



The Effect of Self Medication Practices on Oversight of Potent Drugs Without a Doctor's Prescription

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Abstract

The practice of self-medication is the practice of treating oneself without consulting a doctor. The practice of self-medication according to existing regulations may only be carried out for over the counter drugs and limited over the counter drugs, however, in practice in the field there are many self medication practices using hard drugs without a doctor's prescription. This study aims to analyze the practice of self-medication of hard drugs without a doctor's prescription legally and to analyze its relationship with the supervision carried out by the POM Agency. This study uses a normative juridical method by analyzing cases that occur using existing legal materials, both primary, secondary and non-legal materials. From the research it can be concluded that the practice of self-medication of potent drugs without a doctor's prescription is contrary to existing provisions and can affect the effectiveness of the implementation of supervision carried out by the BPOM.

Keywords: Self-medication, Supervision, Potent Drugs, Doctor's Prescription.

Introduction

In everyday life, if a person experiences complaints related to health conditions such as colds, coughs, fever, pain, etc., then of course he will make efforts to overcome these conditions. Generally, people will make good efforts by way of outpatient treatment, hospitalization at health facilities or by simply trying to treat themselves. Community efforts to self-medicate on their own initiative or on the advice of other people without consulting a doctor are known as self-

medication. In general, sources of self-medication information come from family, friends, neighbours, pharmacists, previously prescribed drugs, or advice from advertisements in popular newspapers or magazines. This trend of self-medication is usually caused by the urge to take care of oneself, feelings of sympathy for family members who are sick, lack of time, lack of affordable health services, financial constraints to pay for medical expenses, ignorance, distrust, the influence of advertising and the large availability of drugs.

Self-medication will be safe if the person using the drug has sufficient knowledge about the dosage, the right time to take the drug, and the side effects and symptoms of an overdose. However, the lack of information regarding drugs owned by the public can cause serious effects such as antibiotic resistance, skin problems, hypersensitivity and allergies. In addition, according to research by Andarini et al, the use of self-medication drugs for a long time in certain diseases tends to be dangerous and is associated with adverse drug reactions. It is common for people to use hard drugs such as antibiotics without a prescription from a doctor to cure their illnesses. These medicines can usually be obtained easily from pharmacies, drugstores/stalls or online. Not only antibiotics, other drugs such as analgesic drugs, anti-inflammatory drugs, antipyretic drugs and antihistamine drugs which are medicines for mild, general and non-acute complaints can be purchased by the public for self-medication. These drugs can be easily obtained without a prescription in almost all pharmacies. (Radius Setiyawan, Samsul Arifin, 2023)

Research M. Rifqi Rohman et. al. showed that 97.5% of pharmacies dispensed amlodipine without a prescription and 92.0% dispensed allopurinol without a prescription. The research also shows that pharmacists do not fully understand the applicable regulations. From this research, it can be said that most of the pharmacies still serve the practice of self-medication of hard drugs without a doctor's prescription. In fact, in accordance with the provisions of the applicable laws and regulations, hard drugs can only be submitted based on a prescription from a doctor and delivered by a pharmacist. The Food and Drug Monitoring Agency (BPOM) in accordance with the mandate of Presidential Regulation number 80 of 2017, is an agency that is tasked with carrying out drug and food control (Achmad Hariri, 2023). One of its duties is to ensure that drugs in circulation always meet the standards and requirements for safety, efficacy/benefits and product quality as well as law enforcement measures through drug control at pharmaceutical service facilities such as pharmacies. Deo Andika's research shows that supervision of the sale of hard drugs by BPOM Pekanbaru has not been implemented properly, because there are still many hard drugs circulating in Pekanbaru City and are detrimental to consumers. In addition,

based on data from BPOM's own monitoring results in 2018 in 5 (five) provinces, a total of 83.52% of pharmacies dispensing antibiotics without a doctor's prescription and 32.75% of pharmacies carry out distribution/distribution activities (selling drugs in large quantities) between others to medical personnel, clinics, health centers, other pharmacies, and stalls (grocery stores). From these data it can be seen that there is a potential for free circulation of antibiotics in society (K. R. Samsul Arifin, 2021). Therefore, the author wants to reveal the implementation of the practice of self-medication of hard drugs without a doctor's prescription that occurs in society and how it affects the effectiveness of the implementation of supervision.

Discussion and Result

The Practice of Self Medication of Strong Drugs Without a Doctor's Prescription That Happens in the Community

The right to health has been guaranteed by the state and is the government's obligation to its citizens as the Indonesian nation aspires to in the Pancasila of the 1945 Constitution of the Republic of Indonesia and has also been stated in Law number 36 of 2009 concerning Health. In Article 4 of the Health Law and its explanation, it has been emphasized that health is the right of every citizen to obtain health services from health care facilities in order to realize the highest degree of health. Self-medication is a form of health effort carried out by the community to improve their health status using pharmaceutical preparations, in this case drugs. Meanwhile, on the other hand, securing pharmaceutical preparations is one of the government's health efforts that is needed to achieve optimal health status. Pharmaceutical preparations security is very necessary in order to protect the public from harm caused by inappropriate use of pharmaceutical preparations and/or not fulfilling the requirements for quality, safety and efficacy. (A. Y. I. Samsul Arifin, 2023)

As mandated in Article 98 paragraph (1) of the Health Law, pharmaceutical preparations must be safe, efficacious/beneficial, of good quality and affordable. For this reason, in order to guarantee safety, efficacy and quality, pharmaceutical preparations must have a distribution permit issued by BPOM before being distributed.

As a pharmaceutical preparation, drugs are prohibited from being procured, stored, processed, promoted and distributed by persons who do not have the expertise and authority. Manufacturing of drugs including quality control, security, procurement, storage and distribution of drugs, drug management, prescription services, drug information services and drug development is part of the work of pharmacy (Satria Unggul, 2021). Pharmacy work itself can only be carried out by pharmaceutical personnel consisting of Pharmacists and Pharmaceutical Technical Personnel (TTK).

Pharmacists and TTKs can practice pharmaceutical services in pharmaceutical service facilities, namely pharmacies, hospital pharmacy installations, health centers, clinics, drug stores, or joint practice. In carrying out pharmaceutical services at pharmacies, pharmacists are required to have a pharmacist registration certificate (STRA), pharmacist license (SIPA) and pharmacy license (SIA). In addition, all pharmaceutical and non-pharmaceutical personnel who work in pharmacies must work in accordance with professional standards, standard operating procedures, service standards, professional ethics, respect patient rights, and prioritize patient quality and safety.

Compliance with pharmaceutical service standards in pharmacies is aimed at improving service quality, guaranteeing legal certainty for pharmaceutical staff and protecting patients and the public from irrational drug use in the context of patient safety. In order to increase safety and accuracy of use as well as secure distribution channels, drugs are classified into over-the-counter drugs, limited over-the-counter drugs, mandatory pharmacy drugs, hard drugs, psychotropics and narcotics. Strong drug list G (*gevaarlijk*) is a drug that is included in the list of dangerous drugs which have the property of treating, strengthening, beautifying, disinfecting and other things for the human body, which can only be submitted by a pharmacist and delivery must be based on a doctor's prescription. The class of over-the-counter drugs are drugs that can be traded freely, while limited over-the-counter drugs are drugs that are included in the W list (*Waarschuwing/warning*) which can be traded freely in limited quantities. In the above drug classification, hard drugs, psychotropics and narcotics must be submitted based on a doctor's prescription. (Satria Unggul, 2021)

Pharmacists in carrying out their practice in pharmacies can serve prescription drugs and can also provide non-prescription drugs or self-medication services. The service in question must be accompanied by providing education to patients who need the drug. In accordance with the provisions, self-medication services are only limited to over-the-counter drugs, over-the-counter drugs, other pharmaceutical preparations, medical devices and BMHP. But apart from these drugs, to increase the availability of drugs needed for self-medication/self-medication, there are drugs that belong to the class of hard drugs that can be dispensed to patients without a doctor's prescription by pharmacists in pharmacies.

These medicines are categorized as mandatory medicines for the Pharmacy. The delivery of these drugs must be given information including dosage and rules for use, contraindications, side effects and other things that need to be considered by the patient and it is mandatory to record the patient and the drugs submitted. From the explanations above, it can be concluded that the medicinal products used by the public in an effort to achieve the highest possible health are products that carry out a lot of regulation regarding their distribution in order to ensure their safety, efficacy and quality. These arrangements are carried out by the government, of course, the aim is

to provide certainty and legal protection for the public and pharmacists in carrying out their practice. Apart from that, it can also be concluded that the practice of self-medication by the community is only permitted to use drugs that fall into the category of drugs that can be obtained without a doctor's prescription, namely the class of over-the-counter drugs, limited over-the-counter drugs, other pharmaceutical preparations such as health supplements and mandatory pharmacy drugs.

Everyone who does self-medication should be aware of the advantages and disadvantages of the medication they are taking. By knowing the benefits and risks, one should be able to assess whether the treatment needs to be done or not. The practice of self-medication will be beneficial if drugs are used rationally but will endanger lives if done otherwise. Basically, people who practice self-medication can benefit from: 1) Easier, because treatment is carried out using drugs that are easy to obtain 2) The costs incurred are less. because you don't have to go to the hospital or doctor first. 3) The quality of treatment is guaranteed, because unconsciously the people who do self-medication will of course choose the best medicine that is proven to be safe, of good quality and gives the expected results 4) Safe, because the drugs used are drugs that have passed a series of tests and the rules/dosage of use are stated In practice, in addition to drugs that are permitted for self-medication, many people still buy hard drugs that should be prescribed but purchased freely.

Some studies that show this include: - Research by Selma Siahaan et.al. stated that the pharmacy was the best place to buy hard drugs/OKT, over-the-counter drugs, vitamins/supplements (> 75%) compared to other places, as many as 36% of respondents admitted that they had bought drugs that should have been with a doctor's prescription without having a prescription and around 15% of respondents bought drugs loud in places where they shouldn't be, namely drugstores, stalls/shops and online. - Djawaria et.al stated that most antibiotics without a doctor's prescription were obtained from pharmacies (51.31%). - Research by Denis Riski Nur Firmansyah et. al showed that out of 42 pharmacies in Tegal City, 39 pharmacies provided dexamethasone, which belongs to the class of hard drugs, in an over-the-counter way without a doctor's prescription. - Sunandar et.al's study regarding the use of non-prescription antibiotics in Kendari showed that patients with a low level of knowledge tended to have used antibiotics without a doctor's prescription (56.44%) and most of the patients obtained antibiotics from pharmacies (94.07%).

The practice of self-medication in the community using hard drugs without a doctor's prescription can also be seen from the following data: - Results of Basic Health Research (Riskesdas) in 2013, 35.2 percent of households in Indonesia keep medicines for self-medication. Of the 35.2 percent of households that kept medicine, the proportion that kept hard drugs was 35.7 percent and antibiotics 27.8 percent. There were 81.9 percent of households keeping hard drugs and 86.1 percent of households keeping antibiotics obtained without a prescription. Nationally, the survey results

show that pharmacies and drugstores/stalls are the main sources of obtaining household medicines.

The 2021 Health Statistics Profile data shows that in the 2019-2021 period, the percentage of the population who had health complaints and had self-medicated in the last month increased. In 2021, 84 out of 100 residents who have health complaints have treated themselves. - Data for the 2020 BPOM Annual Report, shows that from a number of pharmacies examined, 28.92% did not comply with the provisions with the finding that the most frequent cause for the facility to be given a stern warning was because the pharmacy delivered hard drugs (outside DOWA) without a doctor's prescription. Specifically in the province of Gorontalo, the practice of self-medication can be shown from the following data: - Data from Riskesdas 2013 shows that Gorontalo is one of the areas with the highest average household storing medicinal preparations, namely 4 types of drugs for self-medication purposes with the proportion of households storing hard drugs without a prescription 70.8% and antibiotics without a prescription 74.4% - Data from the BPS national socio-economic survey (susenas) in March in 2019-2021, shows the percentage of Gorontalo residents who have health complaints and have self-medicated in a row from 2019 (73.76%), 2020 (73, 85%) and in 2021 (81.58%). - Data from the Gorontalo BPOM Annual Report (Laptah) show that there are still many pharmacies that do not comply with the requirements. Pharmacy data does not meet the conditions in a row from 2019 (29.3%), 2020 (73.8%) and 2021 (74.5%). The violations that cause these facilities to not comply with the provisions are violations of pharmacy regulations, presence of unregistered products, prohibited materials/products and administrative violations.

From the research results, data from the research institute of the Ministry of Health, BPS data and data from BPOM's own supervision both at the central and regional levels, it can be concluded that the practice of self-medication by the community to cure their illnesses is still very common. Even in general or it can be said that most people still buy and use and store hard drugs that should be prescribed by a doctor but are obtained freely without a prescription. (Samsul Arifin, 2021) The practice of self-medication of hard drugs without being preceded by a diagnosis from a doctor related to the disease they are suffering of course can lead to inappropriate therapy/medication and can also trigger irrational use of drugs which can cause harm to society itself.

From these data it can also be concluded that most people buy hard drugs without a doctor's prescription at pharmacies. Pharmacies in accordance with the provisions may only serve the sale/delivery of drugs in the category of hard drugs based on a doctor's prescription, but in practice there are violations of the provisions related to drug services for self-medication. Pharmacists as the person in charge of the pharmacy can also be suspected of having violated the provisions in the pharmaceutical service standards so that it can result in patients/the public not being

protected from irrational drug use which can ultimately threaten the patient's own safety. From the existing data it can also be concluded that there has been an increase in the practice of self-medication in the last three years 2019-2021.

When analyzed further, there was an increase, especially during the Covid-19 pandemic. This is supported by data from BPS which states that in 2021 people who have health complaints will never seek outpatient care, because they will self-medicate (68.11%), for unnecessary reasons (15.11%) and reasons for worry. exposed to covid-19 (13.51%). A study conducted by the Ministry of Health and UNICEF in 2020 also showed public concern because restrictions during a pandemic were the top reason for individuals not using health facilities. In addition, Susenas data also shows that around 0.03 percent of the population who have health complaints do not seek outpatient care on the grounds that health facilities are not operating due to Covid-19.

The Effect of Self-Medication Practices on the Effectiveness of Supervision Implementation

Supervision is one of the elements in management activities which is an activity to adjust the implementation of the plans that have been set previously. In principle, supervision is carried out as a preventive effort whether activities are carried out according to existing regulations. According to Lotulung in Victor Jusuf Sedubun's article, supervision is an effort to avoid mistakes, either intentionally or unintentionally, as a preventive effort, or also to correct them if an error has occurred, as a repressive effort. The Food and Drug Supervisory Agency, abbreviated as BPOM as regulated in Presidential Regulation number 80 of 2017, is an institution that is tasked with carrying out drug and food supervision. In carrying out its duties, one of the functions carried out is to supervise the product while it is in circulation. Supervision during circulation is supervision to ensure that drugs and food in circulation always meet the established standards and requirements for safety, efficacy/benefits, and product quality as well as law enforcement measures.

In carrying out its supervisory duties, BPOM has the authority to impose administrative sanctions in accordance with statutory provisions and carry out intelligence and investigative activities on criminal acts in the field of medicine and food. The POM Agency as mandated in article 10 of the Minister of Health Number 73 of 2016 concerning Pharmaceutical Service Standards in Pharmacies can carry out supervision in the management of pharmaceutical preparations in Pharmacies, in addition BPOM is also mandated to carry out monitoring, providing guidance and guidance on the management of pharmaceutical preparations in Government Agencies and the public.

In addition to using the provisions in these regulations, in carrying out supervision of hard drugs in pharmacies, BPOM also uses other related regulations.

Effective is the extent to which the goals of the group can be achieved. The law is said to be effective if the law has a positive impact, namely it can achieve its goals in guiding or changing human behavior so that it becomes legal behavior. According to Achmad Ali, the effectiveness of the law is related to the extent to which the law is complied with by the target of the law. Meanwhile, the factors that make the regulation effective or not, according to Ruslan, depend on four effectiveness factors, namely: 1. The rule of law or regulation itself 2. Officers who enforce it 3. Facilities that are expected to support the implementation of the rule of law, 4. Community members affected by the scope of the regulation.

The community factor is one of the factors that influence the effectiveness of the law. The community factor is the environment in which the law is enacted or applied. According to the author, one of the factors originating from the community that influences the effectiveness of monitoring the circulation of hard drugs is the practice of self-medication. From the data that has been presented in the discussions above, it can be analyzed that even though supervision has been carried out by BPOM, self-medication services by pharmacies that are not in accordance with the provisions still occur, even increasing during the Covid-19 pandemic. In the research of M. Rifqi Rohman et. al. it was stated that the majority of pharmacists (> 85%) had the perception that hard drugs for chronic diseases (glibenclamide, metformin, amlodipine, captopril, allopurinol and simvastatin) were drugs that could be dispensed without a prescription with the main reason being that patients were used to using them. In addition, in the research by Denis Riski Nur Firmansyah et. al mentioned that knowledge factors, attitude factors, income factors and experience factors influence pharmacists' decisions in selling dexamethasone without a prescription in Tegal City.

The two studies show that in practice pharmacists have not fully complied with the applicable regulations. Besides that, Prasetyo and Dyah Ayu's research also states that there are 6 main factors that influence the sale of antibiotics without a doctor's prescription at community pharmacies from the perspective of pharmacists respectively, namely, factors of belief and experience, factors of legal leniency and sanctions, factors of pressure from outside and similar behavior, financial factors, attitude factors and critical sense factors. As the second factor influencing the sale of antibiotics without a prescription, the leniency of laws and sanctions due to the absence of sanctions and strict supervision causes pharmaceutical staff to feel that there are no real and serious consequences if they serve the sale of antibiotics without a prescription (Samsul Arifin, 2020). From the results of the research presented above, it can be analyzed that the role of the pharmacist as the person in charge of the pharmacy is very influential in terms of the widespread practice of serving hard drugs without a doctor's prescription for self-medication in pharmacies. In addition, BPOM as an institution in charge of supervising drug distribution is felt to have not

performed its function properly so that the practice of selling hard drugs without a prescription is still ongoing.

Conclusion

From the description of the discussion above, it can be concluded that among others, the practice of self-medication is still rife in society, and has even increased during the Covid-19 Pandemic. Self-medication from a legal perspective can only be carried out for the purchase of drugs belonging to the free and limited over-the-counter drugs and the mandatory pharmacy drug class but must be submitted directly by the pharmacist accompanied by related explanations. The practice of self-medication using hard drugs without a doctor's prescription is not legally justified. Self-medication services to the community by pharmacies that are still rampant show that the POM has not been effective enough in supervising the sale of hard drugs on the G list.

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