



**ALTERNATIVES TO ANIMAL
TESTS CONDUCTED FOR
MANUFACTURING OF DRUGS
AND NEED FOR A
CORRESPONDING LEGISLATION**

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Abstract: Every year various manufacturing industries and research laboratories conduct a number of tests on animals in the pre-clinical stage of experimentation to detect the efficacy of a drug, before it is introduced in the market. These animal tests are discouraged by ethicists, environmentalists and supporters of animals rights, as such tests are not only inhuman and unnecessary but the outcome of these trials have proven to be harmful to the environment, are against animal rights and result in wastage of time and money. The article that follows will discuss the problems related to the animal tests that are conducted for manufacturing drugs, the ineffectiveness of such tests on human beings and the negative impact such experiments have on the environment. The article also gives examples of several alternatives to animal

tests which should replace the current practice of performing experiments on animals. The article will conclude by highlighting the need of securing a proper legislation to promote animal rights and prohibit the performing of such tests to manufacture drugs.

Introduction

About 100 million animals are used for research and experiment purposes each year.¹ Experiment on animals is usually conducted to manufacture new drugs for human beings and are conducted by Corporations, Research institutions, Universities and some Government Organisations. More often than not smaller animals are used which include rats, birds, fish, frogs, to name a few for performing such experimentations; typically bigger animals are not used. Before being euthanized these animals are kept in extremely bad conditions and tortured continuously. Such experimentation and killing of animals is unnecessary and a cause of concern as it affects the environment, animal life as well as human life. Also, there is no law present in India which discourages the killing of animals for the purpose of manufacturing of drugs. There are several institutions that are guilty of unnecessary animal torture, but such wrongdoers go unpunished.

Preservation and protection of animal rights is an issue that is as important as human welfare. Unfortunately animal

¹ Meredith Cohn, 'Alternatives to Animal Testing Gaining Ground' *The Baltimore Sun* (Washington, 26 August 2010)
<[http://articles.baltimoresun.com/2010-08-](http://articles.baltimoresun.com/2010-08-26/health/bs-hs-animal-testing-20100826_1_consumer-products-animal-testing-experiments)

[26/health/bs-hs-animal-testing-20100826_1_consumer-products-animal-testing-experiments](http://articles.baltimoresun.com/2010-08-26/health/bs-hs-animal-testing-20100826_1_consumer-products-animal-testing-experiments)> accessed 12 December 2017



rights are not taken as seriously as human rights and hence not much is being done for it. For a long time environmentalists, ethicists and animal rights supporters have discouraged the use of animals for experimentation for the purpose of manufacturing of drugs. But corporations and research institutions have time and again relied on animal tests and have highlighted it's efficiency on human beings; the article that follows challenges the effectiveness of such animal experimentations conducted during the pre-clinical trials and hence proposes to advance several alternatives to such tests, the article also emphasises on the need of securing a legislation for promoting animal rights and prohibiting the performance of such tests for the purpose of manufacturing drugs.

Hence, the paper that follows has the following four-fold purpose:

1. To understand pre-clinical studies, vivisection and use of animals during such tests
2. To recognise negative implications of these tests
3. To emphasize on and suggest the various alternatives to such tests available today
4. To highlight the need for an effective legislation, to discourage animal

experimentation and promote alternatives to it

Preclinical study

Preclinical study or Preclinical trial is a study to test a drug, a procedure, or another medical treatment in animals. The aim of a preclinical study is to collect data in support of the safety of the new treatment. Preclinical studies are required before [clinical trials](#) in humans can be started.²

Before testing a drug in people, researchers must find out whether it has the potential to cause serious harm, also called toxicity. The two types of preclinical research are:³

- *In Vitro*- in a test tube
- *In Vivo*- in the living organism

Usually, preclinical studies are not very large. However, these studies must provide detailed information on dosing and toxicity levels. After preclinical testing, researchers review their findings and decide whether the drug should be tested in people.⁴

Vivisection

While the article addresses animal tests as merely 'animal test' or 'animal experiment', the process of animal

² MeiciNet- medterms medical dictionary, 'Medical Definition of Preclinical Study' <<https://www.medicinenet.com/script/main/art.asp?articlekey=5019>>accessed 15 December 2017

³ U.S. Food and Drug Administration (FDA), 'The Drug Development Process: Step 2: Preclinical Research' <<https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405658.htm>> accessed 17 December 2017

<<https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405658.htm>> accessed 17 December 2017

⁴ U.S. Food and Drug Administration (FDA), 'The Drug Development Process: Step 2: Preclinical Research' <<https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405658.htm>> accessed 26 December 2017



experimentation in scientific terminology is known as *Vivisection*.

Vivisection is the practice of animal experimentation. This can include administering drugs, infecting with diseases, poisoning for toxicity testing, brain damaging, maiming, blinding, and other painful and invasive procedures. It can include protocols that cause severe suffering, such as long-term social isolation, full-body restraint, electric shocks, withholding of food and water, or repeatedly breeding and separating infants from mothers. Essentially, it is using animals in ways that cause distress and/or death in attempts to test the safety of drugs and biological products or of finding treatments, prevention, or cures for human diseases.⁵

Why is there a need of using alternatives to animal experiments?

The following reasons highlight the need for encouraging animal rights and having a law which prohibits or at least limits animal tests;

1. These tests result in violation of animal rights

Countless monkeys, dogs, rats and other animals are burned, blinded, cut open, poisoned, starved and drugged behind closed laboratory doors every year for convenience, for economic reasons and because of old habits. Not only are animal

tests extremely cruel, they are also completely inaccurate because of the vast physiological variations between species. Animal studies teach us nothing about the health of humans because human reactions to illnesses and medications are completely different from the reactions of other animals. Other species absorb, metabolise and eliminate substances differently than humans do. The truth is that testing on animals is just plain bad science which harms humans and other animals alike.⁶

Studies published in prestigious medical journals have shown time and again that animal experimentation wastes lives—both animal and human—and precious resources by trying to infect animals with diseases that they would never normally contract.⁷

More often than not, tests on animals have proved to be wasteful when tested on human beings thereby causing unnecessary loss of animal life.

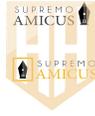
Despite the use of over 115 million animals in experiments globally each year, only 22 new medicines were approved in 2016 by the leading drug regulator, the U.S. Food and Drug

⁵ England Anti-Vivisection Society (NEAVS), ‘What is Vivisection?’ <<http://www.neavs.org/about/vivisection>> accessed 26 December 2017

⁶ People for the Ethical Treatment of Animals (PETA), India ‘Animals used for Experimentation’

<<https://www.petaindia.com/issues/animals-experimentation/>> accessed 25 December 2017

⁷ People for the Ethical Treatment of Animals(PETA), ‘Animal Testing is bad Science’ <<https://www.peta.org/issues/animals-used-for-experimentation/animal-testing-bad-science/>> accessed 23 December 2017



Administration. Many of these are for rare diseases.⁸

PETA US has conducted many undercover investigations in laboratories. Every time it does, physical abuse and neglect are documented. Animals are yelled at, hit, left to suffer after surgery without any painkillers, crammed into small cages, denied veterinary care and more. In India, *one of the largest animal suppliers*, the National Centre for Laboratory Animal Sciences (NCLAS) in Hyderabad, supplies approximately 50,000 animals to laboratories every year and to 175 institutions in India, including pharmaceutical companies and educational institutions. Both NCLAS and the NIN have been under fire from animal protection organisations for years for not maintaining basic animal welfare standards.⁹

According to *The Hindu*, NIN has kept monkeys, who are highly social, in solitary confinement for up to 12 years.¹⁰

2. Animal experimentations do not prove effective on human beings

Animals are used in scientific experimentation based on a presumption that similarities between animals and humans enable data from animal models

to be extrapolated to humans. However, the *differences* between other species and humans make translating data from animals to people problematic.¹¹

The harmful use of animals in experiments is not only cruel but also often ineffective. Animals do not get many of the human diseases that people do, such as major types of heart disease, many types of cancer, HIV, Parkinson's disease, or schizophrenia. Instead, signs of these diseases are artificially induced in animals in laboratories in an attempt to mimic the human disease. Yet, such experiments belittle the complexity of human conditions which are affected by wide-ranging variables such as genetics, socio-economic factors, deeply-rooted psychological issues and different personal experiences. It is not surprising to find that treatments showing 'promise' in animals rarely work in humans. Not only are time, money and animal's lives being wasted (with a huge amount of suffering), but effective treatments are being mistakenly discarded and harmful treatments are getting through. Despite many decades of studying conditions such as cancer, Alzheimer's disease, Parkinson's disease, diabetes, stroke and AIDS in animals, we do not yet have reliable and fully effective cures.¹²

⁸ Cruelty Free International, 'Arguments against animal testing'

<<https://www.crueltyfreeinternational.org/why-we-do-it/arguments-against-animal-testing>> accessed 25 December 2017

⁹ PETA India, 'Animals used for Experimentation'

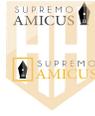
<<https://www.petaindia.com/issues/animals-experimentation/>> accessed 12 December 2017

¹⁰ PETA India, 'Animals used for Experimentation'

<<https://www.petaindia.com/issues/animals-experimentation/>> accessed 12 December 2017

¹¹ National Anti-Vivisection Society, 'The failure of Animal Model' (Chicago, 2012) <<http://www.navs.org/science/failure-of-the-animal-model>> accessed 25 December 2017

¹² Cruelty Free International, 'Arguments Against Animal Testing'



Humans are harmed because of misleading animal testing results. Imprecise results from animal experiments may result in clinical trials of biologically faulty or even harmful substances, thereby exposing patients to unnecessary risk and wasting scarce research resources. Animal toxicity studies are poor predictors of toxic effects of drugs in humans. Humans have been significantly harmed because investigators were misled by the safety and efficacy profile of a new drug based on animal experiments. Clinical trial volunteers are provided with raised hopes and a false sense of security because of a misguided confidence in efficacy and safety testing using animals.¹³

An example of inefficacy of drugs tested on animals, is the reaction of the drug Rezulin on humans. Rezulin (Troglitazone) was a drug intended to treat type 2 (adult-onset) diabetes, was approved by the FDA in the United States in 1997. Rezulin lowered the blood sugar in rats without producing adverse effects, but reports of severe and even fatal liver failure appeared immediately after approval. Due largely to an aggressive

investigation by the *Los Angeles Times* and after four label changes, Rezulin was withdrawn in 2000 after 391 deaths were attributed to the drug.¹⁴

Vioxx, a drug used to treat arthritis, was found to be safe when tested in monkeys (and five other animal species) but has been estimated to have caused around 320,000 heart attacks and strokes and 140,000 deaths worldwide.¹⁵

In another example of human suffering resulting from animal experimentation, six human volunteers were injected with an immunomodulatory drug, TGN 1412, in 2006. Within minutes of receiving the experimental drug, all volunteers suffered a severe adverse reaction resulting from a life-threatening cytokine storm that led to catastrophic systemic organ failure. The compound was designed to dampen the immune system, but it had the *opposite* effect in humans. Prior to this first human trial, TGN 1412 was tested in mice, rabbits, rats, and NHPs with no ill effects.¹⁶

3. Animal experimentations have proven to have a negative impact on the environment

<<https://www.crueltyfreeinternational.org/why-we-do-it/arguments-against-animal-testing>> accessed 26 December 2017

¹³ Tom. L. Beauchamp & David DeGrazia, 'The Flaws and Human Harms of Animal Experimentation' (2015) 24(4) *Camb Q Health Ethics*. <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594046/#fn3>> accessed 16 December 2017

¹⁴ David Willman, 'Deadly Drugs' *Los Angeles Times* (Washington, 20 December 2000) <<http://www.latimes.com/nation/la-122001fda-story.html>> accessed 18 December 2017

¹⁵ Cruelty Free International, 'Arguments Against Animal Testing' <<https://www.crueltyfreeinternational.org/why-we-do-it/arguments-against-animal-testing>> accessed 23 December 2017

¹⁶ Tom. L. Beauchamp & David DeGrazia, 'The Flaws and Human Harms of Animal Experimentation' (2015) 24(4) *Camb Q Health Ethics*. <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594046/#fn3>> accessed 17 December 2017



Typically, facilities that engage in animal testing not only dispose of animals, but also dispose of potentially dangerous chemicals, [food waste](#), and a variety of supplies used during the testing process. Additionally, animal testing also heavily impacts water and air quality.¹⁷

Also, all these animals that are euthanized are not properly discarded thus leading to environmental degradation due to the large amount of toxins contained in these animal bodies.

According to the National Institutes of Health (NIH), waste from their animal testing facilities totalled 1.5 million pounds from 2011 to 2013. In another case, a major pharmaceutical lab was responsible for producing almost 15 tons of animal waste in just one year.¹⁸ As already mentioned, ordinarily smaller animals are tested upon, and larger animals are not generally used for experimentation purposes, this practice leads to ecological imbalance in the environment.

The current loss of species is estimated to be 50 to 500 times higher than the natural background rates found in the fossil record.¹⁹

Considering all of the above stated negative impacts of animal experiments, it becomes highly important to address the issue and secure alternatives to such tests.

Methods to alternate animal tests

Methods that alternate animal experimentations fall into three broad categories. These are called the 3 Rs:²⁰ This concept of three Rs was formulated by British researchers W.M.S. Russell and Rex Leonard Burch in their 1959 book 'The Principles of Humane Experimental Technique'²¹ and they are as follows;

i. Replacement – Which involves replacement of animals and experimenting using other methods, this replacement may either be a complete replacement where animals are not at all

¹⁷ Jai Shroff, 'The Significant Impact of Animal Testing on the Environment' <<https://jaishroff.wordpress.com/2016/11/15/the-significant-impact-of-animal-testing-on-the-environment/>> accessed 27 December 2017

¹⁸ Jai Shroff, 'The Significant Impact of Animal Testing on the Environment' <<https://jaishroff.wordpress.com/2016/11/15/the-significant-impact-of-animal-testing-on-the-environment/>> accessed 27 December 2017

¹⁹ Groff K. Bachli, 'Animal Research is Hazardous Waste'(2014) 3 New England Anti-Vivisection Society Journal <<http://neavs.org/campaigns/environment>> accessed 26 December 2017

²⁰ Johns Hopkins Bloomberg School of Public Health, 'What does alternatives to animal testing

mean?'

<<http://altweb.jhsph.edu/resources/faqs.html#2>> accessed 20 December 2017; Understanding

Animal Research, 'The three Rs' <<http://www.understandinganimalresearch.org.uk/how/three-rs/>> accessed 20 December 2017;

National Centre for the Replacement, Refinement and Reduction of Animals in Research, 'What are the 3Rs?' <www.nc3rs.org.uk/the-3rs> accessed 20 December 2017

²¹ R.L. Burch and W.M.S. Russell, *The Principles of Humane Experimental Technique* (Methuen 1959)



used or a partial replacement where only animal tissues or cells are used.

ii. Reduction- Reduction means to reduce the number of animals to a minimum, to obtain information from fewer animals.

One example of this method can be '**Data Sharing**', this method involves sharing of data and information obtained from testing on animals with other organisations involved in manufacturing same products. This helps reduce costs and also reduce unnecessary killing of animals.²²

Another example of reduction can be substituting animals that have just been killed in place of a living animal; this recommendation was given by Marshall Hall, a British experimental physiologist.²³

iii. Refinement- This method involves refining the way animal experiments are carried out so that animals are not harmed unnecessarily and all proper precautions are taken to cause as little harm as possible. Refinement involves housing animals under proper conditions and maintaining animal welfare.

Various alternatives to animal tests

While the above section underlined the method of alternating animal tests by replacement, reduction and refinement, the following discussion will cover certain examples of alternatives to animal

tests which are in practice and may be adopted.

For a long time, to predict toxicity, corrosivity, and other safety variables as well as the effectiveness of a new product for humans, traditional testing of chemicals, consumer products, medical devices, and new drugs has involved the use of animals. But today, scientists have developed and validated alternative methods shown to lead to safer and more effective products and drugs for humans than animal testing.²⁴

Also, several non-governmental organisations and promoters of animal rights have often spoken against use of animals and hence have also devised methods of alternating these tests with different approaches, some of these alternatives devised by scientists and suggested by ethicists and environmentalists are provided as follows;

- **Three-dimensional human skin equivalents-** Skin corrosivity and irritation can be easily measured using three-dimensional human skin equivalent systems such as EpiDerm and SkinEthic. Additional alternatives include EpiSkin (a model of reconstructed human epithelium) and a variety of sophisticated, computer-based Quantitative Structure Activity Relationship (QSAR) models that predict skin corrosivity and irritation by

²² University of York, 'New Online System Set to Reduce Hundreds of Chemical Tests on Animals' 20 June 2017 <<https://www.york.ac.uk/news-and-events/news/2017/research/new-online-system-set-to-reduce-tests-on-animals/>> accessed 28 December 2017

²³ [Andrew N. Rowan](#), *Of Mice, Models and Men: A Critical Evaluation of Animal Research* (SUNY Press 1984) 265

²⁴ New England Anti-Vivisection Society (NEAVS), 'Animals in Science/Alternatives' <<http://www.neavs.org/alternatives/in-testing>> accessed 27 December 2017



means of correlating a new drug or chemical with its likely activity, properties, and effects with classification accuracy between 90 and 95 percent.²⁵

- ***In vitro* methods and *In silico* models-** Today, because experiments on animals are cruel, expensive, and generally inapplicable to humans, the world's most forward-thinking scientists have moved on to develop and use methods for studying diseases and testing products that replace animals and are actually relevant to human health. These modern methods include sophisticated tests using human cells and tissues (also known as *in vitro* methods), advanced computer-modelling techniques (often referred to as *in silico* models), and studies with human volunteers. These and other non-animal methods are not hindered by species differences that make applying animal test results to humans difficult or impossible, and they usually take less time and money to complete.²⁶
- **Using blood from human volunteers-** Using blood from human volunteers to test for the presence of fever-causing contaminants in intravenous medicines can save hundreds of thousands of

rabbits each year from traditional "pyrogen" tests.²⁷

- **Chemo-synthetic livers-** To eliminate tests conducted on the animal livers, Chemosynthetic livers which are fake livers have been developed and this was announced in 2014 at the 247th National Meeting & Exposition of the American Chemical Society, and this discovery could dramatically alter how drugs are made and tested.²⁸
- **Organs –on-a-chip-** Organs-on-a-chip are tiny cells in 3-D that mimic human organs. They are small micro fluidic devices with hollow channels lined by living human cells. They have several properties that make them more realistic models of human organs than conventional lab-grown cells. These devices are a big step closer to being accurate alternatives to animal tests for new drugs and toxins.²⁹
- **Use of human cancer cells-** The National Cancer Institute (United States) now uses human cancer cells – taken by biopsy during surgeries – to perform first-stage testing for its new anti-cancer drugs. This practice spares the lives of the millions of mice whom

²⁵ European Commission. (n.d.). Joint Research Centre: [QSAR Review Irritation](#)

²⁶ People for the Ethical Treatment of Animals (PETA), India 'Animals used for Experimentation' <<https://www.petaindia.com/issues/animals-experimentation/>> accessed 25 December 2017

²⁷ The Humane Society of the United States, 'Alternatives to Animal Tests' <<http://www.humanesociety.org/issues/cosmetic>

<[_testing/facts/alternatives_animal_tests.html](#)> accessed 29 December 2017

²⁸ Jen Veigas, 'Liver Stand-In Could Replace Animal Testing' *Seeker* (Global, 14 March 2014) <<http://news.discovery.com/animals/liver-stand-in-could-replace-animal-testing-140318.htm>> accessed 21 December 2017

²⁹ Wyss Institute, 'Three 'Organs-on-Chips' Ready to Serve as Disease Models' <<http://wyss.harvard.edu/viewpage/484/>> accessed 20 December 2017, pg.21



the institute previously used every year and gives the institute a much better shot at combating against cancer.³⁰

- **Microdosing-** Microdosing is a technique used for studying the behaviour of drugs in humans through administration of doses so low that it is unlikely to produce any adverse reaction but high enough to allow the cellular response to be suited.³¹ This method helps in determining the efficacy of the compound and whether it is worth continuing with compound development or not. If this technique is appropriately used, it could reduce the number of unwanted drugs going through safety and toxicology testing in animals.³²
- **Fish threshold method-** When testing to determine chemical concentrations that are deadly to fish and other aquatic life, use of the Fish Threshold Method can reduce the numbers of fish used by at least 70 percent compared with standard test methods.³³
- **Plant analysis-** Plant substitution has had limited success in animal research.

Some effects of exposure to certain substances have been demonstrated and the effects *did* relate to humans. A recent study on the effect of pharmaceuticals and their residues as environmental contaminants was performed on *Brassica juncea*, and it demonstrated drug-induced defense responses and activation of detoxification mechanisms as a result of oxidative stress.³⁴

- **Imaging technique-** Magnetoencephalography (MEG), magnetic resonance imaging (MRI), functional MRI (fMRI), magnetic resonance spectroscopy (MRS), positron emission tomography (PET), single-photon emission computed tomography (SPECT), event-related optical signals (EROS) and transcranial magnetic stimulation (TMS) are the techniques offering a view of the human body –in particular, the brain – that cannot be gained by studying animals.³⁵

The above listed alternatives are examples and the list is not exhaustive,

³⁰ Wyss Institute, 'Three 'Organs-on-Chips' Ready to Serve as Disease Models' <<http://wyss.harvard.edu/viewpage/484/>> accessed 20 December 2017, pg.21

³¹ Animal Testing, 'Microdosing' <[Sites.google.com/site/alternativestoanimals/microdosing-human-volunteers](https://sites.google.com/site/alternativestoanimals/microdosing-human-volunteers)> accessed 22 December 2017

³² CCAC, 'Microdosing' <3rs.ccac.ca/en/research/refinement/microdosing.html> accessed 22 December 2017

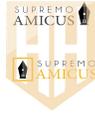
³³ The Humane Society of the United States, 'Alternatives to Animal Tests' <http://www.humanesociety.org/issues/cosmetic_testing/facts/alternatives_animal_tests.html> accessed 24 December 2017

³⁴ T. Arora, A. K. Mehta, V. Joshi, K. D. Mehta, N. Rathor, P. K. Mediratta, and K. K. Sharma 'Substitute of Animals in Drug Research: An Approach Towards Fulfillment of 4R's' (2011) 73(1) Indian J Pharm Sci.

<<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3224398/>> accessed 19 December 2017

³⁵T. Arora, A. K. Mehta, V. Joshi, K. D. Mehta, N. Rathor, P. K. Mediratta, and K. K. Sharma 'Substitute of Animals in Drug Research: An Approach Towards Fulfillment of 4R's' (2011) 73(1) Indian J Pharm Sci.

<<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3224398/>> accessed 19 December 2017



there is a need to recognise and promote several other alternative methods to abandon animal experimentation altogether.

Need for a legislation to prohibit animal experimentation conducted for the purpose of manufacturing of drugs

Let us first look into certain laws operating in India for protection and welfare of animal;

A. Prevention of Cruelty to Animals Act, 1960

The Act prohibits cruel treatment of animals and provides for establishment of an Animal Welfare Board for protecting animals from unnecessary and extreme torture and suffering, and for promoting well-being of animals. The board is also responsible for making rules to promote welfare of animals.

Section 14 of the Act allows the use of animals for experiments if it would help in discovery of knowledge that would be helpful for human beings, animals or plant life.

The act furthermore provides for establishment of a committee for the purpose of control and supervision of animal experiments, for which the committee is empowered to make suitable rules. If the rules are not adhered to, the person or institution may be prohibited from conducting tests on animals.

B. The Ministry of Health & Family Welfare has passed an amendment to Schedule Y of the Drugs and Cosmetics Rules, 1945, which spares animals testing for new drug registrations when complete data from earlier toxicity experiments already exist for drugs approved abroad.

The Gazette notification reads: “3. In Schedule Y to the said rules, in Appendix I, in item 4, after sub-item 4.8, the following note shall be inserted, namely:

Note. Where the data on animal toxicity as per the specifications of Appendix III has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug, the animal toxicity studies shall not be required to be conducted in India except in cases where there are specific concerns recorded in writing.”³⁶

C. The Ministry of Health and Family Welfare issued a Gazette Notification GSR 346 (E), dated 21 May 2014 amending the Drugs and Cosmetics Rules 1945, to ban testing of cosmetics in animals³⁷ : **The new rule 148-C states: Prohibition of testing of cosmetics on animals – ‘No person shall use any animal for testing of cosmetics.’**

³⁶The Gazette of India, No.171, 16 March 2016 <<http://egazette.nic.in/WriteReadData/2016/168612.pdf>> accessed 22 December 2017

³⁷ Ministry of Health and Family Welfare, ‘Guidelines for Implementation of GSR 346 (E)’

(New Delhi, 21 May 2014) <http://ficci.in/sector/73/add_Docs/AniTestGuidelinesFICCIFINAL16092014.pdf> accessed 21 December 2017, pg.1-3



D. The Drugs and Cosmetics Act, 1940
The act regulates the manufacture, import and distribution of drugs. Certain guidelines for the same have also been provided in the act. Section 26 A of this act gives the power to the Central Government to prohibit the manufacture, sale or distribution of drugs and cosmetics in public interest, especially if it involves risk to human beings or animals.

Unfortunately, while these legislations operate towards welfare of animals, they have not proven to be successful in curbing brutal treatment of animals while they are being experimented on and India needs a better structure of law which effectively operates towards care and protection of animals, whether used in experimentation or not.

Also, laws are stricter for using humans in experiments as compared to using animals. Animals are forced to be a puppet in the process of drug testing and no stringent legislation in India has been successful to curb the problem of mistreatment and unnecessary killing of animals during such scientific procedures.

This article thus aims to highlight this inadequacy in law for the purpose of eliminating all forms of torture and mistreatment towards animals that are used for such experiments, and secure a legislation that will protect animal rights and promote alternative methods of animal experimentation for drug testing.

Conclusion

Experiments performed on animals to manufacture drugs involve cruel techniques and unnecessary torture and

killing of animals. These drugs when tested on humans have more often than not, proven to be ineffective. Several animal protection agencies, ethicists, and environmentalists have suggested alternative methods to test drugs, but unfortunately a traditional approach towards drug testing, inconvenience caused by newer methods and increase in costs may be certain impediments in adapting to alternative methods and hence the traditional method of testing drugs on animals in the pre-clinical stage is continuing to hamper animal life, the environment and human welfare too. While there is a need to adopt these alternatives, such is not possible without there being a suitable and effective legislation for the same. This article therefore emphasises on the several available alternatives to animal testing and the need for a fitting legislation to promote animal rights, secure well-being of human beings and protect the environment.