

LEGAL PROTECTION OF CONSUMERS AND LEGAL RESPONSIBILITY OF BUSINESS ACTORS IN THE SALE OF DRUGS ABOVE THE HIGHEST RETAIL PRICE IN PHARMACIES

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Abstract - *This study aims to explore the legal protection of consumers who purchase drugs above the Highest Retail Price (HRP) at pharmacies as well as the legal responsibilities of businesses in selling drugs above the HRP. Based on the prevailing regulations in Indonesia, this study analyzes how laws and government regulations protect the rights of consumers and regulate the obligations of business actors. The research method used is normative legal analysis with a statutory approach. The results show that there is adequate legal protection for consumers, but implementation in the field still requires strict supervision. This study emphasizes the important role of drugs in health services and the potential economic burden borne by consumers if drug prices are set too high. In addition, business actors who violate the price ceiling provisions may be subject to criminal and administrative sanctions in accordance with the applicable regulations.*

Keywords: *Highest Retail Price, pharmacy, pharmacies, medicines, consumer protection.*

INTRODUCTION

Pharmacies play an important role in the public health system. As drug procurement sites and health information centers, pharmacies provide vital services to consumers. Pharmacies provide diverse health services to the community. Not only providing medicines, pharmacies also serve as a source of health information that can be accessed by consumers (Dhananjaya et al., 2020). According to Anisah et al. (2010), pharmacies act as a health information center for the community, providing education and recommendations regarding the safe and effective use of drugs. Thus, pharmacies are important partners for consumers in maintaining and improving their health. The existence of pharmacies that are easily accessible in various regions further strengthens their role as health service providers for the wider community (Amalia, 2019).

In modern societies, healthcare is recognized as a human right, and among these rights, the accessibility and price of medicines are important issues (Darmawan et al., 2022). Medicines play a crucial role in maintaining and improving public health. As a vital component of the healthcare system, medicines play a fundamental role in the prevention, treatment and management of various diseases. Without access to safe, affordable and effective medicines, efforts to maintain individual and community health will be difficult to realize.

Medicines are not only needed to treat illnesses, but also play an important role in preventing more serious health conditions. By taking medications as prescribed, individuals can maintain their health, manage chronic conditions, and prevent complications that can be life-threatening. In addition, medicines are also used in immunization programs to prevent the spread of infectious diseases in the community.

In disease management, medicines are a crucial component in the recovery process. Administering the right medication according to the medical diagnosis can help relieve symptoms, speed up the healing process, and prevent complications. Even for chronic diseases or degenerative conditions, medicines allow patients to remain active and productive in their daily lives (Khayru et al., 2021).

Thus, the availability of medicines that are affordable and accessible to all levels of society is an important factor that is directly related to the overall health and well-being of the population. Equitable access to safe and quality medicines is a fundamental element in realizing a healthy and productive society (Kemarauwana et al., 2022). However, if medicine prices are set at unreasonable levels, this can increase the economic burden on consumers and further threaten public health.

In recent years, issues related to drug prices have often been raised in several countries. Particularly in the process of selling medicines in pharmacies, there are more and more cases where consumers buy medicines at prices that exceed the set maximum retail price (HRP, Highest Retail Price). The Highest Retail Price (HRP) is the maximum selling price limit set by the government for certain medicines to ensure affordability for the public. However, in practice, violations are often found where pharmacies sell medicines above the HRP. Such cases raise questions about how consumers are legally protected and what the legal consequences are for businesses that violate the price ceiling. This phenomenon not only violates the rights and interests of consumers, but is also a factor inhibiting the equitable distribution of medicines and reducing market reliability.

To overcome these problems, each country's legal system has established various regulations related to consumer protection, which serve as an important mechanism in protecting the rights and interests of consumers. For example, in Indonesia, consumer rights are protected through the 'Consumer Protection Law' passed in 1999 and the 'Health Law' passed in 2009, and the drug distribution process is protected.

In particular, the Consumer Protection Law prohibits acts that deceive consumers or encourage unfair transactions, and provides strict legal sanctions for violations. In addition, the Health Law sets clear standards regarding drug pricing and distribution, so that consumers can purchase drugs at reasonable prices.

However, despite the existence of laws and regulations, in reality there are often cases where the price of a medicine exceeds the maximum retail price. This may be due to several factors, among which the legal responsibility of the pharmacy operator (Business Actor) and the lack of awareness of this are cited as the main causes.

Therefore, this study intends to contribute to creating a fairer and more transparent drug distribution environment by reviewing the effectiveness of legal regulations related to consumer protection and clarifying the legal responsibilities of pharmacy operators, focusing on the issue of drug sales that exceed the maximum retail price. Work. The ultimate goal is to protect the rights and interests of consumers and improve public health. Thus, the problem formulation proposed in this study is how is the legal protection of consumers who buy drugs above the Highest Retail Price at pharmacies? What is the legal responsibility if business actors sell drugs above the Highest Retail Price in pharmacies?

RESEARCH METHODS

This research uses a normative legal analysis method with a statutory approach. This normative study observes legal norms and legal principles with an emphasis on legislation related to ensuring legal protection for individuals who are receiving pharmaceutical services at pharmacies, organized by pharmacists. Data is obtained from various legal sources such as laws, government regulations, ministerial decrees, and related legal literature. The analysis is carried out by reviewing and interpreting the legal provisions applicable in Indonesia related to consumer protection and the responsibility of business actors in the sale of drugs.

RESULTS AND DISCUSSIONS

Legal Protection for Consumers

Legal protection for consumers who buy drugs above the HRP at pharmacies includes clear regulations, supervision by relevant institutions, easily accessible complaint mechanisms, and the application of strict sanctions for violators. Consumers who feel aggrieved have various channels to report violations and obtain appropriate compensation (Indaryanti et al., 2023). With this protection, it is expected that consumers can obtain medicines at reasonable and affordable prices in accordance with applicable regulations. The following are regulations related to price ceilings.

1. Law Number 8 Year 1999 on Consumer Protection:
 - a. Article 4 of the Consumer Protection Law mentions consumer rights, including the right to comfort, security, and safety in consuming goods and/or services, as well as the right to obtain correct, clear, and honest information about the conditions and guarantees of goods and/or services.
 - b. Article 7 of Consumer Protection Law obliges business actors to be responsible for providing correct, clear, and honest information regarding the conditions and guarantees of goods and/or services as well as providing compensation, compensation, and/or replacement if the goods and/or services received are not in accordance with the agreement.
2. Regulation of the Minister of Health of the Republic of Indonesia Number 98 of 2015 concerning Drug Prices:
 - a. Sets the price ceiling for generic medicines and certain other medicines.
 - b. Article 3 states that pharmacies are obliged to sell drugs in accordance with the set price ceiling.

Although regulations have set the price ceiling and the obligations of business actors, the reality in the field shows that there are violations. Supervision by the government through the Food and Drug Monitoring Agency in Indonesia (BPOM) and the health office needs to be improved to ensure pharmacies' compliance with the HRP provisions.

Consumers who feel aggrieved can file a complaint with a consumer protection organization such as the Indonesian Consumers Foundation (YLKI) or through the complaint mechanism at the local health office. In addition, consumers also have the right to claim compensation in accordance with the provisions of Article 19 of the Consumer Protection Law.

Legal Responsibility of Business Acts

In Indonesia, pharmacists who sell drugs above the legal maximum retail price (HRP) may be subject to a number of sanctions. These take the form of administrative dispositions such as warnings. A first offense may result in a warning from the health authority. In case of repeated or serious violations, the pharmacist or pharmacy operator may be fined.

In serious cases, the pharmacy may be suspended for a period of time. In case of very serious violations, the pharmacy's business license may be revoked.

Criminal sanctions may be imposed through the courts against pharmacists depending on certain circumstances, and in some cases, pharmacists may face imprisonment (Alfarizi, 2022). In practice, pharmacists are liable for errors or violations related to pharmacy practice. Some examples of serious violations such as those that often occur are violating regulations related to price ceilings, selling drugs without proper prescriptions, or unauthorized use of drugs. The court will consider the evidence to determine whether a pharmacist is guilty or not. If found guilty, the pharmacist may face criminal sanctions, which could include imprisonment. Each case will be assessed individually, and the final sentence will be determined by the specific circumstances of the offense committed by the pharmacist.

In civil litigation, consumers who purchase medicine at a higher price than the usual price can file a civil lawsuit against the pharmacist and seek compensation. The consumer must prove that the pharmacist has violated the law or committed an unlawful act that caused harm to the consumer. Consumers must also submit sufficient evidence to support their civil suit claim. The civil lawsuit process will be conducted through the court. The court will consider the evidence presented by both the consumer and the pharmacist to determine whether the civil claim has merit and whether the consumer is entitled to compensation (Beauchamp & Childress, 2013).

For pharmacists, violations of professional ethics can be examined by the Indonesian Pharmacists Association or the relevant ethics committee, and may be subject to sanctions such as suspension or revocation of qualifications. In Indonesia, these sanctions are intended to encourage pharmacists to comply with price lists and provide medicines at reasonable prices to consumers. Therefore, pharmacists should always comply with the relevant laws and regulations. The following are forms of criminal and administrative sanctions.

1. Criminal Sanctions:

- a. Based on Article 62 of Consumer Protection Law, business actors who violate the provisions may be subject to a maximum imprisonment of 5 (five) years or a maximum fine of Rp2,000,000,000 (two billion rupiah).
- b. Article 197 of Law Number 36 Year 2009 on Health also regulates criminal sanctions for business actors who do not comply with the provisions on the sale of drugs.

2. Administrative Sanctions:

- a. Business actors who violate the HRP provisions may be subject to administrative sanctions in the form of revocation of business licenses, administrative fines, and/or written warnings in accordance with Minister of Health Regulation Number 98 of 2015.

The law enforcement process against business actors who violate the HRP provisions involves various agencies such as BPOM, health offices, and law enforcement officials. Cooperation between these agencies is important to ensure that violations can be dealt with firmly and consistently.

BPOM has a central role in monitoring the circulation of drugs and food in Indonesia. BPOM is responsible for regulating, supervising, and ensuring that pharmaceutical products circulating in the market meet safety, quality, and efficacy standards. In the context of price ceiling enforcement, BPOM conducts routine inspections and supervision of pharmacies, distributors, and drug manufacturers to ensure that the prices set are in accordance with applicable regulations. If violations are found, BPOM has the right to impose administrative sanctions such as warnings, fines, or revocation of distribution licenses.

Health offices at the provincial and district/city levels also have an important role in enforcing price ceilings. Health offices are responsible for supervising and training pharmacies and health service facilities in their area. They work closely with BPOM to conduct inspections and coordinate reports or complaints from the public regarding price ceiling violations. In addition, the Health Office also plays a role in educating pharmacists and businesses on the importance of complying with the price ceiling to protect consumers.

In addition to law enforcement, education and prevention are also an integral part of efforts to address price ceiling violations. BPOM and the health office routinely conduct campaigns and socialization on the importance of complying with the price ceiling, both for business actors and the general public. This education aims to raise awareness about the negative impacts of price ceiling violations, such as increased health costs and risks to patient safety (Rumbewas et al., 2018).

The process of law enforcement against business actors whose provisions are HRP is a complex system that involves various agencies such as BPOM, health offices, and law enforcement officials. Cooperation between these agencies is essential to ensure that violations are strictly and consistently enforced. Through a structured and transparent mechanism, as well as continuous education and prevention efforts, price ceiling violations can be minimized, so that the public can obtain medicines at reasonable and affordable prices.

CONCLUSIONS

This study uses a normative legal analysis approach, focusing on legislation. The research findings show that although there is sufficient legal protection for consumers, the implementation of such protection requires strict

supervision in the field. Business actors who violate the HRP provisions may be subject to criminal and administrative sanctions in accordance with existing regulations. Consumers have adequate legal protection through health regulations and other regulations governing the sale of drugs in accordance with the price ceiling.

There are several suggestions from this study. The government needs to improve supervision of pharmacies through regular inspections and public reporting to ensure compliance with the price ceiling. Education programs for consumers about their rights and complaint mechanisms need to be improved to prevent and address violations. Law enforcement officials need to take firm action against businesses that violate the price ceiling to provide a deterrent effect and ensure compliance in the future. Cooperation between relevant agencies needs to be improved to ensure effective and consistent law enforcement. Thus, through adequate legal protection and strict law enforcement, it is expected that the problem of selling drugs above the price ceiling can be minimized, and consumer rights can be well protected.

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