

## LEGAL PROTECTION FOR CONSUMER OF DRUG PRODUCER THAT DOES NOT HAVE A DISTRIBUTION PERMIT FROM THE FOOD AND DRUG CONTROL AGENCY (BPOM)

Hendra Lazuardi<sup>1\*</sup>, Nur Handayati<sup>2</sup>

<sup>1,2</sup> Universitas Dr. Soetomo Surabaya

E-mail: <sup>1)</sup> [hendralazuardi138@gmail.com](mailto:hendralazuardi138@gmail.com), <sup>2)</sup> [nurhandayati@unitomo.ac.id](mailto:nurhandayati@unitomo.ac.id)

### *Abstract*

*For maintain health in carrying out daily activities, humans consume drugs as a healing solution for the ailments they experience. However, cases of illegal drug distribution threaten the health of someone who accidentally consumes illegal drugs without testing by the Food and Drug Monitoring Agency. The purpose of this research is to analyze the process of granting licenses to the distribution of drugs by BPOM and legal protection for consumers against the distribution of drugs that do not have distribution permits. This type of research is normative legal research with the Statue and Case Approach. Analysis data used descriptive qualitative analysis of existing laws and regulations to find answers to cases of drug trafficking that do not have a distribution permit. The results of the study prove that the process of granting permits for drug distribution by BPOM is carried out in two stages, namely the Pre-registration and Registration stages with the fulfillment of the required statements and documents. The evaluation process is carried out for 100 days for new drug products which is carried out by the Head of the BPOM Agency. Legal protection for consumers against the distribution of drugs that do not have a distribution permit is by imposing a maximum imprisonment of 15 years and a maximum fine of IDR 1,500,000,000.00 for the perpetrator. For producers who do not have the expertise and authority to carry out pharmaceutical practices, they will be fined a maximum of IDR. 100,000,000.00.*

**Keywords:** *Distribution of Illegal Drugs, Distribution Permit, Health*

### 1. INTRODUCTION

Physical well-being stands as an essential human necessity, crucial for executing daily tasks effectively, maintaining enthusiasm, combating fatigue, and warding off illnesses (Firmansyah, 2020). Atmaja, Astra, and Suwiwa (2021) emphasize that a lack of sound physical health hinders the smooth execution of all human pursuits. In the realm of the Human Development Index, wellness emerges as a key metric for gauging human advancement. Furthermore, health assumes the role of a benchmark for evaluating the quality of human resources and the level of individual prosperity within a nation (Ocbrianto, 2012). Codified in Article 1, paragraph (1) of Law No. 36 of 2009 concerning Health, health encompasses a comprehensive state of well-being spanning physical, mental, spiritual, and social dimensions, empowering each person to lead a socially and economically fruitful life. In light of health's pivotal position as an indicator of national progress, governments allocate substantial attention to public health considerations.

The realm of health consists of a twofold perspective: the realm of health endeavors and that of health resources (Samosir, 2021). Among the avenues of health endeavors, healthcare is bifurcated into communal health support and individual health maintenance. The nurturing of individual well-being is labeled as medical preservation. Conversely, within the domain of health resources, lie healthcare establishments and infrastructures like hospitals, health centers, clinics, along with practicing medical professionals and

healthcare personnel, encompassing doctors, nurses, and pharmacists. The execution of healthcare activities is the responsibility of these health resources, and they are held steadfastly accountable to the codes of medicine, ethics, legality, propriety, and respectfulness (Supriadi, 2001).

As per the Law of the Republic of Indonesia, specifically Law Number 36 of 2009 concerning Health, it explicitly states the government's obligation to strategize, regulate, execute, foster, and oversee the implementation of fair and accessible healthcare initiatives for the community. Within the context of the 1945 Constitution, Article 28G, Paragraph 4 underlines the State's responsibility, particularly vested in the Government, for upholding, advancing, preserving, and ensuring human rights. Additionally, Article 28H, Paragraph (1) of the 1945 Constitution enshrines the right of every individual to a life marked by physical and spiritual well-being, a suitable dwelling, a wholesome and salubrious environment, and the right to avail healthcare services.

The establishment of health insurance mandates the government's regulation of treatment protocols. The government formulates policies to oversee the entire treatment spectrum, encompassing surgical interventions, therapeutic procedures, drug administration, and other healing methods. However, the most prevalent form of treatment within communities typically revolves around medication consumption. As elucidated by Lailiyah (2019), medications are substances intended for purposes such as diagnosing, preventing, mitigating, curing diseases, alleviating symptoms, tending to injuries, and addressing physical and spiritual imbalances in both humans and animals, often extending to aesthetic enhancements. The potency of these medications is contingent on individual body conditions and sensitivities, both of which vary widely. Yet, despite this diversity, it is feasible to broadly categorize dosages for different age groups, encompassing infants, children, adults, and the elderly (Kasibu, 2017).

Understanding the pivotal role that drugs play, the government instituted Government Regulation Number 51 of 2009 to address Pharmaceutical Practices. This regulatory framework encompasses the oversight of various aspects including the quality control, security, procurement, storage, and distribution of medications. Additionally, it encompasses services related to prescribed drug administration, drug information, as well as the advancement of drug components and traditional medicine. Notably, the comprehensive spectrum of drug management procedures necessitates the involvement of qualified personnel possessing the requisite expertise and authorized standing, in full alignment with statutory provisions.

One of the problems that often occur in health law that often occurs today is crime in the pharmaceutical sector. Pharmacy is the direct and responsible provision of drugs to achieve results that can improve the quality of life of patients (Wahyudi, 2020). Pharmacy is the art and science concerned with providing natural and synthetic substances suitable for distribution and use in the treatment and prevention of disease (Samosir, 2021). Pharmaceutical care involves not only drug therapy but also decision-making about drug use for each patient. One of the crimes that is often committed in the pharmaceutical industry is to distribute or trade drugs in large quantities without a distribution permit issued by the competent authority, in this case the Food and Drug Supervisory Agency (BPOM).

The widespread presence of illegal drugs in Indonesia serves as an indication of the government's negligence towards matters that are detrimental to the well-being of the

society. Allowing the illicit drug trade to thrive is equivalent to exposing the populace to various harmful risks, effectively nurturing the growth of criminal activities within the society, and diminishing the nation's standing in the eyes of the international community. This situation is exacerbated by factors associated with the likelihood of criminal occurrences, whether they are minor infractions or major offenses.

One of the cases regarding illegal drug distribution was found in Decision Number 94/Pidana Case/2021/Mungkid District Court where a pharmaceutical crime occurred in which a person without expertise and authority had practiced *marfacy* which was contrary to the Regulation of the head of the drug and food regulatory agency regarding criteria and administration of drug registration article 1 paragraph 1 and Law no. 39 of 2009 concerning Health. In this case, the perpetrator who traded drugs did not use the services of a pharmacist and without using a doctor's prescription was given a sanction in the form of a fine of Rp. 20,000,000.- (twenty million rupiah) with the provision that if the fine is not paid it will be replaced by imprisonment for 3 (three) months.

In light of the significant risks posed by the distribution of illegal drugs that have the potential to be consumed by the general public, it is evident that the existing punitive measures prescribed in Decision Number 94/Criminal Case/2021/Mungkid District Court do not appear commensurate with the gravity of the situation. Recognizing that the public, as consumers of these substances, is afforded protection under Law no. 8 of 1999 concerning Consumer Protection, it is imperative to underscore that consumers possess the right to seek restitution for losses incurred during commercial transactions. Addressing these considerations, the upcoming analysis will comprehensively examine the outcomes of Decision Number 94/Criminal Case/2021/Mungkid District Court.

Hence, this paper aims to meticulously explore the procedural nuances of authorizing drug distribution by BPOM and the legal mechanisms extended to consumers confronting the distribution of drugs lacking proper authorization. The overarching goal of this research endeavor is to provide prospective scholars with a foundational framework for the application of theoretical constructs, particularly in dissecting criminal activities related to drug trafficking that involve unapproved distribution. Furthermore, this investigation is poised to serve as a seminal reference for future explorations, concentrating on the legal ramifications surrounding the illicit distribution of drugs in the absence of requisite distribution permissions.

## **2. LITERATURE REVIEW**

### **2.1. Drug**

Drugs encompass substances purposed for employment in contexts such as diagnosing, preventing, mitigating, eradicating, or tending to ailments, injuries, or physical and spiritual imbalances in humans and animals. They can also extend to enhancing the aesthetics of the human form or its components (Anief, 2006). Engaging in self-medication demands a meticulous alignment with the specific ailment. Adhering to the principles of prudent drug utilization involves precise drug selection, accurate dosage, avoidance of adverse effects, absence of contraindications, evading drug interactions, and steering clear of polypharmacy (Depkes RI, 2008). In practical scenarios, errors in self-medication occasionally surface, often rooted in inaccuracies in drug choices and inappropriate dosing. Should these errors persist, they have the potential to jeopardize one's well-being (Depkes RI, 2007).

## **2.2. Drug Distribution Permit**

The term "distribution" encompasses any form of activity or sequence of actions involved in the conveyance or transfer of pharmaceuticals, whether within trade, non-trade, or transfer scenarios. As per the guidelines set forth in BPOM Regulation Number 8 of 2020, governing the Oversight of Online Circulation of Medicines and Foodstuffs, the distribution of pharmaceuticals necessitates the possession of a valid distribution permit, coupled with adherence to stipulated protocols governing pharmaceutical manufacturing and dispensation. Entities functioning within the pharmaceutical sector, including pharmaceutical manufacturers, wholesalers, branch pharmacy wholesalers, and online pharmacies, are mandated to provide periodic reports in accordance with the prevailing legal framework. These reports encompass a range of crucial details, such as:

- 1) Identification of entities, including their names and addresses, involved in the pharmaceutical industry, pharmaceutical wholesaling, branch pharmacy wholesaling, and pharmacy operations.
- 2) Precise recording of the date, month, and year of online pharmaceutical distribution activities.
- 3) The designation of the Pharmaceutical Specialized Entrepreneur (PSEF) and the Uniform Resource Locator (URL) of the pharmacy collaborating with the PSEF in facilitating online pharmaceutical distribution.
- 4) A comprehensive inventory of pharmaceuticals distributed via online platforms.
- 5) Detailed records of online drug transactions.

## **2.3. Legal Protection for Consumers**

Philipus M. Hadjon defines the essence of legal protection as an intertwining of shielding and legal provisions, encompassing both preventive and corrective aspects, whether documented or not. This notion underscores the multifaceted role of law, offering not just fairness and structure, but also assurance, benefits, and serenity. As Rahardjo (2006) asserts, legal protection becomes intertwined with the enforcement of law, constituting a distinct societal mechanism to uphold order. Conversely, Muchsin (2003) contends that legal protection is an endeavor that shields individuals by harmonizing the tenets and rules embodied in behavior, cultivating societal harmony among peers. This study adopts Rahardjo's (2006) conceptual framework concerning legal protection.

## **3. RESEARCH METHODS**

The research employs a normative legal research methodology, focusing on the analysis of applicable laws and regulations relevant to the issue of drug distribution lacking proper permits (Benuf, Mahmudah, & Priyono, 2019).

Two problem-solving approaches are utilized. The statutory problem approach involves a comprehensive examination of all relevant laws and regulations related to the specific legal issue (Marzuki, 2011). Simultaneously, the case study problem approach involves an exploration of court decisions that carry enduring legal significance (Marzuki, 2014).

Primary legal materials encompass authoritative legal texts such as the Civil Code, Health Law (Law No. 36/2009), and Consumer Protection Law (Law No. 8/1999)

(Suardita, 2017). Secondary legal materials, including books, articles, journals, and research papers, provide supplementary explanations for interpreting primary legal materials (Suardita, 2017).

The research methodology relies on library research, encompassing data collection, rigorous reading, and meticulous processing of research materials. Library studies are instrumental in gathering theoretical underpinnings from reference books and prior studies (Supriyadi, 2017; Sarwono, 2006).

The study employs a descriptive qualitative analysis of existing legislation to gain insights into cases of unauthorized drug distribution. This approach is chosen due to its aptness for dealing with theoretical aspects such as legal principles, concepts, and norms, that are pertinent to unpermitted drug distribution scenarios.

## **4. RESULTS AND DISCUSSION**

### **4.1. The process of granting permits for the distribution of drugs by BPOM**

When it comes to promoting medicinal products to the public, pharmaceutical manufacturers are required to secure a distribution permit for the medications they produce. As articulated in the Decree issued by the Head of the Drug and Food Control Agency (BPOM), specifically numbered HK.00.05.3.1950, which pertains to the Criteria and Procedures for Drug Registration, Article 2 underscores that therapeutic products intended for distribution within Indonesia's borders and/or for export purposes must possess a valid distribution permit, attainable through a registration process that adheres to specified prerequisites.

Furthermore, as laid out in Regulation Number 13 of 2021 by the Drug and Food Control Agency (BPOM), specific criteria must be met by pharmaceutical manufacturers to qualify for a distribution permit. These criteria encompass:

- a. Alignment with the governmental declaration of a public health emergency.
- b. Substantial scientific substantiation of the drug's safety and efficacy in preventing, diagnosing, or treating serious and life-threatening diseases or conditions. This validation is rooted in comprehensive non-clinical data, clinical trial outcomes, and established guidelines for managing related illnesses
- c. Compliance with rigorous quality standards and adherence to the stringent Good Manufacturing Practices applicable to pharmaceuticals.
- d. Establishment of a favorable balance between benefits and risks (as determined through a meticulous risk-benefit analysis), substantiated by a comprehensive review of both non-clinical and clinical data for the proposed drug indications.
- e. Demonstrating the absence of approved alternative treatments or management strategies for diseases that could trigger public health emergencies.

The drug registration process is carried out in 2 stages, namely the pre-registration stage and the registration stage. In the pre-registration application for drugs, the registration screening includes determining the registration category, determining the evaluation path, determining the evaluation fee, and determining the registration documents. Pre-registration requests are made by:

- a. Fill out the form as listed in Appendix II which is an integral part of this Regulation of the Head of the Agency;

- b. Submit proof of pre-registration fee payment; And
- c. Attach the documents as listed in Appendix XIII which is an integral part of this Regulation of the Head of the Agency.

The issuance of Pre-registration results (HPR) is a process that should not exceed 40 days from the moment the application is received, as stipulated in Article 33. The HPR carries significant weight as it remains in effect for an entire year from the date of issuance. Should any insufficiencies be identified in the document, a formal request for supplementary data is communicated in writing to the Applicant, allowing a grace period of up to 20 days for response.

Throughout the intricate stages of pre-registration and registration, the Registrant formally presents their requests in written format to the Head of the Agency. These requests are accompanied by an array of documents covering both pre-registration and registration aspects. To account for the associated costs, applications for pre-registration and registration are accompanied by fees that contribute to non-tax state revenue. This financial aspect necessitates prompt attention, with payment required no later than 10 days after the issuance of the Public Service Payment Order (SPB-LP), as prescribed by established legal norms.

Several documents are fundamental to the registration process, including:

- a. Part I: Encompassing an array of administrative documents, comprehensive product information, and intricate labeling specifics.
- b. Part II: Delving into a detailed quality-focused document compilation.
- c. Part III: Addressing the array of nonclinical documents that underscore the product's attributes.
- d. Part IV: Encompassing a thorough compilation of clinical documentation, thereby presenting a holistic view of the product's clinical relevance.

In the course of the registration procedure, an extensive 100-day review will be executed for the New Registration of New Drugs, Biological Products, Generic Drugs, and Branded Generic Drugs. These categories are targeted for participation in national health programs, requiring accompanying documentation that fulfills program prerequisites or showcases prequalification results from the World Health Organization.

As the registration process unfolds, a comprehensive evaluation will be undertaken for pharmaceutical products submitted under the aegis of the Head of the BPOM. This assessment will be conducted with due regard to:

- a. The outcomes emanating from the comprehensive evaluation of registration documents and/or recommendations from TPON (comprising Efficacy Safety Assessment Team, Quality Assessment Team, and Product Information and Label Assessment Team).
- b. The insights drawn from on-site inspections conducted locally at the facilities responsible for pharmaceutical production.

The results of these considerations will determine whether the drug product is given approval or rejected. If approved, an approval letter will be issued which can be used by

drug manufacturers to manufacture drugs on a commercial scale; or carry out the entry of Imported Drugs. Approval is notified in writing to the registrant through a Distribution Permit, export special approval or Variation Registration approval. Meanwhile, for products that are rejected, applicants can submit a written request for review to the Head of the Agency for a maximum period of 6 months from the date of the rejection letter and can only be done once. The validity period of distribution permits and special export approvals is valid for a maximum of 5 (five) years as long as they comply with the provisions of laws and regulations.

#### **4.2. Legal Protection for Consumers against distribution of drugs that do not have a distribution permit**

The vital role of drugs in curing disease causes drug distribution in society to be of particular concern. Communities as consumers or drug users have the right to obtain consumer protection rights. Consumer protection laws are formed for the benefit of consumers, both physically and socio-economically. According to Law no. 8 of 1999, Consumer Protection is all efforts that guarantee legal certainty to provide protection to consumers. Regarding the physical aspects of consumers related to the security and safety of their bodies and or souls in the use of consumer goods or services. Meanwhile, in socio-economic terms, every consumer can obtain optimal results by using their economic resources in using goods or services for their needs for life.

In accordance with article 3 of Law no. 8 of 1999 concerning Consumer Protection, there are several objectives of protecting consumers, including:

- 1) “Increasing consumer awareness, ability and independence to protect themselves
- 2) Raising the dignity of consumers by preventing them from negative excesses in the use of goods and/or services
- 3) Improving consumer empowerment in selecting, determining, and demanding their rights as consumers;
- 4) Creating a consumer protection system that contains elements of legal certainty and information disclosure as well as access to information;
- 5) Growing awareness of business actors regarding the importance of consumer protection so that honest and responsible attitudes grow in doing business;
- 6) Improving the quality of goods and/or services that guarantee the continuity of the business of producing goods and/or services, health, comfort, security and consumer safety.”

Where in article 4 of Law no. 8 of 1999 also regulates consumer rights, namely:

- 1) “The right to comfort, security and safety in consuming goods and/or services;
- 2) The right to choose goods and/or services and obtain said goods and/or services in accordance with the exchange rate and the conditions and guarantees promised;
- 3) Right to correct, clear and honest information regarding the conditions and guarantees of goods and/or services;
- 4) The right to have their opinions and complaints heard about the goods and/or services used;
- 5) The right to obtain proper advocacy, protection and efforts to resolve consumer protection disputes;

- 6) The right to receive guidance and consumer education;
- 7) The right to be treated or served properly and honestly and not discriminatory;
- 8) The right to receive compensation, compensation and/or reimbursement, if the goods and/or services received are not in accordance with the agreement or not as they should be;
- 9) The rights regulated in the provisions of other laws and regulations”

The government as a policy implementer in Indonesia has a responsibility to guarantee the consumer's right to protection from the public. Based on Law no. 8 of 1999 Article 29 states that: The government is responsible for fostering the implementation of consumer protection which ensures that the rights of consumers and business actors are obtained and the obligations of consumers and business actors are carried out” (Paragraph 1). In addition, "Guidance by the government on the implementation of consumer protection as referred to in paragraph (1) is carried out by the Minister and/or related technical ministers." (Verse 2)

Meanwhile, several parties supervise the implementation of consumer protection. The following is Article 30 of Law no. 8 of 1999, namely: “Supervision of the implementation of consumer protection and the implementation of the provisions of the laws and regulations are carried out by the government, the public and non-governmental consumer protection institutions” (Paragraph 1), “Supervision by the government as referred to in paragraph (1) is carried out by the Minister and /or related technical minister.” (Paragraph 2), “Monitoring by the public and non-governmental consumer protection institutions is carried out on goods and/or services circulating in the market” (Paragraph 3), “If the results of the supervision as referred to in paragraph (3) turn out to deviate from the applicable laws and regulations and endanger consumers, the Minister and/or technical minister take action in accordance with the applicable laws and regulations” (Paragraph 4) and “the results of supervision carried out by the community and non-governmental consumer protection institutions can be disseminated to the public and can be submitted to the Minister and technical ministers” (Verse 5)

In the Health Law, legal protection is explained as a form of health effort where in article 1 of the Health Law Number 36 of 2009 it is stated that: public health in the form of disease prevention, health promotion, disease treatment, and health restoration by the government and/or the community”

So it can be interpreted in forming a healthy and prosperous society, it is necessary for the government's role in preventing, improving health and health protection. The government, represented by the Food and Drug Supervisory Agency (BPOM), has the duty to provide efforts to protect consumers for the distribution of drugs and food that do not have a distribution permit, which can be carried out in a preventive and repressive manner in efforts to enforce the rule of law (Noviantari 247-257: 2021 ). Preventive legal action is a preventive measure taken before the crime occurs. Meanwhile, repressive legal action is an effort that is carried out after the crime has occurred. In terms of countermeasures against the circulation of illegal drugs and food that do not have a distribution permit, then, efforts to protect the law are needed. Efforts to protect the law that can be carried out include those that have been regulated in the Law, namely:

- 1) Preventif Action

In carrying out preventive efforts in providing consumer protection efforts for the distribution of drugs and food that do not have a distribution permit, supervision is carried out to ensure that all work has been carried out properly or in accordance with what was previously planned. The supervision efforts carried out by BPOM in preventing the circulation of illegal drugs and food are listed in Article 3 of Presidential Regulation No. 80 of 2017 concerning the Drug and Food Control Agency, namely:

- a. BPOM makes arrangements and stipulations of norms, standards, procedures and criteria for drugs and food regarding distribution permits in the field of control before circulation and supervision during circulation.
- b. BPOM carries out drug and food supervision related to distribution permits, before they are circulated and during circulation on a regular basis. Control before Distribution is control of Drugs and Food before distribution as a preventive measure.
- c. BPOM coordinates with central and regional government agencies in supervising drugs and food, especially regarding distribution permits, as well as providing better technical guidance and supervision in the field of drugs and food.
- d. BPOM cooperates with government apparatus to conduct outreach to the public about the impacts and dangers arising from drugs and food that do not have a permit, by disseminating information through advertisements or slogans in the mass media and print media, or providing information or education directly to the public through a government-held meeting.

## 2) Repressive Action

This repressive effort is carried out based on statutory regulations that have been specifically regulated, especially with regard to criminal law. In this case a special regulation is needed to carry out repressive actions. For cases of distribution of illegal drugs, refer to Law Number 36 of 2009 concerning Health which clearly describes the provisions for personnel entitled to procure, store, process, promote and distribute drugs and medicinal substances. Where in this Law provides legal certainty for anyone who deliberately produces or distributes pharmaceutical preparations and/or medical devices that do not have a distribution permit with a maximum imprisonment of 15 (fifteen) years and a maximum fine of Rp. 1,500,000. 000.00 (one billion five hundred million rupiah). In addition, manufacturers or sellers of medicines who do not have the expertise and authority to practice pharmacy are subject to a maximum fine of Rp. 100,000,000.00 (one hundred million rupiah).

In the decision Number: 94/PID.SUS/2021/PN MKD it can be seen that the Legal Protection provided by the Government to Actors selling drugs illegally, namely without having to be accompanied by a doctor's prescription, has been subject to a fine of Rp. 20,000,000.- (twenty million rupiah), provided that if the fine is not paid then it is replaced by imprisonment for 3 (three) months. Then there is evidence in the form of illegal drugs that were obtained without a permit which it is clear will be confiscated to be destroyed by the relevant agencies. This proves that legal protection in the decision Number: 94/PID.SUS/2021/PN MKD is carried out in the form of fines and confiscation of illegal drugs to improve the attitude or

behavior of the convict and on the other hand the punishment is also intended to prevent other people from possibly committing prohibited acts. In addition, the deprivation can be a means of preventing the public from obtaining drugs illegally. Another legal protection given to the public is by providing a means of reporting for people who know or suspect that illegal drug sales are being carried out through the "HaloBPOM" Call Center.

## **5. CONCLUSION**

In light of the in-depth exploration conducted in alignment with the research problem, several crucial takeaways emerge from this study: Firstly, the intricate journey of granting authorization for drug circulation, overseen by BPOM, involves a dual-phase approach - Pre-registration and Registration. Both stages necessitate meticulous adherence to the requisite declarations and documentation. For emerging drug products, a thorough 100-day evaluation period is orchestrated under the vigilant supervision of the BPOM Agency's Head. Approval culminates in the acquisition of the coveted distribution permit and a corresponding endorsement letter. Conversely, a rejection opens a brief six-month window for reconsideration, accessible only once. Secondly, the assurance of legal protection for consumers in the context of drug distribution devoid of proper permits is fortified through rigorous measures. This encompasses the possibility of a prison term extending up to 15 years, coupled with a maximum fine of Rp. 1,500,000,000.00 (one billion five hundred million rupiah) for transgressors. Additionally, manufacturers or vendors devoid of the requisite expertise and authority mandated for pharmaceutical practice face potential fines reaching up to Rp. 100,000,000.00 (one hundred million rupiah), aligning with the parameters defined within Law no. 36 of 2009.

Conclusively, the insights garnered from this research offer tangible recommendations for practical application: Firstly, a compelling proposal necessitates the government to provide a lucid and unambiguous framework regarding the imposition of sanctions, particularly as outlined in Law no. 36 of 2009. Notably, this is pertinent in cases of illicit drug trafficking, often encompassing multiple articles and degrees of gravity. Secondly, an advisable course of action involves enhancing the clarity surrounding the legal safeguards extended to individuals negatively affected by illicit drug activities. This could be effectuated through intensified public awareness campaigns, effectively disseminating information about illegal drugs and avenues available for affected individuals to seek restitution and protection against such illicit activities.

## **REFERENCES**

- Anif, M. (2006). *Medicine Concoction Science*. Gadjah Mada University Press.
- Atmaja, P. M. Y. R., Astra, I. K. B., & Suwiwa, I. G. (2021). Physical Activity and Community Healthy Lifestyle as an Effort to Maintain Health during the Covid-19 Pandemic. *Undiksha Journal of Sports Science*, 9(2), 128–135. <https://doi.org/10.23887/jiku.v9i2.31409>
- Benuf, K., Mahmudah, S., & Priyono, E. A. (2019). Legal Protection of Financial Technology Consumer Data Security in Indonesia. *Reflections on Law: Journal of Legal Studies*, 3(2), 145–160. <https://doi.org/10.24246/jrh.2019.v3.i2.p145-160>

- Republic of Indonesia Ministry of Health. (2007). *Kompendia Free Drugs Directorate of Drug and Food Control*.
- Republic of Indonesia Ministry of Health. (2008). *Indonesian Health Profile*. Indonesian Ministry of Health.
- Firmansyah, B. (2020). *Patients Affected by Heart Disease*. Malang Muhammadiyah University.
- Kasibu, S. D. G. (2017). *The relationship between the level of public knowledge and the use of prescription and non-prescription drugs in the Kota Maksum II sub-district, Medan Area sub-district*. North Sumatra University.
- Lailiyah, A. (2019). *The Level of Public Knowledge About the Use and Storage of Limited Free and Free Medicines at the Sambeng Farma Pharmacy*. Muhammadiyah Gresik University.
- Marzuki, P. M. (2011). *Legal Research*. Kencana Prenada Media Group.
- Marzuki, P. Mahmud. (2014). *Legal Research*. Kencana Prenada Media Group.
- Muchsin. (2003). *Legal Protection and Certainty for Investors in Indonesia*. Graphics Light.
- Ocbrianto, H. (2012). *Community Participation in Posyandu in Toddler Health Service Efforts (Case Study in Posyandu Nusa Indah Ii Rw 11 Meruyung Village, Limo District, Depok)*. University of Indonesia.
- Rahardjo, S. (2006). *Law Studies (6th ed.)*. PT Citra Aditya Bakti.
- Samosir, F. (2021). *Juridical Review of the Responsibilities of Drug Traffickers Without a Permit (Case Study of the Decision of the Supreme Court of the Republic of Indonesia Number 1570 K/Pid.Sus/2020)*. *Journal of Law and Society Al-Hikmah*, 2(4), 750–771.
- Sarwono, J. (2006). *Quantitative and Qualitative Research Methods*. Science House.
- Suardita, I. K. (2017). *Introduction to Legal Materials (PBH)*. Simdos. Unud. Ac. Id, 3.
- Supriadi. (2001). *Indonesian Medicinal Plants: Their Uses and Efficacy*. Indonesian Torch Foundation.
- Supriyadi, S. (2017). *Community of Practitioners: Alternative Knowledge Sharing Solutions between Librarians*. *Lentera Pustaka: Journal of Library Studies, Information and Archives*, 2(2), 83. <https://doi.org/10.14710/lenpust.v2i2.13476>
- Wahyudi, A. R. (2020). *Literature Study: An Overview of Pharmacists' Understanding, Experience, Expectations About Clinical Pharmacy Services at Pharmacies*. Banjarmasin Muhammadiyah University.

### **Copyrights**

Copyright for this article is retained by the author(s), with first publication rights granted to the journal.

This is an open-access article distributed under the terms and conditions of the Creative Commons Attribution license (<http://creativecommons.org/licenses/by/4.0/>).