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Corporate Responsibilities Related to Pharmaceutical Industry Compliance in the Use of Test Animals in Indonesia

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Abstract

This study aims to analyze corporate responsibility in ensuring the compliance of the pharmaceutical industry with regulations governing the use of laboratory animals in Indonesia, emphasizing aspects of legal, ethical, and technical adherence to animal welfare principles. This study adopts normative juridical research method employing both statuory and conceptual approaches. The data were gathered through library research, comprising primary legal materials for instance like laws and regulations, additionally secondary legal materials including books, journal articles, as well as online references. The findings indicate that although Indonesia has established several regulations such as Law No. 18 of 2009 jo. No. 41 of 2014, Government Regulation No. 95 of 2012, Minister of Health Regulation No. 75 of 2020, and BPOM Regulations No. 10 of 2022 and No. 20 of 2023, their implementation within the pharmaceutical industry remains suboptimal due to weak enforcement and monitoring mechanisms. Therefore, the establishment of an integrated compliance system combined with ethical and technical oversight is essential to ensure that the use of laboratory animals is conducted transparently, responsibly, and in accordance with the 3R and 5F principles.

Keywords: laboratory animals, legal compliance, animal welfare.

A. Introduction

The increasing need for public access to health services has created a phenomenon in the pharmaceutical industry sector. This phenomenon is characterized by an increasing demand for pharmaceutical products and services globally. By 2025, the global pharmaceutical market reached around USD 1,772.65 billion and is expected to grow to USD 3,033.21 billion by 2034 with a significant combined annual growth rate. This development cannot be separated from the increasing burden of chronic diseases such as diabetes,

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cardiovascular, and cancer as the cause of approximately 71% of total global deaths.[1] This condition encourages the pharmaceutical industry to continue to develop innovative drugs to reduce mortality and improve quality of life. In addition, in the midst of the challenges of chronic diseases and the threat of new infectious diseases, the pharmaceutical industry plays an important role in the research and production of cutting-edge medicines. Increasingly fierce global competition encourages the acceleration of innovation and market expansion, thus making the pharmaceutical industry a major force in the health system and the international economy.

Research and development activities in the pharmaceutical industry are driven by increasingly fierce competition. Along with this, the need for preclinical test methods has also developed as an important part of drug development. Preclinical trials are the process of testing on animals to assess the safety and effectiveness of health products before they are given to humans. Animal testing can also be used to predict drug toxicity to humans.[2] Animals used in experiments, often referred to as test animals, experimental animals, or laboratory animals are animals that are specifically kept for the purposes of research, testing, and other scientific purposes.[3]

Not all animals can be used as test animals. According to reports on the use of test animals in research and research activities, several countries such as Canada and the European Union routinely publish annual reports through official institutions, namely the Canadian Council on Animal Care in Canada and The Commission to the European Parliament and Council in the European Union. From the European Union report, it was revealed that during the period 2015–2017 the highest types of animals used in the study included mice, aquatic animals, and rats. The animals used as test animals were chosen because they have significant similarities in anatomical, physiological, and genetic components to humans.[4]

As data released by Cruelty Free International, states that more than 192 million animals have been used in scientific experiments. The organization also mentioned China, the United States, and Japan as the largest test animal users in the world.[5] The contribution of animals in this research test activity still plays a crucial role and until now has not been completely substituted by other alternative methods. The use of this test animal is due to

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[1] *"Pharmaceutical Market Size Expected to Reach USD 3,033.21 Bn by 2034"*, https://www.globenewswire.com/news-release/2025/02/07/3022874/0/en/Pharmaceutical-Market-Size-Expected-to-Reach-USD-3-033-21-Bn-by-2034.html, diakses pada tanggal 17 April 2025.

[2] Haryati, Arum, and Rara Lammia. "Narrative Review: The Potential of Organ-On-Chips (OOC) as an Animal Substitute in Pre-Clinical Evaluation of Drug Effectiveness and Toxicity." *Conference on the Integration of Islamic and Science Interconnections* 5, no. 1 (2023): 24-30.

[3] Heni Dwi Untari, Basuki Rochmad Suryanto, Zaza Famia, and Suprihatin. "Optimizing the Application of Animal Welfare Principles in Test Animals at Bbvet Wates to Support Laboratory Diagnosis". *Proceedings of Animal Disease Investigation.* (2018): 209-217.

[4] Wahyuwardani, Sutiastuti, S. Noor, dan B. Bakrie. "Animal Welfare Ethics in Research and Testing: Implementation and its Barrier." *Indonesian Bulletin of Animal and Veterinary Sciences 30*, no. 4 (2020).

[5] *"Facts and Figures on Animal Testing",* https://crueltyfreeinternational.org/about-animal-testing/facts-and-figures-animal-testing, diakses pada tanggal 17 April 2025.

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the limitations of the study of the effects of gene manipulation in *vitro*.[6] Although this method has become standard in the development of health products, the practice of animal testing is increasingly in the spotlight, especially related to ethical issues and the protection of animal welfare.

The ethical issue in the use of test animals in the global pharmaceutical industry is still a major challenge that encourages the application of strict regulations and animal protection principles. To answer this challenge, various countries and international institutions have adopted the 3R principle which was introduced in 1959 by Russell and Burch as an ethical standard in research.[7] The 3R principle is an ethical approach to the use of test animals that includes the *replacement* of animals with alternative methods, the reduction of the number of animals used, and the *refinement* of procedures to minimize the pain suffered by the animals. In addition, the 5F principle, which is the five basic freedoms that must be guaranteed for test animals, namely freedom from hunger and thirst, discomfort, pain, injury or disease, freedom to express natural behavior, and freedom from fear and stress are also applied by countries that have formalized regulations on the use of test animals.

Institutions such as the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) require the application of this principle in preclinical trials to ensure animal welfare while maintaining the validity of research results. Several countries such as the United States, Canada, Australia, South Korea, and France have also formulated and made the use of test animals in their regulations.[8] These regulatory efforts are an important reference for other countries, including Indonesia, which must be able to adapt to international standards as it becomes involved in the global pharmaceutical supply chain.

Along with the demands for adjustment to international standards in the use of test animals, Indonesia is also facing the dynamics of the growth of the domestic pharmaceutical industry which is quite rapid. By 2025, the industry is projected to experience significant growth of 6.5% to 7%, as part of the government-driven chemical, pharmaceutical, and textile industry (IKFT) sector to support the national economic growth target of 8% in the next five years.[9] Despite facing challenges such as overspending on imported raw materials and exchange rate fluctuations, some local pharmaceutical industries are still working to improve their performance, including product expansion and distribution, especially in the pharmaceutical, supplement and herbal products sectors, targeting young demographics.[10]

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[6] Wahyuwardani, Sutiastuti, S. Noor, dan B. Bakrie. "Animal Welfare Ethics in Research and Testing: Implementation and its Barrier." *Indonesian Bulletin of Animal and Veterinary Sciences* 30, no. 4 (2020).

[7] Intan, Putri Reno, and Khariri Khariri. "Appropriate Utilization of Laboratory Animals for Drug and Vaccine Testing." In Proceedings of the National Seminar on Biology, vol. 6, no. 1, pp. 48-53. 2020.

[8] Karima Syahda Malik and Slamet Tri Wahyudi. "Formulation of Criminalization Policy Against Cosmetic Manufacturers Using Animal Testing". *Kertha Semaya: Journal of Legal Science, vol. 12* (2024).

[9] "Pharmaceutical-Textile Industry Predicted to Grow Faster by 8%, This is the Ministry of Industry's Move", https://www.cnbcindonesia.com/news/20241217112803-4-596591/industri-farmasi-tekstil-diramal-tumbuh-mepet-8-ini-jurus-kemenperin, accessed on April 17, 2025.

[10] "Growing 2.5% in the First Quarter, Pharmaceutical Industry Faces Raw Material Challenges", https://www.gpfarmasi.id/detailpost/tumbuh-2-5-pada-kuartal-i-industri-farmasi-hadapi-tantangan-bahan-baku, accessed on April 19, 2025.

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In Indonesia, animal trials are still a common method in pharmaceutical product research, especially in the preclinical phase to evaluate the toxicity and effectiveness of drugs before they are used in human clinical trials. Until now, rats and other animals are still widely used in Indonesian laboratories. Rats account for about 74% of the total use of animals.[11] Biomedical and pharmaceutical research utilizes these animals in a wide range of scientific studies and clinical trials. For example, PT Bio Farma, a national pharmaceutical company that also uses test animals, is responsible for conducting preclinical tests on animals for the Covid-19 vaccine before proceeding to the clinical trial stage for humans.[12] This shows that the use of test animals is still an important and irreplaceable stage in the development of drugs and vaccines in Indonesia.

From a business law perspective, the pharmaceutical industry has a responsibility to carry out its business activities not only based on economic interests, but also by paying attention to ethical and legal aspects considering that the products they produce are directly related to public health. By law, the pharmaceutical industry is obliged to comply with strict regulations, including by adhering to ethical principles of animal welfare properly and correctly. Compliance with ethical standards in the use of test animals is part of *compliance*, which requires the pharmaceutical industry to not only comply with applicable formal regulations, but also uphold moral principles, research ethics, and recognized international standards. This ensures that every testing process is carried out responsibly, transparently, and in accordance with human values and animal welfare.

Research that discusses animal welfare in research and drug production activities has previously been conducted by Fitriya Nur Annisa Dewi, Huda Shalahudin Darusman, and Joko Pamungkas in 2022 with an article entitled "Standardization of Animal Welfare Assurance for the Advancement of Biomedical Research." In the article, the authors focus on the importance of national standardization in ensuring the welfare of test animals in the field of biomedical research through strengthening regulations, establishing animal ethics commissions, and updating national ethics guidelines to be in line with international standards with reference to the 3R and 5F principles. The research makes an important contribution to the development of animal welfare policies at the academic and institutional levels, especially related to biomedical research in Indonesia.

However, the study only highlights the academic scope and has not discussed in depth the responsibilities of corporations, especially in the pharmaceutical industry that uses test animals for drug research and development. In addition, the legal *compliance aspect* has not been the main focus in the discussion, even though this aspect has an important role in ensuring the responsible implementation of animal welfare principles. Therefore, this

[11] "The Use of Experimental Animals Must Be in Accordance with Research Ethics", https://bskdn.kemendagri.go.id/website/penggunaan-hewan-uji-coba-harus-sesuai-etika-penelitian/ accessed on April 19, 2025.
[12] *"Indonesian COVID-19 Vaccines to Undergo Strict Human, Animal Testing"*, https://www.thejakartapost.com/news/2020/06/15/indonesian-covid-19-vaccines-to-undergo-strict-human-animal-testing.html , diakses pada tanggal 20 April 2025.

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research is here to fill this gap through a comprehensive analysis of corporate responsibilities in ensuring the pharmaceutical industry's compliance with the regulation of the use of test animals in Indonesia, by emphasizing the integration of legal, ethical, technical, and transparency aspects within the scope *of corporate compliance*.

Thus, this article explores the question of how regulations in Indonesia regarding the use of test animals by the pharmaceutical industry and the form of corporate responsibility in ensuring legal and ethical compliance with the use of test animals in the Indonesian pharmaceutical industry.

B. Research Methods

The research method applied in this study is in the form of normative law (normative juridical law). This method views that law is seen as a system of norms consisting of principles, principles, and rules where laws and regulations, doctrines, and agreements are the main source. The legislative approach by examining various legal provisions related to the issue being researched as well as a conceptual approach based on legal doctrines and principles that develop in the legal discipline, was chosen as the approach in this study.[13] The types of data sources in the study are primary legal materials that are binding and secondary legal materials that are positioned to explain and clarify the content of primary legal materials.[14] The primary legal sources in this study include Law No. 18 of 2009 jo. Law No. 41 of 2014, Government Regulation No. 95 of 2012, Permenkes No. 75 of 2020, as well as BPOM Regulation No. 10 of 2022 and No. 20 of 2023. Meanwhile, the secondary legal materials in the research consist of books, scientific articles, and internet sources that are continuous with the issues being studied. Data collection was taken by means of literature studies, by examining various relevant literature. Descriptive analysis, by presenting a systematic description of objects and subjects based on the results of the study obtained is the data analysis technique used in this study.[15] This research focuses on corporate responsibility and the implementation *of corporate compliance* in the national pharmaceutical industry sector related to the use of test animals, using international references that are only used as a contextual complement. The stages of this research include collecting and analyzing literature data, analyzing legal materials, synthesizing the results of studies or discussions, and ending by drawing conclusions.

C. Results and Discussion

a. Regulations in Indonesia regarding the Use of Test Animals by the Pharmaceutical Industry

Drug research and development in Indonesia is a common practice among pharmaceutical companies, with extensive use of test animals. Test animals are

[13] Widiarty, W. *Textbook of Legal Research Methods*. Yogyakarta: Publika Global Media, 2024.
[14] Gunardi. *Textbook of Legal Research Methods*. Jakarta: Damera Press, 2022.
[15] Pringgar, Rizaldy Fatha, and Bambang Sujatmiko. 2021. "Library Research for Augmented Reality-Based Learning Modules in Student Learning". *IT-Edu: Journal of Information Technology and Education 5* (1):317-29.

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considered essential to ensure the safety and effectiveness of a health product before it is marketed. Nonetheless, this practice poses ethical challenges and requires strict oversight from the government to prevent violations of animal rights. In Indonesia, regulations regarding the use of test animals have been regulated through various laws and regulations, research codes of ethics, and technical guidelines. The regulations are not solely made to protect animals from inappropriate treatment, but also to guarantee that pharmaceutical research activities produce accurate data and are in line with international standards.

One of the important regulations that regulates the use of test animals is Law of the Republic of Indonesia Number 18 of 2009 which was later amended by Law Number 41 of 2014 concerning Animal Husbandry and Health. This law basically regulates livestock and animal health, including aspects of animal welfare. Not only for farm animals, but also includes test animals. Article 27 paragraph (1) explains that test animals are animals that are specifically kept for the purposes of research, testing, educational activities, and the production of biomedical materials, or developed as model animals for the study of diseases in humans. In the chapter on Animal Welfare in this law, it is emphasized that there is an obligation to pay attention to the principles of animal welfare in their maintenance and utilization. Then, Article 66 paragraph (2) outlines that every form of exploitation and utilization of animals must be carried out responsibly so that animals avoid persecution and abuse. Animal abuse is defined as an act committed to gain profit or satisfaction by treating animals beyond the limits of their biological and physiological capabilities.[16] Article 66A, which is an addition to Law Number 41 of 2014, expressly prohibits all kinds of mistreatment or abuse of animals, so that the use of animals for research should not cause excessive suffering. This article emphasizes that animal welfare must be the main consideration in every research practice. Then, Article 67 places the responsibility for animal welfare not only on individuals or owners, but also on the state through the central and regional governments as well as the community in general. Furthermore, Article 74 emphasizes that the use of animals in research activities must be carried out under the supervision of a competent veterinarian, while still being based on ethical principles and paying attention to aspects of animal welfare. The utilization includes the use of test animals, including the use of animal organs, which must be carried out by applying *comparative medicine*. This comparative science examines the characteristics, causes, and management of structural or functional disorders in humans, animals, and plants for the benefit of all living things.[17]

Another relevant regulation is Government Regulation of the Republic of Indonesia Number 95 of 2012 concerning Veterinary Public Health and Animal Welfare.

[16] "Criminal Threats to Animal Abuse Perpetrators", https://www.hukumonline.com/berita/a/ancaman-pidana-bagi-pelaku-penganiayaan-hewan-lt62ece59c73080/, accessed April 21, 2025.
[17] Intan, Putri Reno, and Khariri Khariri. "Appropriate Utilization of Laboratory Animals for Drug and Vaccine Testing." *In Proceedings of the National Seminar on Biology, vol. 6*, no. 1, pp. 48-53. 2020.

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This regulation provides clarity on ensuring hygiene, sanitation, and safety of animal products so as not to endanger human health, while ensuring that various activities involving animals are carried out in accordance with the five principles of animal freedom.[18] This includes the use of test animals in research, testing, and teaching. In Chapter III concerning Animal Welfare, Article 83 paragraph (3) letter h states that the principle of animal welfare must be applied in comparative medicine practice. Thus, when animals are used as research objects to compare the veterinary and human aspects of medicine, the protection of animals must still be maintained. Article 84 paragraph (1) b provides an obligation for individuals who are side-by-side with animals as part of their work to apply the principles of animal welfare, so that researchers, laboratory technicians, and teaching staff who interact with test animals have legal and moral responsibilities. Article 92 letter a prohibits the use of animals beyond their limited capabilities, including making them test animals without a valid basis, so research with test animals may only be carried out according to the provisions. One of these provisions is to use healthy and quality animals, which are bred and raised in a controlled environment.[19] Furthermore, Articles 97 to 98 detail the regulation of comparative medical practice for test animals, with the emphasis that the principle of animal freedom must be applied and research activities may only be carried out directly by veterinarians or the supervision of competent veterinarians and adhere to the professional code of ethics. This code of ethics serves as a guide for veterinarians to carry out the practice in accordance with the principles of professionalism and moral values.[20] The purpose of this provision is to ensure that the implementation of comparative medicine is carried out professionally in accordance with the established standards, while ensuring the protection of animal welfare used in research and scientific testing activities.

The Minister of Health of the Republic of Indonesia has issued Regulation of 2020 Number 75 of 2020 which establishes a Research Ethics Committee to ensure that health research conducted on human and animal subjects is carried out in accordance with research ethics. This rule applies equally to all other fields. KEPPKN is mandated to conduct, supervise, and enforce health research ethics at the national level. In consideration, this regulation clearly states that research in the health sector, both involving humans and using test animals as subjects, is obliged to comply with the principles of research ethics. This is because before a finding can be applied for the benefit of human health, it is necessary to conduct research through *in vitro* or *in vivo* mechanisms where this mechanism involves humans or animals as part of the scientific

[18] Boy, three. "Legal Protection of Pet Abuse Crimes According to the Perspective of Criminal Law in Indonesia (Study of Decision Number: 320/PID. SUS/2020/PT. DKI)." *Journal of Adigama Law 4*, no. 2 (2021): 3768-3788.
[19] Yusuf, M., M. R. Al-Gizar, Y. Y. A. Rorrong, D. R. Badaring, and H. Aswanti. "Experiments understand the care and welfare of experimental animals." Journal of Biology of FMIPA Biology Study Program (2022): 1-109.
[20] Jubilia, Agatha Arai, dan I. Wayan Suardana. "Application Of Veterinary Ethics in Indonesia." *Veterinary Science and Medicine Journal* (2024): 256-264.

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process. The Health Research Ethics Committee (KEPK) has a role to review and evaluate research protocols as a basis for providing ethical approval before research activities are carried out.[21] Furthermore, Article 4 paragraph (2) letter a number 4 emphasizes that KEPPKN is in charge of compiling national guidelines for research ethics that include humans and test animals as research subjects. The ethics of using test animals is within the scope of KEPPKN's work which is crucial in ensuring uniform ethical standards nationally.

In addition, the Food and Drug Supervisory Agency Regulation Number 20 of 2023 concerning Guidelines for Preclinical Pharmacodynamic Tests for Traditional Medicine was issued to improve the previous regulation. This regulation is the official reference for the implementation of preclinical trials in proving the scientific efficacy of traditional medicine. To be accepted in formal health services, traditional medicines need to be scientifically proven regarding their safety and efficacy, using pharmacodynamic tests. Pharmacodynamic testing is the process of proving the effect or efficacy of a product on test animals that is carried out through scientific methods.[22] This test is carried out using test animals through a scientific method that pays attention to Good Laboratory Practice (GLP) and research ethics based on the 3R principle. The laboratories used must meet Good Veterinary Laboratory Practice standards, ranging from buildings, facilities, to waste systems, while animal management procedures are explained in detail ranging from marking, handling techniques, blood collection, to euthanasia and destruction procedures. The guidelines also outline that test animals are a key component of preclinical pharmacodynamic testing methodologies, with animal selection based on standard models of disease and the use of males with a total of 5–8 animals per test group.

Another regulation issued by BPOM is Regulation Number 10 of 2022 concerning Guidelines for In Vivo Preclinical Toxicity Tests. This regulation provides technical provisions for the implementation of non-clinical toxicity tests with test animals to assess the safety of drugs before the clinical stage in humans. In general, in vivo preclinical toxicity testing is a test that uses test animals in the laboratory to assess potential toxic effects on biological systems and obtain data on the relationship between the dose and the specific response of the prepared being tested.[23] The 3R and GLP principles are the basis for its implementation. The animals used must be healthy, disease-free, according to age and weight standards, and go through an acclimatization period to reduce stress. The regulated forms of toxicity tests include acute, subchronic,

[21] Susilawati, Tri Nugraha, Erindra Budi Cahyanto, and Usman Sudarmaji. "Digitization of Ethics Review Services: A Governance Study of the Research Ethics Committee." *Indonesian Journal of Medical Ethics 5*, no. 2 (2022): 57.
[22] Nurfitri and L. Venita. "Pharmacodynamic Test Method as One of the Proofs of the Efficacy of Natural Medicines as an Alternative Option for Thalassemia Therapy." *HEALTHY: Journal of Health Sciences Research Innovation 2*, no. 1 (2023): 1-10.
[23] Pramesti, Dinda Intan, Nawafila Februyani, and Titi Agni Hutahaen. "Acute Toxicity Test of Lemongrass (Cymbopogon citratus) and Basil (Ocimum basillicum) Extract Cough Syrup in Vivo in Mice (Mus musculus)." *Indonesian Journal of Health Science 3*, no. 2 (2023): 340-347.

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chronic, teratogenicity, irritation, sensitization, and carcinogenicity. Each test regulates the minimum number of animals, the method of administering the test substance, and clinical and biological monitoring to detect toxic signs. This guideline also opens up opportunities to use other validated valid methods according to laboratory needs.

Based on a study of various regulations in Indonesia, it can be seen that although the legal framework has regulated the use of test animals, there are still a number of aspects that have not been adequately accommodated. Unfortunately, special and specific regulations that comprehensively regulate the use of test animals, including detailed provisions regarding test animal welfare standards, are not yet in Indonesia's possession. Overall, the existing regulations and guidelines are still limited and are not equipped with technical documents that provide an elaboration of the work procedures of the ethics commission and the application of animal welfare principles, both in research activities and the use of test animals. Not only that, law enforcement mechanisms and regulations regarding sanctions for violations or *non-compliance* are also not clearly available.[24]

In addition, there are still many research institutions in Indonesia that use animals in research and testing activities but do not have an ethics committee, so a number of studies are carried out without ethical *clearance*. This condition makes it difficult to supervise the application of animal welfare principles, such as the 3R and 5F principles. In addition, the lack of strict sanctions from institutions for animal welfare violations has contributed to the low awareness of researchers in applying ethical standards for testing on animals. Until now, Indonesia also does not have an *official statement or published data* regarding the quantity of animals used in research and testing, so the aspects of transparency and accountability are still not optimal.[25] New regulations that are more comprehensive, specific, and integrated are needed to ensure the welfare, accountability, and ethics of the use of test animals in research in Indonesia.

b. Forms of Corporate Responsibility to Ensure the Protection and Welfare of Animals in the Use of Test Animals in the Pharmaceutical Industry

The pharmaceutical industry is the largest sector in the use of test animals. Pharmaceutical researchers state that the use of test animals contributes to providing an understanding of the mechanism of action of a product as well as in setting safe dosage limits for humans.[26] Despite its significant contribution to the advancement of science, this practice raises dilemmas and debates due to the view that it is unfair when

[24] Dewi, Fitriya Nur Annisa, Huda Shalahudin Darusman, and Joko Pamungkas. "Standardization of Animal Welfare Assurance for the Advancement of Biomedical Research." *Policy Brief Tropical Agriculture, Marine and Biosciences 4*, no. 4 (2022): 375-380.
[25] Wahyuwardani, Sutiastuti, S. Noor, dan B. Bakrie. "Animal Welfare Ethics in Research and Testing: Implementation and its Barrier." *Indonesian Bulletin of Animal and Veterinary Sciences 30*, no. 4 (2020).
[26] Nuragustini, Supardi, dan Handoyo Prasetyo. "Criminalization Policy of Animal Testing in Cosmetics Production in Indonesia*". International Journal of Social Science and Human Research, vol. 7* (2024).

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animals should be harmed in order to provide greater utility to humans.[27] Therefore, corporations engaged in the pharmaceutical industry are required to show accountability or a form of responsibility that must be shown in research activities involving test animals. This accountability includes compliance with applicable legal provisions. In addition, this responsibility is not only oriented to regulation *(legal),* but also to the ethical *(ethical),* technical *(technical) (transparency) (technical) (technical) (technical) ()* (technical) () (technical) ()) (technical) ())] (technical) (*transparency) ()*

Based on Black's Law Dictionary, the term *comply* is interpreted as an act to carry out obligations, adjust, implement, or accommodate something. From this understanding, *legal compliance* can be understood as a form of compliance that comes from legal provisions, so in general *compliance* is defined as compliance with the rule of law.[28] In this context, companies engaged in the pharmaceutical industry are obliged to comply with various provisions that provide regulations in the use of test animals in research activities. These provisions include Law No. 18 of 2009 in conjunction with Law No. 41 of 2014, Government Regulation No. 95 of 2012, Permenkes No. 75 of 2020, as well as BPOM Regulations No. 10 of 2022 and No. 20 of 2023. These rules require companies to obtain official permits in any research activities involving animals, report test results transparently, and ensure that the entire process runs according to the animal welfare principles set by the government.

In terms of the pharmaceutical industry in Indonesia, as reported by The Jakarta Post in its article entitled *"Indonesian Covid-19 Vaccines to Undergo Strict Human, Animal Testing"* which discusses the use of test animals in the development of the Covid-19 vaccine involves the national pharmaceutical industry such as PT Bio Farma and the Eijkman Institute. Prototypes or initial forms of vaccines are required to be tested on animals in accordance with the provisions of the Food and Drug Supervisory Agency (BPOM), which emphasizes the importance of conducting research in a transparent, safe, and responsible manner.[29] This shows that corporations are not only required to meet scientific requirements, but also ensure compliance with legal, ethical, and technical aspects in the use of test animals. *Legal compliance* serves as a normative instrument that binds pharmaceutical companies not only to follow scientific standards, but also to ensure that the use of test animals is carried out in accordance with the applicable laws in Indonesia. In this case, the successful implementation of safe and

[27] Hasina, Raisya, Siti Rahmatul Aini, Iman Surya Pratama, Mahacita Andanalusia, Yoga Dwi Saputra, Baiq Dwiyan Nugrahani, and Yazid Maula Arzaqi. "Training on Basic Handling of Experimental Animals for Laboratories of various Pharmaceutical Universities in NTB Province." *Journal of Abdi Insani 10*, no. 3 (2023): 1203-1211.
[28] Destyarini, Normalita. "Legal Compliance in Pharmaceutical Electronic System Operators in Indonesia." *Crepido 5*, no. 1 (2023): 42-53.
[29] *"Indonesian COVID-19 Vaccines to Undergo Strict Human, Animal Testing"*, https://www.thejakartapost.com/news/2020/06/15/indonesian-covid-19-vaccines-to-undergo-strict-human-animal-testing.html , diakses pada tanggal 13 September 2025.

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responsible pharmaceutical industry practices can be seen based on how strong the legal system that governs it.[30]

In addition to the legal aspect, corporations also bear responsibility for ethical compliance in the use of test animals. This responsibility for ethical compliance means acting and behaving in harmony with generally recognized moral values.[31] The article revealed criticism from animal protection groups against the practice of animal testing in vaccine development, which shows moral sensitivity in society. This requires that research not only comply with formal regulations, but also pay attention to ethical principles, such as respect for living beings, namely test animals. The 3R framework in this test is an important principle that is between scientific interest and research ethics. *Replacement* emphasizes the use of alternative approaches to reduce the use of animals. *Reduction* focuses on minimizing the number of animals used. Meanwhile, *Refinement* aims to improve animal welfare by optimizing experimental methods to reduce pain, stress, and suffering. The application of this principle guarantees the use of animals only when necessary, while prioritizing welfare and maintaining the validity and integrity of research.[32] By applying these ethical standards, corporations not only avoid social conflicts, but also build moral legitimacy in the eyes of society.

Furthermore, the form of technical compliance is also an important aspect in ensuring the welfare of test animals. Technical compliance is an important aspect in ensuring the welfare of test animals, so preclinical tests must follow strict operational procedures with validated methods and facilities according to standards. Strict supervision, such as the one carried out in the article, namely PT Bio Farma, which uses animals as test subjects for the Covid-19 vaccine, shows that there are technical controls to ensure the security, accuracy, and reliability of the data. The maintenance of test animals must also pay attention to the condition of the cage, sanitation, food, water, ventilation, lighting, as well as temperature and humidity regulation. All of these aspects require the support of trained personnel through special training so that maintenance is in accordance with scientific and ethical standards.[33] Animal storage facilities must also be clearly separated from other areas and equipped with separate door access and an isolated air circulation system.[34] Thus, the pharmaceutical industry is not only

[30] Garnetavegi, R. F., and Sakti, M. (2025). A Comparative Study of Consumer Protection in Telepharma Services Related to the Role of Indonesian and German Pharmacists: Supervision and Authority of Pharmacists. *Journal of Research and Service Locus*, *4*(6), 2502-2509.
[31] "Exploring Current Ethical and Social Responsibility", https://www.dconsulting.id/mengeksplorasi-tanggung-jawab-etis-dan-sosial-saat-ini/#:~:text=Tanggung%20jawab%20etis%20merujuk%20pada,dan%20perlindungan%20hak%20asasi%20manusia, accessed September 15, 2025.
[32] K Sunil Kumar dan Prashant Tiwari. The 3R's Approach in Preclinical Pharmacology: Promoting Animal Welfare and Scientific Ethics. *Cambridge: Cambridge Scholars Publishing*, 2025.
[33] Stevani, H. *Pharmacy Practicum Teaching Materials Module*. Jakarta: Health HR Center, 2016.
[34] Dewi, Niluh Puspita, Puspa Dwi Pratiwi, Deniyati, Muhammad Subhan A. Sibadu, Shabran Hadiq, Dwi Endah Kusumawati, Magfirah, Ayu Wulandari, Windi Susmayanti, Chyntia Tresna Nastiti, Arlan K. Imran, Suhrah Febrina Karim, Muh Taufiqurrahman, and Muladi Putra Mahardika. *Industrial Pharmacy.* Bandung: CV Media Sains Indonesia, 2024.

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obliged to comply with laws and ethical norms, but also to ensure that technical standards are met.

However, Prof. Dr. dr. Eti Nurwening Sholikhah from Gadjah Mada University highlighted that test animal laboratory facilities or accommodations that have accreditation in Indonesia are still very minimal, causing long queues for researchers.[35] In addition, the pharmaceutical industry in Indonesia in general still does not implement comprehensive information disclosure regarding the practice of using test animals. This lack of public transparency is reflected in the lack of official reports containing data on the number of animals used in research and testing activities.[36] This causes the information available to the public to focus more on formal legal aspects, such as clinical trial permits from BPOM, without open reporting on the welfare of test animals or the application of the 3R *(Replacement, Reduction, Refinement) principle.* This lack of openness has the potential to cause criticism from community groups or animal protection organizations, as well as weaken the moral legitimacy of the pharmaceutical industry. The lack of disclosure of information related to the use of test animals shows the pharmaceutical industry's low transparency to the public. In fact, the public or consumers have the right to information as a form of protection for their interests. Legal consequences can arise when business actors (in this case the pharmaceutical industry) violate obligations that result in violations of the public's or consumers' rights to information, so that business actors can be held accountable for the losses caused.[37]

Meanwhile, when compared to practices in the international pharmaceutical industry, there are higher standards in terms of transparency. Some international industries often include information about the use of test animals on their *websites*. For example, AstraZeneca, a multinational pharmaceutical and biotechnology company from the United Kingdom-Sweden affirmed its commitment to transparency and ethics in the use of animals for research through the 3R principle. This transparency can be seen, namely that in 2023, more than 97% of the animals used are rodents or fish, most of them are rats (84%), while other animals such as dogs and primates are less than 1%. AstraZeneca is also a signatory to the *Concordat on Openness in Animal Research* in the UK and has the Council for Science and Animal Welfare (C-SAW) which oversees animal welfare policy and awards the 3R efforts.[38] This commitment was recognized by *Understanding Animal Research*, which awarded AstraZeneca *Leader in Openness* status in May 2024, making it the first pharmaceutical company to be awarded for its

[35] "Laboratory Facilities for Test Animals in Indonesia Are Still Minimal", https://ugm.ac.id/id/berita/23454-fasilitas-laboratorium-hewan-uji-di-indonesia-masih-minim/, accessed on September 21, 2025.
[36] Wahyuwardani, Sutiastuti, S. Noor, dan B. Bakrie. "Animal Welfare Ethics in Research and Testing: Implementation and its Barrier." *Indonesian Bulletin of Animal and Veterinary Sciences 30*, no. 4 (2020).
[37] Nurdin, Melinda, and Muthia Sakti. "The urgency of halal labeling of over-the-counter drug products in an effort to protect consumers." *USM Law Review* 7, no. 1 (2024): 314-332.
[38] "Responsible Care and Use of Animals in Research", https://www.astrazeneca.com/sustainability/ethics-compliance/animals-in-research.html , diakses pada tanggal 22 September 2025.

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dedication to openness in ensuring the use of animals is ethically and scientifically conducted.[39]

Therefore, compliance with legal, ethical, technical, and transparent aspects is important for the pharmaceutical industry in Indonesia. The application of the 3R and 5F principles, standard operating procedures, adequate laboratory facilities, and trained personnel ensure the responsible use of test animals and minimize risks to animals. By harmonizing all these aspects, the pharmaceutical industry not only protects animal welfare but also supports the development of safe and reliable health. However, the existing Indonesian legal system is still general and has not specifically regulated the corporate *compliance mechanism* in the use of test animals by the pharmaceutical industry. In this case, strengthening the law is very important through the formation of a law that specifically *(lex specialis)* strictly regulates research ethics standards, corporate compliance governance, and strict supervision mechanisms, so that the implementation of animal welfare principles can be guaranteed in research activities by the pharmaceutical industry in Indonesia.

D. Kesimpulan dan Rekomendasi

Based on the results of the analysis, Indonesia already has various regulations regarding the use of test animals that have been regulated in various regulations such as Law No. 18 of 2009 jo. Law No. 41 of 2014, Government Regulation No. 95 of 2012, Permenkes No. 75 of 2020, as well as BPOM Regulations No. 10 of 2022 and No. 20 of 2023. However, its application in the field is still not optimal because there is no law enforcement mechanism and national standards that comprehensively regulate the welfare of test animals, especially in the context of the pharmaceutical industry. Corporate responsibility in this case includes compliance with legal, ethical, technical, and public transparency aspects. Such compliance is not only formal, but also reflects a moral responsibility to ensure the welfare of test animals in accordance with the 3R and 5F principles. The implementation *of compliance* that is integrated with ethical and technical supervision is very important so that the practice of using test animals in the pharmaceutical industry runs responsibly and transparently.

To be able to realize these ideals, it is necessary to develop new regulations that specifically regulate corporate governance and accountability in the use of test animals. This includes certification obligations, ethical audits, and transparent public reporting. The government together with regulatory agencies such as BPOM and KEPPKN can play an active role in building a certification and licensing system for the pharmaceutical industry that uses test animals, as best practices at the international level. Thus, Indonesia not only strengthens law enforcement and ethics in biomedical research but also increases the competitiveness of the national pharmaceutical industry based on the principles of

[39] "Leaders in Open 2024-2027", https://www.understandinganimalresearch.org.uk/news/leaders-in-openness-2024-2027, accessed on September 22, 2025.

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humanity, transparency, and scientific sustainability.

Thus, this research contributes to strengthening the corporate law paradigm in Indonesia through the integration of *corporate compliance principles* with the values of Corporate ComplianceAnimal Welfare. This approach is expected to be the basis for the formation of regulations that are more responsive, fair, and oriented towards corporate compliance responsibilities. In addition, it is necessary to establish a special regulation that expressly regulates the compliance mechanism and supervision of the use of test animals by the pharmaceutical industry, so that the principle of animal welfare can be guaranteed in pharmaceutical research and development practices in Indonesia.

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