# Legal Responsibility of Pharmaker for Medication Error in Hospital

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Abstract. The incidence of medication errors in Indonesia has not been recorded accurately and systematically. Medication errors are very bad for patients. Cases of medication errors can be resolved through criminal or civil law. The purpose of this study is to describe what can cause medication errors in pharmacist services in hospitals and the legal responsibility of pharmacists for medication errors that occur in hospitals. The results showed that medication errors can occur in every process of medication, both in the process of prescribing, reading the prescription (transcribing), preparing to dispensing the drug, as well as in the process of using the drug (administration). Factors that cause medication errors can be in the form of poor communication, both in writing (in prescriptions) and orally (between patients, doctors and pharmacists), unsupportive drug distribution systems (computerized systems, drug storage systems, etc.), human resources human (lack of knowledge, excessive work), lack of education to patients, and the role of patients and their families is lacking. Based on Article 46 of the Law of the Republic of Indonesia Number 44 of 2009 concerning Hospitals, hospitals are responsible for all losses that befell patients as a result of medication errors in pharmacists at the hospital. This is because above the pharmacist there is still a bigger container, namely the hospital as the person responsible for medical errors that occur in the hospital.

Keywords: Pharmacist, Medication error, Accountability

# 1 Introduction

Hospitals have a very strategic role in efforts to accelerate the improvement of public health status. The hospital as a health service provider institution that provides full health services by providing inpatient, outpatient and emergency services. Health services at the hospital have 5 revenue centers, including emergency services, outpatient and inpatient services, laboratory installations, radiology installations and pharmaceutical installations.[1]

Hospitals as health service institutions aim to improve quality and provide services based on health service standards. Therefore, hospitals are required to provide safe and quality services according to specified standards. In an effort to provide a safer service process, hospitals are required to implement patient safety.

Health services are a process between patients and health workers who interact with each other to achieve the goal of healing and a better degree of patient health[2]. During the health service process, one of which is treatment, there are errors that may occur caused by health workers, better known as medication errors.

In the Decree of the Minister of Health of the Republic of Indonesia Number 72 of 2016 concerning Pharmaceutical Service Standards in Hospitals, it is stated that medication errors are events that are detrimental to patients due to drug use while in the care of health workers, which can actually be prevented [3]. So far, there have been many medication errors due to misreading prescriptions. Writing a prescription that is too bad, causing the pharmacist to misread. There were many cases like this but the doctor did not realize it because he thought the pharmacist could read.

The incidence of medication errors in Indonesia has not been recorded accurately and systematically, but the incidence of medication errors is very often found in various health care institutions in Indonesia, especially in hospitals. Minister of Health of the Republic of Indonesia Number 129 of 2008 which requires that there is no occurrence of drug administration errors is 100% (zero defect). Even though there are not many cases of medication errors reported in hospitals, previous research has shown that many medication errors are often unidentified and unreported, causing the iceberg phenomenon.

An example of a medication error case is the case of Mrs. Susilowati. Mrs. Susilowati, who had just given birth, was in a coma for 2 (two) days[4]. After conducting an examination it turned out that the patient was taking the wrong drug. Patients should take drugs containing methylergotamyne, one of its functions is to control bleeding after childbirth or delivery and accelerate the return of the uterus (uterus) to normal, while the drugs given by the pharmacy are drugs that contain glibenclamide, which functions to lower blood sugar levels (for diabetics). Coma patients are caused because the patient's body is unable to cope by releasing hormones that raise blood sugar levels, because the patient is not diabetic.

Medication errors are very bad for patients because patients can experience losses or can experience something fatal such as loss of the patient's life if the case is severe. In the realm of law, medication error cases can be resolved through criminal or civil law depending on the severity of the case. The formulation of the problem in this study is:

- 1. What can cause medication errors in pharmacist services in hospitals?
- 2. What is the legal responsibility of pharmacists for medication errors what happened in the hospital?

#### 2 Method

This type of research is library research. Library research is research conducted by way of literature study in the form of secondary data as the basic material for research by conducting a search of regulations and other literature related to the problem under study [5]. This research includes library research because this research is faced directly with the data or text presented, not with field data or through eyewitnesses in the form of events, researchers only deal directly with sources that are already in the library or ready-to-use data, as well as secondary data. used.

The approach used in this study is a normative approach. The normative approach is a literature-based approach, which focuses on the analysis of primary legal materials and sec[1]ondary legal materials. This study uses a normative approach because this study aims to provide a detailed explanation that is systematic, corrects and clarifies a rule of law governing a particular field of law.

The data source used in this research is secondary data. Secondary data are data sources that do not directly provide data to data collectors, for example through other people or through documents. This study uses secondary data as the main reference because it consists of primary legal materials, secondary legal materials, and tertiary legal materials.[6]

This research data collection technique was carried out through conventional and online literature searches. Conventional literature searches are carried out by looking for library materials at the library, purchasing books, journals and attending scientific activities (seminars). Online searches are done with a search engine for something via the internet. This research uses conventional and online library search techniques because it is useful for obtaining a theoretical basis by studying and studying books, laws and regulations, documents, reports, archives and other research results both printed and electronic related to the object of study.

The data analysis method used in this research is qualitative. Qualitative data analysis is an effort that intends to understand phenomena about what is experienced by research subjects such as behavior, perceptions, motivations, actions and others holistically and by means of descriptions

in the form of words and language, in a special context that is natural with using natural methods [7]. This study uses qualitative data analysis because the data will be presented in a narrative-descriptive manner, not in the form of numbers or numbers.[8]

#### 3 Discussion

#### 3.1 Causes of Medication Errors in Pharmacist Services at Hospitals

Patient safety is a global and national issue for hospitals, an important component of health care quality, the basic principles of patient care and a critical component of quality management. The incidence of medication errors is one measure of achieving patient safety. Medication errors to date remain one of the health problems that have many impacts on patients, ranging from mild risks to even the most severe risks, namely causing death.[9]

Medication errors can happen anywhere. Within each link there are several actions, each action has the potential to be a source of error[10]. Every health worker in this chain contributes to errors. Medication error is something that is not correct, done through ignorance or unintentional, errors, for example in calculations, judgments, speaking, writing, actions and others or failure to complete the planned action as intended or incorrect use of the action plan to achieve the goal.[11]

Medication errors are all conditions or events that can cause the distribution of medication not as expected which can harm the patient. Medication error is an error that occurs in the provision of treatment services to patients which causes failure in treatment so that it can have the potential to endanger patient safety in treatment. Medication error is one of the causes of significant errors in the Emergency Room [12]. Medication errors, among others, can occur in the following situations:

- a. Incomplete patient information, for example there is no information about a history of allergies and previous drug use.
- b. Not given proper drug information, for example how to take or use the drug, frequency and duration of administration to warning if side effects occur.
- c. Communication errors in prescribing, for example pharmacists who misread doctor's prescriptions, misread drug names that are relatively similar to other drugs, misread decimals, read unit doses, and unclear prescription abbreviations.
- d. Labeling of drug packaging is unclear so that the risk of being read wrongly by patients.
- e. Environmental factors, such as dim lighting in the pharmacy or drug room, to an uncomfortable workplace atmosphere that can lead to medication errors.

Medication errors can occur in every treatment process, both in the process of prescribing, reading prescriptions (transcribing), preparing to drug delivery (dispensing), and in the process of using drugs (administration). Errors in prescribing and dispensing are two things that often occur in medication errors. The prescription service flow at the hospital starts from the patient consultation with the doctor[13]. At this stage the doctor will determine the history, diagnosis, therapy, and writing prescriptions. At the prescribing stage, prescribing errors can occur by doctors. Then the prescription is given to the patient and handed over to the pharmacist at the pharmaceutical installation. The pharmacist or pharmacist assistant will screen the prescription or examine the prescription with the aim of preventing or overcoming problems that may occur in prescription writing, then proceed to the dispensing stage, which is preparing, dispensing and administering the drug and explaining how to use the drug to the patient, during this process Dispensing errors may occur.

# a. Prescribing

Medication errors in the prescribing phase are errors that occur during the prescribing phase. This phase includes :

a. Recipe error.

- b. Error due to unauthorized.
- Error due to incorrect dosage.
- d. Errors due to indications are not treated.
- e. Errors due to the use of drugs that are not needed.

#### b. Transcribing (Recipe Translation)

During the transcribing phase, errors occurred when reading the recipe for the dispensing process, including misreading the recipe because the writing was not clear. Mistakes in translating prescription and signature orders can also occur in this phase. Types of medication errors that include transcription errors, namely:

- a. Error due to erroneous monitoring.
- b. Error due to adverse drug reaction.
- c. Errors due to drug interactions.

### c. Dispensing (Medicine Preparation)

Errors in the dispensing phase occurred during preparation to prescription submission by pharmacists. One possibility for an error to occur is taking the wrong drug from the storage shelf because the packaging or drug name is similar or it can also occur due to nearby. In addition, it was wrong in calculating the number of tablets to be concocted, or wrong in providing information. Types of drug errors that include dispensing errors are:

- i. Error due to dosage form.
- ii. Errors due to the manufacture or preparation of the wrong drug.
- iii. Error due to faulty drug delivery.

#### d. Administration

Errors in the administration phase are errors that occur in the drug use process. This phase can involve pharmacists and patients or their families. Types of drug errors that include administration errors are:

- i. Error due to negligence in giving medication.
- ii. Error due to erroneous delivery time.
- iii. Error due to incorrect delivery technique.
- iv. Mistakes for not complying.
- v. Error due to incorrect delivery route.
- vi. Error for failing to receive medication.

Factors that cause medication errors can include:

- a. Poor communication, both in writing (in prescriptions) and verbally (between patients, doctors and pharmacists).
- b. Drug distribution system that is not supportive (computerized system, drug storage system, and so on).
- c. Human resources (lack of knowledge, excessive work).
- d. Education to patients is lacking.
- e. The role of the patient and his family is lacking.

The causes of drug errors are communication, labeling, confusing patient names, human factors, and packaging design. Errors related to human factors, among others, related to lack of knowledge, lack of performance, fatigue, infusion speed errors, and errors in preparing drugs. The classification of the sources of error occurs in the health care system in 3 (three) main domains, namely human, organizational and technical.

#### 3.2 Pharmacist's Legal Responsibility for Medication Errors That Occur in Hospitals

The hospital as a business entity organization in the health sector has an important role in realizing optimal public health status. Therefore, hospitals are required to be able to manage their

activities by prioritizing the responsibilities of professionals in the health sector, especially medical personnel and pharmaceutical staff in carrying out their duties and authorities. This responsibility can be either criminal or civil which has a relationship [14]. This relationship is positive in the sense that an act of this type can be subject to civil penalties or criminal penalties.

The medical services provided by health workers at the hospital are not always able to produce the results expected by all parties. There are times when this service occurs due to the negligence of health personnel which causes havoc such as disability, paralysis or even death. When this happens, the patient or his family often demands compensation. This request for compensation is due to the consequences that arise, both physical and non-physical. The opportunity to claim compensation now has basic provisions. The Law of the Republic of Indonesia Number 44 of 2009 concerning Hospitals is the legal basis for someone to hold the hospital responsible in the event of a health worker's negligence which causes harm[15].

Practical experience was not easy to sue the hospital. However, this provision on hospital responsibility serves as a starting point for the legal basis for the community to obtain compensation resulting from the negligent actions of health workers at the hospital. Law of the Republic of Indonesia Number 44 of 2009 concerning Hospitals was made with the aim of facilitating public access to health services, being able to provide protection for patient safety, society, the hospital environment and resources in hospitals and being able to improve quality, maintain service standards hospitals as well as providing legal certainty to patients, the public, hospital human resources and the hospital.

The Law of the Republic of Indonesia Number 36 of 2009 concerning Health regulates matters relating to the negligence of health workers in Article 29 and Article 58. Article 29 stipulates that in the event that a health worker is suspected of committing negligence in carrying out his profession, the negligence must be resolved first through mediation. Article 58 Paragraph (1) regulates the right of every person to demand compensation against a person, health worker and/or health provider who causes losses due to errors or negligence in the health services they receive. Based on these provisions, it appears that the claim for compensation, either as a result of an error (intentional) or due to negligence in health services, and the prosecution is aimed at a person, health worker or health provider (hospital).

The Law of the Republic of Indonesia Number 44 of 2009 concerning Hospitals which was issued almost at the same time and complements the Law of the Republic of Indonesia Number 36 of 2009 concerning Health, the Law of the Republic of Indonesia Number 35 of 2009 concerning Narcotics and Government Regulation Number 51 of 2009 concerning Pharmacy Work defines the hospital as a form of integrated health services involving many professions including pharmacists.

Based on the Law of the Republic of Indonesia Number 44 of 2009 concerning Hospitals, the hospital is responsible for all losses suffered by patients as a result of medication errors in the hospital, as specified in Article 46 of the Law of the Republic of Indonesia Number 44 of 2009 concerning Housing Sick. The provisions of Article 46 of the Law of the Republic of Indonesia Number 44 of 2009 concerning Hospitals are the juridical basis for patients to hold the hospital responsible if a pharmacist medication error occurs which causes a loss.

Based on the formulation of Article 46, several things can be interpreted. First, the hospital is responsible for losses, limited to the consequences of medication errors in the hospital pharmacists. Second, the hospital is not responsible for all patient losses, if it is proven that there was no medication error action by the pharmacist at the hospital. Third, the hospital is not responsible for the deliberate actions of pharmacists that cause harm to someone not the responsibility of the hospital and fourth, the hospital is responsible for the actions of pharmacist medication errors, if the negligence is committed and occurs in the hospital.

There are several criteria for determining hospital responsibility for patients due to medication errors pharmacist :

- 1. Mild medication errors (mild medical errors), such as a patient experiencing an allergy due to an incorrect drug administration by a pharmacist, compensation in the form of the hospital will be fully responsible for the patient's recovery and the pharmacist will receive a warning in the form of a first warning letter (SP 1).
- 2. Moderate medication error (medium medical error), for example if the pharmacist makes a mistake in administering the drug to a patient and results in the patient having to be hospitalized, then the patient gets compensation in the form of free hospitalization and free medication until the patient is declared healthy by the hospital illness and a warning to the pharmacist in the form of a second warning letter (SP II).
- 3. Severe medication error (fatal medical error), for example if a patient dies as a result of a pharmacist's negligence, the patient's heirs receive compensation and the pharmacist is dismissed.

Claims for compensation can be submitted by the patient to the hospital based on Article 58 Paragraph (1) of the Law of the Republic of Indonesia Number 36 of 2009 concerning Health which states that everyone has the right to claim compensation from a person, health worker or health provider who causes losses due to errors or negligence in the health services they receive. The pharmacist is only responsible for the errors of the pharmacist assistant, while the responsibility is to the patient, the hospital bears all the losses suffered by the patient, namely in the form of therapy for the patient's recovery until complete recovery. This is because above the pharmacist there is still a bigger container, namely the hospital as the person responsible for medical errors that occur in the hospital.

## 4 Conclusion

Based on the discussion, the authors provide conclusions, namely:

First, Medication errors can occur in every medication process, both in the process of prescribing, reading the prescription (transcribing), preparation to drug delivery (dispensing), as well as in the process of drug use (administration). Factors that cause medication errors can be in the form of poor communication, both in writing (in prescriptions) and orally (between patients, doctors and pharmacists), unsupportive drug distribution systems (computerized systems, drug storage systems, etc.), human resources human (lack of knowledge, excessive work), lack of education to patients, and the role of patients and their families is lacking.

Second, Based on Article 46 of the Law of the Republic of Indonesia Number 44 of 2009 concerning Hospitals, hospitals are responsible for all losses that befell patients as a result of medication errors in pharmacists at the hospital. This is because above the pharmacist there is still a bigger container, namely the hospital as the person responsible for medical errors that occur in the hospital.

#### **References:**

- [1] Rini Sasanti Handayani MJH. Kajian Praktik Kefarmasian Apoteker pada Tatanan Rumah Sakit". Kesmas, Jurnal Kesehatan Masyarakat Nasional 2013;7.
- [2] Wahyudi S. Tanggung Jawab Rumah Sakit Terhadap Kerugian Akibat Kelalaian Tenaga Kesehatan Dan Implikasinya". Jurnal Dinamika Hukum 2011;11:178 12 6.
- [3] Siti Anisah WMF. Tanggungjawab Hukum Dokter Dan Apoteker Dalam Pelayanan Resep". Media Farmasi 2016;13.

- [4] Zahra Wafiyatunisa RZO. Kejadian Medication Error pada Fase Prescribing di Poliklinik Pasien Rawat Jalan RSD Mayjend HM Ryacudu Kotabumi". Jurnal Kesehatan Unila 2017;1. https://doi.org/https://juke.kedokteran.unila.ac.id/index.php/JK/article/download/1717/16.
- [5] Waluyadi. Cara Praktis Menulis Skripsi Dan Tesis Ilmu Hukum. Yogyakarta: Deepublish; 2022.
- [6] Muhamad Azhar KB. Metodologi Penelitian Hukum sebagai Instrumen Mengurai Permasalahan Hukum Kontemporer". Jurnal Gema Keadilan 2020;7.
- [7] Sugiyono. Metode Penelitian Kuantitatif Kualitatif, dan R.&D. Bandung: Alfabeta; 2018.
- [8] Moleong LJ. Metode Penelitian Kualitatif, Cetakan ke-36. Bandung: PT. Remaja Rosdakarya Offset; 2017.
- [9] Arlitadelina IGAD. Analisis Pelanggaran Apoteker Di Rumah Sakit Pada Kasus Administrasi Error Berujung Pidana". Jurnal Hukum Kesehatan Indonesia 2021;01.
- [10] Yakub. Pengantar Sistem Informasi. Yogjakarta: Graha Ilmu; 2019.
- [11] Ikhwanul Muslimin M. Pengaruh Kualitas Pelayanan Terhadap Kepuasan Pasien Pada Rumah Sakit Umum Daerah Kota Cilegon". Jurnal Ilmiah Manajemen Kesatuan 2020;8.
- [12] Gayatri Citraningtyas PW. Gambaran Kejadian Medication Error Di Instalasi Gawat Darurat RSU Elim Rantepao". Pharmacon 2019;8:29 20 201–2.
- [13] Donsu YC. Faktor Penyebab Medication Error Pada Pelayanan Kefarmasian Rawat Inap Bangsal Anak RSUP PROF. In: Manado" DRRDK, Pharmacon, editors. Jurnal Ilmiah Farmasi, vol. 5, 2016, p. 12939–12526.
- [14] Prodjodikoro W. Tindak-Tindak Pidana Tertentu Di Indonesia. Bandung: PT Refika Aditama; 2012.
- [15] Octarina D, Efendi A. Penelitian Hukum. Jakarta: Sinar Grafika; 2018.