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Legal Analysis of Preventive and Repressive Legal Protection for Pharmacy Personnel in Dealing with Drug Stockouts in Hospitals

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Abstract

Drug stockouts represent a significant systemic challenge in hospital healthcare systems, potentially generating severe legal consequences for pharmaceutical personnel. In practice, pharmacists frequently face a dilemma between their professional obligation to ensure the availability of medicines and the structural limitations of national pharmaceutical supply chains. This study aims to analyze preventive and repressive legal protections for pharmaceutical personnel in dealing with legal risks arising from drug stockouts in hospitals. The research employs a normative juridical method with statutory and case approaches, examining relevant regulations such as Law Number 17 of 2023 concerning Health, Minister of Health Regulation Number 73 of 2016 concerning Pharmaceutical Service Standards in Hospitals, and related court decisions. The results indicate that preventive legal protection for pharmacists remains insufficient due to the absence of clear regulatory mechanisms defining professional responsibility during force majeure conditions, such as supply chain disruptions. Meanwhile, repressive protection largely depends on judicial interpretation regarding negligence and the causal relationship between drug stockouts and patient harm. Therefore, a comprehensive legal protection model is required, encompassing standardized stock management procedures, strengthened pharmaceutical governance in hospitals, and the formal recognition of the force majeure doctrine within health law as a legitimate legal defense for pharmaceutical personnel.

Keywords

Drug Stockouts, Health Law, Legal Protection, Pharmaceutical Personnel.

1. Introduction

Drug availability is essential to healthcare delivery, and hospitals are responsible for ensuring continuous access to safe, effective, and affordable medicines (Ahmed & Tamim, 2025). However, hospital pharmacy systems frequently face drug stockouts, particularly for essential medicines such as antibiotics and chemotherapy agents. These shortages can disrupt patient care and increase the risk of legal disputes. Pharmacists are often perceived as responsible for drug unavailability, although stockouts commonly result from factors beyond their control, including supply chain disruptions, delays in raw material imports, and broader systemic challenges within the national pharmaceutical distribution system (Kanike, 2023).

A 2024 report by the Indonesian Food and Drug Agency (*Badan Pengawas Obat dan Makanan*/BPOM) found that essential medicine stockouts affected approximately 35% of drugs that should be consistently available in hospitals, reflecting significant weaknesses in the national pharmaceutical supply chain (Miller et al., 2021; Adak, 2024). Indonesian regulations place pharmacists at the center of hospital drug management. Minister of Health Regulation Number 73 of 2016 assigns responsibility for the procurement, storage, and distribution of medicines. However, it does not clearly define the limits of legal liability when shortages result from external factors such as supply chain disruptions or systemic failures. This regulatory ambiguity creates uncertainty regarding accountability, particularly when pharmacists are expected to manage outcomes influenced by factors beyond their control.

Recent literature has extensively documented the growing global concern regarding drug shortages and their implications for healthcare system resilience. Studies emphasize that pharmaceutical supply chain vulnerabilities, including reliance on imported raw materials and inefficient procurement systems, are major contributing factors to recurring stockouts (Fox et al., 2014; Caulder et al., 2015). In addition, Tucker and Daskin (2022) as well as Yadav (2015) highlight that these structural weaknesses significantly compromise the stability of medicine availability across healthcare systems.

Within the Indonesian context, health policy studies further underline the urgency of strengthening pharmaceutical governance to ensure equitable access to essential medicines (Kohler, 2014; Ayuningtyas, 2018). However, while governance and supply chain issues have been widely discussed, less attention has been given to the legal protection of healthcare workers operating within these constrained systems. Syarbaniati et al. (2025) argue that pharmaceutical personnel often experience disproportionate legal exposure during stockout events, facing malpractice allegations even when systemic and structural factors are the primary causes.

Consequently, scholars increasingly advocate for the incorporation of the force majeure doctrine into health law frameworks, alongside the development of stronger preventive legal protections for pharmacists without compromising patient safety (Wibowo & Nyorong, 2023). This regulatory ambiguity creates a serious risk of legal uncertainty and potential criminalization of pharmaceutical personnel when patients experience treatment delays or adverse outcomes due to drug shortages (Prasetyo & Barkatullah, 2012). In several documented cases, healthcare workers have faced legal proceedings related to alleged negligence, despite the absence of direct fault. This condition underscores a critical tension between professional responsibility and systemic limitation.

Despite extensive literature on pharmaceutical supply chain disruptions and drug shortages, a key gap remains in integrating these operational issues with legal accountability frameworks. Existing studies primarily address systemic inefficiencies and governance reforms (Yadav, 2015; Tamon et al., 2025). Meanwhile,

they largely overlook the juridical limits of pharmaceutical personnel liability under systemic failure conditions. Moreover, the application of doctrines such as *force majeure* in healthcare pharmaceutical management is still underexplored. Limited empirical and normative analysis also exists on how Indonesian health law can clearly define responsibility to protect pharmacists from unjust legal exposure while ensuring patient safety obligations.

Based on this background, this study aims to analyze the forms of preventive and repressive legal protection available to pharmaceutical personnel when facing legal risks caused by drug stockouts in hospitals. This study addresses three main research questions. First, it examines how existing health regulations establish the legal protection framework for pharmaceutical personnel in cases of hospital drug stockouts. Second, it analyzes the systemic and structural factors that contribute to drug stockouts in hospitals and how these conditions increase the legal vulnerability of pharmaceutical personnel. Third, it investigates the forms of preventive and repressive legal protections available for pharmaceutical personnel in handling legal disputes arising from drug unavailability.

2. Methods

This study employed a normative juridical research method with a descriptive-analytical specification. The normative juridical approach was used to examine and interpret the legal norms governing the protection of pharmaceutical personnel, particularly in relation to the occurrence of drug stockouts in hospitals (Soekanto, 2007). Through this approach, the study focuses on analyzing how existing legal frameworks regulate the responsibilities, limitations, and protections afforded to pharmacists in healthcare service settings. Meanwhile, the descriptive-analytical approach is applied to systematically describe the relevant legal provisions and critically analyze their implementation in practical pharmaceutical service operations within hospitals.

This research adopts two main legal approaches, namely the statutory approach and the case approach. The statutory approach is conducted by examining various applicable laws and regulations related to pharmaceutical services, health governance, and the legal responsibilities of healthcare workers. This includes an in-depth analysis of regulatory instruments that define the scope of pharmaceutical practice and accountability. In addition, the case approach was used to review relevant court decisions concerning the liability of healthcare or pharmaceutical personnel in medical practice, particularly cases that involve allegations of negligence or professional responsibility in the context of drug management (Marzuki, 2021).

The legal materials used in this study consist of primary and secondary sources. Primary legal materials include Law Number 17 of 2023 concerning Health, Minister of Health Regulation Number 73 of 2016 concerning Pharmaceutical Service Standards in Hospitals, the Indonesian Criminal Code, and relevant judicial decisions. Secondary legal materials are obtained from academic books, peer-reviewed journal articles, and previous research discussing health law, pharmaceutical law, and legal protection mechanisms for healthcare professionals (Mertokusumo, 2007). In addition, this study incorporates reports from national and international health organizations that address pharmaceutical distribution systems and drug availability issues.

Data collection was carried out through library research by reviewing legal documents, scientific literature, and other relevant written sources. The collected materials were then analyzed qualitatively through interpretation, comparison, and systematic examination of legal norms in relation to actual pharmaceutical service practices. This analytical process aims to construct a comprehensive understanding

of the existing legal protection framework for pharmaceutical personnel in dealing with drug stockout situations in hospital settings.

3. Results

3.1. Regulatory Analysis and the Legal Protection Framework

The regulation of drug availability and the protection of pharmaceutical personnel are not merely matters of national administrative compliance; they represent a fundamental intersection between human rights, global health policy, and occupational safety. Within the Indonesian legal system, the obligation to provide medicines in healthcare facilities is strictly stipulated in Law Number 17 of 2023 concerning Health. This statute mandates that healthcare providers actively guarantee drug availability as a core component of fulfilling the public's constitutional right to health. This overarching legal obligation is further operationalized by Minister of Health Regulation Number 73 of 2016, which dictates the rigorous standards for drug management in hospitals, encompassing meticulous planning, procurement, storage, and precise distribution to patients (Wirtz et al., 2019).

However, the existing normative framework does not clearly distinguish between drug stockouts caused by professional negligence and those resulting from systemic failures beyond the control of pharmaceutical personnel. As a consequence, pharmacists may remain exposed to administrative, civil, or even criminal liability despite having performed their duties in accordance with professional standards and applicable regulations. In such circumstances, a thorough understanding of professional duties, functions, and the legal basis of professional authority becomes essential to minimize the risk of criminalization of pharmacists in the exercise of pharmaceutical practice (Rifai & Prastopo, 2025). Nevertheless, these individual efforts alone are insufficient to fully address the problem, as there are still no explicit legal provisions defining the limits of pharmaceutical personnel's liability when drug shortages arise from factors beyond their control. Consequently, legal uncertainty persists, and the protective function that health regulations are intended to provide remains suboptimal.

However, a critical analysis reveals a normative tension within this framework. While the law mandates drug availability, it frequently assumes a flawlessly functioning supply chain, placing the immediate legal burden of compliance squarely on frontline hospital management and pharmaceutical personnel. When systemic failures occur, the regulation provides little guidance on how to apportion liability. From an international perspective, global organizations emphasize that essential medicines must be available at all times in adequate amounts, in appropriate dosage forms, with assured quality, and at affordable prices within functioning health systems (Bigdeli et al., 2014; World Health Organization, 2023).

This principle is deeply embedded in the WHO Essential Medicines Policy and the WHO Model List of Essential Medicines, which serve as foundational benchmarks for many countries, including Indonesia, in formulating drug procurement and distribution policies. Furthermore, the protection of healthcare workers from undue legal and psychological stress is explicitly addressed by the International Labour Organization (ILO) under the Occupational Safety and Health Convention. This convention underscores the critical importance of occupational safety and the necessity of protection from work-related pressures, including systemic failures that pose severe, unmerited legal risks to individual workers (Mahendradhata et al., 2021; International Labour Organization, 2022). The dissonance between the WHO's mandate for continuous drug availability and the ILO's mandate for worker protection becomes starkly apparent during a supply crisis.

3.2. Systemic Causes of Drug Stockouts and Vulnerability

Although strict regulations mandate the continuous provision of medicines, empirical field practices consistently reveal that drug stockouts are a frequent and disruptive occurrence across various Indonesian healthcare facilities (Arrasily et al., 2025; Fanda et al., 2025). These shortages are rarely the result of localized negligence; rather, they are typically caused by profound systemic vulnerabilities. Key drivers include complex pharmaceutical supply chain disruptions, an acute national overreliance on imported Active Pharmaceutical Ingredients (APIs) often exceeding 90% in Indonesia, bureaucratic delays in procurement systems, and significant discrepancies between epidemiological drug demand planning and actual distribution realization by national distributors (Fox et al., 2014). In the Indonesian healthcare system, drug requirement planning is generally conducted through the rigid Drug Requirement Plan (*Rencana Kebutuhan Obat/RKO*) mechanism and procured via the government's highly centralized e-catalogue system. However, these mechanisms have proven structurally inflexible and have not been entirely successful in preventing drug stockouts at the hospital level, particularly during sudden surges in demand or global supply shocks (Ayuningtyas, 2018).

This recurring stockout issue generates severe, immediate legal implications for pharmaceutical personnel, particularly when patients fail to receive necessary, life-saving treatments. Under such circumstances, pharmaceutical personnel (especially the responsible pharmacist) are left in a highly vulnerable and legally perilous position. By virtue of their license and the regulations governing hospital pharmacy, they are legally presumed responsible for drug availability (Albert, 20120). Consequently, when a patient suffers harm due to a delayed or missed dose, the immediate legal assumption often points to professional negligence or malpractice by the pharmacist, even though the root causes of the shortages, such as an international factory shutdown or an e-catalogue distribution failure, are entirely beyond their professional control or jurisdiction. Thus, a robust and realistic legal protection framework is urgently required to provide legal certainty and prevent the unjust criminalization of pharmaceutical personnel executing their duties within a flawed systemic environment.

From a legal perspective, these systemic failures challenge the traditional principle of professional accountability because liability may be attached to the occurrence of patient harm rather than to the actual source of the failure. Consequently, pharmaceutical personnel may face allegations of negligence even when medicine shortages originate from factors entirely outside their operational authority or professional control, including supply chain disruptions and procurement failures (Fox et al., 2014). This situation creates a fundamental mismatch between legal responsibility and practical control over medicine availability, highlighting the need for a more proportionate framework of professional accountability.

3.3. Preventive and Repressive Legal Protections

This urgently needed legal protection framework must be structurally analyzed through two primary, interconnected approaches: preventive legal protection and repressive legal protection. Preventive legal protection aims to proactively construct a defensive administrative shield to prevent legal disputes from occurring or escalating. In the context of pharmaceutical services, preventive protection cannot rely solely on good intentions; it must be materialized through the strict, auditable implementation of Standard Operating Procedures (SOPs) in drug management. This includes the execution of regular, independent pharmaceutical audits, aggressive inventory tracking, and, most importantly, the maintenance of meticulous, transparent documentation regarding the hospital's drug procurement efforts (Wibowo & Nyorong, 2023). For instance, if an essential drug is unavailable, the pharmacist must have documented proof of timely ordering, follow-ups with

distributors, and formal notifications to the medical staff regarding the shortage. Through these rigorous administrative mechanisms, pharmaceutical personnel can effectively demonstrate before any legal or disciplinary board that they have exhaustively fulfilled their professional obligations in accordance with prevailing pharmaceutical service standards, thereby transferring liability away from individual professional negligence and highlighting the systemic supply failure.

Nevertheless, preventive legal protection should not be interpreted merely as a compliance obligation. Proper documentation, inventory monitoring, and communication records also function as important legal evidence demonstrating that pharmaceutical personnel have fulfilled their professional duties in accordance with applicable standards. Documentation serves to show that pharmacists' decisions and interventions were conducted professionally, transparently, and in a manner that can be traced and evaluated, thereby reinforcing accountability (Canaday & Yarborough, 1994). Likewise, communication records with distributors, healthcare professionals, and hospital management provide evidence that pharmaceutical personnel have taken reasonable and appropriate measures to address medicine shortages and fulfill their professional responsibilities (Seden et al., 2013). In the event of a legal dispute, such records become crucial in distinguishing unavoidable drug stockouts caused by systemic factors from instances of professional negligence or misconduct.

Conversely, repressive legal protection functions as a vital resolution and defense mechanism once a legal dispute or malpractice claim has formally materialized. This protection can be executed through various formal channels, prioritizing non-litigation routes such as medical dispute mediation or resolution via professional organizational ethics boards (the Indonesian Pharmacists Association), or judicial proceedings if mediation fails (Syarbaniati et al., 2025). In a formal legal context, the current framework is severely lacking because it treats drug stockouts merely as a failure to provide service. To provide genuine repressive protection, pharmaceutical personnel and their legal counsel must be able to utilize specific, robust legal arguments, most notably the formal integration of the *force majeure* (Act of God or uncontrollable event) doctrine into health law malpractice defenses. If a critical drug stockout occurs due to external macroeconomic or geopolitical factors completely beyond the hospital's or pharmacist's professional control, such as a national distribution collapse, an international shortage of raw pharmaceutical materials, or sudden regulatory import halts the *force majeure* doctrine must be legally recognized by the courts as an absolute and valid defense against malpractice, negligence, or breach of contract claims initiated by patients.

The effectiveness of repressive legal protection depends on the ability of legal institutions to recognize the distinction between professional negligence and systemic supply-chain failure. Without such recognition, dispute resolution mechanisms may fail to provide adequate protection and could contribute to the unjust criminalization of pharmaceutical personnel. Therefore, legal protection for pharmaceutical personnel cannot be viewed in isolation as merely protecting the worker. It must be constructed through the seamless, realistic integration of national health regulations, robust and transparent hospital pharmacy management systems, and fair, specialized medical dispute resolution mechanisms that understand supply chain realities (Islam, 2024). This comprehensive approach will not only provide necessary legal certainty for pharmaceutical personnel, preventing an exodus from the profession due to liability fears, but also ensure that healthcare services remain fundamentally and sustainably oriented toward patient safety and overall healthcare quality.

4. Conclusion

Drug stockouts in hospitals represent a systemic challenge that is often beyond the direct control of pharmaceutical personnel, yet pharmacists remain exposed to

legal liability when treatment delays lead to adverse patient outcomes. This condition highlights the need for clearer boundaries of responsibility within hospital drug supply systems. The findings indicate that preventive legal protection can be strengthened through transparent pharmacy management systems, accurate and comprehensive administrative documentation, and effective internal hospital supervision. In addition, repressive protection requires formal recognition of force majeure principles within health law and the strengthening of out-of-court dispute resolution mechanisms to ensure fair handling of liability cases.

The implication of this study is that regulatory reform is urgently needed to clearly delineate the scope of liability of pharmaceutical personnel during drug supply disruptions, thereby balancing professional accountability with systemic constraints in healthcare delivery. Establishing such legal clarity is essential to provide legal certainty for pharmacists while maintaining patient protection standards within hospital services. However, this study is limited to a normative legal approach and does not incorporate empirical data from hospital practice, such as real-world stockout frequency, institutional responses, or litigation cases involving pharmaceutical personnel. Future research is therefore recommended to explore empirical hospital supply chain dynamics, stakeholder perspectives, and comparative legal frameworks in other jurisdictions to develop more operational and evidence-based models of pharmaceutical liability protection.

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Ethical approval was obtained for this study. The manuscript represents original work and has not been previously published, nor is it under consideration by another journal.

Data Disclosure Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.



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