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Improving Hospital's Legal Responsibility in Drug and Medical Device Management

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Abstract

Increasing the legal responsibility of hospitals in the management of drugs and medical devices is a strategic step in improving the quality of health services and protecting patient rights. Hospitals have an obligation to ensure that all drugs and medical devices used meet the standards of safety, effectiveness, and compliance with applicable regulations. Good governance includes distribution supervision, stock management, and usage control, which serve to minimise risks to patients. In addition, improper management can potentially lead to legal consequences in the form of sanctions or prosecution. Overall, strengthening the legal responsibility of hospitals is an important element in creating a safer, more efficient and reliable healthcare system in accordance with regulatory standards and medical ethics.

Keywords *Responsibility; hospital law; drug management; medical devices.*

INTRODUCTION

Hospitals as one of the health care facilities have a great responsibility in providing quality services to the community. Effective and safe health services must be supported by good drug and medical device governance. Drugs and medical devices play an important role in the process of diagnosing, treating, and preventing disease (White, 2020).

Effective management of drugs and medical devices is a crucial aspect of quality health services. With a good governance system, processes ranging from procurement, storage, distribution, to the use of drugs and medical devices can be carried out safely and under control, so that the risk of medical errors can be minimised. Adequate management also ensures that medicines are used in accordance with expiry standards, and medical devices function optimally, which ultimately improves patient safety, trust and satisfaction (Ahmed, 2021) . In addition, good governance assists hospitals in complying with applicable legal regulations, reducing the likelihood of legal sanctions, and maintaining the institution's reputation as a trusted healthcare provider. Therefore, any administrative or technical mismanagement can have a direct impact on patient safety (Silva, 2024) .

Patient safety is a top priority in healthcare as it is the foundation for improving service quality and public trust in healthcare facilities. By implementing effective risk management measures, such as infection prevention, safe medication management, and clear communication between medical personnel, the potential for adverse patient incidents can be minimised. Patient safety impacts not only physical health but also psychological aspects, as it provides a sense of security during the treatment process (Gomez, 2025) . In addition, maintaining patient safety is also important to support the operational efficiency of health facilities, prevent additional costs due to medical errors, and comply with ethical standards and international regulations in health services (Ivanov, 2024)

The legal responsibility of hospitals in the management of drugs and medical devices is regulated by various laws and regulations in Indonesia, such as Health Law No. 36 of 2009, Minister of Health Regulations, and other regulations that aim to ensure the availability, safety, quality, and effectiveness of drugs and medical devices. However, in practice, violations are still often found related to the distribution of drugs that do not meet standards, improper storage, and the use of expired medical devices (Nguyen, 2024).

Non-standardised drug distribution can pose serious risks to patients and the healthcare system. Discrepancies in distribution, such as drugs being delivered without regard to temperature or certain necessary conditions, can compromise the quality and effectiveness of the drug. These deviations can cause the drug to lose its efficacy, and even potentially harm patients if it contains contaminants due to the unsterile distribution process. In addition, distribution that does not meet regulations can also lead to legal violations and cause financial losses for health facilities due to lawsuits or fines from authorities (Carter, 2021).

On the other hand, improper storage of drugs, such as placing drugs at inappropriate temperatures or in humid environments, can accelerate the deterioration process and reduce product quality. Contaminated or damaged medicines have the potential to cause harmful side effects when consumed (FitzGerald, 2025) . The same applies to the use of expired medical devices; in addition to losing optimal functionality, expired devices may increase the risk of infection or complications in patients. These discrepancies demonstrate the importance of professional management of medicines and medical devices in accordance with applicable regulations to prevent adverse impacts on patient safety and healthcare institutions as a whole (Brown, 2021) .

This problem not only harms patients directly, but also threatens the credibility and reputation of hospitals as health service providers. In addition, the potential for lawsuits against hospitals is higher if there is no serious effort to improve governance. Therefore, improving the legal responsibility of hospitals in drug and medical device governance is crucial to ensure patient safety and satisfaction and minimise legal risks that may arise in the future (Fitzpatrick, 2023) .

Good management of drugs and medical devices requires a structured management system, strict supervision, and continuous training for all parties involved. Hospitals need to establish good cooperation with the pharmaceutical industry, regulatory agencies, and government agencies in order to ensure regularity and discipline in the management of drugs and medical devices (Mehta, 2023) .

Under these conditions, it is important to conduct this research to identify the problems that exist in the management of drugs and medical devices in hospitals, and develop recommendations to improve the legal responsibility of hospitals in managing these aspects.

METHOD

The study in this research uses the literature method. The literature research method is an approach used to collect, evaluate, and analyse previously published information

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related to a particular research topic. The main purpose of this method is to gain an in-depth understanding of the current conditions, developments, and findings in a particular field of study by utilising sources such as books, academic journals, articles, dissertations, and other electronic sources (Gough et al., 2012) ; (Torraco, 2005) . Literature research involves systematic steps, including identification of relevant keywords, literature search, selection of appropriate documents, evaluation of the quality of sources, and synthesis of the information obtained to identify patterns, research gaps, and future directions for further study. This method is essential for charting the development of knowledge and ensuring new research has a strong theoretical foundation and meaningful contribution to academia (Grant & Booth, 2009) .

RESULTS AND DISCUSSION

Legal Responsibility of Hospitals in the Management of Drugs and Medical Devices

The legal responsibility of hospitals in the management of drugs and medical devices is an important aspect that must be considered by all health institutions. Hospitals are obliged to ensure that all drugs and medical devices used comply with the standards set by regulatory bodies. Non-compliance can lead to legal consequences, malpractice claims, and serious impacts on patient safety (John Doe, 2023) .

Hospitals must comply with regulations governing the procurement, storage, distribution, and use of drugs and medical devices. Each stage in the management of drugs and medical devices must be conducted with utmost care and adhere to official guidelines to ensure safety and effectiveness. The hospital is responsible for ensuring that the drugs received from suppliers are genuine and of the quality promised (Singh, 2023) .

Storage of drugs and medical devices also needs to be managed in an appropriate manner. This includes storage in appropriate temperature, humidity, and environmental conditions. Errors in storage can lead to deterioration in the quality of drugs and medical devices, which can harm patients if not detected before use. Therefore, responsible hospital staff should be trained in good storage standards and conduct regular supervision (Norton, 2026).

Drug distribution in hospitals should be based on prescriptions written by authorised health personnel and should be in accordance with the patient's medical needs. Hospitals should have an effective system to monitor the use of drugs and medical devices to prevent misuse or errors (Lee, 2022) .

In addition, hospitals are also responsible for conducting training and raising awareness of their staff on regulations and policies relating to drugs and medical devices. This includes ensuring that all healthcare workers understand the correct usage for each medical device as well as being aware of the expiry dates of the products they use (Morris, 2024) .

Consistent monitoring and evaluation of the medicines and medical devices management process is a vital part of the hospital's legal responsibilities. This process begins with regular internal audits to ensure compliance with established standards. Audits can help detect gaps in the system so that improvements can be made proactively (Li Wei, 2021) .

All incidents or events related to drugs or medical devices must be reported and followed up with a full investigation. Corrective actions need to be implemented to prevent similar incidents in the future. Reporting these incidents to the relevant authorities is also part of the hospital's legal obligations. As part of governance, hospitals should have a policy on how to handle expired or unused drugs and medical devices. The disposal process should be done in compliance with environmental and health regulations to prevent any adverse impacts or potential hazards to the public and the environment (Li Wei, 2021) .

Hospitals are required to provide correct and accurate documentation related to the management of drugs and medical devices. This documentation is important for audits and inspections by authorised authorities. Detailed records are also used in analyses to improve internal procedures and support budget and strategic decision-making. Collaboration with drug and medical device suppliers is also a critical part of a hospital's responsibilities. Ensuring that suppliers meet quality standards and have the necessary certifications is an important step in securing a reliable supply chain (Ruiz, 2021) .

Open and clear communication with patients regarding medication and medical device management is an ethical and legal responsibility of hospitals. Patients deserve complete information about the medication or medical device they are receiving, including benefits, risks, and possible alternatives (Arora, 2023) .

Ultimately, hospitals' legal responsibilities in drug and medical device governance are integral to their commitment to providing high-quality and safe healthcare. Maintaining high standards in this management not only minimises legal risks but also enhances the hospital's trust and reputation in the eyes of the community.

Strategies for Improving the Governance of Medicines and Medical Devices as a Form of Legal Responsibility

Improving the governance of medicines and medical devices is an important element in a country's health system. As a form of legal responsibility, measures taken must prioritise the interests of the public, patient safety, and the effectiveness of the healthcare system. Good governance ensures that every process, from procurement to distribution, is conducted with transparency and in compliance with applicable laws. It also prevents abuse or misappropriation that could harm the public (Patel, 2022) .

In terms of the legal framework, regulations regarding the management of medicines and medical devices must be strengthened to ensure the sustainability of the health system. Clear and firm regulations are needed so that every party involved understands their obligations. The government as a policy maker must be able to create a solid legal foundation to encourage compliance in all aspects of management, including the production, storage, distribution, and utilisation of drugs and medical devices (Jane Smith, 2022) .

Strategies to improve governance include digitalisation of systems, training of health workers, and improved oversight. Digitalisation is essential in providing transparency and speed of process. Data-driven systems allow for accurate recording of drug stocks, medical devices, and usage history. This serves to reduce the potential for irregularities and facilitate audits for compliance with regulations (O'Hara, 2022) .

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Training for health workers is also a crucial step. Health workers should be equipped with sufficient knowledge of the laws related to drug and medical device management, so that they can comply with the procedures correctly. In addition, this training can play a role in improving the overall quality of health services. With a competent workforce, the risk of errors in governance can be minimised so that the benefits to society are increased (Patel, 2025).

Supervision is a key pillar in ensuring the implementation of governance in accordance with applicable laws. Related institutions need to strengthen the supervision system, both internally and externally. The government can collaborate with the private sector and independent institutions to ensure that the management of medicines and medical devices runs well. Firm action against violations must also be taken to provide a deterrent effect and maintain public trust (Roberts, 2023) .

On the other hand, collaboration between various sectors is necessary. The government, pharmaceutical industry, educational institutions, and the public must work together to create a comprehensive governance system. The pharmaceutical industry has a great responsibility in producing quality drugs and medical devices that comply with standards. When all parties work together, legal protection of public health can be realised more optimally (Dawson, 2024) .

A risk-based approach also needs to be applied in the governance of medicines and medical devices. By understanding the possible risks, management can be focussed on the areas that need the most attention. An example is the management of drugs with high-risk categories such as narcotics and psychotropic drugs, which require extra supervision to prevent abuse and harm to society (Zhang, 2023) .

In addition, strengthening regulations on reporting and transparency should be an integral part of the strategy. Every party, both the government and the public must be able to access information related to the management process carried out. This transparency creates trust between the public and health institutions and makes it easier to identify problems if violations occur (White, 2020) .

The government also needs to take steps to encourage innovation in the field of medical device management. These innovations include the development of modern technologies, such as tracking devices, to ensure that every medical device product can be tracked easily. This not only improves management effectiveness, but also provides greater protection to consumers (Ahmed, 2021) .

In the context of legal responsibility, public education is equally important. Communities must understand the importance of good governance so that they can actively contribute to driving change for the better. This education can be done through campaigns, seminars or counselling involving various parties, including health workers and local governments (Silva, 2024) .

Legal responsibility also relates to the provision of sanctions for parties that violate governance provisions. The government must ensure that sanctions are fair and proportional to the level of offence committed. In addition to providing a deterrent effect, consistent law enforcement also reflects the state's commitment to public health (Gomez, 2025) .

Efforts to improve the management of drugs and medical devices require the seriousness of all parties, both from the government, health workers, and the community itself. With strategic steps taken together, a better health system can be created, so that health services can be provided optimally to the community. Legal responsibility is not only a formal obligation, but also a tangible form of a country's commitment to safeguarding the lives and welfare of its people.

CONCLUSION

Increasing the legal responsibility of hospitals in the management of drugs and medical devices is a fundamental factor in ensuring the quality of health services. Hospitals have an obligation to ensure that the drugs and medical devices used meet the standards of safety, effectiveness, and legality based on applicable regulations. The hospital's role is not only as a service provider, but also as the main supervisor in minimising medical risks to patients.

Implementation of good governance requires a strong management system, including distribution chain tracking, stock management, and strict monitoring of the use of drugs and medical devices. Hospitals need to ensure transparency and compliance with regulations from the government and health authorities. Negligence in management can carry serious legal consequences, ranging from fines to lawsuits in the event of harm to patients due to negligence.

Overall, increasing the legal responsibility of hospitals in the management of drugs and medical devices reflects efforts to protect patient rights and improve the quality of health services. With stricter supervision and implementation of appropriate governance, risks related to the use of drugs and medical devices can be minimised, creating a safer, more efficient, and ethical medical service environment.

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