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THE ROLE OF THE GOVERNMENT IN SUPERVISING THE CIRCULATION OF NON-PRESCRIPTION DRUGS THROUGH ONLINE SALES IN THE PERSPECTIVE OF LAW NUMBER 8 OF 1999 CONCERNING CONSUMER PROTECTION

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Abstract: *Distribution of drugs without prescriptions through online sales has become a rapidly growing trend. This makes it easier for people to get medicine, but also poses potential risks to consumer health and safety. The aim of this research is to analyze the government's role in monitoring the distribution of non-prescription drugs through online sales in the perspective of Law Number 8 of 1999 concerning Consumer Protection. This research uses normative research methods. The data collection technique in this research is literature study. The data that has been collected is then analyzed in three stages, namely data reduction, data presentation and drawing conclusions. The research results show that in the perspective of Law Number 8 of 1999 concerning Consumer Protection, the government's role in monitoring the distribution of non-prescription drugs through online sales includes protecting consumers from unregistered, unauthenticated or counterfeit drugs. The government is responsible for ensuring that medicines sold online are safe, registered and meet established quality standards. Apart from that, the government also needs to monitor the practice of selling drugs without a prescription online to prevent drug abuse and protect consumers from unwanted health risks. This monitoring effort can be carried out through regulations, inspections and collaboration with related parties, such as drug control agencies and the community.*

Keywords: *Government, Supervision, Distribution of Non-Prescription Medicines, Online Sales, Consumer Protection.*

INTRODUCTION

The rapid development of technology has changed many aspects of human life, including the way people buy medicines. Today, with the advent of electronic trading platforms and specialized websites, buying drugs without a prescription online has become a popular option for many people. This phenomenon is triggered by various factors, including convenience, accessibility, and the variety of choices offered online. Now, people can easily search and buy medicines without the need to leave home. However, these changes also bring new challenges, especially related to the safety and authenticity of drugs sold online.

In selling over-the-counter drugs online, one of the challenges is that it is difficult to verify the authenticity of the product, and often consumers are vulnerable to purchasing counterfeit drugs or drugs that do not meet established health standards. This can have a negative impact on the health of consumers, as the use of counterfeit or low-quality drugs can result in serious or even life-threatening side effects (Subiyakto & Markoni, 2023). Therefore, it is important for governments to play an active role in supervising and regulating the sale of drugs online, in accordance with the existing legal framework, to protect consumers from risks that may arise and ensure that drugs purchased online are safe and of high quality.

The government makes consumer protection efforts in supervising the circulation of non-prescription drugs through online sales implemented in various policies, one of which is Law Number 8 of 1999 concerning Consumer Protection. Law Number 8 of 1999 concerning Consumer Protection contains consumer protection from unsafe, unhealthy, and inappropriate products and services. The law also regulates consumer rights and obligations, the responsibilities of producers and traders, and consumer protection agencies. This law aims to protect consumers from unsafe, unhealthy, and inappropriate products and services, as well as improve the quality of products and services available in the market (Pemasela & Gerungan, 2023).

Previous research by (PRATAMASYAH, n.d.) found that BPOM supervision in order to protect

consumers carries out very strict supervision related to the free circulation of hard drugs online, starting from pre-market to post-market and conducting cyber patrols using data crawler tools to take down advertisements or stores that sell free hard drugs online, and the obstacle experienced by BPOM is that there are too many online media that must be monitored every day whose names are disguised and others.

Other research by (Siregar & Darmawan, 2023) found that there are still consumers who buy hard drugs without a doctor's prescription at pharmacies. The reason consumers buy hard drugs without a doctor's prescription at pharmacies is the low level of public knowledge, especially related to drug classes so that they do not know the drug class and the requirements for buying hard drugs, the next reason is to get these drugs easily and quickly and the costs incurred are smaller / fewer. The efforts made by BBPOM in Banda Aceh in preventing the practice of buying and selling hard drugs in pharmacies are educating pharmacy business actors both by direct education to pharmacy facilities and conducting technical guidance education and supervising pharmacies by requiring pharmacy business actors to routinely report the sale of drugs to BBPOM every month.

The novelty of this study is to examine the role of the government in supervising the circulation of non-prescription drugs in the perspective of Law Number 8 of 1999 which has never been studied before in the context of online sales. This research provides a deeper understanding of the importance of consumer protection in the context of online drug sales, and highlights the need for government involvement in regulating and monitoring these practices in accordance with existing legal frameworks. In addition, this research can also provide a foundation for improved policies and surveillance strategies that are more effective in maintaining public safety and health related to the use of non-prescription drugs online. The purpose of this study is to analyze the role of the government in supervising the circulation of non-prescription drugs through online sales in the perspective of Law Number 8 of 1999 concerning Consumer Protection.

MATERIALS AND METHODS

This study used normative research methods. Normative research methods are research methods that focus on the study of norms or rules that apply in society and become a reference for everyone's behavior. This method uses normative case studies in the form of legal behavior products, for example reviewing laws (Tan, 2021). The data collection technique in this study is by literature study. The literature study was conducted by exploring laws and regulations related to drug control, consumer protection, books, journals, and scientific articles related to drug control, online sales, and consumer protection. The data that has been collected is then analyzed in three stages, namely data reduction, data presentation and conclusions.

RESULTS AND DISCUSSION

In the modernization era like now, technological developments have been significant in influencing various aspects of life, especially in the trading and buying and selling sectors. The phenomenon of online sales or e-commerce has become a very popular trend in recent years (Reza, 2016). The advancement of e-commerce in Indonesia is influenced by several factors such as, the first is the rapid development of smartphones because in the current era most people have smartphones. Second, the purchasing power of the Indonesian people from year to year is getting higher. Third, people who are increasingly technologically literate so that it is easy to adapt to new technology. In addition, this is also due to the Covid-19 pandemic in recent years. The pandemic has an impact on the community in meeting their needs because it requires people to reduce transactions directly and switch to using e-commerce platforms as a prevention in the transmission of the Covid-19 virus (Maulana et al., 2021).

In addition to these supporting factors, the rapid pace of online sales is also due to the conveniences offered, as quoted in (Srisadono, 2018), such facilities include:

1. The process of business transactions can be done online, allowing customers to buy products or services easily without the need to come directly to a physical place.

2. Online sales provide a variety of payment options, both domestic and international, via credit card, bank transfer, or other digital payment methods, making it easier for consumers from various locations.
3. Businesses can easily expand their market coverage with more flexible business expansion, without being limited by geographical boundaries.
4. Digital promotional media in online sales are more affordable and interactive, allowing businesses to reach a larger audience at a lower cost.
5. Information related to operational costs, including product prices, discounts, and shipping costs, can be clearly accessed by consumers, increasing transparency in business transactions.
6. Products or services can be presented digitally, making it easier for consumers to explore and buy without having to interact directly with the goods or services.
7. Online sales systems streamline the distribution process, ensuring products reach customers more quickly and efficiently through integration with logistics service providers.
8. Online sales provide a means to disseminate information about the uniqueness of products, expand the area of market share with the aim of achieving profits and more competitive competitiveness globally.

Because of this convenience, online sales have penetrated into various sectors, including the sale of medicines (Ekadipta et al., 2022). Like the market in general, online sales also provide various types of products and services that can be purchased. Included in this are medicines, vitamins, medical devices, and others (Siswanto et al., 2022). A drug is a substance used in the diagnosis, treatment, prevention, cure, or reduction of symptoms of disease in animals or humans. Alternative interpretations of treatment include combinations of elements or materials used by the organism, either internally or externally, to prevent, reduce, or cure disease (HIDAYAT, 2024). Meanwhile, based on Health Law number 17 of 2022, drugs are defined as ingredients or mixtures of ingredients, including biological products, that are used to affect or investigate physiological systems or pathological states with the aim of diagnosis, prevention, cure, recovery, health improvement, and contraception for humans.

The purchase of drugs online is mostly without a doctor's prescription, as it is known that pharmacy is basically always related to prescriptions, and drugs are health products that in their use must follow procedures and requirements. This is in accordance with the Minister of Health Regulation number 9 of 2017 concerning pharmacies, that drugs should be used based on a doctor's prescription, and the party providing the drug must have a license as a pharmacist. Then Law number 11 of 2008 concerning Electronic Information and Transactions (ITE) in Article 9 emphasizes that business actors who offer products through Electronic Systems must provide complete and correct information about contract terms, manufacturers, and products offered. This includes providing appropriate information about the ingredients, distribution permits, forms, efficacy, and side effects of drugs to consumers (Utami & Herwastoeti, 2022). However, due to the high market demand in the use of drugs can encourage fraudulent behavior of some entrepreneurs, who may use substances that do not comply with health standards or even harmful to increase production and profits of enterprises (Rizki, 2023).

According to (Rahmawati, 2017) Products sold online are not guaranteed safety, efficacy / benefits and quality because it cannot be ascertained whether produced by an official manufacturer or not. WHO estimates that more than 50% of drugs sold over the internet are counterfeit products. Because the source is unclear, the product is confirmed to be circulating without going through the correct regulatory process, and is suspected of using unqualified raw materials.

The circulation of drugs sold online without a doctor's prescription has a risk of harming patients due to lack of supervision from doctors and pharmacists in the use and storage of the drug. Weak health conditions in patients and society cause difficulties in making their own decisions regarding the

use of hard drugs. The risk of misuse, overdose, contraindications, and adverse drug side effects that can be detrimental to public health can occur if there is no adequate supervision (Yuningsih, 2021). The danger of circulating hard drugs and certain drugs online, if not immediately addressed, can have serious impacts that threaten the younger generation and national defense (Ariestiana, 2020).

In an effort to overcome these problems, Indonesia as a state of law upholds legal principles in regulating its citizens through its policies. The principle of the rule of law emphasizes that every state apparatus must act on the law, and every citizen is obliged to obey the applicable law (Biroli, 2015). The law is considered as a means and infrastructure to ensure a sense of security and provide legal certainty for all aspects related to human actions. One of the functions of law is to regulate various aspects of citizens' lives, including ensuring their safety through the rule of law. The State has the responsibility to protect the interests and welfare of its citizens and maintain stability, security, and order in society (Hidayat et al., 2023).

Government involvement has a very important role in both law enforcement and consumer protection, and this is reflected in Law Number 8 of 1999 concerning Consumer Protection (UUPK). According to Article 29 paragraph 1 of the Law, the Government is responsible for fostering the implementation of consumer protection that guarantees the achievement of the rights of consumers and business actors as well as the implementation of consumer and business obligations. According to (Hidayat, 2024) consumer protection when related to the legal system involving regulatory principles and policies aims to ensure the safety and welfare of consumers. This means that the fundamental purpose of consumer protection is to increase consumers' sense of security.

In the UUPK, what is meant by consumer protection is all efforts that ensure legal certainty to provide protection to consumers. Article 4 of the Law focuses on consumer rights, several aspects of which include:

1. The right to comfort, security, and safety in consuming goods or services. This right aims to support the safety of consumers in using a commodity or service by protecting them from potential losses that may occur during product consumption.
2. The right to choose goods or services and obtain such goods or services in accordance with the exchange rate and conditions and guarantees promised. This right aims to give consumers the freedom to choose products according to their needs, without being burdened by external influences.
3. The right to true, clear and honest information about the conditions and guarantees of goods or services. This right aims to provide consumers with transparent and accurate information, allowing them to understand well a product before making a purchase.

Consumer rights protection provided by the government through the UUPK can ensure that consumers get true and clear information about products, as well as provide security and safety in purchasing drugs without a prescription through online sales. Then the UUPK regulation not only involves aspects of consumer protection, but also provides provisions regarding prohibitions for business actors in producing and trading goods or services, such as in Article 8 of the UUPK, especially in paragraph (3) which states that business actors are prohibited from trading damaged, defective or used and contaminated pharmaceutical and food preparations, with or without providing complete and correct information. The ban stresses on the importance of maintaining the quality of traded products, including in the category of medicines. Then, the Government showed its responsibility in consumer protection by establishing the Food and Drug Supervisory Agency (BPOM) which has the authority to oversee the official list and quality of drugs. Through Presidential Decree Number 166 of 2000 and Number 103 of 2001, the government established BPOM which has the task, among others, to grant permits and supervise drug circulation and supervise the pharmaceutical industry (Utomo, 2017).

The Food and Drug Supervisory Agency has a legal basis in the regulations contained in BPOM Regulation Number 21 of 2020 concerning BPOM Organization and Work Procedures, which later underwent changes in BPOM Regulation Number 13 of 2022. Article 1 of the regulation explains that BPOM is a non-ministerial government institution that carries out government duties in the field of Food and Drug supervision. BPOM's mission in general is to protect public health from the risk of circulating unqualified products, as well as products that are unsafe and unfit for consumption.

BPOM has the authority as stipulated in Article 5 of the BPOM Regulation, namely the first authority to issue product distribution permits and certificates in accordance with standards and requirements for safety, efficacy / benefit, and quality, as well as testing Drugs and Food in accordance with the provisions of laws and regulations. The process of granting distribution permission for a drug involves several stages, ranging from collecting administrative requirements, the registration process addressed to the Head of BPOM, laboratory tests to determine the suitability of the drug for distribution in Indonesia, to receiving a decision on whether or not the drug is suitable for distribution or requires improvement. Drug registration involves steps such as submitting an application for registration, analysis of trials and clinical trials, assessment of the quality, effectiveness, and safety of the drug, and granting distribution authorization. All these stages are carried out to ensure the safety of drugs that will circulate in Indonesia, ensure their efficacy in curing or treating diseases, and meet high quality without causing negative side effects for users, and ensure compliance with laws and regulations and established standards (Subiyakto & Markoni, 2023).

Then in an effort to reduce the risk of counterfeit drug circulation in Indonesian society, the drug manufacturing process must follow the guidelines of Good Manufacturing Practices (CPOB). CPOB aims to ensure the quality of drugs consistently, in accordance with the quality standards specified in the distribution permit and product specifications. CPOB as a guide for the pharmaceutical industry provides instructions and examples in applying good drug manufacturing methods to all aspects and series of drug production processes. CPOB covers all aspects of production and quality control, and is the basis for ensuring that drugs are made and controlled consistently in accordance with quality standards that are in accordance with the intended use and requirements in the distribution permit (Gondokesumo & Amir, 2021).

Furthermore, the second authority of BPOM is to conduct intelligence and investigations in the field of Drug and Food supervision in accordance with the provisions of laws and regulations. The supervision in question is divided into 2, namely supervision before circulation and supervision during circulation. Paragraph 3 explains that supervision before circulation is the supervision of drugs and food before circulation as a preventive measure to ensure that drugs and food in circulation meet the standards and requirements for safety, efficacy / benefit, and quality of products set. Meanwhile, Paragraph 4 explains that supervision during circulation is the supervision of drugs and food during circulation to ensure that drugs and food in circulation meet the standards and requirements for safety, efficacy / benefit, and quality of specified products and law enforcement actions. Therefore, BPOM is not only involved in granting distribution permits and supervision before the product is circulated, but also actively conducts supervision and law enforcement as long as the product is on the market. This aims to provide maximum protection to consumers and ensure that circulating products still meet safety and quality standards.

The third authority of BPOM involves the provision of administrative sanctions in accordance with the provisions of laws and regulations. In this case, control by BPOM becomes very important to prevent drug abuse and ensure consumer protection from potential risks that can harm them. As an effort to eradicate and control the circulation of drugs, BPOM routinely conducts investigations and investigations and follows up violations of certain aspects of drugs and food. When approved by the authorities, other law enforcement agencies are also involved in implementing applicable laws. Joint

operations are often conducted with the involvement of the police to increase the effectiveness of law enforcement against drug and food-related violations (Widyaningrum & Wijaya, 2023).

One form of strict action against violations committed by manufacturers is to recall products that have been marketed. This action is taken when the product does not meet the quality requirements that have been determined and have been marketed to the public. The product recall is not only a sanction, but also as a firm action from the government through BPOM to protect consumer rights from forms of fraud that can be carried out by producers (Sudewi et al., 2020).

Although the government has a significant role in regulatory policies to protect consumers and ensure the quality and quality of drug circulation before and after circulation, there are still many cases of counterfeit drugs that are vulnerable to circulation among consumers who are not experienced in making buying and selling transactions through online causing losses that are very difficult to replace for victims. This loss is mainly due to the difficulty of catching the perpetrators of the crime, even the perpetrators can often carry out their actions without being traceable where they are (William, 2022). Therefore, further supervision efforts are needed, which can be done through several ways. First, strict enforcement of regulations needs to be implemented, including providing strict sanctions for violators who circulate counterfeit drugs. The existence of clear sanctions can be a deterrence (prevention) and provide a deterrent effect to business actors who are potentially involved in the circulation of counterfeit drugs. Secondly, routine inspection activities are also an important step in supervision. Through this activity, the government can actively inspect and supervise the drug production process, maintain quality standards are met, and detect the potential circulation of counterfeit drugs early. Third, public participation in reporting findings or irregularities related to the drugs they obtain can be a valuable source of information for the government to identify and respond to cases of counterfeit drugs more quickly.

These measures, which include strict enforcement of regulations, routine inspection activities, and public participation, are expected to increase the effectiveness of supervision of the government's role in controlling the circulation of non-prescription drugs through online sales. This joint effort is expected to create a safer and more controlled environment, this not only supports consumer protection, but also has a positive impact on people's welfare in the context of health security. In addition, better supervision is expected to prevent the risk of spreading counterfeit drugs, increase consumer confidence, and ultimately improve public welfare in health aspects.

CONCLUSION

The government has an important role in overseeing the circulation of non-prescription drugs through online sales. The government's task in this supervision involves protecting consumers from risks that may arise from the use of unregistered, inauthentic, or counterfeit drugs. Government responsibilities include aspects of safety, presence in official lists, and compliance with established quality standards. In addition, the government should also control the practice of selling over-the-counter drugs online to prevent drug abuse and ensure that consumers are protected from potential adverse health risks. This monitoring effort can be carried out through strict regulatory enforcement, routine inspection activities, as well as collaboration with drug regulatory agencies and active community participation.

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