



LEGAL EFFECTIVENESS OF SUPERVISION OF HARD DRUGS WITHOUT A DOCTOR'S PRESCRIPTION AT PHARMACIES

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Abstract

Drug supervision aims to protect the public from hazards caused by inappropriate use of drugs and or hazards from drugs that do not meet quality, efficacy, and safety requirements. For this reason, strict and comprehensive supervision by the Food and Drug Administration (BPOM) is required. Hard drugs are one class of drugs whose delivery must be based on a doctor's prescription and delivered by a pharmacist at a pharmaceutical service facility such as a pharmacy. In practice, there are still many sales of hard drugs without a doctor's prescription in pharmacies, so the supervision carried out by BPOM to enforce this regulation needs to be questioned for its effectiveness. This research is a type of empirical legal research. The data obtained from the research were analyzed qualitatively and descriptively to conclude. Data/information is obtained from the results of surveys and interviews with pharmacy owners, pharmacists in charge of pharmacies, and BPOM Gorontalo officers.

Based on the research results, the implementation of supervision of hard drugs through inspection by BPOM Gorontalo officers in pharmacies has been carried out by established mechanisms and procedures. However, the legal effectiveness of implementing BPOM supervision of the sale of hard drugs without a prescription in pharmacies can be considered ineffective. The ineffectiveness of the law is because most pharmacies still do not comply with the rules for selling hard drugs based on a doctor's prescription, sanctions that are not yet firm, and socialization that is not optimal. The ineffectiveness of the law is influenced by the factor that the rules for hard drugs without a prescription are not clear and there are still unsynchronized, the factor of the implementation of examinations by officers which still needs to be improved, especially regarding the provision of guidance or socialization of regulations related to hard drugs, the factor of services for self-medication of hard drugs without a prescription that is not by pharmaceutical service standards and the Covid-19 pandemic factor.

Keywords: supervision, BPOM, hard drugs, pharmacy

1. Introduction

One form of health effort is the security of pharmaceutical preparations and medical devices. This effort is also a crucial factor in realizing the highest degree of health for the community. The safeguarding of pharmaceutical preparations is carried out to

protect the public from the dangers of inappropriate use of pharmaceutical preparations and/or those that do not meet quality, safety, and efficacy requirements and to ensure their equitable and affordable availability.

Pharmaceutical preparations include drugs, medicinal materials, traditional medicines, and cosmetics. Law No. 36/2009 on Health (Law 36/2009) emphasizes that pharmaceutical preparations must be safe, efficacious, of good quality, and affordable, and must have a distribution license issued by the Food and Drug Supervisory Agency. For this reason, appropriate and comprehensive supervision is needed to safeguard pharmaceutical preparations.

Inappropriate, ineffective, and inefficient use of drugs is a common problem worldwide, especially in developing countries (Chaturvedi VP et al., 2012). According to estimates from the WHO, more than 50% of drugs worldwide are prescribed, dispensed, or sold incorrectly, and half of all patients fail to use medicines appropriately (WHO, 2004). The impacts of irrational drug use include decreased quality of drug therapy that can lead to increased morbidity and mortality, microbial resistance, and increased risk of unwanted drug effects; waste of resources that further leads to reduced drug availability and increased cost of treatment; and psychological effects on patients that can lead to dependence on a drug (Ofori-Asenso & Agyeman, 2016).

In some parts of Indonesia, when experiencing health-related complaints, people can still easily obtain medicines at pharmacies, drugstores, and even roadside stalls to overcome their health problems. The types of drugs that can be purchased at pharmacies are very diverse, ranging from analgesics, drugs for chronic diseases such as diabetes and hypertension, to other hard drugs. In addition to this convenience, drug delivery at pharmacies is often not accompanied by clear information on proper use and potential side effects.

Based on research by M. Rifqi Rohman et. al., some findings show there are still many violations in the delivery of hard drugs in pharmacies in Indonesia. The study showed that most pharmacies handed over drugs such as amlodipine (97%) and allopurinol (92%) without a doctor's prescription (Rokhman et al., 2017). Data from the Central Statistics Agency (BPS) also shows that there has been an increase in the percentage of the population who have health complaints and do self-medication in the 2019-2021 period, this can be seen from the 2021 health statistics profile data, an increase in percentage from 71.46% in 2019, then increasing to 72.19% in 2020 and 84.23% in 2021 (Badan Pusat Statistik, 2021). From these data, it is illustrated that people still prefer to do self-medication instead of going to health facilities and easily get medicine even without a prescription at the pharmacy.

By Minister of Health Regulation No. 917 of 1993 concerning Compulsory Drug Registration, drugs are classified into free drugs, limited free drugs, compulsory pharmacy drugs (OWA), hard drugs, psychotropic drugs, and narcotics. To Article 21 Paragraph 2 and Article 24 Letter c of Government Regulation No. 51 of 2009 concerning Pharmaceutical Work (PP 51/2009), hard drugs can only be obtained based on a doctor's prescription at a pharmaceutical service facility and also the delivery can only be done by a pharmacist. Hard drugs, by Decree of the Minister of

Health No. 02396/A/SK/VIII/1986 of 1986 concerning the Special Mark of Hard Drugs, are required to include a special mark in the form of a red circle with a black border with the letter K touching the border and include the sentence "Must be prescribed by a doctor". These provisions show that basically to obtain hard drugs at pharmacies, a prescription from a doctor is required. When comparing the phenomenon that occurs in the community with the existing regulations, it is clear that there is a gap in the enforcement of existing regulations. This gap may indicate that the government's supervision of the sale of hard drugs has not worked well.

Supervision is one of the main functions of management which is an activity to adjust between implementation and previously established plans (Indar, 2022). In principle, supervision is carried out as a preventive effort whether activities are carried out according to existing regulations. According to Lotulung, supervision is an effort to avoid mistakes, both intentional and unintentional as a preventive effort, or also to correct them if mistakes have occurred as a repressive effort (Victor Jusuf Sedubun, 2014). The implementation of supervision is included in law enforcement efforts. Law enforcement is intended to improve order and legal certainty in society. Law enforcement must be carried out appropriately and effectively to measure the success of the state, especially in protecting citizens (Sanyoto, 2008).

There are three interrelated elements in the implementation of pharmaceutical practice. These three elements are products (pharmaceutical preparations including drugs), pharmaceutical facilities, and pharmaceutical personnel (Desrina Shesha Annisa, 2020). So the supervision of drugs in pharmaceutical facilities such as pharmacies is not only related to the product (drug) but is directly related to the facility and the pharmaceutical personnel practicing in it. By Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency (Perpres 80/2107), the Indonesian Food dan Drug Authority or BPOM is one of the institutions mandated to supervise drugs and food products (Wikipedia, n.d.-a). One of BPOM's roles is to supervise products after they are in circulation. This supervision aims to ensure that drugs and food in circulation meet established safety, efficacy, and quality standards. BPOM also acts in law enforcement by imposing administrative sanctions by applicable regulations. In addition, BPOM has the authority to conduct intelligence activities and investigations into criminal acts related to drugs and food.

Several studies have shown that the supervisory performance carried out by BPOM has not gone well. Rusydi Ridha's research states that health law enforcement in the field of drugs and food has not been effective (Ridha, 2017). Kalid et al. research shows that the supervision carried out by BPOM Aceh on hard drugs has not been maximized (Khalid et al., 2022). In addition, the effectiveness of BPOM supervision is in the spotlight of the community due to the discovery of several deaths in children allegedly due to the presence of hazardous substances in the syrup drug mixture (Kemalasari et al., 2023). Based on the descriptions above, the author is interested in examining the extent of the legal effectiveness of BPOM in conducting supervision, especially on the sale of hard drugs without a doctor's prescription at pharmacies.

Effective is the extent to which the objectives of the group can be achieved. The law is said to be effective if the law has a positive impact, which can achieve its goals of guiding or changing human behavior so that it becomes legal behavior. According to Achmad Ali, legal effectiveness is related to the extent to which the law is obeyed by the target of the law. According to him, the factor that has a major influence on the effectiveness of a law is the ability and efficiency of law enforcers in carrying out their roles, authorities, and functions, both in explaining their duties and in enforcing the rule of law itself (Achmad Ali, 2017b). This theory, in this study, the author wants to analyze legal effectiveness in BPOM supervision activities as part of enforcing regulations related to the sale of hard drugs without a prescription in pharmacies. The research will discuss the extent to which BPOM carries out its function in conducting supervision, how pharmacies comply with the rules for the delivery of hard drugs without a prescription, and what factors affect legal effectiveness in the sale of hard drugs without a prescription in pharmacies.

2. Research Methods

This research is an empirical juridical research. The empirical method is used to see how the law applies as a norm to certain legal events in society. This research was conducted in pharmacies in Gorontalo Province and the Food and Drug Supervisory Agency in Gorontalo (BPOM Gorontalo). The informants in this research are pharmacy owners and pharmacists in charge of pharmacies in the Gorontalo area and BPOM Gorontalo officers. Primary data were obtained from interviews and survey results of pharmacists in pharmacies. The data obtained, both primary and secondary, were processed and then analyzed using descriptive qualitative methods. The data/information collected is explained, described, and described by the formulation of this research problem, then used to draw a conclusion based on the analysis that has been carried out.

3. Results and Discussion

3.1. Legal Effectiveness in BPOM's Supervision of Non-Prescription Sales of Hard Drugs in Pharmacies

Implementation of Pharmacy Supervision by the POM Center in Gorontalo

BPOM Gorontalo is one of the BPOM technical implementation units in Gorontalo Province. By Article 4 of BPOM Regulation No. 19 of 2023 concerning Organization and Work Procedures of Technical Implementing Units at BPOM, one of the main tasks and functions carried out by BPOM Gorontalo is the inspection of pharmaceutical service facilities in Gorontalo Province. The supervised facilities consist of pharmacies, hospital pharmaceutical installations, health centers, clinics, drug stores, or joint practices. By the provisions of Article 11 Paragraph 1 of BPOM Regulation No. 24 of 2021 concerning Supervision of the Management of Drugs, Medicinal Materials, Narcotics, Psychotropic Substances, and Pharmaceutical Precursors in Pharmaceutical Service Facilities (PerBPOM 24/2021), drug

management supervision activities in pharmaceutical service facilities are carried out through inspection by officers. In conducting drug management checks at pharmacies, BPOM Gorontalo officers are guided by technical guidelines and provisions of laws and regulations related to facility and product supervision and are guided by the established Standard Operating Procedures (SOP). By the SOP, officers who can conduct inspections in pharmacies must have qualifications, among others: have attended appropriate training and have been qualified according to the level of drug supervision inspector, have good communication skills, understand the laws and regulations relating to supervision and be able to operate a computer.

In carrying out routine checks, all types of drugs managed in pharmacies will be checked by officers, including narcotics, psychotropic drugs, precursors, OOT, antibiotics, vaccines, other CCPs, hard drugs, limited free drugs, and over-the-counter drugs. The inspection aims to check the availability of drugs, as well as to ensure the quality, efficacy, and safety of drugs, and to prevent irregularities in drug management. The inspection is carried out using pharmacy inspection tools which include checks related to aspects of the legality of facilities, procurement, receipt, storage, delivery, return, and recording and reporting. If a violation is found, by its authority in Article 4 letter c of Perpres 80/2017, BPOM can impose administrative sanctions by the provisions of laws and regulations.

In the interval 2020-2022, from a total of 183 pharmacies in Gorontalo (Kementerian Kesehatan RI, 2022), BPOM Gorontalo inspected 90 pharmacies in 2020, 69 pharmacies in 2021, and 191 pharmacies in 2022. Of the number of pharmacies inspected, most pharmacies were declared not meeting the requirements. Consecutively from 2020-2022, pharmacies that did not meet the provisions amounted to 68%, 86%, and 54% of the total pharmacies inspected each year. Pharmacies that do not meet the provisions can be caused by expired licenses, distributing unregistered / prohibited products, procuring drugs from unauthorized sources, storage conditions for products that do not comply with the provisions, managing drugs that are not suitable for sale / damaged/expired, poor recording and documentation, destruction is not by the provisions, and also includes the delivery of hard drugs without a doctor's prescription (outside OWA list).

Based on data from BPOM Gorontalo, most pharmacies still deliver/sell hard drugs without a doctor's prescription from 2020-2022. Sequentially from 2020-2022, pharmacies that sold hard drugs without a prescription amounted to 69%, 90%, and 66% of the total pharmacies inspected each year. By the supervision guidelines, pharmacies that fulfill the provisions are given follow-up in the form of guidance, while pharmacies that do not fulfill the provisions are given follow-up in the form of administrative sanctions. Based on BPOM Gorontalo data, most pharmacies are given administrative sanctions. In 2020, 95.5% of pharmacies inspected were given administrative sanctions. In 2021 97.1% of pharmacies were given sanctions, as well as in 2022 around 91% of pharmacies inspected were given administrative sanctions. Administrative sanctions given are warnings, strong warnings, and temporary suspension of activities. By BPOM data, no pharmacies have been given sanctions recommending license revocation.

Legal Obedience

Achmad Ali stated that to assess effectiveness in the field of law, we need to evaluate the extent to which legal rules are obeyed. The law is said to be effective if the purpose of the rule of law can be achieved. Drug supervision by the provisions of Law 36/2009 aims to protect the public from dangers caused by improper use of drugs and or dangers from drugs that do not meet quality, efficacy, and safety requirements. Related to this research, the supervision of the sale of hard drugs without a doctor's prescription in pharmacies carried out by BPOM is intended to protect the public from the risk of hard drugs that are not guaranteed safety, efficacy, and quality as well as irregularities in the management of hard drugs.

In carrying out its function as a supervisory agency, according to the author, BPOM Gorontalo has carried out its duties and authorities by the mandate given to it by the state. BPOM Gorontalo can be said to have carried out the stages of supervision properly starting from planning, implementing supervision, and providing follow-up, to monitoring and evaluating the pharmacies inspected. However, when analyzed from the results of pharmacy supervision obtained from BPOM itself, it can be concluded that the supervision carried out is still not effective, especially regarding the implementation of enforcement of the rules for selling hard drugs without a doctor's prescription.

Ineffective supervision is indicated by the data that there is no significant decrease or decrease to below 50% of pharmacies that violate the provisions between 2020-2022. Most (>50%) pharmacies continue to commit violations that are likely to be the same from year to year. In addition, it can also be seen that most, if not all, of the pharmacies inspected, continued to sell hard drugs without a doctor's prescription from 2020 to 2022. When analyzed based on the follow-up that has been given, it can also be seen that from 2020-2022 there was no decrease in violating pharmacies even after being given administrative sanctions. Pharmacies given administrative sanctions are still around 90% of the number of pharmacies inspected from 2020-2022. In addition, based on BPOM data from 103 pharmacies that were repeatedly inspected in 2020-2022, 65% of pharmacies still repeated violations related to the sale of hard drugs in the next inspection.

From the data submitted by BPOM officers above, it is clear that the compliance of pharmacies with the rules for selling hard drugs is still very low. This is supported by information summarized from interviews with owners and pharmacists in charge of pharmacies as well as information from questionnaires that have been filled out by pharmacists who own and/or are in charge of pharmacies.

Based on information from questionnaires filled out by pharmacists who own and/or are responsible for pharmacies, most of them stated that they had been inspected by BPOM officers and had received administrative sanctions, including warnings, strong warnings, and temporary suspension of activities. Most of the informants stated that they had followed up and made improvements to the officer's findings according to the follow-up letter received. Furthermore, to the question of whether after receiving sanctions the pharmacy still sells hard drugs without a prescription, some informants stated that they had not sold hard drugs without a prescription, especially antibiotics,

but some stated that they still sold hard drugs without a prescription. Based on information from interviews with pharmacy owners, the prohibition on the sale of hard drugs without a prescription is felt to be very burdensome for pharmacies, especially related to the prohibition of drug delivery between fellow pharmacies and drug delivery to medical personnel such as doctors and nurses, which causes findings related to these violations by officers to be repeated.

Based on the data from BPOM Gorontalo, and the results of interviews and questionnaires above, it can be concluded that the supervision carried out by BPOM Gorontalo has not had a significant impact on the compliance of pharmacies with the rules for selling hard drugs. Thus, according to the author, it can be said that the legal effectiveness of BPOM Gorontalo's supervision of the sale of hard drugs without a doctor's prescription has not been effective because most pharmacies still do not comply with the rules for the delivery of hard drugs which must be based on a doctor's prescription.

The ineffectiveness of the law in the implementation of BPOM Gorontalo's supervision of non-prescription hard drugs can cause the legal certainty of the community to obtain protection from the state not fulfilled. People who consume hard drugs can face higher risks from the dangers of using hard drugs that are not appropriate and/or do not meet the quality, efficacy, and safety requirements in their efforts to achieve optimal health status.

Sanctions

If we view the law as a rule, then we must recognize sanctions as one of its essential elements. Sanctions are reactions, consequences, or consequences of violations or deviations from social rules, both legal and nonlegal rules. Sanctions are also a powerful tool of power to enforce the observance of certain social rules. According to Achmad Ali, external sanctions are an essential element of the law that distinguishes it from illegal social rules. With sanctions, society is brought to comply with the rule of law. With sanctions, public obedience to the law can be maintained (Achmad Ali, 2017a).

By Article 4 paragraphs b and c of Perpres 80/2017, BPOM has the authority to conduct intelligence and investigation in the field of drug and food control and the authority to impose administrative sanctions by the provisions of laws and regulations. If the sale of hard drugs is carried out by a person who does not have the expertise and authority to carry out pharmaceutical practices, by the provisions of Article 198 of Law 36/2009, he/she can be punished with a maximum fine of Rp. 100,000,000 (one hundred million rupiah). However, if the sale of hard drugs occurs in a pharmacy that has a license and a pharmacist as the person in charge, legally the criminal elements in Article 198 of Law 36/2009 cannot be fulfilled. For this reason, regarding violations of provisions related to the sale of hard drugs in pharmacies, BPOM can only impose administrative sanctions.

The provision of administrative sanctions by BPOM is regulated in BPOM Regulation No. 19 of 2020 concerning Guidelines for Follow-up Supervision of Drugs and

Medicinal Materials. By this regulation, facilities that have been supervised are given follow-up in the form of technical guidance and/or administrative sanctions. Follow-up in the form of administrative sanctions that can be given to pharmaceutical service facilities such as pharmacies include warnings, strong warnings, temporary suspension of activities, and recommendations for license revocation.

Based on data from BPOM Gorontalo, in 2020 from several pharmacies inspected 95.5% of pharmacies were given administrative sanctions with details of 33.3% of pharmacies given warnings, 52.2% of pharmacies given strong warnings and 10% of pharmacies given sanctions Temporary suspension of activities. In 2021, 97.1% of pharmacies inspected were given administrative sanctions with details of 36.2% of pharmacies given warnings, 58% of pharmacies given strong warnings and 2.9% of pharmacies sanctioned with temporary suspension of activities, as well in 2022 from around 91% of pharmacies inspected were given administrative sanctions with details of 38.7% of pharmacies given warnings, 45% of pharmacies given strong warnings and 7.3% of pharmacies sanctioned with temporary suspension of activities.

Based on information from interviews and questionnaires, it is also known that most pharmacies have received administrative sanctions, be it warnings, strong warnings, or temporary suspension of activities. The pharmacy has also followed up with improvements sent to BPOM. However, during the inspection in the following years, the same violations were still found.

From the data and information above, it can be concluded that the imposition of administrative sanctions on pharmacies has not caused any change in compliance or the deterrent effect for pharmacies that commit violations. According to the author, it could be that many pharmacies are still non-compliant because there are no pharmacies that have been given the heaviest sanction in the form of license revocation according to BPOM's authority. Direct monitoring after improvements made by pharmacies are not carried out continuously by BPOM may also be one of the causes. The lack of firmness of BPOM in imposing sanctions by its authority against pharmacies that commit repeated violations and the absence of awareness from pharmacies to comply with the rules can be the cause of ineffective law in the implementation of BPOM supervision of the sale of hard drugs without a prescription in pharmacies.

Socialization

Legal effectiveness is closely related to the awareness and legal obedience of citizens. One way to make the law effective is determined by how the law is communicated. In functioning the law as a tool of social engineering, the process of socialization of legislation is very important so that the law or rule of law applies effectively.

Socialization aims to make the community aware of the presence of a law or regulation, the community knows the contents of the law or regulation, and so that the community can adjust both their mindset and behavior to the objectives desired

by the law or regulation. Likewise, regarding laws or regulations that threaten sanctions, maximum or as much socialization should be carried out to the public so that the public knows the severity of the threats that can be imposed on offenders who violate them (Achmad Ali & Wiwie Heryani, 2015).

By the mandate of Article 29 of Permenkes 9/2017 concerning Pharmacies and Article 10 of Permenkes 73/2016 concerning Pharmaceutical Service Standards in Pharmacies, in addition to being carried out by the Minister of Health, head of the provincial health office and the head of the district/city health office in stages according to their authority, BPOM is also carried out. BPOM has been mandated to provide guidance and guidance on the management of pharmaceutical preparations to government agencies and the community in the field of supervision of pharmaceutical preparations.

According to the results of interviews with BPOM Gorontalo officers, the ineffective implementation of hard drug regulations by pharmacies is partly because the results of supervision have not been used as a basis for guidance followed up with guidance by related BPOM sections or by other related institutions. Activities that have not been synchronized internally and externally can cause coaching activities to pharmacies and the public, especially related to hard drugs, cannot be carried out optimally. In addition, according to officers, guidance activities related to laws and regulations related to drug management in pharmacies can only be carried out on a limited basis. Usually, activities in the form of meetings can only be carried out once or twice a year and even then they cannot involve all parties in the pharmacy and cannot invite all pharmacies due to budget constraints. As a form of guidance, information related to laws and regulations that are violated in drug management activities by pharmacies is conveyed at the closing meeting of the inspection and in every follow-up letter sent to the pharmacy.

Based on information from the questionnaire, most pharmacists stated that BPOM has conducted guidance and coaching activities for pharmacists related to the management of hard drugs. This is also supported by the results of interviews, all of which stated that they had been given guidance and coaching. According to the pharmacy owners interviewed, it was the pharmacists who participated in the coaching activities and then they conveyed the rules to them.

By the results of the interviews and questionnaires above, according to the author, BPOM in Gorontalo has conducted guidance related to drug management, especially the sale of hard drugs without a doctor's prescription in pharmacies, but the guidance activities carried out have not been maximized. Coaching has not involved all pharmacy parties, especially pharmacy owners, and guidance to the public regarding the dangers of inappropriate or irrational use of drugs has not been widely carried out, which is likely to be the cause of ineffective supervision. In addition, because coaching pharmacies is also the responsibility of related agencies and professional organizations, coordination and cooperation between parties are needed to increase the knowledge and awareness of pharmacy business actors, pharmacists, and the public about regulations related to drugs, especially hard drugs.

3.2. Factors Affecting Legal Effectiveness in Supervising the Sale of Hard Drugs Without a Prescription at Pharmacies

The ineffectiveness of the law in the implementation of supervision carried out by BPOM Gorontalo on the sale of hard drugs in pharmacies is certainly influenced by many complex factors. According to Soerjono Soekanto, the factors that can affect the effectiveness of law enforcement are the legal factors themselves, law enforcement factors, facilities or facilities that support law enforcement, community factors, and cultural factors (Soerjono Soekanto, 2019).

Regulations Regarding Prescription Drugs

The legal substance factor or the rule of law itself is a factor that determines the functioning of law in society. The measure of effectiveness can be seen from whether the existing regulations are systematic enough, synchronized hierarchically and horizontally there is no conflict, whether the regulations are sufficient, and whether the issuance is by the requirements.

Based on information obtained from the questionnaire, some informants stated that the rules related to the sale/delivery of hard drugs were not clear and adequate, and some stated that they were clear and adequate but stated that there was still a need for more socialization. Informants who stated that the existing regulations are unclear and inadequate argued that the regulations limit pharmacists in providing services to the community, there has been no renewal of the OWA list, and pharmacists need to be given the authority to deliver hard drugs outside the OWA list to patients on a limited basis, especially to accommodate small communities who cannot afford to see a doctor and reasons for lack of socialization.

Based on the results of the interviews, related to the rules on the delivery of hard drugs must be with a doctor's prescription, the pharmacy owner informants stated that the existing rules were very burdensome, especially the rules for selling drugs between pharmacies. Meanwhile, the pharmacists interviewed stated that the existing rules limit the practice of pharmacists, especially for self-medication services, the existing rules are ambiguous even though in terms of competence/capacity pharmacists can hand over hard drugs, rules related to the prohibition of hard drugs need to be reviewed because it is possible that the regulations are made not based on the profession but based on case studies and there are already rules on OWA list but they are not updated. According to information from BPOM Gorontalo officers, in general, there are no obstacles in the implementation of supervision rules, especially for hard drugs, but according to the officers, BPOM regulations related to drug management are too rigid compared to the Minister of Health's regulations on pharmaceutical service standards.

Based on the results of the interviews and questionnaires above, the author concludes that the rules related to the delivery of hard drugs based on a doctor's prescription are still not clear and adequate for pharmacists and are burdensome for pharmacy owners. Rules stating that hard drugs must be prescribed by a doctor limit

the practice of services to people who do self-medication, even though pharmacists can deliver hard drugs according to their expertise.

By Article 3 paragraph 1 and Article 4 paragraph 1 of Law No.419/1949 on Hard Drugs, pharmacists who lead pharmacies are not prohibited from delivering, selling, and possessing List G hard drugs and List W hard drugs. Meanwhile, the provisions of Law 36/2009 on Health do not mention specific rules related to the delivery of hard drugs based on a doctor's prescription. Provisions for the delivery of hard drugs based on a doctor's prescription are only contained in government Regulations, Ministerial Regulations, and Agency Regulations which are hierarchically under the Law.

According to Article 21 paragraph (2) and Article 24 letter c of PP 51/2009, Kepmenkes No. 02396/A/SK/VIII/86, and PerBPOM 24/2021, the delivery of hard drugs to patients can only be done based on a doctor's prescription and delivered by a pharmacist. These rules are not in sync with the provisions in Law 419/1949 on Hard Drugs, which states that pharmacists can deliver hard drugs even without a doctor's prescription. This lack of clarity and synchronization allows pharmacists in pharmacies to disobey the rules regarding the delivery of hard drugs with a doctor's prescription. Such disobedience may lead to ineffective legal effectiveness in the supervision of hard drugs in pharmacies.

Inspection by Officers

Law enforcement factors and facilities that support the implementation of their duties, affect whether or not legal performance is effective. Law enforcers are those who are directly or indirectly involved in law enforcement. While the means or facilities that support law enforcement include educated and skilled human resources, good organization, adequate equipment, sufficient finance, and so on. According to Achamad Ali, whether a rule of law is effective or not depends on whether the legal apparatus is optimal and professional in enforcing the law, besides that the optimal socialization factor also affects effectiveness.

By information obtained from BPOM Gorontalo officers, the implementation of pharmacy supervision has been carried out through a series of processes. Starting from planning, preparation, conducting inspections, reporting, providing follow-up, monitoring the completion of CAPA to evaluating follow-up. A series of supervision processes have been carried out based on the authority given and guided by established mechanisms and procedures. Officers who carry out inspections are also officers who have met the required competencies and in carrying out inspections officers have been provided with facilities in the form of facilities and infrastructure that support supervisory activities. Apart from supervising pharmacies, BPOM officers have also conducted socialization related to drug management.

Based on the information that can be summarized from the questionnaire, related to the implementation of pharmacy inspections by BPOM Gorontalo officers, most pharmacists stated that officers never notify the pharmacy of their arrival, officers always show their identification and assignment letter, officers explain the purpose of

the inspection and the scope to be examined, officers conduct a physical examination of drugs and related documentation, officers examine various aspects of drug management, after each inspection the officer explains the results and findings of the inspection, the officer provides an opportunity for the pharmacy to confirm the findings, the officer provides a copy of the inspection results, and the officer has sent follow-up inspection results. In addition, based on the results of the questionnaire, informants stated that apart from conducting inspections, BPOM had also conducted socialization.

From the information above, it can be concluded that BPOM officers have carried out pharmacy inspections by the provisions of established mechanisms and procedures. Regarding the competence of the inspectors, based on the results of the interviews, the informants stated that the officers who came to the pharmacy had good competence and could explain regulations well. In addition, based on interviews, informants said that the facilities and infrastructure used by BPOM officers were quite good.

Based on the things described above, the author argues that the factor of Gorontalo POM Center officers who have worked by their duties and functions and carry out their authority properly and have been equipped with good supporting facilities affects the effectiveness in supervising the sale of hard drugs without a prescription in pharmacies. However, it is still necessary to improve coordination and cooperation between agencies that also supervise pharmacies and maximize socialization so that the rules for selling hard drugs based on a doctor's prescription can run more effectively.

Self-medication

Community factors where the law is enforced and cultural factors that exist in society greatly affect the effectiveness of the law. These factors will be analyzed for their influence on legal effectiveness in this study through the practice of self-medication that is common in pharmacies.

Self-medication is an attempt by people to treat themselves without consulting a doctor. The increasing trend of self-medication can be attributed to the urge for self-care, sympathy for sick family members, lack of time, lack of health services, financial constraints, ignorance, misunderstanding, extensive advertising, and availability of drugs. Self-medication will be safe if the person using the medicine has sufficient knowledge about the dosage, timing of consumption, and side effects in overdose, but due to lack of information related to the medicine consumed it can cause serious effects such as antibiotic resistance, skin problems, hypersensitivity and allergies (Bennadi, 2014).

Pharmacies are not only a means to practice the pharmacist profession through pharmaceutical preparation services to the community, but also a business place whose purpose is to make a profit. Often this business aspect is prioritized so that for this purpose pharmacies provide access and convenience for the public to obtain drugs at pharmacies. This practice of serving the needs of self-medication then

makes pharmacies take actions that are not by the provisions of the pharmaceutical service standards.

By the provisions in Permenkes 73/2016, pharmacists in nonprescription drug services or self-medication services can only provide appropriate free or limited free drugs and provide education to patients who need these drugs. However, in practice, many pharmacies serving the public who do self-medication violate the provisions by providing hard drugs other than the OWA list without a prescription and not providing a complete explanation regarding the use of the drugs provided. These practices can certainly cause harm to the community.

Based on data from the BPS national socio-economic survey (Susenas) in Marchin 2019-2021, the trend of Gorontalo people practicing self-medication has increased. The percentage of Gorontalo residents who have health complaints and have self-medicated has increased from 73.76% in 2019 to 73.85% in 2020 and increased again to 81.58% in 2022. According to BPOM Gorontalo data, there was also an increase in the sale of hard drugs, especially in 2021. Based on BPOM data, it can be concluded that in the 2020-2022 period, the public's habit of self-medicating hard drugs is still very high.

Based on information obtained from questionnaires and interviews, most informants stated that self-medication by the community was one of the drivers that led to the practice of selling hard drugs without a prescription at pharmacies. Informants argued that people do self-medication because they have generally used the same medicine and need the medicine. In addition, according to the informants, the delivery of hard drugs for self-medication can be done by pharmacists as long as the patient is given correct information and education.

Based on the things described above, it can be concluded that self-medication has become a habit in the community when they experience problems with their health. Self-medication supported by pharmacy services that are not by the established pharmaceutical service standards certainly affects the legal effectiveness in enforcing the rules on the sale of hard drugs without a prescription at pharmacies carried out by BPOM Gorontalo. The implementation of pharmaceutical service standards in pharmacies is aimed at improving service quality, ensuring legal certainty for pharmaceutical personnel, and protecting patients and the public from irrational use of drugs in the context of patient safety. If in the service of self-medication, this is not applied, then there is no certainty for the community to get protection from the dangers of using hard drugs.

Covid-19 Pandemic

According to Wikipedia.id The Covid-19 pandemic is the event of the spread of coronavirus disease 2019 (Coronavirus disease 2019 abbreviated as Covid-19) worldwide in all countries (Wikipedia, n.d.-b). Covid-19 is an infectious disease caused by a coronavirus named SARS-CoV-2 (*Severe Acute Respiratory Syndrome Coronavirus 2*) (Kementerian Kesehatan RI, 2020). The Covid-19 pandemic has changed the order that has been carried out by humans in all countries in the world.

The Covid-19 pandemic affects not only health services but also public services around the world. This pandemic has led to the birth of new laws that affect people's lives so that people can continue to live well amid a pandemic.

A country needs effective legal instruments to control the pandemic in its country to ensure the fulfillment of the basic needs of its citizens (Indar et al., 2021). As a measure of prevention and control of Covid-19, the government has issued various regulations, including Law No. 6 of 2018 concerning Health Quarantine, Government Regulation No. 21 of 2020 concerning PSBB in the Context of Accelerating Covid-19 Handling, Presidential Decree No. 11 of 2020 concerning the determination of Covid-19 Public Health Emergencies, Presidential Instruction No. 4 of 2020 concerning Refocussing Activities, Budget Relocation, and Procurement of Goods and Services in the Context of Accelerating Covid-19 Handling, Minister of Health Regulation No. 9 of 2020 on Guidelines for Large-Scale Social Restrictions in the context of Accelerating the Handling of Covid-19, Circular Letter of Menpan RB No. 19 of 2020 on Adjusting the Work System of State Civil Apparatus in Efforts to Prevent the Spread of Covid-19 in Government Agencies, and various other regulations and policies.

Based on information from interviews with BPOM Gorontalo officers, during the Covid-19 Pandemic period regulations related to restrictions on the movement of people in an area, refocusing the budget for handling Covid-19, adjusting the ASN work system (Work From Office or Work From Home) and especially due to considerations of officer safety in the field, the implementation of supervision carried out by BPOM Gorontalo was also adjusted. During the pandemic period, based on policies issued by the center, the pharmacy inspection target was reduced by around 20-25 percent from that set at the beginning of the year. Regarding the implementation of the inspection, a policy was also issued to conduct online or desktop inspections if local inspection is not possible at the facility. Supervision guidelines are also adjusted to pandemic conditions. The focus of supervision is also more focused on service facilities that manage Covid-19 vaccines, Covid-19 drugs and Covid-19 supporting drugs. In addition, during the local inspection, officers are required to use personal safety equipment (such as masks, face shields, and gloves), strictly implement health protocols and inspection activities are carried out in such a way that contact with other people in the facility is limited and the inspection time is more accelerated than usual.

Based on data obtained from the BPOM Gorontalo, we can see the effect of the pandemic on the number of pharmacies inspected. In 2020, only around 90 pharmacies were inspected out of 183 existing pharmacies and there was another decline in 2021 to 69 pharmacies. In addition, the data also shows a high increase in non-compliant pharmacies and pharmacies selling hard drugs without a prescription, especially in 2021. This increase may be due to an increase in the purchase of hard drugs without a prescription for self-medication purposes during the Covid-19 pandemic. This is supported by BPS Susenas data which shows an increase in the percentage of Gorontalo residents practicing self-medication as stated above. In addition, based on the BPS survey in 2021, the reasons why residents who have health complaints have never had outpatient care, namely because they self-

medicate (68.11%) because they do not need to (15.11%), and because they are worried about being exposed to COVID-19 (13.51%) (Badan Pusat Statistik, 2021).

Based on information summarized from the questionnaires, most informants stated that drug sales in pharmacies increased during the pandemic because people were afraid to see a doctor or healthcare facility and preferred self-medication. Meanwhile, based on information summarized from interviews, informants generally stated that there was no effect on the sale of hard drugs because sales were the same as before the pandemic. According to informants, what has increased significantly is the sale of vitamins or health supplements to maintain the body's immunity. According to informants, Covid-19 drugs, which are classified as hard drugs, are only delivered by certain pharmacies and are under strict supervision.

Based on the data and information above, it can be concluded that the Covid-19 pandemic is one of the factors that affect the effectiveness of the implementation of supervision carried out by BPOM Gorontalo. During the Covid-19 pandemic, there was an increase in the purchase of drugs, including hard drugs, by the public, which encouraged many violations of the provisions on the sale of hard drugs. On the officer side, the Covid-19 pandemic has caused limitations in conducting supervision. This has caused the rules for the delivery of hard drugs with a doctor's prescription cannot be effectively enforced during the Covid-19 Pandemic period.

4. Conclusion

The implementation of supervision has been carried out by BPOM in Gorontalo by its duties and authority properly. Examination by officers has been carried out by established mechanisms and procedures. However, legal effectiveness in the implementation of supervision of the sale of hard drugs without a prescription in pharmacies can be said to be ineffective. The ineffectiveness of the law can be caused by the fact that most pharmacies still do not comply with the rules for selling/delivering hard drugs based on a doctor's prescription, sanctions that are not yet firm, and socialization that has not been maximized.

The factor of hard drug regulations that are not clear and there is still a lack of synchronization, the factor of the implementation of examinations by officers still needs to be improved, especially regarding the provision of guidance or socialization of regulations related to hard drugs, the factor of services for self-medication of hard drugs that are not by pharmaceutical service standards and the Covid-19 pandemic factor, affecting legal effectiveness in the implementation of BPOM Gorontalo supervision of the sale of hard drugs without a doctor's prescription in pharmacies.

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