



The Unseen Victims: Animal Rights *vis-à-vis* Animal Testing in Cosmetics and Pharmaceutical Industries in India

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Abstract. Despite the growing global recognition of animal rights, the continued use of animal testing in cosmetic and pharmaceutical industries raises concerns about the effectiveness of laws aimed at preventing cruelty. Animals are often subjected to inhumane testing in the name of safety and efficacy, reflecting industry practices that prioritise profit over welfare. In India, animal testing for cosmetics has been banned, along with the import of such products, through amendments to the Drugs and Cosmetics Rules, 1945. This has created a compliance obligation for manufacturers and importers to adopt alternative methods such as in-vitro testing, computational toxicology, and reconstructed human tissues. Non-compliance attracts penalties including fines, seizure, and licence revocation, aligning India with international standards like the EU. In contrast, pharmaceutical testing retains a complex legal status. Animal experimentation remains permissible and often mandatory for toxicity and efficacy evaluation, but is strictly regulated by CPCSEA under the ethical framework of the “3Rs” — Replacement, Reduction, and Refinement. Violations may lead to withdrawal of research approval. This sectoral approach reflects a broader legal shift recognising animals as sentient beings while balancing public health, scientific progress, consumer protection, and constitutional values.

Keywords: Animal Testing, Cosmetics Regulation, Pharmaceutical Research, Drugs and Cosmetics Rules 1945, Animal Welfare Law.

1 Introduction

Since over 150 years, the animals are used for the purpose of examining whether the medicines are safe for consumption by humans or not. By doing this, it has become a tradition to use these animals for testing the new medicines which are of toxic nature before these are brought to the market for consumption by humans. According to the theories of evolution, it is stated that “rodents should give every bit as valid indications of human reactions as dogs, suggesting that results obtained from simple laboratory

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mice and rats may be as directly translatable to man as those from more highly developed non-primate animals”.[1]

Animal testing has been a core and debated part of biomedical research since Antiquity. The early Greeks, like Aristotle and Galen, conducted dissections and vivisections on animals because of social inhibitions against using human corpses for dissections. In those days, the *Scala Naturae*, — a hierarchy placing humans closer to the divine, justified the use of animals as tools for understanding anatomy.[2] From the Renaissance to the 20th century, figures like Andreas Vesalius, William Harvey, Claude Bernard, Louis Pasteur, and Robert Koch advanced medicine through animal research, later guided by the Principles of Humane Experimental Technique.[3] While animal studies aid safety assessment, extrapolation to humans has limits, poor design wastes lives, and ethical concerns persist. The principle of 3 ‘R’s has been adopted in India as per the mandate provided by the Committee for the Purpose of Control and Supervision of Experimentation in Animals (CPCSEA). India has also included a fourth ‘R’.[4] The fourth ‘R’ represents the rehabilitation for the animals that have been used for testing the drugs. It is estimated that about 100 million animals are used in research each year worldwide, and data shows that this number is not decreasing despite the efforts to do so.[5]

The objective of this paper is to study whether the Indian law governing the testing of animals in the cosmetics as well as pharmaceutical sectors is clear, consistent, and effectively implemented. In this regard, some of the important legislations, such as the Prevention of Cruelty to Animals Act, 1960 as well as the Drugs and Cosmetics Act, 1940, along with some of the rules, such as the Cosmetics Rules, 2020, are studied to check whether they are working effectively in a cohesive manner or are creating confusion. In addition, the paper also talks about whether the law provides a balance between protecting public health through ensuring that medicines are both safe as well as effective, while at the same time protecting animals from unnecessary harm. It also examines the effectiveness of the implementation of the rules, particularly the role of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) in the monitoring and implementation of the rules. The paper aims to identify gaps in the system and improve the rules for a more balanced and effective regulatory system.

The methodology of research is doctrinal and comparative in nature. The doctrinal method is followed by analysing the statutes, rules, and interpretations governing animal testing in India. The comparative method is followed by briefly analysing the regulatory developments in other countries, like the European Union, to understand global best practices in the regulation of animal testing. The subject of research is the legal regulation of animal testing in the cosmetics and pharmaceutical industries of India at the national level. The methodology of research is limited to doctrinal and comparative analysis and does not involve any empirical research or stakeholder interviews.

2 Conceptual and Constitutional Framework of Animal Testing in India

‘Sentience’ (taken from Latin term *sentire*, meaning ‘to feel’) is a concept which has greater importance in the fields of animal ethics, the science and policy of animal welfare, and bioethics. The meaning of term ‘Sentience’ can be understood two senses i.e. one in broader sense and the other in narrower sense. In a broader sense, the term sentience can be understood as the capacity for any type of subjective experience: any capacity which is called as ‘phenomenal consciousness’ by various philosophers.[6] In this perspective, an animal is sentient if it has "something it's like" to be that animal, at least in some circumstances (such as when it is completely awake). The ability to have subjective experiences with positive or negative valence—that is, sensations that feel good or undesirable, such as pain, pleasure, stress, anxiety, boredom, hunger, thirst, pleasure, warmth, joy, comfort, and excitement can be defined more narrowly as sentience.[7] The phrase ‘Animal Sentience’ used in animal welfare science and animal ethics, usually refers primarily to subjective experiences with an attractive or unpleasant quality, such as experiences of distress, discomfort, pleasure, frustration, anxiousness, fear, happiness and relief.[8]

Taking into consideration the understanding of the concept of ‘animal sentience’, the Indian judiciary has recognised the rights of the animals. In the case of *Animal Welfare Board of India v. A. Nagaraja*,[9] the Supreme Court of India banned *jallikattu* in Tamil Nadu and prohibited bullock-cart races in Maharashtra and Punjab and thereby recognised the right to life of animals. The Court expanded the scope of Article 21 and observed that animal life and dignity fall within the broader meaning of “life” under Article 21 of the Constitution of India. The Court established that the right under Article 21 is not just a right provided to human beings but also a right available to animals and must be interpreted in light of compassion, dignity, and constitutional morality. The judgment marked a progressive shift in Indian constitutional jurisprudence by recognising animal welfare as an integral constitutional value, strengthening the link between Fundamental Rights, Directive Principles, and the Fundamental Duty under Article 51A(g) to show compassion towards living creatures.[10]

3 Regulatory Framework of Animal Testing in Cosmetics and Pharmaceutical Industry

In recent times, the use of animals for biomedical research has been criticised by the animal rights activists and public alike. Several countries have come-up with the laws to sensitise the practice of animal testing in cosmetics and pharmaceutical industry.

In animal testing, there is a debate between two approaches:

Approach ‘A’ – Animal testing is acceptable (Minimisation of suffering and no alternatives): Animal testing is said to be acceptable if the suffering is minimised and if there are no other alternatives to achieve the human benefits.

Approach 'B' – Animal testing is unacceptable: Animal Testing is not acceptable because it just induces pain to the animals not providing any benefit to the human beings as there is no evidence to prove the results of animal testing are beneficial.[11]

In India, animal testing is governed by the Prevention of Cruelty to Animals Act, 1960, and its amendments, amendment to the Drugs and Cosmetics Rules, 1945. Regulatory bodies like the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) set guidelines for ethical treatment. The inducement of unnecessary pain to animals is forbidden by the Prevention of Cruelty to Animals Act, 1960. The preservation of the environment and ecology is ensured by the Wildlife (Protection) Act which also ensures the protection of the wild animals, birds, and plant species of the country. India is the first country in South Asia to ban animal testing in drugs and cosmetics.[12] The ban has been imposed by amending the Drug and Cosmetics Act, 1940 in 2014 and by including Rule 148-C in the Drugs and Cosmetics Rules, 1945 imposes ban on animal testing by the companies and Rule 135B imposes ban on importing those drugs and cosmetics to India which have been tested on animals.

The imposition of the ban on animal testing has consequences on licensing. Under Rule 148-C of the Drugs and Cosmetics Rules, animal testing for cosmetics is prohibited. If a company conducts such testing, it cannot obtain or continue a manufacturing licence under the Drugs and Cosmetics Act. Further, under Rules 85 and 85-A of the 1945 Rules, the licence may be suspended or cancelled for violation of the law. Section 18(a) (i) of the 1940 Act also prohibits the manufacture or sale of cosmetics made in contravention of the Rules. Additionally, under Rule 135-B of the 1945 Rules, cosmetics tested on animals cannot be imported into India, and authorities may refuse or cancel the import licence.[13] In this manner, the ban helps to protect animal rights. By revoking or denying manufacturing or import licenses for products tested on animals, the law enforces accountability and ensures that animal cruelty is avoided in the cosmetics industry.

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 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. In this manner, the law safeguards animal rights by requiring that experiments should not be conducted when alternative methods of teaching and research, such as models, books, and films, are sufficient enough to replace animal experiments.

In the pharmaceutical industry, the ban on animal testing is not absolute. If there are no alternative methods, then the companies might carryout animal testing by minimising the sufferings of animals.[14] Therefore, in pharmaceutical industry, approach A as mentioned above is followed. Thus, it can be said that India follows “sectoral ethical gradualism” model which means that the law treats animal testing differently in different sectors.[15] This is clearly reflected in cosmetics and

pharmaceutical industries in India. In cosmetics industry, the ban on animal testing is absolute as the law considers it is unnecessary. But in pharmaceutical industry, it is not the case. As mentioned earlier, there is no absolute ban on animal testing in pharmaceutical industries. The combination of the absolute and non-absolute ban on animal testing shows that the law reflects a transition from “property-based animal status” to “sentience-based statutory protection” [16] which means that the law at present is treating animals not just as mere property but as sentient beings and thereby recognising their right to life. Now, through statutory protections and judicial interpretation, the law increasingly acknowledges that animals can feel pain and suffering, and therefore deserve legal safeguards. This marks an important conceptual transition in Indian animal welfare law.

4 Legal Implications and Industry Impact

Though the ban on animal testing ensures the protection of the rights of the animals, it has certain implications on the cosmetics and pharmaceutical industries. The companies now have to ensure that their products manufacturing comply with the prohibition on cosmetic animal testing and the regulatory requirements for pharmaceutical testing.[17] Multinational companies have to adhere to the standards with regard to the Indian laws, if they are interested in exporting their products to India. The companies now have to opt for alternative methods to test the cosmetics and the drugs. It involves huge research and development costs, including investment in technology and training of employees.

However, non-animal-based systems could be very costly in the beginning. This could be a concern for small companies. In the pharmaceutical industry, the maintenance of animal systems within strict regulatory guidelines also incurs considerable expenses. Thus, in any way the companies choose to go, there are expenses involved. However, there are certain benefits in terms of trade and export as well. In many countries across the world, especially in Europe, it is prohibited to sell cosmetics that have been tested on animals. Therefore, by prohibiting the testing of cosmetics on animals, India is promoting its international image in terms of ethics as well. The Indian cosmetics industry can gain international recognition as far as foreign markets are concerned, and the organisations can sell their products without any issues related to the ethics of international trade.

Ethical branding is the next significant industry impact. As the consumers at present are very well aware of the animal welfare issues and are becoming responsible and sensitive towards the protection of animal rights, the organisations that manufacture such cruelty-free products can promote themselves as ethical brands.[18] However, at the same time, the problem of the uncertainty of the regulations is also there, which is affecting the businesses. The ambiguity in the exemptions provided to the pharmaceutical industries, the regulations related to the approval of the alternative methods pose as a problem to the businesses. The time required to design the alternative methods of testing the drugs and cosmetics, the time required to prove that there is no effective alternative method other than the animal testing methods affects the profitability of the businesses.[19] The animal testing regime in India poses both

challenges and opportunities for businesses. While it adds to regulatory compliance and perhaps costs for businesses in the short term, it may also be a catalyst for ethical innovations, trade opportunities, and brand reputation. More clarity in legislation and institutions may aid in maximising these opportunities and minimising any uncertainty.

5 Gaps and Challenges

However, there are some challenges in the implementation of the rules and regulations related to animal testing in India. One such challenge is the lack of enforcement. Although there is a prohibition on animal testing in the cosmetic industry and there have been some regulations set in other industries as well, the enforcement agencies lack the required knowledge in this area. They do not have the required number of people and the required knowledge to handle the situation. In addition, there is no inspection and follow-up action in this area.[20] The government is simply relying on the self-reporting mechanism in this area. There is a huge gap between the rules and the actual implementation.

Another major problem facing the industry in India is the lack of proper infrastructure in validating alternative methods of testing. In situations where there are limitations of conducting animal tests, companies are encouraged to make alternative methods of testing, such as in-vitro testing, computer modelling, and human cell-based testing. However, India still lacks proper government-funded facilities and funding structures to promote alternative methods of testing and validating alternative methods of testing. Although international standards are changing, India is taking its time to adopt alternative methods of testing.[21] This is affecting small companies and research institutions in India, as they are still using animal testing methods even when they are willing to abide by ethical standards. However, there is also ambiguity when it comes to pharmaceuticals. Unlike cosmetics, pharmaceuticals are not totally prohibited from being tested on animals. In fact, it is required that they be tested on animals prior to human clinical trials to ensure the safety and efficacy of the drug.[22] However, there is no clear definition of “necessity” in the law and when the alternatives must be used instead of the animals. This is confusing to some pharmaceutical companies. Some pharmaceutical companies may still test on animals because they are afraid that if they do not, their products will not be approved.

Another structural concern is the issue of ‘overlapping jurisdictions.’ The Ministry of Health and Family Welfare regulates the sale of drugs and cosmetics through the Drugs and Cosmetics Act. On the other hand, the animal testing is regulated by the ‘CPCSEA,’ which is a statutory Committee of the Department of Animal Husbandry and Dairying (DAHD), Ministry of Fisheries, Animal Husbandry and Dairying (MoFAH&D), under the Prevention of Cruelty to Animals Act.[23] In the case of overlapping jurisdictions, there is the scope of the problem of coordination. For example, the pharmaceutical company is allowed to conduct the experiment by the drug controller and is also required to adhere to the regulations of the ‘CPCSEA’ with regard to the conduct of animal experiments. In some cases, there is the scope of the lack of complete synchronisation.[24] However, there is a need to clarify some provisions of

the legislation. Most of the provisions of the legislation are under secondary legislation, not under primary legislation. This sometimes poses a problem, especially in the understanding of the legislation, as not all of the stakeholders are aware of the same. More definitions, as well as stronger detailed provisions regarding penalties, would be very helpful. A clearer system would be beneficial in helping the industry and the authorities understand the law better.[25] Without this clarity, the problems are likely to persist. However, the pertinent issue that comes up at this stage is whether India is adequately equipped in terms of alternative testing systems to fully support the shift from animal testing. Although the ban on cosmetic animal testing is a very good move in terms of ethics, the supporting environment for the shift is still in its early stages in India. There are very few well-funded and internationally accredited alternative testing facilities in India.[26] Advanced non-animal test systems such as organ chip technology, high-throughput in vitro test systems, and advanced computational toxicology are still in the early stages of development in India. This makes companies rely on foreign labs and technology, which is more costly and time-consuming.

Furthermore, the validation and acceptance of alternative methods also require technical know-how and the issuance of standardized guidelines. If the regulatory authorities are slow in accepting the alternative methods, the industries would still use animal models for the purpose of safety assessment, especially in the drug industry. It is also possible that small and medium-scale industries and research organizations would not be in a position to use the latest alternative methods. Hence, though the legal position is conducive for the implementation of the three Rs, India's preparedness in terms of infrastructural facilities, funding, and technical know-how in the field of validation is still in the developing stage.

6 Conclusion and Way Forward

India has a unique model in the area of animal testing regulations. In the cosmetic industry, the law has taken a stance of absolute prohibition. It has clearly prohibited animal testing and the use of animal-tested products through the Drugs and Cosmetics Rules formulated under the Drugs and Cosmetics Act. The law has taken a stance of controlled necessity in the pharmaceutical industry. The pharmaceutical industry is allowed to conduct animal testing, and it is strictly regulated by the Prevention of Cruelty to Animals Act. The law has recognised that there is no necessity for animal testing in the cosmetic industry, whereas in the drug industry, some phases of drug development require animal testing as part of validation.

At a deeper level, the framework reveals the following important change in the ethical and constitutional landscape: the law is now changing from its traditional property law approach to animals to one that treats animals as sentient beings capable of suffering. This is because the law's interpretation of Article 21 and the law of animal welfare have now strengthened the moral trend. The law's protective and oversight mechanisms have the following objective: to minimise pain and provide humane treatment. Although animals have not been granted personhood status under the law, the law is now changing to the realisation that animals are not objects for human use

and consumption. This is an important sign that there is now a growing congruence between constitutional values, scientific knowledge, and morality.

However, in some sectors, such as the pharmaceutical industry, there is a need for gradual change. An absolute ban on animal testing in pharmaceutical production may have implications for safety, research, and innovation in the field of pharmaceuticals. However, dependence on animal testing for pharmaceutical production is neither scientifically preferred nor ethically acceptable in the long term. Therefore, in this case, it is recommended that there be a gradual reduction but not an absolute ban on animal testing in pharmaceutical production. The timeline for reduction, increased funding for alternative methods, and incentives for research centers are some of the steps that may be taken to ensure that there is a gradual reduction in animal testing but no absolute ban. Additionally, it is recommended that there be clear guidelines from regulatory bodies on when it is mandatory to use animal testing and when it is possible to use alternative methods.

Harmonisation with global standards is equally important. In many countries around the world, especially in Europe, they have been very stringent in banning animal testing for cosmetic products and are increasingly investing in alternative models of research. India can reap a lot in terms of trade opportunities for both industries and animal welfare groups worldwide by developing its validation systems and making its regulatory standards similar to those of the global alternative models for animal testing. India can develop a positive image in before the scientific community worldwide in this regard. Coordination, more effective enforcement powers, and clarity of laws are also important for the success of this undertaking. Education and training in alternative technologies are also important for the success of this undertaking. In addition, public awareness and consumer behaviour are also likely to contribute to the success of this movement toward cruelty-free practices in research and production.

The approach of India is a step in the right direction in the incorporation of ethics in the system of regulatory governance. It is, however, important to understand that the success of the system will depend on the enforcement of the law, scientific preparedness, and policy coherence. It is essential to understand that the advancement and growth of technology should not come at the expense of unnecessary suffering. It is thus essential to understand that the law evolves in a manner consistent with human advancement as well as animal dignity. It is essential to understand that the law should thus be employed in a manner consistent with the advancement of technology and compassion, such that they grow together and not in opposition to one another.

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