

LEGAL ANALYSIS OF CONSUMER PROTECTION IN THE USE OF DRUGS WITHOUT A DOCTOR'S PRESCRIPTION IN PHARMACIES IN MAJALENGKA REGENCY

Endang Kuswara^{1*}, Endang Sutrisno², Sanusi³

^{1,2,3}Master of Law Study Program, Swadaya Gunung Jati University, Cirebon, Indonesia
dede.koeswara1706@gmail.com^{1*}, ending.sutrisno@ugj.ac.id², sanusi@ugj.ac.id³



DOI: <http://dx.doi.org/10.33603/hermeneutika.v3i2>

Diterima: January 20, 2025; Direvisi: January 30, 2025; Dipublikasikan: February 28, 2025

Abstract: Pharmacies, as business actors in the drug distribution chain, play an important role in providing adequate education and information to consumers, in accordance with established regulations. However, the reality in the field often shows practices that are far from ideal. One manifestation is the availability of drugs in pharmacies that can be purchased with or without a doctor's prescription. The purpose of the research in this study is to analyze the legal study of the use of drugs without a doctor's prescription by pharmacies based on the Health Law and to examine and provide an ideal concept related to legal protection for patients who get drugs without a doctor's prescription at pharmacies. This study uses a normative legal approach with a descriptive analytical nature. Data were collected through literature studies to obtain secondary data from primary, secondary, and tertiary legal materials. Field research was also conducted to obtain primary data that supports secondary data. Data analysis was conducted using qualitative analysis techniques. The results of the study show that the legal analysis of the provision of drugs without a doctor's prescription highlights the importance of strict regulations to protect public health in accordance with the Health Law. Prescription drugs may only be provided with a doctor's prescription to prevent side effects, drug resistance, and abuse. Pharmacies are responsible for complying with the rules, providing education, and providing clear information to patients. Regulations also protect patients who are harmed by pharmacy negligence, with the right to demand justice and compensation. Strict supervision, public education, and consistent enforcement of the law are needed to ensure safe drug management, in addition pharmacies are expected to improve services for public safety.

Keywords: Collatera Consumer Protection, Drug Use, Without Prescriptio

I. INTRODUCTION

One of the activities carried out by banks is lending, both credit for consumptive purposes to meet customer needs and satisfaction, as well as productive credit such as in financing. Over-the-counter drugs are often the primary choice for people seeking quick solutions to health problems (Purba, 2023). Unfortunately, without sufficient understanding, the use of such drugs has the potential to be dangerous, either due to unexpected side effects, incorrect drug interactions, or the risk of misuse. Pharmacies, as business actors in the drug distribution chain, play an important role in providing adequate education and information to consumers, in accordance with established regulations. However, the reality in the field often shows practices that are far from ideal. Non-compliance with regulations, weak supervision, and low consumer awareness of their rights give rise to various problems. One manifestation is the availability of drugs in pharmacies that can be purchased with or without a doctor's prescription.

This convenience also raises challenges in terms of consumer protection, especially regarding the use of drugs without a doctor's prescription. This practice has the potential for significant health risks, especially if consumers do not have an adequate understanding of the type of drug, dosage, or side effects. This is where the law plays a crucial role in ensuring that consumer rights are protected, while enforcing responsible service standards from pharmacies.

Research related to the problem of using drugs without a prescription has previously been carried out by other researchers, but substantially there are still differences with the research by Siti Rohani, Scientific Journal of the Faculty of Law, University of Mataram 2021, entitled "Legal Review of the Sale of Hard Drugs Without a Doctor's Prescription"

Research conducted by Siti Rohani, discussing the legality of selling hard drugs without a doctor's prescription is legal according to positive law in Indonesia if the drug is a type of over-the-counter drug, limited free drug and a type of mandatory drug from a pharmacy, other than that it is not legal according to positive law in Indonesia.

Looking at the object or scope of research conducted by Siti Rohani, so there are similarities and differences with this study. The similarities are related to the problem of Without a Doctor's Prescription, while the difference is that the sale of hard drugs without a doctor's prescription is legal according to positive law in Indonesia if the drug is a class of over-the-counter drugs, limited free drugs and the class of Compulsory Pharmacy Drugs other than that it is not legal according to positive law in Indonesia while the object (focus) of this study is about consumer protection in the use of drugs without a doctor's prescription in pharmacies. Based on these differences, it can be said that this study is not a re-examination of research that has been conducted by other researchers. The identification of the problems and objectives of this research is very relevant because it not only analyzes consumer protection in the use of drugs without a doctor's prescription, but also attempts to provide an ideal concept in drug management in pharmacies, so that it can run safely, responsibly, and protect the rights and safety of consumers.

II. RESEARCH METHOD

The approach method used in this research is normative juridical. The specification of this research uses descriptive analysis. Data sources come from primary data and secondary data. Data collection methods include interviews, Document Studies or Library Materials. The data analysis method used in analyzing data is a qualitative analysis technique (Soemitro, 2013).

III. RESULT AND DISCUSSION

A. Implementation of the Prudential Principle in Sharia Microfinance Institutions (Micro Waqf Bank) SPECIFICALLY at Kempek Cirebon.

As previously stated in relation to data from various sources, the principle of prudence in the Sharia Micro Financial Institution (Micro Waqf Bank) KHAS Kempek Cirebon has not been fully implemented, this is the author's conclusion because in its work practices, such as filling out forms which only including the potential customer's economic income, not applying collateral.

B. Legal Review of the Use of Drugs Without a Doctor's Prescription by Pharmacies Based on the Health Law

Purchasing drugs without a prescription has significant legal implications for all parties involved. Consumers can suffer health harm, while pharmacies and pharmaceutical personnel can face legal consequences, whether administrative, civil, or criminal. Therefore, compliance with pharmaceutical regulations and consumer protection is very important to ensure safety and fairness in health services.

Legal review related to the use of drugs without a doctor's prescription by pharmacies based on the Republic of Indonesia Law Number 17 of 2023 concerning Health reflects the government's commitment to increasing protection for the community in terms of health. This law emphasizes that pharmaceutical services must be carried out by prioritizing patient safety and complying with applicable ethical standards and regulations.

One of the main points regulated in this law is the obligation of pharmacies to comply with service standards, including in the delivery of drugs that require a doctor's prescription. The related articles strengthen supervision of the distribution of hard drugs that must not be dispensed without a prescription, in order to prevent misuse, drug resistance, and serious health risks. This regulation is in line with the principle of consumer protection which places public safety as the main priority (Yasin, 2014).

However, there are still challenges in implementing this provision, especially in terms of supervision and law enforcement. Many pharmacies, for economic reasons or ignorance, still provide prescription drugs without a doctor's prescription. This not only violates the provisions of Law Number 17 of 2023, but also threatens the safety of consumers who may not understand the risks of using drugs carelessly.

We are fully aware that in most areas of society today, human behavior has been normalized so that law encompasses all areas. The penetration of law into society is so thick, resulting in demands for changes and developments in the law itself and its relationship to other social problems will also become more intensive. To enforce these provisions, the role of the Food and Drug Supervisory Agency (BPOM) is very important. BPOM together with local governments have the responsibility to ensure that pharmacies carry out their operations in accordance with regulations. Law enforcement must be carried out firmly against violations that occur, by providing administrative or criminal sanctions as regulated in the law (Sutrisno, 2009).

In addition, public education is one of the important aspects regulated in Law Number 17 of 2023. This education aims to increase public awareness of the importance of using drugs based on doctor's recommendations. With better understanding, the public can reduce dependence on uncontrolled use of non-prescription drugs.

Overall, Law Number 17 of 2023 concerning Health provides a strong legal basis for regulating the use of drugs without a doctor's prescription in pharmacies. However, its effective implementation requires synergy between the government, pharmaceutical service providers, and the community. With consistent law enforcement and strengthening public

awareness, the risks posed by this practice can be minimized, so that the community can enjoy optimal health protection.

In the context of implementation, Law Number 17 of 2023 also opens up opportunities to strengthen technology-based supervision. The health information system can be used to monitor drug distribution more transparently and accurately. With data integration between pharmacies, BPOM, and other related agencies, the government can more easily detect violations, such as the sale of prescription drugs without a doctor's prescription. This step also allows for faster and more appropriate sanctions to be imposed on parties who violate regulations.

In addition, it is important to highlight the role of pharmacists in ensuring compliance with this law. As health workers who have the authority in pharmaceutical services, pharmacists must commit to carrying out their professional responsibilities. The Indonesian Pharmacist Code of Ethics mandates that pharmacists must prioritize the interests of patients and comply with laws and regulations. Failure to comply with the rules not only impacts patient safety but also tarnishes the reputation of the pharmacist profession as a whole.

From the community's perspective, health literacy must continue to be improved. Adequate understanding of the dangers of using drugs without a doctor's prescription, such as uncontrolled side effects and the possibility of antibiotic resistance, can encourage more responsible behavior. Law Number 17 of 2023 also mandates the importance of promotive and preventive efforts in health services, including through public education campaigns.

In the long term, harmonization between regulation, supervision, and education is the key to the successful implementation of Law Number 17 of 2023 in regulating the use of drugs without a doctor's prescription. With strategic steps involving all stakeholders, it is hoped that the practice of selling hard drugs without a prescription can be minimized. This not only increases consumer protection, but also encourages the creation of a safer, fairer, and quality health system in Indonesia.

Law Number 17 of 2023 concerning Health brings significant changes to the regulation of drug use in Indonesia. This regulation aims to ensure public access to safe, effective, and quality drugs, while protecting the public from the risks of using drugs that do not meet standards.

In this law, the use of drugs is regulated by emphasizing three main principles: strict supervision of prescription drugs, easy access to essential drugs, and empowerment of the community in the wise use of drugs. One important provision is that prescription drugs may only be given based on a doctor's prescription, in accordance with the Article governing the distribution and use of certain drugs. This aims to prevent the misuse of prescription drugs that can cause serious side effects, antibiotic resistance, or other risks that endanger public health.

In addition, this law strengthens the role of the Food and Drug Monitoring Agency (BPOM) as the main institution responsible for overseeing the safety, quality, and distribution of drugs in Indonesia. BPOM is given the authority to monitor, take action, and impose sanctions on parties who violate regulations, including pharmacies that sell prescription drugs without a doctor's prescription.

This law also emphasizes the importance of educating the public. Education is carried out through health promotion that targets awareness of the dangers of indiscriminate drug use. The government works with health workers to provide accurate information on the safe use of drugs, especially in areas with limited access to health services. However, although Law No. 17 of 2023 has provided a strong legal basis, its implementation still faces a number of challenges. One of them is the weak supervision of drug distribution at the pharmacy level

and other health service providers. The limited number of supervisory officers and supervisory infrastructure are obstacles to ensuring compliance with this regulation.

The law also regulates the development of a technology-based health system to facilitate drug monitoring and distribution. For example, the use of a pharmaceutical information system to monitor the circulation of prescription drugs in real time is expected to help minimize the risk of violations.

The provisions related to drug use in Law No. 17 of 2023 provide a comprehensive legal framework to protect the public from the risks of uncontrolled drug use. However, the effectiveness of its implementation is highly dependent on the synergy between the government, health service providers, and the community in implementing the principles that have been set.

Based on the results of an interview with Holid Maja pharmacy officer Lidya Sugiri regarding the use of drugs without a doctor's prescription based on Law Number 17 of 2023 concerning Health, the following results were obtained:

Based on Law Number 17 of 2023 concerning Health, the use of drugs without a doctor's prescription must follow the provisions that have been set. There are drugs that are indeed allowed to be given without a prescription, such as over-the-counter drugs and limited over-the-counter drugs. However, for hard drugs, pharmacies are required to ask for a doctor's prescription.

The use of drugs without a doctor's prescription is an important issue in the world of health that must be managed properly. In practice, the provision of drugs without a doctor's prescription has been clearly regulated by laws and regulations. Certain drugs, such as over-the-counter drugs and limited over-the-counter drugs, are allowed to be given directly to the public without a prescription. However, for hard drugs, strict regulations apply, where pharmacies are required to ask for a doctor's prescription before giving them to patients. This aims to ensure the use of drugs that are safe, in the right dosage, and according to indications, so as to avoid the risk of misuse and adverse side effects.

In a society that is developing, it will always be characterized by change, however we define this development and whatever indicators we use for a society in development, it is to be able to guarantee that the changes that occur and are experienced by the society can be passed through in an orderly manner (Sutrisno, 2007). Compliance with these provisions is not only the responsibility of pharmacies, but also requires awareness from the community. Unfortunately, many still assume that all types of drugs can be purchased and used without consulting a doctor, which sometimes causes problems such as inappropriate or excessive use of drugs.

Pharmacies, as one of the front lines in drug distribution, have a strategic role in educating the public about the importance of following these rules. In addition to ensuring that drugs are given correctly, pharmacies also function as partners in maintaining patient safety through monitoring the use of drugs, especially those classified as hard drugs. With understanding and cooperation between pharmacies, the public, and health workers, it is hoped that drug use can be carried out more wisely and responsibly, in accordance with the principles stipulated in the Health Law. The goal is not only to prevent the negative impacts of drug abuse, but also to support efforts to improve the quality of health as a whole.

C. Protection for Patients Who Get Medicines Without a Doctor's Prescription at the Pharmacy

Government Regulation Number 28 of 2024, concerning The Implementing Regulations of Law Number 17 of 2023 concerning Health generally regulate the principles of safe and effective pharmaceutical services, while details regarding the procedures for

dispensing drugs, including those based on doctor's prescriptions and Minister of Health Regulation No. 72 of 2016 on Standards of Pharmaceutical Services in Hospitals, emphasizes the importance of dispensing drugs based on doctor's prescriptions as part of safe, appropriate and effective pharmaceutical services for patients in hospitals. Based on Article 2 of the Regulation of the Minister of Health of the Republic of Indonesia Number 73 of 2016 concerning Pharmaceutical Service Standards in Pharmacies, it states that the Regulation of Pharmaceutical Service Standards in Pharmacies aims to:

- a. improve the quality of Pharmaceutical Services;
- b. guarantee legal certainty for pharmaceutical personnel; and
- c. protect patients and the public from irrational use of drugs for the sake of patient safety .

This article emphasizes the main objective of pharmaceutical service standards in pharmacies, namely to ensure that pharmaceutical services provided by pharmacists and other pharmaceutical personnel in pharmacies are of high quality. The services in question cover various aspects, including drug management, providing information to patients, and implementing clinical pharmacy services. A pharmacy as a health facility is expected to be at the forefront of providing quality pharmaceutical services, both from a clinical perspective and from a pharmaceutical preparation management perspective.

The principle of pharmacist responsibility if an error occurs is based on the professional code of ethics , laws and regulations , and legal principles applicable in the field of pharmacy. Errors in pharmaceutical services can be in the form of errors in drug management, drug administration, or inappropriate information, which can have an impact on patient health . The responsibility of pharmacists reflects the profession's commitment to maintaining public health and improving the quality of pharmaceutical services. Errors that occur must be a lesson to improve the quality of service and prevent future risks (Fiqri, 2021).

Based on the results of an interview with a pharmacist at a pharmacy in Maja District, Majalengka, regarding the pharmacist's responsibility if there is an element of error in providing medication to patients in accordance with the explanation of the Government Regulation. Number 28 of 2024 concerning the Implementing Regulations of Law Number 17 of 2023 concerning Health, Mrs. Yati who was met on the 7th December 2024, said that if there is an error in giving medicine by a pharmacist, then not only the pharmacist will be responsible but also the owner of the business. But in this case, we are always careful in giving medicine to consumers or patients, not carelessly, and I don't think we have any make such mistakes because we really provide medicine according to the disease suffered by the patient or consumer.

In the context of health law in Indonesia, the recognition and protection of patient rights is a fundamental principle. These rights, which include access to information, privacy, and safe and quality health services, have been regulated in various regulations and laws. The theory of legal protection in the context of health services plays an important role in guaranteeing patient rights, especially related to the use of drugs. In pharmaceutical practice, the provision of drugs without a doctor's prescription is an issue that needs serious attention because it can have implications for patient safety and the legal responsibility of health workers. Legal protection is present as a framework that ensures justice, security, and responsibility in every action involving the provision of drugs in pharmacie (Damayanti, 2023).

This theory is rooted in the principle that every individual has the right to receive safe health services, including the use of drugs according to medical needs. Legal protection provides assurance that patients are not only protected from errors or negligence in administering drugs, but also from potential drug abuse that can endanger their health. In this

context, pharmacies and pharmaceutical personnel have a dual role: as professional service providers and as guardians of compliance with regulations.

Health law, as the basis of legal protection, regulates various aspects related to drug administration, starting from drug classification, distribution mechanisms, to the responsibility of health workers in providing education and information to patients. In situations where prescription drugs are given without a doctor's prescription, the law serves to assess whether the action is carried out according to the permitted procedure or violates applicable regulations. This aims to prevent adverse effects on patients while providing legal certainty to all parties involved.

Legal protection also functions as a monitoring tool for the implementation of operational standards in pharmacies. With the theory of legal protection, it is expected that all parties understand and carry out their respective roles correctly, so that a drug service system is created that is not only effective, but also safe and ethical. This theory is an important foundation in efforts to improve the quality of public health while maintaining the integrity of pharmaceutical practices amidst existing challenges.

The relevance of the theory of legal protection to the case of patients who receive drugs without a doctor's prescription at the pharmacy lies in the role of law as a regulator and protector in the interaction between patients, pharmacies, and health workers. Legal protection functions to ensure that every patient receives health services that meet standards, including in the provision of safe, appropriate drugs that do not violate applicable regulations.

The theory of legal protection refers to human rights, where every individual has the right to receive fair treatment and protection for their health. In the context of providing drugs without a doctor's prescription, this theory emphasizes the importance of strict supervision of pharmaceutical practices to avoid potential drug abuse and adverse effects that can harm patients. Health law provides clear limitations, for example regarding the classification of drugs that may be given without a prescription, as well as the obligation of pharmacists to provide education to patients.

On the other hand, the theory of legal protection also serves to provide a basis for patients to claim their rights if there is a loss due to negligence or violations committed by pharmacies or health workers. With clear rules, patients have the assurance that they not only receive services according to procedure, but can also file a lawsuit if their rights are violated.

In addition, the relevance of this theory includes the professional responsibilities of pharmacists regulated by law. Pharmacies and health workers are required to understand and apply the principles of patient protection in every service provided. This involves providing clear information about drug use, refusing to provide prescription drugs without a prescription except under certain conditions, and recording drug administration completely to ensure accountability.

Overall, the theory of legal protection is a foundation that connects patient rights, pharmacy obligations, and government responsibilities in creating a safe and integrated health care system. This theory not only protects patients from unwanted risks, but also encourages professionalism in pharmacy practice and increases public trust in the health system.

IV.CONCLUSION

This legal review highlights the importance of strict regulation in the provision of drugs without a doctor's prescription by pharmacies in accordance with Law Number 17 of 2023 concerning Health. Prescription drugs may only be provided with a doctor's prescription to prevent side effects, drug resistance, and misuse. Pharmacies play an important role in ensuring compliance with regulations, including in emergencies. Legal protection for patients who are harmed due to pharmacy negligence is also regulated, providing a legal basis for

claiming compensation. Government supervision and public education are needed to prevent drug abuse. Implementation of laws, effective supervision, and comprehensive education are the keys to safe and responsible drug services.

Legal protection for patients receiving drugs without a doctor's prescription aims to ensure safety, quality of service, and compliance with health regulations. Pharmacies are required to comply with the rules by only selling over-the-counter drugs and limited over-the-counter drugs without a prescription, as well as providing competent pharmacists for education and consultation. This regulation prevents drug abuse and health risks due to inappropriate use. If negligence occurs, such as giving hard drugs without a prescription or inadequate information, patients have the right to legal protection. This protection is expected to improve pharmacy service standards, information transparency, and public safety.

REFERENCES

- Damayanti, S., & Maradona. (2023). Legal protection of patient rights in health services in Batu City. *Unes Law Review Journal*, 6(2), Artikel 1627. <https://doi.org/10.31933/unesrev.v6i2>
- Figri, H. (2021). *Pharmacist's responsibility for providing drugs without a doctor's prescription at the Sukajadi District pharmacy, Pekanbaru City based on Government Regulation Number 51 of 2009 concerning pharmaceutical work* (Skripsi, Universitas Islam Riau). <https://repository.uir.ac.id/15355/>
- Government Regulation Number 51 of 2009 concerning Pharmaceutical Work.
- Law of the Republic of Indonesia Number 17 of 2023 concerning Health.
- Presidential Regulation Number 72 of 2012 concerning the National Health System.
- Purba, N. (2023). Qualitative study of the implementation of self-medication services at Bintang Farma Pharmacy. *Suara Forikes Health Research Journal*, 14(2), 302. <https://forikes-ejournal.com/index.php/SF/article/view/sf14212>
- Rahman, Y. (2014). Review of the Constitutional Court decision in the 2004 Presidential Election PHPU dispute (Constitutional democratic state perspective). *Jurnal Konstitusi*, 11(4), 652. <https://doi.org/10.31078/jk1143>
- Regulation of the Minister of Health Number 14 of 2021 concerning Standards for Business Activities and Products in the Implementation of Risk-Based Business Licensing in the Health Sector.
- Regulation of the Minister of Health Number 3 of 2020 concerning Hospital Classification and Licensing.
- Regulation of the Minister of Health Number 72 of 2016 concerning Standards Service Pharmacy in Hospitals.
- Regulation of the Minister of Health Number 73 of 2016 concerning Pharmaceutical Service Standards in Pharmacies.
- Republic of Indonesia Law Number 8 of 1999 concerning Consumer Protection.
- Soemitro, R. H. (2013). *Legal research methodology and jurimetrics*. Jakarta: Ghalia Indonesia.
- Sutrisno, E. (2007). *Legal culture in protecting environmental pollution*. Cirebon: Swagati Press.
- Sutrisno, E. (2009). *Anthology of law and globalization*. Yogyakarta: Genta Press.
- The 1945 Constitution of the Republic of Indonesia.