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Research Article

Criminal Responsibility of the Pharmacist in the Pharmaceutical Services in Indonesia

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ABSTRACT: Medical malpractice has a long history in Indonesia, with fatal consequences for patients due to negligence from the health practitioner. This study aims to ensure legal certainty in pharmaceutical practice according to laws and regulations. Also, to provide criminal law sanctions for pharmacists in pharmaceutical practices that lead to criminal acts. The method used was qualitative empirical normative research with a literature study. This research was conducted qualitatively based on data triangulation which resulted from three ways: interview, participant to observation, and review of organizational records (document records). Data collection usually uses qualitative research observation, documentation, and interview methods. This study discusses legal provisions related to health and pharmaceutical services and interviews with ten people at Dr. Wahidin Sudirohusodo Regional General Hospital, Makassar, and five people from Wamena Regional General Hospital, Jayawijaya Regency, Papua. Our study exhibited that implementing a pharmacist's practice was based on the prevailing laws and regulations. The pharmaceutical practice in question starts from planning, procurement, storage, distribution, evaluation, and provision of drug information and monitoring of drug side effects. These practices are based on Government Regulation No. 51 of 2009 article 4. This regulation is stated to protect patients and the public in obtaining and stipulating pharmaceutical preparations and pharmaceutical services. In addition, to maintain and improve the quality of implementation of pharmaceutical work by using developments in science and technology as well as laws and regulations; and provide legal certainty for patients, communities, and pharmaceutical workers. In the criminal responsibility of pharmacists in pharmaceutical services that have resulted in illegal acts, there have not been cases that have reached court proceedings. Nevertheless, there are cases where actions that have resulted in criminal acts have occurred in the field. Still, mediation can resolve them to reach a consensus with unique mediation.

KEYWORDS: Criminal responsibility; Safety service; Pharmacist; Law enforcement; Health

1. INTRODUCTION

Health is an essential part of human life and must be the main priority of sustainable national development to achieve national welfare. Health initiatives are any activity to maintain and improve health, and the place used to organize it is called a health facility (Kumar & Preetha, 2012). Medical supplies, including pharmaceutical preparations, such as drugs, medicinal ingredients, traditional medicines, and cosmetics are required to carry out health initiatives. In hospitals, pharmaceutical work includes planning, manufacturing, quality control of pharmaceutical preparations, security, procurement, storage, and distribution of drugs, drug management, prescription drug services, drug information services, drug development, medicinal ingredients, and traditional medicines (Palomar-Fernández & Álvarez-Díaz, 2020). These pharmaceutical works need special attention to prevent the occurrence of malpractice which is undoubtedly detrimental to patients. The use of drugs needs to be closely monitored and supervised by professionals as well as the use of radiopharmaceutical products that are widely developed today (Fawwaz et al., 2021; Fawwaz et al., 2020).

The essence of medical service is the provision of aid or provision of assistance. It is based on the two most fundamental ethical principles: doing good and not harming. These two principles are implied in the legal provisions of article 1354 of the Civil Code. Medical service is a legal relationship between a medical service provider and a medical service recipient (patient), both of whom are traditional subjects that have rights and obligations to one another. These legal rights and obligations create legal responsibility for both parties. As mentioned in the article 7 of law no. 36 regarding health in 2009, patients have the right to receive balanced and responsible health information and education (Mahendradhata et al., 2017).

In criminal law, a health worker may be subject to the threat of article 351 of the Criminal Code. The criminal threat is imposed on a person (including health workers) who can cause another person (patient) disability or death due to negligence or carelessness. To find out whether an element of failure or neglect in a person's actions, it is necessary to prove it according to criminal law procedures. The threat of punishment for such acts is a maximum imprisonment of five years.

There are increasing malpractice cases in health services in advancing science and information technology, including medication errors. Previous study from the New York Department of Health showed the death rate due to

medication errors impacted up to 1000 people per year (Kohn, Corrigan, & Donaldson, 2000). Inappropriate drug administration, wrong dosage, similarity in writing or sounding of drug names, incorrect usage methods, and miscalculation of dosages are examples of frequent medication errors (Tariq, Vashisht, Sinha, & al., 2021). There are critical points that both physicians and pharmacists must understand in writing prescriptions. It must be written clearly and thoroughly to avoid misperceptions between either party when interpreting a prescription. Communication failure and misinterpretation between physicians and pharmacists are factors that cause medical errors that can be fatal for patients (Velo & Minuz, 2009).

Based on medication error identification of polyester patients' receptions in hospital pharmacist Bayangkara III Manado, the potential dispensing phase raises the Medication Error, i.e., outside drug administration instructions 8.13%, the drug delivered less than 1.81%, and etiquette writing 0.30% incorrect or incomplete (Tiansi, Gayatri, & Weny, 2019). Hence, in this study, we aim to ensure the legal certainty in pharmaceutical practice following laws and regulations and ensure criminal law sanctions for pharmacists in pharmaceutical practices that lead to criminal acts.

2. EXPERIMENTAL SECTION

2.1. Research sites

This research was conducted at the Public Service Agency of Dr. Wahidin Sudirohusodo General Hospital, Makassar, Indonesia, considering being an educational hospital where pharmaceutical services are quite complex. The mobility of health services supports this hospital to the community, which is increasingly intensive, comprehensive, and quite complicated. The second site was the Wamena Regional General Hospital, Jayawijaya, Indonesia, which has complex services in the eastern region of Indonesia.

2.2. Research approach

The approach used in this research is the empirical normative approach, which is conducted by studying various legal provisions related to health and pharmaceutical services. It assumes that hospital health services consisting of medical and non-medical personnel work by following the standard guidelines, namely the obligation to be careful, respect patients' rights, and work by the expertise with existing competency standards. Different perspectives still exist towards malpractice in the community, especially for pharmacists in hospitals and law enforcement in Indonesia.

This type of empirical normative legal research departs from vague norms that do not specifically explain criminal liability for pharmacists who commit malpractice based on Law Number 29 of 2004. The types of approaches in this research are the statute approach, the analytical approach to the legal concept, and the case approach. Sources of legal materials used are primary legal materials, secondary legal materials, and tertiary legal materials, providing guidance and explanation for primary and secondary legal materials. The source of legal materials from normative legal research results from research through library research (Soekanto & Mamudji, 2003; Waluyo, 2002).

2.3. Population and sample

In this study, the population and samples were ten pharmacists who performed pharmaceutical services at the Dr. Wahidin Sudirohusodo General Hospital, Makassar, and five pharmacists at the Wamena Regional General Hospital, Jayawijaya.

2.4. Types and sources of data

Table 1. The following types and sources of data were used in this study

No.	Type of data	Description
1.	Primary data	Primary data was directly obtained from conducting research, and the results were obtained through interviews with related parties in this study problem.
2.	Secondary data	Secondary data was data obtained from books, writings, papers, documents, and various health and pharmacy legislation.
3.	Field data	Field data was obtained by conducting interviews with the department interviewing the hospital committee and the hospital therapy secretary.

2.5 Data collection

Two data collection techniques were used; the literature review and interview. A literature review was conducted to find a theoretical and legal basis for the study's objective by studying laws and regulations related to health and pharmacy. Furthermore, the authors conducted direct interviews with ten pharmacists at the Dr. Wahidin Sudirohusodo Regional General Hospital and five pharmacists at the Wamena Jayawijaya Regional General Hospital. They observed firsthand the pharmacy practice taking place in the hospitals.

2.6. Data analysis

The data analysis technique used is through case studies obtained through in-depth interviews and review of related documents. A literature review is carried out to understand and examine its contents in-depth and then make notes according to the studied problems, either directly or indirectly (Soemitro, 2000). The primary and secondary data obtained in this study will be analyzed qualitatively. The following steps: Before analyzing the data, secondary data were obtained through library documentation and primary data. Please write down the method used in this research, so that this research

can be repeated by others with relatively the same results. Do not forget to write the update reference that explain the methods.

3. RESULTS AND DISCUSSION

3.1 Pharmaceutical services at the Dr. Wahidin Sudirohusodo general hospital

The services provided by the hospital can be divided into two, namely primary and supporting services. The primary services consist of medical, nursing, and pharmaceutical services, including outpatient and inpatient services. The primary services cannot carry out their functions without supporting services, including the medical support unit and other service support units.

Patient services at the Dr. Wahidin Sudirohusodo General Hospital cover general patient care for health insurances, cooperative patients, and patients with disabilities (Poor). Clinical pharmacy services include drug information services, drug counseling, and monitoring of side effects of particular drugs for cancer drugs.

All of the pharmaceutical supplies at the Dr. Wahidin Sudirohusodo General Hospital are placed in the warehouse after passing various checks to maintain security from disturbances, such as lost items and contaminated storage conditions, such as temperature and humidity. Also, to ensure easier to monitor pharmaceutical supplies. The medical devices in circulation include dental and heart materials, consumable medical devices, and medical gases, such as O_2 (liquid and solid).

3.1.1 Planning

The plan for pharmaceutical supplies at the Dr. Wahidin Sudirohusodo General Hospital is every three months, complete with types, quantities, specifications, and prices. The planning uses the consumption method based on last month's usage data, the disease cycle, priorities, remaining supplies, development plans, and hospital formularies.

3.1.2 Procurement

The drug procurement system at the Dr. Wahidin Sudirohusodo General Hospital Pharmacy Installation consists of regular procurement, namely procurement that is carried out every month. Besides, there is also an annual procurement (DIPA budget) and a dropping system.

The regular procurement system is usually carried out every month. Still, the planning is carried out every three months based on consumption data (based on the previous quarter's usage data) and considering the presence of diseases that often endanger at certain times. The monthly procurement consists of medicines and regular medical devices. Meanwhile, the tender is carried out once a year for procurement on a project basis. Usually, funds are adjusted according to the government's allocated or budgeted funds, as for what is included in the tendered items, such as consumable medical devices (AMHP) and consumable medical materials (BMHP). Apart from that, the dropping system is a donation and assistance system. The medicines included in the assistance have tuberculosis drugs (package I, II, and III), human immunodeficiency virus (HIV) drugs.

3.1.3 Storage

In general, the storage system for drugs and medical equipment in the pharmacy warehouse of the Dr. Wahidin Sudirohusodo General Hospital uses an alphabetical storage system because it has the advantage, among others, to make it easier to find a drug item when it is needed. The storage is separated from other pharmaceutical supplies, especially hazardous and toxic materials (B3), medical gases, and cancer drugs. For class B3, storing is by putting a logo with the sign of the hazardous material on the storage area. For medical gases, they are stored in a place away from sources of ignition and in a well-ventilated area. Likewise, the storage of the cytostatic drug group is separated and placed in a particular room with a security sheet in the storage area.

The distribution of drugs and medical equipment in each depot and pharmacy is carried out once a month according to each depot and pharmacy's request using the online system or the hazardous materials (B2) form. Depots and pharmacies may request drugs and medical supplies when supplies are empty every week. This problem can happen due to patients who seek treatment more than usual. In the end, the stock is insufficient for a month.

3.1.4 Reception

Receipt of the pharmaceutical goods is carried out with the following procedure (**Figure 1**):

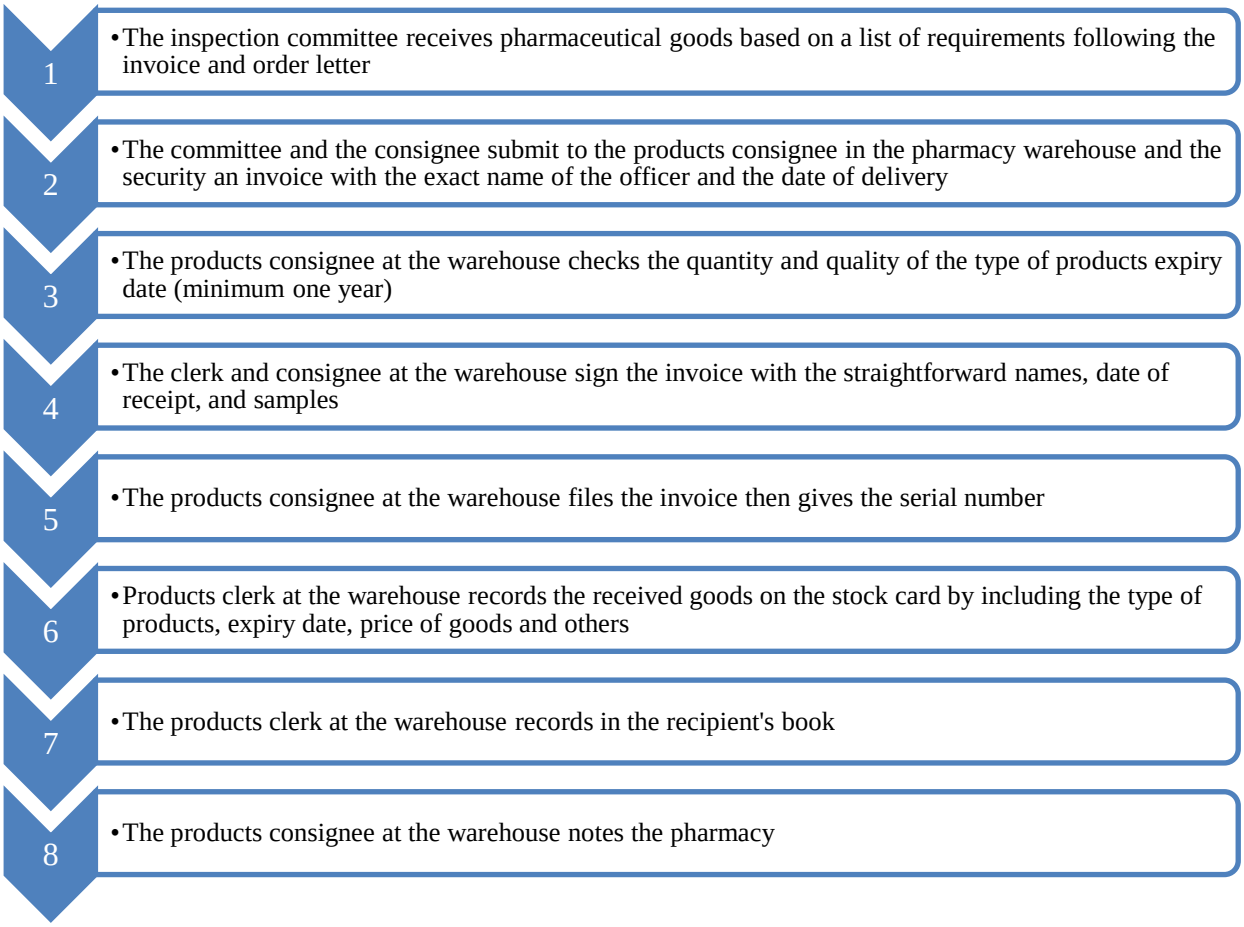

Figure 1. The procedure of reception the pharmaceutical products

3.1.5 Distribution

Products that have entered the pharmacy warehouse are then distributed to all pharmacies and depots that have been decentralized. The distribution is done by the warehouse department using a computerized administration system that allows the availability of drugs and medical devices that are ready to use in every pharmacy and depot. This automated system can also control the amount of stock in each pharmacy, depot, and warehouse. Every request and release of pharmaceutical materials in drugs and medical devices are computerized online and recorded in detail.

3.2 Pharmaceutical services at the Wamena Regional general hospital

The drug management process at the Wamena Regional General Hospital includes planning, procurement, storage, distribution, and evaluation, which are integral parts that cannot be separated from each other.

3.2.1 Planning

In the results of the study, it is known that the plan for drug needs at the Wamena Regional General Hospital was only prepared based on the budget provided by the Regional Government through the Regional Budget, so that it is constrained, especially in the procurement of medicines used by medical specialists.

This planning happened because the Jayawijaya Regency Regional Government provided a portion of the Regional Revenue and Expenditure Budget (APBD). Since it was expanded from 2007 to 2010, Jayawijaya Regency did not have a definitive regent due to the absence of a Pharmacy and Therapy Committee Team which could provide input to the Regent as the taker Policy. Drug planning was carried out by a district integrated drug planning team formed by a Decree from the Regent or an official who represented him. Drug planning can be calculated using the consumption and morbidity methods (Directorate General of the National Agency of Drug and Food Control, 2001).

3.2.2 Procurement of drugs

The results showed that drug procurement management at the Wamena General Hospital has not yet referred to lead time considerations. The procurement is dependent on transportation availability using such a large number of aircrafts or carriers that sometimes float. Also, the implementation of drug procurement does not refer to the Presidential Decree No. 80 of 2003 concerning the procurement of goods and services in Article 10 stating that the procurement value is more than Rp. 50,000,000 - (Fifty Million Rupiahs) and an auction committee must be formed.

3.2.3 Storage

The research results at the Wamena General Hospital show that the spatial arrangement for drug storage has not been maximally followed by the instructions of the National Agency of Drug and Food Control (NA-DFC) due to

limited space. Some medicine items are still stored on the floor along with used cardboard boxes and expired medicines that have not been cleared away immediately. In storing drugs, it is necessary to pay attention to the acceptance of drugs from suppliers (Drug Wholesalers), record drug stocks, and monitor drug quality.

3.2.4 Drug distribution

Drug collection from each depot and pharmacy unit is carried out every Monday and Thursday using the order book according to the drug vacancies needed in each depot and pharmacy signed by the pharmacist. If there is a drug emptiness at the pharmacy unit, it will be purchased using cash, and if there is no cash, then a loan will be made to the supplier (Drug Wholesaler), which will be covered in the following year.

3.2.5 Prescription services

Prescription services for outpatients and health insurances are carried out at the hospital pharmacy by submitting the complete medicine accompanied by drug information. Regional Health Insurances of patients are served at the Belicia Pharmacy appointed by the Regional Government, paid by a claim system quarterly. Society Health Insurance participants use Society Health Insurance cards, while Regional Health Insurance participants are not served or do not get the Society Health Insurance.

For inpatients, the prescription service is carried out at each depot with a unit dose system so that there is no waste in administering the drug. If the patient can go home, the bill's amount will be calculated based on its usage and the claim used in its collection.

3.2.6 Evaluation

Drug evaluation is carried out on the assessment of drug management, which will be carried out by recording and reporting each drug mutation at the hospital pharmacy institution, which can be carried out simultaneously.

3.3 Pharmacist crime and criminal responsibility

Medical malpractice has a long history in Indonesia, with fatal consequences for patients who have overdosed on medications due to negligence or lack of education from pharmacists. We conducted field research at General Hospital on Medicine Information pharmacists involved in drug administration and delivery at the hospital. It led to a finding where a patient asked a Medicine Information pharmacist for an analgesic drug and diazepam without a prescription. The pharmacist handed over the medicine according to the patient's request. A few hours later, the patient began to experience Steven Johnson's Syndrome adverse effects (redness, swelling), requiring immediate medical attention to prevent possible fatal consequences. In this event, the patient's family protested that the pharmacist who had given the drug should be fined. The patient was quickly treated at the hospital. However, healing was expected to take an extended period due to the effects of skin peeling.

According to legal science, in the above cases, medical malpractice can be defined as an act of negligence by a health care provider, which deviates from accepted standards, public and medical practice that causes injury to the patient. Medical malpractice lawsuits may be filed against a hospital or individual medical practitioners such as doctors, surgeons, dentists, pharmacists, or healthcare staff implicated in causing injury or death. These suits usually cover misdiagnosis, prescribing errors, and negligence during surgery, childbirth, and other treatment inadequacies in the care given to patients.

In this instance, the pharmacist committed a crime which can be charged under Law no. 7 of 1963 and Regulation of the Minister of Health No. 1332/Menkes/SK/X/2002 concerning the Procedure for Granting Licensing for Pharmacists that deliver drugs without a doctor's prescription and commit negligence in carrying out their profession (Depkes, 2002).

Based on the research of pharmaceutical practices at the Dr. Wahidin Sudirohusodo General Hospital and an interview with a pharmacist, there was an error in the delivery of medication to the patient in the prescription service pediatric department provided with a similar-named drug for an adult patient. The error occurred mixed up a drug package for 480 mg cotrimoxazole with a drug package for 500 mg ciprofloxacin. The pediatric patient's family realized the mistake and prevented the drug from being administered while highlighting it to the patient's nurse, who immediately had the drug packages exchanged and replaced with the pharmacy department.

To determine whether drug service by a pharmacist or pharmacy staff can be categorized as an error or negligence depends on if carelessness and inaccuracies occur in the service process. Thus, even though pharmacists carry out compounding, preparing, labeling, and dispensing medications based on a doctor's prescription, they must be accountable for any associated negligence. It follows the teaching of criminal responsibility, which states that the incidence of criminal responsibility is due to a criminal act, and a criminal act is an act that is prohibited by criminal law. Regarding determining an act called a criminal act, our criminal code adheres to the principle that a statutory rule must determine every criminal act called the legalities principle.

In the following interview by the internist care room, there was a reading and delivery of the wrong drug to the patient's family who took a prescription order to be redeemed at the internist pharmacy. In the prescription written by the doctor, it is not very clear and challenging to read. The drug has many similarities in writing so that the pharmacy staff misreads and is not consulted with the doctor who writes the recipe. Hence, the pharmacy staff themselves interprets the drug. After the patient's family brings the drug, the drug is immediately drunk, and after one hour, there is a rejection or allergic reaction. After being reported to the doctor on duty, it was found that the wrong drug was consumed, so the patient was immediately quarantined to follow the progress of the allergic reaction and directly given the antidote and stopped administering the wrong medication. Another incident involved a prescription written by a doctor that was

difficult to read, resulting in the pharmacist's misinterpretation. The patients do not consult or reclarify the prescription drug and dose-frequency instructions with the doctor. It resulted in a medication error where the wrong medication was dispensed to the patient. When the patient consumed the incorrect medication, they developed an immediate allergic reaction. It was reported to a doctor on duty at a medical center who stopped taking medicine and treated the patient for their adverse reaction.

These cases show that criminal liability can occur in pharmacy services conducted negligently, resulting in adverse to fatal consequences for patients. According to the article 359 of the Criminal Code, "whoever because of his mistake causes person dies, it is imprisoned for a maximum of five years or a maximum imprisonment of one year". It is a generally accepted provision that provides a legal basis for criminal charges against a legal subject who commits an act that causes a person to die. The same is true for actions that cause severe injury or illness. Whether it is a criminal act or not will be determined by the extent to which the pharmacist or pharmacy staff acts carelessly and is not thorough in causing negligence or error.

One of the issues in law enforcement is the lack of legal action taken on criminal acts or related activities committed by a doctor or pharmacist that can harm their patients. Although criminal cases occur, it is tough to prove malpractice because of the lack of facilities, infrastructure, and human resources. In addition, no strategy the police have pursued in qualifying an offense can be categorized as an event or act that violates statutory provisions. Hence, we suggest that for law enforcement to reveal pharmacist criminal acts properly, the patient (community) should understand pharmacists' function and role in pharmaceutical practice in hospitals. Both administer drugs, quality assurance, drug side effects, and drug information, and the police as investigators must provide experts to reveal pharmacist malpractice cases. To avoid criminal liability problems against pharmacists in the pharmacy practice, pharmacists' actions should be based on pharmacist service standards and competency tests regulated in the applicable laws.

4. CONCLUSION

Implementation of pharmacist practice in the hospital follows the pharmaceutical service standards stipulated by the applicable laws, which include: planning, procurement, manufacturing, quality control of pharmaceutical preparations, security, storage and distribution of drugs, drug management, drug services on doctor's prescription, drug information service as well as drug development, medicinal ingredients, and traditional medicines. There is no material or formal violation of pharmacists' actions due to pharmacists' deliberate or negligent actions. The pharmacist's activities carried out with medical action (informed consent) can still be resolved using unique mediation to no conviction. Based on the above conclusions, we suggest that for law enforcement to reveal pharmacist criminal acts properly, the patient (community) should understand pharmacists' function and role in pharmaceutical practice in hospitals. Both administer drugs, quality assurance, drug side effects, and drug information, and the police as investigators must provide experts to reveal pharmacist malpractice cases. Furthermore, we suggest that all pharmacists' actions should be based on the service standards and competency regulated in the applicable laws to avoid criminal liability problems against pharmacists in the hospital.

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