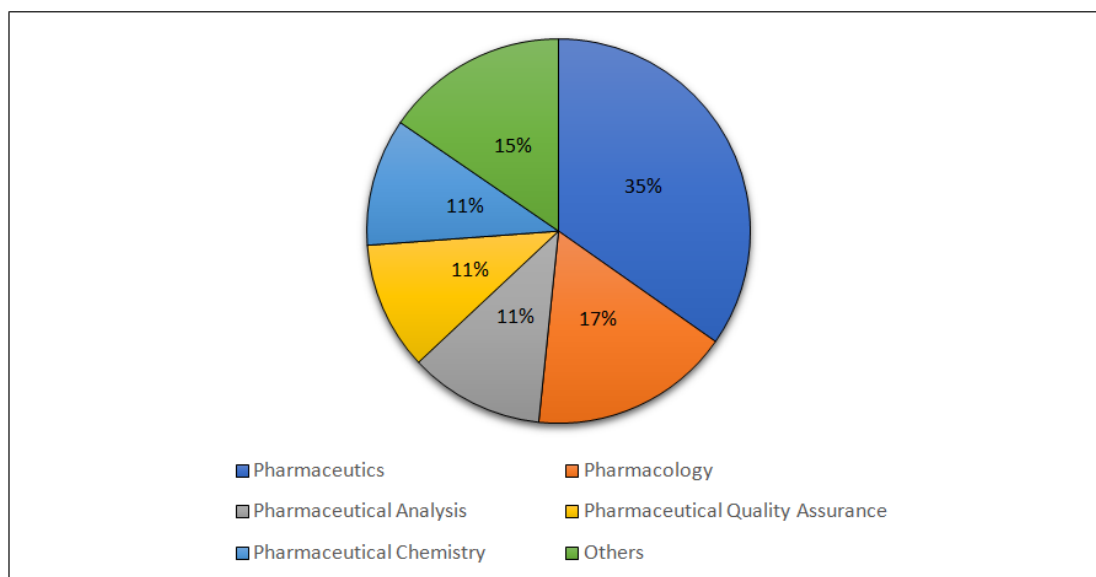
PCI has also informed all PCI approved institutions that whenever animal experiments are conducted using simulations, the requirement of animal house and its registration with CPCSEA is not required for such institutions [42]. The revised PCI syllabus for the undergraduate course (Bachelor of Pharmacy) prescribes practice school and project work for students in their seventh and eight semesters respectively [43]. The inclusion of practice school and project work in the curriculum is an innovative step toward making students ready for higher studies and employment. However, interested students may not take animal-related studies for practice school and project work if pharmacy institutions discontinue their registration with CPCSEA.

The CPCSEA constitutes an IAEC of nine members for each establishment involved in the breeding and use of laboratory animals for experimental purposes [44]. There are five internal members and four CPCSEA-nominated external members in the IAEC. All internal members are of science background, including one veterinarian. The CPCSEA-nominated external members are the Main Nominee, Link Nominee, Scientist from outside the institute, and Socially Aware Nominee. IAEC should be reconstituted every five years with the replacement of half of the internal members at the time of such reconstitution. The CPCSEA conducts two to five-day residential training courses at headquarters for applicants before recognizing them as CPCSEA Nominees. There

is a waiting period of years for this training course. There is a need to reduce this waiting period by conducting more such training courses in various regions of the country on a regular basis. The duration of this training course should be long enough to cover every aspect of animal care. Furthermore, a refresher course should be conducted for already appointed nominees to provide recent advances in the field of animal welfare and animal experimentation.

The IAEC has to ensure compliance with all regulatory requirements at the institute [45]. It reviews and approves research protocols involving small animals. IAEC also has a duty to monitor the research studies. A minimum of two meetings of IAEC in a calendar year should be conducted by the institute even if there is no agenda for the same [46]. Six members form a quorum for the meetings. The presence of CPCSEA-nominated external members except Link Nominee is mandatory at all the IAEC meetings. A Link Nominee can attend meetings in the absence of the main nominee. However, it requires written notice of the main nominee to the IAEC chairman clearly mentioning his unavailability to attend the meeting. A Link Nominee should be invited once a year. The presence of external members is mandatory for the validity of the IAEC meeting. This stringent requirement for quorum is causing delays in conducting IAEC meetings. There is an urgent need to review and revise the standard operating procedure of IAEC for the removal of hurdles in research studies.

It is made compulsory for all CPCSEA-registered institutes to have a permanent or full-time veterinarian to ensure twenty-four hour care and well-being of laboratory animals [46]. There is no requirement for such full-time veterinarians on poultry farms where veterinary medical care is outsourced. This governmental discrimination between laboratory animals and other animal species to achieve animal welfare is confusing, as welfare is equally essential for all animal species. The compliance of this full-time veterinarian for laboratory animal house is possible only in research institutes housing animals throughout the year. The majority of educational institutes house animals only for some months of the year, and therefore, the appointment of full-time veterinarians adds to unnecessary expenses of the institute. There is a need to review the policy of full time veterinarians and outsourcing of veterinary medical care should be permitted on a case-to-case basis.



**Fig. 3. Pharmacy postgraduate specializations with percentage of seats in India**

The accreditation of educational institutes in India is regulated by two national bodies, namely the National Accreditation and Assessment Council (NAAC) and the National Board of Accreditation (NBA) [47]. There are nine criteria identified by the NBA for accreditation of pharmacy programmes. One of them is facilities and technical support. Institutions are expected to provide adequate infrastructural facilities, including animal houses, in order to achieve program outcomes. Similar to this, one of the accreditation criteria for NAAC accreditation is innovation and extension. It is expected that institutions should have facilities such as animal houses to support research. Nowadays, accreditation from the NAAC or the NBA has become mandatory for Indian institutions. It is therefore becoming necessary for institutions to run animal house facilities which can be utilized only for research activities and not for teaching purposes.

While well-designed and performed animal experiments are required to impart skills in animal studies, humane treatment of animals is also essential. Alternative approaches to providing theoretical information about animal experiments, such as apps, photographs, software, videos, and so on, should be used in the initial phase of training. Undergraduate students should be allowed to observe postgraduate and doctoral students conducting animal studies. It is also possible to provide individualised instructions to only those students who are interested in being experts in animal

experiments. Animals that survive after research studies can be used for educational purposes. Adequate veterinary care should be available, and establishments should strictly adhere to the rules specified for animal handling, accommodation, care, treatment, and transportation. Preclinical pharmacologists and their organisations must create a stronger and more cohesive campaign to combat the growing threat of animal use bans to pharmacy education. Furthermore, the interests of animals used in pharmacy research and education, as well as the responsibilities of those who conduct it, must be clearly understood.

## 9. CONCLUSION

The problem of animal welfare is just as important as human welfare. There has been strict implementation of animal welfare regulations in India for the last decade. The Pharmacy Council of India has restricted animal experimentation for pharmacy education. However, the alternative approaches are not set up and adopted by the majority of institutions. As a result, students are losing their interest in animal experimentation and are not selecting this area of pharmacy for higher studies and future careers. This will create many difficulties in the long run, such as the unavailability of trained manpower for animal experimentation in the field of research. In order to address this issue, the government should provide financial support to institutions to set up animal-alternative technologies with proper teacher training.



Furthermore, critical review of animal experimentation-related regulations is necessary to maintain a proper balance between animal welfare and research in pharmacy.

## CONSENT

It is not applicable.

## ETHICAL APPROVAL

It is not applicable.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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