# CRIMINAL SANCTIONS AGAINST PHARMACISTS WHO SELL ANTIBIOTIC DRUGS WITHOUT A DOCTOR'S PRESCRIPTION: IN PERSPECTIVE OF HEALTH LAW IN INDONESIA

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#### ABSTRACT

The problem of antibiotic resistance is very complex in Indonesia and will continue to increase every year a pharmacist does them. The purpose of this study was to analyze the criminal law aspects of pharmacists who sell antibiotics without a doctor's prescription from a perspective legal in Indonesia. This type of research is normative legal research; the data obtained will be analyzed descriptively qualitatively. The results showed several examples of errors in pharmaceutical services that needed assessment whether it could be said to be malpractice or not, several errors in prescription assessment: Pharmacists received prescription drugs but did not perform screening/ assessment; The pharmacist accepts the doctor's prescription, but the writing is dubious/unclear, but the pharmacist does not fulfil his obligation to confirm with the doctor who wrote the prescription; and Misinterpreting or reading prescriptions, so that the drugs given are not following the doctor's prescription. For criminal liability, a pharmacist must first be identified as the perpetrator of a crime. Accountability is asked for or not; it is a second issue, depending on the parties' policy concerned to decide whether it is necessary to demand accountability. This problem concerns a criminal act (pharmacist) subject, which legislators have generally formulated.

Keywords: Pharmacists, Antibiotic Drugs, Criminal Sanctions, Health Law.

### **INTRODUCTION**

Health is one of the elements of welfare that must be realized (Yuanita et al., 2018), following the Indonesian people's ideals referred to Pancasila and the Preamble to the 1945 Constitution of the Republic Indonesia (Iversen et al., 2019). Replaceable and very supportive in the framework of efforts to provide good health services for humans. The sale of drugs is beneficial for people in curing their illnesses (Sambala et al., 2010). Antibiotics are derived from all or certain parts of microorganisms and are used to treat bacterial infections (Leekha et al., 2011). Antibiotics are not effective against viruses. In addition to killing microorganisms or stopping the reproduction of bacteria, antibiotics can lead to resistance. Resistance is the ability of bacteria to neutralize and weaken the working power of antibiotics. Apart from impacting morbidity and mortality, resistance also has a very high negative economic and social impact (Aslam et al., 2018).

Initially, resistance occurred at the hospital level, but gradually it also developed in the community, especially Streptococcus pneumoniae (SP), Staphylococcus aureus, and Escherichia coli (Davies & Davies, 2010). Treatment with antibiotics without a doctor's prescription, not only in developing countries but also in developed countries. The rest in European countries such as Romania and Lithuania also found a high prevalence of self-medication with antibiotics (Volpato et al., 2005). A study conducted in Brazil showed that 74% of the 107 pharmacies visited, including 88% of pharmacies registered by the Municipal Health Secretary, sell antibiotics without a doctor's prescription (Torres et al., 2019).

Research in Riyadh, Saudi Arabia, also shows the high use of antibiotics without a doctor's prescription, namely 77.6%. The highest use of antibiotics was to treat sore throat and diarrhoea (90%), followed by urinary tract infections (75%), acute bronchitis (73%), otitis media (51%) and acute sinusitis (40%). Metronidazole (89%) and ciprofloxacin (86%) were generally given for diarrhoea and urinary tract infections, while amoxicillin/clavulanate was given (51%) for other cases. Not even one from pharmacists was asking about a history of antibiotic allergy or providing information about antibiotics. Only 23% asked about pregnancy status when administering antibiotics to treat urinary tract infections (Abdulhak et al., 2011).

The availability of antibiotics for self-medication may increase and includes oral or topical use. Unnecessary use of antibiotics may result in people using drugs with unclear indications to contribute to anti-microbial resistance development (Arifin et al., 2020). Antibiotic abuse, including failure of therapy, overdosing, or reuse of remaining antibiotics, can potentially expose patients to optimizing antibiotics' therapeutic dose. Some antibiotics are not enough to kill infectious bacteria to make the environment resistant to these antibiotics. Microorganisms resistant to several agents anti-infective are increasing worldwide (Llor & Bjerrum, 2014). Antibiotic abuse can occur because it is easily obtained without a doctor's prescription. This practice can harm patients who may use antibiotics for specific indications and become ineffective for treating infectious disease (Lockhart et al., 2019).

The problem of antibiotic resistance is very complex in Indonesia and will continue to increase every year. Infectious diseases account for more than 13 million deaths per year in developing countries (Wall, 2019). Infectious diseases in Indonesia are still among the top ten diseases, so in 2050 deaths due to antibiotic resistance will reach 10 million per year and become the highest cause of death among other causes. The high and inappropriate use of antibiotic drugs in Indonesia will increase the incidence of resistance (Dadgostar, 2019). According to the Antimicrobial Resistance Control Committee, Indonesia's bacterial resistance level continues to increase from 2013, 2016, to 2019. The resistant bacteria have increased from 40 per cent, 60 per cent, and 60.4 per cent in 2019. The increase in the incidence of resistance is due to the use of uncontrolled antibiotics. Resistant bacteria can occur due to the misuse of antibiotics (Nurmala & Gunawan, 2020).

One of the causes of antibiotic resistance is the irrational use of antibiotics. One of the irrationalities of using antibiotics is buying and selling antibiotics in pharmacies without a doctor's prescription, which involves pharmacists. With such conditions, it is necessary to find out how the law will respond to these problems. One of the laws related to antibiotic abuse activity is the criminal law. Criminal law has the objective of protecting the interests of individuals or human rights and society (Tulkens, 2011). The purpose of criminal law in Indonesia must be following the philosophy of Pancasila, which can bring interests fair to all citizens (Manullang, 2015).

Criminal law has a function to regulate community life or to organize community life (Perkins & Taylor, 1996). Special criminal law's function is to protect the public interest against acts intended to rape them with criminal sanctions, sharper than the sanctions contained in other laws. In Indonesia, the source of criminal law is the Criminal Code, which regulates general criminal law. In particular, criminal law is also regulated in various related laws and regulations. In the case of selling antibiotics without a doctor's prescription, the legal source that can be used is Law Number 36 of 2009 concerning Health. From the problems above, the purpose of the study is to analyze the aspects of criminal law against pharmacists who sell antibiotics without a doctor's prescription from a perspective legal in Indonesia.

## **RESEARCH METHODS**

The type of research in this paper is a type of normative research. Normative legal research is legal research that places law as a norm system building (Natalis, 2020). The system of norms in question refers to the principles, norms, rules of legislation, court decisions, agreements and doctrine (Simanjuntak, 2019). In normative legal research, the law is applied from various aspects of theory, philosophy, comparison, structure, consistency, general explanation and explanation of each article, formality and binding strength of laws, and the language used is the language of the law (Theofany, 2018). So, it can be concluded that normative legal research has a broad scope. Normative legal research methods are usually known as prescriptive methods because this method must always be accompanied by recommendations or suggestions to look for new norms or complement the norms being studied to make them better. Furthermore, legal research is carried out by examining library materials, or secondary data is called normative juridical research or literature law research (Umarama et al., 2020).

Data analysis is descriptive qualitative in nature because the data collected is data in the form of words (descriptive) obtained from interviews and official documents in the form of laws and regulations related which are then analyzed qualitatively which are objective and interpretive, and carried out to understand and assemble the data obtained and has been classified systematically, then be deduced. Conclusions drawn are made by using deductive thinking, draws namely a way of thinking which is fundamental to general matters and the specific conclusions.

### **RESULTS AND DISCUSSION**

Antibiotics were first introduced for treatment in humans in 1940, and during the last 60 years, antibiotics have been widely used and abused (Serwecińska, 2020). Chemotherapy drugs used systemically to treat bacterial infections are called anti-microbial or, more specifically, "*anti-bacterial*" (Melander et al., 2018). Vuillemin first coined the term antibiotic in 1889 and originally meant antagonism between living things. Waksman was also the first to introduce antibiotic terminology. Since then, antibiotics have been widely used by clinicians to treat various infectious diseases (Ribeiro et al., 2019).

Antibiotics, which Paul Ehlrich first discovered in 1910, are still the mainstay of medicine in treating infectious disease cases (Routh, 1998). During the last five decades, its use has increased tremendously, both in Indonesia and in developed countries such as the United States. The Center for Disease Control and Prevention in the USA states that there are 50 million

antibiotics prescriptions, an unnecessary 150 million prescriptions each year to raise a new problem in increasing antibiotic resistance incidence (Iskandar et al., 2020). Antibiotic resistance is defined as no bacterial growth inhibition by systemic administration of antibiotics at average doses or minimum inhibitory levels (Barker, 1999). Antibiotics are drugs that are well known, both by the medical community and the public. Unfortunately, almost all of them know antibiotics wrongly, and it is evident that antibiotics are the most widely used drugs (misused) inappropriate use of antibiotics. Editorial is the biggest irrational prescribing problem globally, from then until now, in hospitals and the community (Carlet et al., 2012).

Irrational use of drugs is one of the health problems in Indonesia, especially in hospitals. It not only has detrimental effects in the clinic, leading to the selection of resistant bacteria, antibiotics are not sages also raises the problem of nosocomial infection, especially by bacteria that are resistant to several antibiotics at once. Infectious diseases caused by bacteria that fail to respond to treatment result in prolonged illness, an increased risk of death and a longer length of stay in the hospital (Dawes et al., 2012). When the response to treatment is slow or even fails, the patient becomes infectious for a long time (carrier). The following logical consequence is increased morbidity and mortality followed by increased length and cost of hospitalization. The impact of irrational use of other drugs, besides the increasing incidence of side effects such as allergies in allergic patients and drug interactions, is undoubtedly a waste; this provides a greater chance for the resistant strains to spread to others. The ease of transportation and globalization greatly facilitates the spread of resistant bacteria between regions, countries, and even continents. All of this, in turn, increases the number of infected people in the community (Goetz & Graham, 2004).

Antibiotic resistance can be congenital or acquired. In congenital resistance, all bacterial species can be resistant to a drug before the bacteria come into contact with the drug (Landecker, 2013). What is clinically severe is acquired resistance, where bacteria that have been sensitive to a drug become resistant. Resistance occurs when bacteria change in one way or another that causes decreased or reduced effectiveness of drugs, chemical compounds or other substances used to prevent or treat infections bacteria that can survive and reproduce pose more harm. The minimum inhibitory level determines the bacteria's sensitivity to germs to stop bacteria's development (Munita et al., 2016).

Today's pharmaceutical services development demands a paradigm shift that pharmaceutical work is focused on drugs and patient-oriented. Therefore, the government made rules to ensure patient safety by considering the context of new pharmaceutical services in the form of Regulation of the Minister of Health (PMK) Number 35 of 2014 concerning Standards for Pharmaceutical Services in Pharmacies as a result of the revision of the previous PMK Number 1027 of 2004. Recently, it was stated that one of the duties of a pharmacist is clinical pharmacy service which includes drug information services and patient counselling. However, the new regulation does not make the use of antibiotics legal, even though pharmacists can provide antibiotic drug information services or counselling about the use of antibiotics; this is because, according to the regulations on antibiotics, to get antibiotics, you must go through a doctor's prescription. Therefore, counselling for patients in the form of using antibiotics without a doctor's prescription is only limited to advising to direct the patient to a doctor and as far as explaining the good and bad uses of antibiotics that are not appropriate, because if a pharmacist chooses an antibiotic, then this right will violate the law about the Circulation of Antibiotics. Pharmacy comes from Greek (apothecia), which means "storage". In Dutch, a pharmacy is called Apotheke, which means a place to sell and mix medicines (Arimbawa et al., 2014). A pharmacy is also a place for pharmacists to practice the pharmacy profession and be a retailer. Pharmacy is a type of retail whose commodities consist of pharmaceutical supplies, including drugs and medicinal ingredients, including other medical equipment supplies. In this case, the pharmacy can be said to have a role in distributing pharmaceutical supplies and medical supplies from suppliers to drug users (Wingfield et al., 2004). The essential purpose of a pharmacy's existence is to optimize a healthy life for the general public. Article 1 Number 4 of the Minister of Health Regulation (PMK) Number 9 of 2017 concerning Pharmacy also states the meaning of pharmacist, namely a pharmacy graduate who has graduated as a pharmacist and has taken the oath of office a pharmacist.

Pharmacists are also called pharmacies. According to the Decree of the Minister of Health Number 1332 / Menkes / SK / X / 2002 concerning pharmacists, it reads, pharmacists are graduates of pharmacy who have passed and have taken an oath of position as pharmacists based on applicable laws and regulations and have the right to perform pharmaceutical work in Indonesia as a pharmacist. In other words, a pharmacist is someone who has expertise and authority in the field of pharmacy, both in pharmacies, hospitals, industry, education, and other fields that are still related to the pharmaceutical field. As for the duties and obligations of a pharmacist, among others are (1) Responsible for the manufacturing process of drugs, even though pharmacist assistants make drugs; (2) His presence on duty is regulated by Law Number 36 of 2009 concerning Health; (3) Must be at the place during pharmacy opening hours; (4) Must explain to consumers about the content of the drug being redeemed. The assistant or pharmacist cannot represent this explanation; (5) Discuss and discuss prescription drugs directly to the doctor, not an assistant or pharmacist; and (6) Must maintain patient recipes' confidentiality.

The safeguarding of pharmaceutical preparations and medical devices is carried out to protect the public from the dangers caused by the use of pharmaceutical preparations and medical devices that do not meet the requirements of quality and safety or efficacy (Van-Norman, 2016). Pharmaceutical preparations in the form of drugs and medicinal raw materials must meet the requirements of Indonesian pharmacopoeia or other standard raw materials (Kartini et al., 2019). Pharmaceutical preparations in traditional medicines and cosmetics and medical devices must meet the specified standards and requirements. Pharmaceutical preparations and medical devices must meet the specified standards and requirements. Pharmaceutical preparations and medical devices must meet the specified preparations and medical devices must meet the specified standards and requirements. Pharmaceutical preparations and medical devices must meet the specified standards and medical devices must meet objectivity and completeness requirements and not be misleading (Setianto & Wahyuningrum, 2019). The government has the authority to revoke the distribution permit and order the withdrawal from the circulation of pharmaceutical preparations and devices medical that have obtained a distribution license, which is subsequently proven not to meet the quality and safety or usefulness requirements, can be confiscated and destroyed following the provisions of laws and regulations (Gardner, 1996).

Based on Article 108 of Law Number 36 of 2009 concerning Health, pharmaceutical practices that include manufacturing include quality control of preparations pharmaceutical, security, procurement, storage and distribution of drugs, drug services on doctor's prescription, drug information services, and development drugs, medicinal ingredients and drugs (Herman & Susyanty, 2012). Traditional must be carried out by health workers who have the expertise and authority to follow statutory regulations (Grujić et al., 2020).

The pharmacist is a professional calling to devote oneself to humanity in the health sector, requires a high degree of knowledge obtained from formal education, its primary orientation must be shown for the benefit of society. Prof. Dr Valerine stated that there are 3 (three) kinds of responsibilities in a profession: (1) moral responsibility. Professional ethics and morals are very close, considering that ethics requires morals as a foundation or foundation in producing certain attitudes. Pharmacists as individuals or groups in taking action must also adhere to good morals, manifested in the form of the Indonesian Pharmacist Code of Ethics. Responsibility following the values and norms that apply in the profession's environment concerned (professional code of ethics), which is personal or institutional for an institution that is the association/professional engagement concerned. Conscience is a manifestation of personal moral responsibility (Zulham, 2018).Meanwhile, the form of institutional moral responsibility is the sanction of the institution concerned.

Moral responsibility can become a legal responsibility if the values that live in society are raised and outlined in statutory regulations; (2) Legal responsibility. The responsibility becomes a burden on the profession to carry out its duties without violating legal signs. The form of legal responsibility is in the form of sanctions; and (3) Professional Technical Responsibility is a demand for the profession to carry out its duties in a manner in professional accordance with the criteria applicable technical in the relevant professional field, either in general terms or in special provisions applicable in the institution concerned. The sanction for those who cannot be accounted for technically is an assessment of their ability (Tamvada, 2020).

The form of the legal relationship between consumers, pharmacists, and pharmacies begins with the fundamental relationship between pharmacists and consumers in the form of a sale and purchase agreement. Action from the pharmacist that results in a loss to the consumer has the right to ask for compensation. Pharmacists are liable for losses from consumers. A lawsuit can be filed based on a default or unlawful act. If a lawsuit is filed based on default, the strength is feeble because only the parties bound by the contract can sue each other. Another legal remedy that can be filed is a lawsuit based on an illegal act. A lawsuit based on the law does not require a contractual relationship between the consumer and the pharmacist so that the other party can also be liable. So, it is necessary to investigate whether the errors that arise are due to negligence on the pharmacist. The proof system used in pharmacist liability is regulated in Article 28 of the Consumer Protection Law, using a reverse proof system. Consequently, the pharmacist must prove whether or not there is a mistake in him (Marzuki, 2020).

If consumers want to keep buying antibiotics without a prescription from a legitimate doctor, the pharmacy should refuse it. Not only because of the pursuit of profit, but consumer safety is also at stake. Regarding this matter, the business owner, in carrying out his business activities, must comply with Article 7 of the Consumer Protection Law, which states that: (1) Good faith in carrying out business activities; (2) The right to provide accurate, transparent and honest information regarding the condition and guarantee of goods and services and to provide an explanation of the use, repair, maintenance; (3) Treating or serving consumers honestly and adequately and not discriminatory; (4) Provide compensation for losses resulting from the use, use and utilization of traded goods and services; and (5) Provide compensation, compensation or replacement if the goods or services received or used are not following the agreement. Meanwhile, consumers as buyers have rights in the form of (1) The right to comfort, security and safety in consuming goods and services; (2) The right to choose goods and services and to obtain these goods and services following the exchange rates and conditions and guarantees promised;

(3) Right to correct, straightforward and honest information regarding the condition and guarantee of goods or services; (4) The right to have their opinions and complaints heard about the goods or services used; (5) The right to be treated or served truthfully and honestly and non-discriminatory; and (6) The right to get compensation, indemnification/replacement, if the goods and services received are not by the agreement or not as it should be.

The pharmacist is one of the professions that play an essential role in the medical world, especially medicine because a pharmacist is a pharmacy expert. You could say a pharmacist is a Pharmacist. Meaning that pharmacists do not only take care of technical matters related to pharmacies, but pharmacists are also responsible for the entry and exit of drugs in pharmacies. The provision of medicines by the requirements is at the core of implementing health efforts that doctors and health services must carry out with expertise and authority whose quality must be continuously improved. However, on the other hand, drugs can be detrimental to health if they do not meet the requirements when misused or if they are misused. Therefore, unlike other trading commodities, drug distribution is regulated in such a way as to ensure safety, quality and accuracy of use. Protection needs to be given special or given to the people, police, industrial waste, especially in the danger of narcotics and drug abuse. In this case the pharmacy becomes one of how someone misuses drugs, and it is the pharmacist's responsibility if there is an error in the sale of these drugs, one of which is the list G drug which is a problem in its free circulation.

In practice, there are many unscrupulous persons. Who are not responsible for the spread of over-the-counter G List drugs. Pharmacies as a means of service of hard drugs legally are widely expected in the service of hard drugs illegally in the form of service of prescription drugs without a basic prescription, thus responding to the Indonesian government has enacted a law on the protection of public health in order to make the perpetrators more responsible. This law aims to protect the people's rights to comfort, security, and safety for the wider community.

Health law can be said to have experienced rapid development in Indonesia. Knowledge about health needs to be developed to anticipate the many obstacles in this era of globalization. This development is inseparable from the development of organizations professional in the field of medical / health law. Indeed, there are still many laws that must be adjusted to develop health efforts and science and technology regarding the law. Besides the necessary legislation and public health protection, as well as pharmacists. Increased procurement and management of health personnel, particularly pharmacies and pharmacists, to support increased health efforts. In this case, it becomes an essential aspect of drug use because the abuse of these drugs can cause many losses in financial and health losses. Moreover, many people have become victims until now because they have bought drugs from drug stores. Who does not have a business license, and many drugs that are sold are illegal?

Health is a human right that will continue to be attached to each individual, and the state must provide protection related to these rights' human. In life, humans must maintain health in order to feel good physically and mentally. Health development is directed at enhancing the degree of health, including the state of community nutrition in improving the quality and standard of living and the people's intelligence and welfare in general. More precisely, health is a condition free from various types of diseases both physically, mentally, and socially (Irmansyah et al., 2009).

The concept of human rights clearly explains the position of the state in terms of human rights. The state as an entity with power is considered capable of carrying out the mission of advancing human rights globally. The consequence of this is that the state will always be required to carry out its obligations in the context of advancing human rights. In human rights principles, the state is a duty bearer, and every individual under its jurisdiction is a rights holder. The primary obligation that the state must carry is the obligation to respect, the obligation to fulfil, and the obligation to protect. The state is also obliged to control and guarantee human rights implementation for every individual under its jurisdiction (Backer, 2011).

Every health effort cannot always give patients satisfaction well; it can lead to disability or even death. This kind of catastrophe cannot be avoided altogether, giving rise to legal problems if the patient sues the service provider, which must be assessed whether the catastrophe is malpractice or risk from pharmacists' actions in pharmaceutical services (Asadi-Lari et al., 2004). Likewise, legal problems that occur for the health community need understanding by law enforcers, including the court, in making decisions on the emergence of suspected malpractice. In general, patients' demands based on a result that occurs or results that befall them, while the medical malpractice lawsuit in pharmacy services is an indispensable cause that led to the patient's demands (Mello & Zeiler, 2008).

Every health worker in deciding on a medical action must be based on awareness, responsibility and high morals by their respective professional ethics. One of the health workers who have the authority to administer drugs to patients is a pharmacist. The pharmacist has expertise and authority in the pharmacy field, both in pharmacies, hospitals, industry, education, and other fields related to the pharmaceutical field. Pharmacists are also undergraduate health professionals. Pharmacists are part of the health workforce as pharmaceutical personnel. The relationship between doctors and other health workers, including pharmacists, has a dominant position. Patients generally tend to be passive. Article 11 of Law Number 36 of 2009 concerning Health regulates the functions and duties of pharmacists. Pharmacist practice is not a job that anyone can do. However, it can only be done by certain professional groups of pharmacists who are competent and meet specific standards and have received permission from the competent institution and work by the standards and professionalism applied by professional organizations.

Health services provided by medical staff to patients are the professional actions of medical personnel. Medical action is an action that is full of risks. This risk can occur due to something that cannot be predicted or the risk of wrong medical action. It is said that it is wrong if medical personnel do not perform their work by the medical profession's standards and medical procedures. If a medical officer commits an act of wrongdoing, then the medical staff can be categorized as having committed malpractice to involve aspects of criminal law (Pietra et al., 2005).

In maintaining health, of course, it is often found that several actions that threaten health can be in the form of deliberation, negligence, or accident. Matters like this can be categorized as malpractice which emphasizes more on the crime of malpractice. The Health Law does not include the definition of malpractice. The Criminal Provisions in Chapter XX it is stipulated in Article 190 that the head of health service facilities who practice or work at health service facilities deliberately do not provide First aid to patients in an emergency as referred to in Article 32 paragraph or Article 85 paragraph shall be punished with imprisonment for a maximum of 2 (two) years and a maximum fine of Rp. 200,000,000 (two hundred million rupiahs). If the act as referred to in paragraph (1) results in disability or death, the head of the health service facility or health worker shall be punished with imprisonment of a maximum of 10 (ten) years and a maximum fine of one billion rupiahs.

Article 63 of Law Number 36 of 2009 concerning Health regulates efforts to cure diseases and efforts to restore health as a measure of malpractice according to the criminal provisions contained in article 190 above. Article 63 of Law Number 36 of 2009 concerning Health states that: Disease healing and health recovery are held to restore health status due to disease, restore bodily functions due to disabilities or eliminate disabilities. Disease healing and health recovery shall be carried out using medication or treatment. Medicine and care can be carried out based on medical science and nursing science or other reliable means. The implementation of medication and or treatment based on medical science can only be carried out by health personnel who have the expertise and authority to do so. The government shall provide guidance and control over the implementation of medication and or treatment based on other accountable methods.

The establishment of legislation in health services is necessary; this is done to prosecute malpractice cases with strict provisions. Some examples of errors in pharmaceutical services that need to be assessed whether it can be said to be malpractice or not, some mistakes in the prescription assessment: The pharmacist receives a prescription but does not perform the screening assessment; The pharmacist accepts the doctor's prescription, but the writing is dubious unclear, but the pharmacist does not carry out his obligation to confirm with the doctor who wrote the prescription; and Misinterpreting or reading prescriptions, so that the drugs given are not by the doctor's prescription.

The mistakes mentioned above can have a negative impact (loss, disability, death) on the patient, and in general, the errors are distinguished in the first 2 (two) parts of the impact of the harm due to the risk of the drug is called drug injury. Secondly, adverse effects on the patient due to human error (pharmacist), which is better known as a medication error. By looking at the definitions above, it can be concluded that the presence or absence of malpractice is not determined based on the "end result" but the basis of "the process".

There are significant differences between ordinary crime and medical crime: In ordinary criminal acts, the main concern is the effect (gevolg), while the significant medical crime is not the result but the cause. Even though the consequences are fatal, there is no element of fault/negligence, so the action cannot be blamed. Criminal acts can usually be drawn as a direct line between cause and effect because the case is clear, people stabbed another person's stomach with a knife until his stomach was injured. In every medical procedure, such as surgery, there will always be a risk of something negative, requiring informed consent patients' consent. Pharmacists who are deemed to have committed negligence that has resulted in alleged malpractice by the patient are responsible for their actions. A person is considered capable of being responsible if that person is aware of the actual action, he has done and the consequences of his action. An action can be categorized as pharmacist's malpractice if it fulfils the formulation of a criminal offence. The act must be a disgraceful act, and the wrong mental attitude is carried out, namely in the form of carelessness or negligence (Meirosa, 2021).

To be convicted of a pharmacist, the malpractice he has committed must have the following elements: Committing a criminal act; Able to be responsible; deliberately or negligently; and No excuses are forgiving. There is a desire for the law to be upheld the values fought for through the relevant legal instruments can be realized. For criminal liability, a pharmacist must first be identified as the perpetrator of a crime. Accountability is asked for or not. It is a second issue, depending on the parties' policy concerned to decide whether it is

necessary to demand accountability. This problem concerns the subject of a criminal act (pharmacist), which legislators have generally formulated (Suseno, 2019).

According to Roeslan Saleh, criminal responsibility is defined as the continuation of an objective reproach in a criminal act and subjectively meets the requirements to be convicted for his actions. What is meant by objective reproach is that an act committed by a person is an act that is prohibited (Rahman & Handoyo, 2019). The prohibited act that is meant here is an act that is indeed contrary or prohibited by law, both formal law and material law. Meanwhile, subjective reproach refers to the person doing the forbidden act, or it can be said that a personal reproach is a person who commits an act that is prohibited or contrary to the law.

#### CONCLUSION

The legal relationship between consumers and pharmacists originates in the form of a sale-purchase agreement. The establishment of legislation in health services is necessary; this is done so that crimes prosecuted malpractice can occur be with strict provisions. Some examples of errors in pharmaceutical services that need to be assessed whether it can be said to be malpractice or not, some mistakes in the prescription assessment: The pharmacist receives a prescription but does not perform the screening/ assessment; The pharmacist accepts the doctor's prescription, but the writing is dubious/unclear, but the pharmacist does not carry out his obligation to confirm with the doctor who wrote the prescription; and Misinterpreting or reading prescriptions, so that the drugs given are not by the doctor's prescription. The mistakes mentioned above can have a negative impact (loss, disability, death) on the patient, and in general, the errors are distinguished in the first 2 (two) parts of the impact of the harm due to the risk of the drug, which is called drug injury. Secondly, adverse effects on the patient due to human error (pharmacist), which is better known as a medication error. By definition above, it can be concluded that the presence of malpractice is not determined based on the "result" but the basis of "process". To be convicted of a pharmacist, the malpractice he has committed must have the following elements: Committing a criminal act; Able to be responsible; Deliberately or negligently; and No excuses are forgiving. In law enforcement, there is a desire for the law to be upheld the values fought for through the relevant legal instruments can be realized. For criminal liability, a pharmacist must first be identified as the perpetrator of a crime. Accountability is asked for or not; it is a second issue, depending on the parties' policy concerned to decide whether it is necessary to demand that accountability. This problem concerns the subject of a criminal act (pharmacist), which legislators have generally formulated.

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