The Impact of CCSEA on Drug Discovery: A Regulatory Review

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***Abstract*—The ethical use of animals in scientific research has become a subject of increasing concern, prompting regulatory bodies to implement stringent guidelines to safeguard animal welfare. In India, the Committee for the Control and Supervision of Experiments on Animals (CCSEA), under the authority of the Prevention of Cruelty to Animals Act, 1960, plays a pivotal role in overseeing and regulating animal experimentation. The guidelines and Standard Operating Procedures (SOP) established by CCSEA emphasize the use of the least sentient animals, the reduction of animal numbers, minimization of pain, and promotion of alternatives to animal use wherever possible. Institutional Animal Ethics Committees (IAECs) are mandated to ensure compliance with these rules and are authorized to approve small animal research proposals, with large animal protocols requiring direct CCSEA approval. This review explores the legal framework, ethical principles, and organizational mechanisms enforced by CCSEA, highlighting their impact on animal-based research in India, especially in educational and pharmaceutical institutions. A significant shift is observed in the use of non-animal models for academic training, supported by recent mandates from the Medical Council of India (MCI) and Pharmacy Council of India (PCI). Technological advancements like computer simulations, virtual labs, and imaging techniques have been adopted as effective alternatives, thereby reducing the dependency on live animal experimentation.**

***Index Terms*—CCSEA, Drug discovery, Ethics, IAEC, SOP,**

I. INTRODUCTION

In the pharmaceutical industry, identifying and developing a new drug remains a tedious and expensive process. The process begins with identifying and validating the potential molecular or cellular pharmacological target, then moves on to often lengthy preclinical and clinical research, resulting in an array of regulatory approvals. Without any question, using experimental animal models allows researchers to better understand the causes, pathophysiology, and general characteristics of identical diseases in humans. Similarly, animal models help in the discovery of safe and effective treatments and therapies for such illnesses and their related symptoms [1]. Approximately 90% of the many animal species employed for research are rats, mice, and specially bred birds. However, there has been a growing recognition of the sentience of animals that is, their ability to experience pain, emotions, and suffering. Which has led to increasing resistance to animal experimentation. This opposition comes not only from the general public but also from many within the scientific community [1]. Since animals, especially higher animals, are able to experience pleasure and pain just like humans, using them as resources and causing them to endure intolerable suffering is morally wrong. This realization marked the beginning of the ethical evaluation of non-human animals, which led to the development of a new field known as animal ethics [2]. The Committee for Control and Supervision of Experiments on Animals (CCSEA) is a key regulatory body in India that regulates the ethical use of animals in research. The

Prevention of Cruelty to Animals Act of 1960, which gives the CCSEA its authority, stipulates that the committee's responsibility is "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." [3]. This review examines how the CCSEA recommendations are being used and assess how they have affected animal research methods in India.

II. CCSEA – LEGAL AND ORGANIZATIONAL FRAMEWORK

The Prevention of Cruelty to Animals Act 1960 approved the formation of a committee to supervise experiments on animals. The Committee for the Control and Supervision of Experiments on Animals (CCSEA) was established in accordance with that provision. Under the 1998 Breeding of and Experiments on Animals Rules and the Experiments on Animals Amendment Rules, the CCSEA acquired a power to establish rules regarding on the conduct of animal experiments, to permit any of its officers to conduct inspections at any time, and to restrict an individual or organization from conducting animal experiments. Its chairperson, former minister and well-known animal rights activist Ms. Maneka Gandhi, implemented significant changes concerning how experiments on animals were carried out in the nation. The recommendations stated clearly that all labs conducting animal research have to register with the CCSEA and adhere to a set of guidelines. The CCSEA appointed its nominees to carry out these rules; these individuals were mostly animal rights activists [4]. According to the regulations, organizations that conduct biomedical research must register with CCSEA, form an Institutional Animal Ethics Committee (IAEC), have their Animal House Facilities inspected, and have specific research projects approved by CCSEA (for large animals) or IAEC (for small laboratory animals) prior to starting. These rules also restrict the breeding and trading of animals used in such experiments [4].

III. KEYGUIDELINES AND SOP

CCSEA's Ethical Guidelines for Using Animals in Scientific Research

Principle 1: Animal experiments are allowed only to advance knowledge, save or prolong life, reduce suffering, improve well-being, or combat diseases in humans, animals, or plants.

Principle 2: Use the least sentient animals that can provide valid results. Minimize animal numbers for statistical accuracy, and consider non-animal alternatives with proper justification if not used.

Principle 3: Experiments should avoid or minimize animal pain. Researchers must assume animals feel pain like humans unless scientifically proven otherwise. Adequate sedation, anaesthesia, or pain relief must be used for procedures causing more than minor discomfort.

Principle 4: Persons engaged in animal experimentation have a moral responsibility for the welfare of the animals after their use in experiments. They must provide care or rehabilitation and may euthanize animals only if:

(a) the animal is paralyzed or unable to function or perceive its surroundings, or

(b) it suffers from severe, ongoing pain with no relief.

(c) Euthanasia is also allowed if keeping the animal alive poses a threat to humans or other animals.

Principle 5: Animals must be housed, fed, and cared for in species-appropriate conditions that support their health and comfort. A trained veterinarian or qualified scientist must oversee their care, with veterinary attention provided whenever needed [5].

Standard Operating Procedure (SOP)

According to the guidelines in the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 “Institutional Animals Ethics Committee" refers to an organization made up of a number of individuals whom the Committee has approved and registered for the purpose of regulating and overseeing animal experiments carried out in a facility that is set up and run in compliance with the protocols prescribed by the Committee [5]. IAEC shall include a scientist from different biological discipline cum chairperson, scientist from different biological discipline, Biological Scientist, one veterinarian involved in the care of animals, scientist in charge of animal House facility cum member secretary, scientist from outside the institute, One non-scientific socially aware person, One main nominee of CCSEA, one link nominee of CCSEA [6]. In January 2010, the CCSEA published the Standard Operating Procedures (SOP) for Institutional Animal Ethics Committee (IAEC). The

IAEC is authorized to allow experiments on small animals under the Rules for Breeding of and Experiments on Animals (Control & Supervision). Only proposals for large animal experimentation need to be submitted to CCSEA for approval. As a result, it's important that every IAEC member understands the current regulations and guidelines. Any approval given by IAEC is legally invalid if it does not follow the current CCSEA guidelines and rules [5].

IV. IMPACT

The adoption of alternative non-animal models plays a crucial role in reducing and replacing animal experiments, particularly in educational settings. These alternatives not only uphold ethical standards but also ensure scientifically valid and reproducible outcomes. Validated non-animal methods must be prioritized wherever applicable. In recent years, the Medical Council of India (MCI) and the Pharmacy Council of India (PCI) have emphasized the replacement of live animal experiments in biomedical education with advanced technologies. This includes the use of computer-aided learning tools, virtual labs, and simulation software to teach pharmacological and physiological concepts to undergraduate and postgraduate students. These approaches ensure students gain the necessary skills without the ethical concerns involved in animal use. The Indian Animal Welfare Act, 2011, strongly enforces penalties for conducting experiments without proper authorization or for violating approved protocols. These developments highlight that CCSEA is moving toward stricter regulation of animal use, especially in educational contexts, and encourages the integration of humane, validated non-animal methods across all areas of biomedical research. The ultimate goal is to balance scientific advancement with ethical responsibility [7].

V. CONCLUSION

The implementation of CCSEA guidelines has significantly reduced the use of laboratory animals for academic purposes in our pharmacy research institution. By promoting ethical standards, encouraging the adoption of validated alternative methods, and mandating strict oversight, the guidelines have led to a shift toward humane and scientifically advanced practices. Increased awareness, training of faculty and students, and the availability of computer-based simulations have further contributed to minimizing animal use while maintaining the quality of research and education. This change reflects our institution's commitment to responsible science and compliance with national regulations.

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