

Consumer Protection in the Health Sector: The Legal Responsibilities of Pharmacists

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ABSTRACT

This study aims to analyse the legal protection of patients in cases of pharmacist negligence in Indonesia, focusing on civil, criminal and administrative liability. Pharmacists have a strategic role in healthcare, but their negligence can have a serious impact on patient safety. Civil law protection allows patients to sue for damages under Article 1365 of the Civil Code, while criminal protection serves to provide a deterrent effect through the application of sanctions on negligence that causes serious injury or death. On the other hand, administrative law through regulations such as Permenkes No. 74/2016 provides supervision of pharmaceutical practices with sanctions ranging from reprimands to revocation of practice licences. This study found that although the regulatory framework is in place, its implementation still faces obstacles such as lack of supervision, low legal awareness of pharmacists, and barriers to legal access for patients. Using a normative juridical approach, this study recommends increased supervision, legal education, and ease of legal access to improve the effectiveness of patient protection.

INTRODUCTION

The pharmacist profession has a strategic role in health services, especially in ensuring that patients get the right drugs and according to their medical needs. Pharmacists are responsible for ensuring that every medicine given is in accordance with the prescription issued by the doctor, providing information related to dosage and usage rules, and providing warnings about side effects or interactions with other drugs that may arise (Nimesh, 2020). This role is crucial, given that errors in drug administration or inadequate information can have fatal consequences for patients, both in the short and long term (Soetomo, 2019).

In Indonesia, pharmacist negligence in the course of professional duties may be classified as a form of malpractice, which can result in harm to patients. Pharmacist negligence within the context of pharmaceutical practice has become a significant issue in Indonesia's healthcare system, particularly due to its direct implications for patient safety (Partha Sutema & Maharjana, 2021). As healthcare professionals responsible for the distribution and provision of information regarding pharmaceuticals, pharmacists play a central role in ensuring the

quality of pharmaceutical services. In practice, there exists a risk of negligence that can cause both financial and health-related losses to patients. Such instances may include dispensing medication not in accordance with prescriptions, providing inaccurate information regarding dosages, side effects, or drug interactions, and deviations from established standards of service (Soetomo, 2019).

Indonesia has established a legal framework to protect patients from pharmacist negligence. Law No. 17 of 2023 concerning Health explicitly mandates healthcare professionals to deliver quality services consistent with standards (Articles 3 and 12). Law No. 8 of 1999 concerning Consumer Protection entitles patients, as consumers, to receive safe and high-quality services. In addition, Ministry of Health Regulation No. 74 of 2016 concerning Standards of Pharmaceutical Services at Pharmacies stipulates that pharmacists are obligated to adhere strictly to the standards governing drug dispensing to ensure patient safety (Wahyudi et al., 2023).

Pursuant to Law No. 17 of 2023 on Health and Law No. 8 of 1999 on Consumer Protection, every patient possesses the right to legal protection when receiving healthcare services, including against risks

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arising from pharmacist negligence. Such negligence may encompass, *inter alia*, the improper dispensing of medications, provision of incorrect dosages, or omission of essential information regarding side effects and drug interactions. The repercussions of such negligence can be severe, potentially endangering patient lives (Prananda, 2022).

Legal protection for patients necessitates strict regulation and effective enforcement. The primary objective of legal protection is to guarantee patients' rights to health services that are safe, professional, and free from negligence. Existing regulations have, in principle, established a legal foundation for protecting patients against pharmacist negligence; nevertheless, implementation is frequently hindered by a lack of supervision and suboptimal law enforcement. Stricter oversight is required to ensure that pharmacists fulfill their duties in accordance with established standards. Should instances of pharmacist negligence not be met with firm legal action, the quality of healthcare services may deteriorate, and patients' rights to safe and high-quality services may be compromised (Hidayat, 2020).

Although the legal framework appears sufficiently comprehensive, its implementation still encounters numerous obstacles. Previous studies have indicated that oversight at the ground level remains inadequate, resulting in many violations going undetected. Pharmacists often lack sufficient understanding of their legal obligations, including the risks of negligence that may adversely affect patients. Additionally, aggrieved patients frequently face challenges in accessing legal remedies, whether due to limited information regarding their rights or the perception that legal processes are complex and burdensome (Hidayat, 2020).

As a consequence, cases of pharmacist negligence resulting in significant harm often remain unreported or are difficult to substantiate, especially due to the lack of adequate documentation. This situation raises concerns about the effectiveness of existing regulations to provide protection and ensure healthcare professionals' accountability. Such conditions reveal a gap between established legal norms and their practical application, ultimately creating ongoing risks for patient safety.

This study aims to analyze the legal protection afforded to patients in cases of pharmacist negligence, specifically concerning civil, criminal, and administrative liability. It also seeks to examine the mechanisms of legal protection implemented to ensure patient safety and pharmacist accountability in pharmaceutical practice. Furthermore, the study endeavors to evaluate the effectiveness of the

supervision and implementation of such protections, while also identifying challenges that arise in practice. Thus, this research is expected to provide a comprehensive overview of the efforts to legally safeguard patients within the realm of pharmaceutical practice.

RESEARCH METHOD

This research uses a normative juridical approach to examine the role of law in providing protection to patients from pharmacist negligence. The normative juridical approach is used to explore how existing laws and regulations in Indonesia provide protection to patients and ensure legal responsibility for pharmacists. By emphasising the study of legal documents and theories, this approach is particularly relevant to understanding the role of regulation in health law and pharmacist liability in pharmaceutical practice (Soekanto & Mamudji, 2009).

This research also uses a statutory approach and a conceptual approach. The statutory approach is conducted by examining laws relating to pharmaceutical services, such as Law No. 17 of 2023 on Health and Law No. 8 of 1999 on Consumer Protection. Meanwhile, the conceptual approach aims to understand key concepts in health law and patient protection that can provide a theoretical basis for pharmacists' responsibilities (Marzuki, 2017).

This study utilizes secondary data obtained through a literature review. The sources of secondary data include statutes and regulations, legal doctrines, academic books, journal articles, as well as other relevant reference materials. The data collected encompass regulations governing pharmaceutical practice and consumer protection within the health sector. Among the regulations analyzed is Ministry of Health Regulation No. 74 of 2016 concerning Standards of Pharmaceutical Services in Pharmacies, which underscores the importance of pharmacist professionalism in ensuring patient safety.

The data analysis is conducted qualitatively, employing a normative legal research methodology. The collected data are analyzed to explore and interpret the legal protection afforded to patients in instances of pharmacist negligence. This approach enables the researcher to relate the collected data to legal theories described in the literature review. Through this technique, the study aims to provide a clear understanding of the effectiveness of the regulatory framework and the potential challenges associated with its implementation in practice (Marzuki, 2017).

RESULT AND DISCUSSION

The focus of this research is the legal protection of patients in the face of pharmacist negligence in pharmaceutical practice in Indonesia. Pharmacists have the responsibility to ensure that the drugs dispensed are in accordance with the doctor's prescription, inform the patient about the rules of consumption, as well as explain the side effects and interactions that may occur. In Indonesia, legal protection of patients from pharmacist negligence is guaranteed by various laws and regulations, such as Law No. 17 Year 2023 on Health and Law No. 8 Year 1999 on Consumer Protection. In addition, there are pharmaceutical service standards implemented in pharmacies to maintain patient safety in receiving medicines (Soetomo, 2019).

Legal protection for patients related to pharmacist negligence can be seen from three main aspects: protection in terms of civil law, criminal law, and administrative law. Civil law includes the patient's right to compensation, criminal law includes sanctions against pharmacists who are negligent in carrying out their duties, and administrative law includes supervision of pharmaceutical practices in accordance with established standards (Hidayat, 2020).

Civil Law Protection of Patients from Pharmacist Negligence
Civil legal protection enables patients who have suffered harm due to a pharmacist's negligence to file a lawsuit on the grounds of tortious act. Should the negligence of a pharmacist result in substantial financial or health-related losses to a patient, the patient is entitled to compensation for such damages. In this regard, civil legal protection provides the guarantee that any injurious negligent act must be borne by the responsible party. Article 1365 of the Indonesian Civil Code (KUHPerdata) offers the legal basis for patients to claim damages resulting from pharmacist negligence. Pharmacists, as healthcare professionals delivering pharmaceutical services, are obligated to comply with professional standards as stipulated in Ministry of Health Regulation No. 74 of 2016. A pharmacist's act of negligence that causes harm may thus be construed as an unlawful act. Pursuant to Law No. 17 of 2023 concerning Health, protection of patients encompasses access to safe and quality healthcare services (Article 4 paragraph (1) letter c).

These provisions affirm that patients have the right to pharmaceutical services that adhere to established safety standards. Furthermore, the principle of justice enshrined in Article 3 letter h of the Health Law guarantees that patients may obtain compensation should their rights be infringed upon by pharmacist negligence.

Civil legal protection in cases of pharmacist negligence is vital to ensure that all individuals, including pharmacists, are held accountable for acts that may cause harm to others. Pharmacist negligence may be interpreted as the failure to meet the professional standards expected in pharmaceutical practice, which could have fatal consequences for patients. Accordingly, civil law provides grounds for patients to claim compensation for damages suffered as a result of such negligence. This is consistent with the fundamental civil law principle that every person has an obligation not to harm others, and that any breach of this duty entitles the injured party to seek compensation (Wahyudi et al., 2023).

In cases of pharmacist negligence, patients who have suffered losses are entitled to claim damages. This process typically requires the plaintiff to prove that the pharmacist's negligence directly caused actual harm, whether physical or financial (Samuels, 1996). In such instances, patients must demonstrate that the pharmacist failed to meet the expected standard of care, for example by dispensing the wrong medication or failing to provide adequate information regarding drug side effects. Thus, civil law serves as a mechanism for enforcing patient rights and ensuring that pharmacists are held responsible for their conduct. It also creates incentives for pharmacists to improve the quality of their services, thereby reducing the risk of future negligence (Kusumawati et al., 2023).

Legal liability for pharmacist negligence functions both as a compensatory mechanism for patients and as a means to enhance accountability in the practice of pharmacy. The possibility of legal action is expected to encourage pharmacists to perform their duties with greater caution and professionalism. It also promotes the improvement of pharmaceutical practice standards through enhanced training, education, and stricter oversight by regulatory bodies (Birsanu et al., 2022). Consequently, civil legal protection ensures justice for aggrieved patients and contributes to the overall enhancement of healthcare service quality.

Criminal Law Protection in Pharmacist Negligence Cases
Criminal law protection in cases of pharmacist negligence can be applied if the negligence causes serious harm or death to the patient. Article 359 of the Criminal Code stipulates criminal sanctions for anyone whose negligence causes death or serious injury to another person. In the realm of pharmacy, pharmacists' negligence that results in serious harm to patients, such as administering the wrong medicine or inappropriate dosage, may be subject to

criminal sanctions. Based on Article 359 of the Criminal Code, anyone whose negligence causes the death of another person may be subject to criminal punishment. The application of criminal law in cases of pharmacist negligence is important because criminal sanctions aim to provide a deterrent effect to pharmacists to carry out their duties more carefully. However, the application of this criminal law requires strong evidence that shows significant negligence (Arlitadelina et al., 2021).

Law No. 17 of 2023 reinforces this aspect by stipulating that healthcare professionals, including pharmacists, must provide services in accordance with established quality standards and within their respective authorities (Article 3 letter d and Article 12). The enforcement of criminal law is aimed at creating a deterrent effect for offenders while simultaneously protecting the public from the risks associated with substandard healthcare services.

Criminal legal protection against pharmacist negligence, from the perspective of justice theory, is intended to provide redress for patients who have suffered harm as a result of the pharmacist's slack of due care. Justice theory emphasizes that every individual, including patients, is entitled to equal legal protection regardless of social or economic status. Pharmacist negligence may thus be construed as a violation of the patient's right to receive safe and high-quality healthcare services. Accordingly, criminal law plays a significant role in upholding the accountability of pharmacists, ensuring that they act in accordance with established professional standards, and delivering justice to harmed patients (Wahyudi et al., 2023).

Criminal law also functions as a deterrent for pharmacists and other healthcare professionals. The threat of criminal sanctions is intended to encourage pharmacists to exercise greater caution in the conduct of their pharmaceutical practice. Such deterrence not only serves to punish offenders but also to prevent the recurrence of negligence in the future. In this context, the enforcement of criminal law acts as an effective instrument to enhance pharmacists' awareness and responsibility regarding patient safety (Agustina, 2019). Thus, criminal law contributes to the improvement of healthcare service quality and to the protection of patients.

Moreover, the enforcement of criminal law in cases of pharmacist negligence underscores the primacy of patient safety within the healthcare system. Criminal law serves both as a punitive mechanism and as an educational tool for pharmacists concerning their professional responsibilities. By imposing stringent sanctions for acts of negligence, criminal law compels pharmacists

to adhere to established standards of practice and to commit to the provision of safe services. This, in turn, fosters a culture of accountability among pharmacists, ultimately enhancing overall patient safety and well-being (Prananda, 2022).

Administrative Legal Protection and Supervision of Pharmaceutical Practices

In the administrative realm, legal protection of patients can be carried out through supervision of pharmaceutical service standards. Administrative sanctions can be imposed on pharmacists who violate professional practice standards as stipulated in Permenkes No. 74/2016. Permenkes No. 74/2016 on Pharmaceutical Service Standards in Pharmacies stipulates that every pharmacist is obliged to follow strict service standards in administering drugs to patients. In case of violation of these standards, pharmacists may be subject to administrative sanctions, ranging from reprimands to revocation of practice licences. This administrative legal protection aims to ensure that every pharmaceutical practice is carried out in accordance with patient safety standards.

Law No. 17 of 2023 affirms the importance of governmental oversight in ensuring the quality of healthcare services through the implementation of a registration and accreditation system for healthcare facilities (Article 19 paragraph (2) letter f). Administrative sanctions, such as warnings, fines, or revocation of practice licenses, may be imposed on pharmacists who fail to comply with regulations. The primary objective of such measures is to promote adherence to healthcare standards and protect patients from the risks of malpractice. Article 12 of the Health Law also regulates the guidance and supervision of healthcare professionals' competence as a preventive measure against violations.

Administrative legal protection plays a critical role in safeguarding patient safety by ensuring that all actions in the provision of healthcare services, including pharmaceutical practice, comply with established standards (Soetomo, 2019). In cases of pharmacist negligence, administrative law focuses on ensuring that pharmacists fulfill their duties in accordance with the established safety standards. Ministry of Health Regulation No. 74 of 2016 concerning Standards for Pharmaceutical Services provides a normative framework governing pharmaceutical services at pharmacies, covering procedures related to procurement, storage, and dispensing of medicines to patients. These regulations are specifically designed to minimize the risk of medication errors, such as dosage mistakes or dangerous drug interactions, which could endanger patients.

From an administrative law perspective, the supervision of pharmacists' compliance is a key element in ensuring the implementation of these standards. The government, through competent authorities, is responsible for conducting regular oversight of pharmaceutical practices. Administrative sanctions may be applied to pharmacists found in violation of these provisions, including warnings, administrative fines, or revocation of their practice licenses. Such measures are intended to encourage accountability and to ensure that only competent pharmacists who meet professional requirements are permitted to practice. These regulations provide protection both for patients and for pharmacists themselves by offering clear guidelines about professional duties and limitations (Mounika, 2014).

The theory of patient safety within the administrative legal framework also emphasizes the importance of risk prevention. Through supervision and enforcement of administrative law, the government ensures that pharmacists' actions are grounded in the principles of diligence and high professionalism. Moreover, administrative regulations require pharmacists to document all actions taken, so that in the event of negligence, responsibility can be traced and corrective measures applied (Sutrisno & Fajarini, 2016). Thus, administrative legal protection establishes a system aimed both at sanctioning violations and at preventing errors in pharmaceutical service delivery, thereby maximizing patient safety.

Regulatory Effectiveness in Legal Protection and Implementation Challenges

Although existing regulations have provided a basis for legal protection of patients from pharmacist negligence, this study found that there are several obstacles to its implementation. The main obstacles include lack of supervision at the field level, low legal awareness among pharmacists, and limited legal access for patients to file claims (Saputri, 2022). To improve the effectiveness of the regulation, there needs to be stricter supervision from the authorities, as well as increased education for pharmacists on their legal obligations in maintaining patient safety (Prananda, 2022).

Law Number 17 of 2023 concerning Health provides a robust legal foundation for the organization of pharmaceutical services in Indonesia. Nevertheless, the implementation of this law encounters various challenges, particularly regarding supervisory mechanisms at the field level. Article 19 paragraph (3) of the Law explicitly

underscores the importance of supervision, yet in practice, such oversight has not been optimally executed. This suboptimality is due to several impediments, both in terms of human resources and the lack of a well-integrated supervisory system.

A fundamental issue in the enforcement of this regulation is the weakness of supervision over pharmacists at their practice sites, which ultimately affects the quality of healthcare services delivered to the community. The absence of strict oversight permits violations of service standards to occur without the imposition of firm sanctions. Therefore, effective supervision is crucial to guaranteeing the application of professional standards and the provision of legal protection for the public (Sutrisno & Fajarini, 2016). Furthermore, the low level of legal awareness among pharmacists exacerbates the issue (Pratita & Bachtiar, 2022). As identified in various studies in health law, pharmacists' understanding of legal provisions and their professional responsibilities remains limited. This deficiency results in non-compliance with the standards of service as regulated by legislation, thereby posing potential harm to patients (Anita & Kuswanto, 2022).

Enhancing regulatory effectiveness requires the reinforcement of legal norms and the fortification of oversight mechanisms through integration with technological advancements. Article 21 of the Health Law mandates the adoption of information technology within the national health system. The use of such technology can facilitate monitoring and evaluation of pharmacists' performance as well as real-time reporting of violations occurring in practice.

Legal education and ongoing training for pharmacists play a significant role in cultivating awareness and increasing compliance with legal provisions. Training programs must focus on enhancing technical competence and building understanding of the legal consequences associated with violations or malpractice. Thus, pharmacists will be more accountable in the fulfillment of their professional duties and in prioritizing patient safety (Suleman et al., 2016).

The government is obliged to strengthen supervision by leveraging technology, such as digital audits and online reporting systems, to ensure that each pharmacist operates in accordance with established standards. These measures serve as both preventive and detective efforts, permitting the rapid and transparent detection and handling of non-compliance. Effective oversight will narrow the space for deviant actions which may cause public harm (Omboni & Caserini, 2018).

Facilitating legal access for patients who feel aggrieved by pharmaceutical services is a fundamental pillar of an equitable legal protection system. The principle of access to justice must be realized by providing complaint mechanisms that are transparent, straightforward, and free from undue procedural burdens. In health law, the responsibilities of the state and healthcare providers encompass ensuring legal channels for patients to register complaints or disputes without requiring engagement in complex legal proceedings. This is consistent with the principles of consumer protection and the right to safe and high-quality healthcare services, as enshrined in national legislative instruments.

Furthermore, to realize the principle of substantive justice, the provision of supplementary legal instruments such as pro bono legal aid and non-litigation dispute resolution mechanisms (such as mediation) is highly relevant and should be implemented in pharmaceutical service cases. These instruments offer avenues for dispute resolution that are faster, more efficient, and equitable, particularly benefitting patients from vulnerable or economically disadvantaged groups. As stated by Wiguna et al. (2020), such initiatives not only alleviate the burdens on patients but also enhance the accountability of healthcare institutions, including pharmacies, in ensuring the comprehensive legal rights of patients.

While Law No. 17 of 2023 provides a comprehensive legal framework, its implementation still necessitates tangible support in the form of technology-based oversight and continuous legal education. Additionally, the synergy between regulation, oversight, and patients' legal access must be operationalized collectively. Only through such integrative efforts can the protection of patients and the elevation of pharmaceutical service standards be effectively secured as intended by the law.

CONCLUSION

This study aims to examine the role of law in providing protection for patients from the risks of pharmacist negligence in Indonesia, with a focus on civil, criminal, and administrative legal aspects. The findings indicate that Indonesian legislation has established a legal foundation for patient protection in cases of pharmacist negligence; however, several challenges remain in its implementation.

From the perspective of civil legal protection, this research reveals that patients who suffer harm due to pharmacist negligence may file civil claims through tort actions based on Article 1365 of the Indonesian Civil Code (KUHPerdata). This legal basis grants patients the right to claim compensation

as a form of accountability for the losses incurred. Civil legal protection ensures that any negligent action by a pharmacist resulting in loss or damage can be financially indemnified.

In regard to criminal legal protection, the study finds that cases where pharmacist negligence leads to serious injury or death may result in criminal sanctions, pursuant to Article 359 of the Indonesian Penal Code (KUHP). Criminal law serves a deterrent function, ensuring that pharmacists perform their duties with due care and professionalism. Such criminal sanctions also act as a form of protection for patients from risks arising from pharmacist negligence in the provision of healthcare services.

Regarding administrative legal protection, the findings show that existing regulations, such as Minister of Health Regulation No. 74 of 2016 on Standards of Pharmaceutical Services, set out mandatory standards for pharmacists to ensure patient safety. Violations of these standards may result in administrative sanctions, ranging from warnings to revocation of the pharmacist's license to practice. This administrative legal protection establishes control over the quality of pharmaceutical services, ensuring that pharmacists are held accountable for maintaining safe and compliant practice standards.

To enhance legal protection for patients against pharmacist negligence, strategic measures are required. These include the formulation of more detailed regulations to clarify the legal responsibilities of pharmacists and mechanisms for compensating harmed patients. Moreover, oversight of pharmaceutical practice must be tightened to ensure conformity with established service standards, by strengthening the roles of healthcare institutions and professional associations in ensuring pharmacists' competence and legal compliance. Legal education for pharmacists should also be prioritized to improve their understanding of professional obligations and practice standards, thereby fostering greater professionalism and caution in practice.

The accessibility of legal recourse for aggrieved patients should be improved by providing dedicated legal aid institutions in the health sector. Such measures are essential to ensure equal opportunities for patients in seeking justice. In addition, strengthening communication between physicians and pharmacists remains crucial to preventing prescription errors, which are often a significant cause of negligence. By implementing these steps, legal protection for patients will become more effective, thereby ensuring patient safety and accountability in pharmaceutical services.

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