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LEGAL PROTECTION FOR CONSUMERS DUE TO THE FREE MARKETING OF DRUGS IN PALU CITY

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Abstract: The rapid advancement of science and technology today has significantly influenced the development of medicines, as seen from the emergence of various types of drugs freely circulating in the market. The Health Law grants the government authority to supervise matters related to public health, providing a foundation for regulating the supervision of drug production, procurement, and proper manufacturing practices. The research questions posed are: What are the responsibilities of producers and pharmacies in freely marketing drugs to consumers? To what extent is legal protection available to consumers for the sale of drugs freely sold in pharmacies? This research aims to determine the responsibility of producers and pharmacies in the free sale of drugs and to assess the legal protection available to consumers who may be harmed by the sale of freely marketed drugs in pharmacies. This study employs empirical legal research, which is based on field observations and interviews with various stakeholders and relevant institutions. The Department of Health is responsible for the supervision and regulation of the standards and/or requirements related to safety, efficacy, and quality of pharmaceutical preparations, medical devices, and household health supplies. This supervision is supported by BPOM (The National Agency of Drug and Food Control), a non-ministerial institution that issues drug circulation permits. Pharmacies, as business entities that distribute drugs to the public, are responsible for ensuring the proper circulation permits for pharmaceutical preparations, medical devices, and household health supplies. Legal protection for consumers concerning the circulation of freely marketed drugs is regulated under the Health Law, which includes provisions on the security and supervision of pharmaceutical preparations. If violations occur, the drugs are withdrawn from circulation and destroyed by the business entity (pharmacy) as part of the repressive measures outlined in the Consumer Protection Law. Business entities are responsible for compensating any damage, pollution, and/or losses suffered by consumers due to the consumption of goods and/or services produced or traded, with dispute resolution available through both litigation and non-litigation means.

Keywords: Consumer Protection, Drug Marketing, Palu City

INTRODUCTION

Health is one of the basic human needs, alongside food, housing, and education. When in good health, individuals can live, grow, and be more productive. In the health sector, the awareness and ability of every citizen to live a healthy life is a key factor in achieving a society with an optimal level of public health. Therefore, the National Health System states that "health development is implemented with the aim of achieving the ability for every citizen to live healthily, in order to realize an optimal level of public health.

The rights of citizens encompass not only physical and material rights but also intangible rights, such as the right to feel secure from any disturbances and the right

to obtain information that allows them to acquire accurate knowledge about all goods and services offered to them.

In the field of health, particularly concerning pharmaceuticals, we have witnessed, in conjunction with advancements in science and technology, a proliferation of drug products available on the market with various brands and types. This development also extends to traditional medicines, which have increasingly evolved and are now commonly found in local pharmacies. Pharmaceuticals that are freely circulated and readily available for sale are not only sold in pharmacies and licensed drugstores but also in kiosks. Therefore, to meet the public's need for medications, it is essential to have oversight on the distribution of pharmaceutical products by the relevant authorities.

In relation to this phenomenon, consumers who are not registered and do not meet pharmaceutical standards will have a close connection; thus, there is a need for consumer protection as outlined in Law No. 8 of 1999 concerning Consumer Protection, Article 1, Paragraph 1, which states: "Consumer protection is all efforts that guarantee legal certainty to provide protection to consumers." According to Article 39 of Law No. 23 of 1992 concerning Health, the safeguarding of pharmaceutical products and medical devices is organized to protect the public from dangers arising from the use of pharmaceutical products and medical devices that do not meet quality, safety, or efficacy requirements.

In addition, consumer rights are regulated in Article 4 of the Consumer Protection Act No. 8 of 1999 (UUPK). The rights of consumers, as outlined above, must fundamentally be upheld. One of the key factors in enforcing consumer rights or interests is the effort to demonstrate the attitude and behavior of the consumers themselves, thereby becoming responsible consumers.

In the practice, consumer rights and interests are often not enforced, either due to ignorance or reluctance on the part of the consumers to exercise them, or due to the actions of the producers. In the relationship between consumers and producers, there is a transfer of ownership or enjoyment of goods or services. The transfer of goods or services is generally driven by consumer needs for goods and services, as well as the producer's interest in providing information about the goods or services they produce. Accurate and responsible information (informative information) is a fundamental need for consumers before they can make a decision to engage in, postpone, or refrain from a transaction for their livelihood.[1]

The relationship between consumers can be viewed as a contractual relationship, and the definition or legal requirements for the validity of a contract, as well as its consequences and types, are outlined in Articles 1313-1351 of the Indonesian Civil Code (KUHPerdata), specifically in Chapters V through VII of Book III of the Civil Code. The provisions regarding certain obligations arising from agreements prescribed by law are also contained therein. Under Article 1365 of the Civil Code, businesses are liable for any damages suffered by consumers due to defective or damaged products.

The Health Law grants the government authority to oversee matters related to health. This law serves as the foundation for regulating the supervision of drug production, procurement, and proper manufacturing practices. Consumers who suffer harm from

[1] A.Z. Nasution (1996) *Konsumen dan Hukum*, Penerbit Pustaka Sinar Harapan, Jakarta, hlm. 63

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consuming, using, or utilizing such goods and/or services may hold the relevant producers or business actors accountable, as regulated in Articles 19-28 of Law No. 8 of 1999 on Consumer Protection.

According to Gunawan Widjaja and Ahmad Yani[2]: the public's desire and demand to protect themselves from low-quality goods have driven serious efforts to consider consumer protection, thereby initiating a movement to realize these aspirations.

Article 8(1)(a) of the Consumer Protection Law No. 8 of 1999 stipulates prohibitions for business actors, specifically that "business actors are prohibited from producing and/or trading goods and/or services that do not meet or are not in accordance with the standards required by applicable laws and regulations." Violations of this prohibition are classified as unlawful acts. The purpose of this regulation is to promote order in commerce and to create a healthy business climate, ensuring fair competition among business actors.

Based on the above explanation, the author is very interested in examining the following: What are the responsibilities of the health department and pharmacies in freely marketing drugs to consumers? To what extent is legal protection provided to consumers regarding the sale of over-the-counter drugs in pharmacies?

METHOD

This research is empirical in nature, meaning it is based on experience and observations drawn from field data and information obtained through direct interviews with various sources and relevant institutions related to this study. The research location is in the city of Palu and its surrounding areas.

ANALYSIS AND DISCUSSION

A. Responsibilities of the Health Department and Pharmacies in the Over-the-Counter Marketing of Drugs to Consumers

Health is a fundamental right for every individual. As one of the most important assets in human life, oversight of all activities related to the health sector is crucial for the government to advance public welfare[3]. According to Law No. 17 of 2023 on Health, the objectives of health care administration are as follows:

1. To promote healthy living behaviors;
2. To enhance access to and quality of health services and health resources;
3. To improve the management of human resources in a manner that is effective and efficient;
4. To meet the public's needs for health services;
5. To strengthen health resilience in response to outbreaks or epidemics;
6. To ensure the availability of sustainable and equitable health funding, managed transparently, effectively, and efficiently;
7. To achieve the development and utilization of sustainable health technology; and
8. To provide protection and legal certainty for patients, health care personnel, and the public.

[2] Gunawan Widjaja dan Ahmad Yani (2001), *Hukum Tentang Perlindungan Konsumen*, Penerbit Gramedia Pustaka Utama, Jakarta, hlm 15-16

[3] Leli Juwanti, Marta Tilov (2018), Perlindungan Hukum Terhadap Konsumen Atas Penjualan Obat-Obatan Ilegal Secara Online, *Jurnal Niagawan*, 7(3) : 167

Every citizen has the right to a healthy life, encompassing physical, mental, and social well-being, and to receive information and education regarding health services as well as access to quality, safe, and affordable health care, as stipulated in health legislation. The public is also entitled to protection from health risks, particularly for consumers or individuals when purchasing or obtaining medications that are readily available through pharmacies, online platforms, and licensed drugstores.

One crucial component of health care is the availability of traditional medicine as part of public health services. This is because medications are used to save lives, restore, or maintain health. In health care services, medications are a vital component, necessary for most health efforts. Today, increasing public awareness and knowledge about health also drives the demand for more professional health services, including medication services. Unfortunately, there are still individuals who sell or distribute medications freely in the community without proper authorization. This is often due to the complex procedures required to obtain such authorization, resulting in the sale of these medications being considered illegal. [4]

The role of the National Agency of Drug and Food Control (BPOM) in overseeing and authorizing drugs and food products is crucial, as BPOM is the government agency designated to regulate and authorize products intended for distribution to the public or consumers. Nowadays, there is a vast array of food and drug products circulating in the community, which poses a phenomenon where consumers may not be aware of the potential consequences if these products lack proper authorization or suitability from BPOM[5].

According to Presidential Regulation No. 80 of 2017 concerning the National Agency of Drug and Food Control (BPOM), Article 1 states that BPOM is a non-ministerial government agency responsible for overseeing drugs and food. BPOM operates under and is accountable to the President through the minister responsible for health affairs. BPOM's mandate is to conduct governmental duties in the field of drug and food supervision in accordance with applicable laws and regulations. Drugs and food, as mentioned in paragraph (1), include drugs, drug ingredients, narcotics, psychotropics, precursors, addictive substances, traditional medicines, health supplements, cosmetics, and processed food (Article 2 of Presidential Regulation 80/2017).

Based on an interview with Mrs. Titi Hapsari, Sub-Coordinator of Pharmaceutical Affairs for Food and Beverages at the Health Department, it was stated that the circulation of drugs in the city of Palu is regulated by licenses issued by BPOM, and the Health Department is tasked with overseeing the distribution of drugs within the community. If drugs are found to be circulating without proper authorization and are sold in pharmacies or licensed drugstores, the Health Department provides guidance and support to business operators or pharmacies with operational permits. The aim is to ensure that each drug being distributed or sold is properly registered by verifying the registration label and expiration date against BPOM data. This measure is part of the Health

[4] Merry Anggraini (2019), *Perlindungan Konsumen Terhadap Peredaran Obat Tradisional Tanpa Izin di Indonesia*, Skripsi Fakultas Hukum Universitas Sriwijaya Inderalaya, Sumatera Selatan,hlm. 1

[5] Wahyu Simon Tampubolon, Peranan dan Tanggung Jawab Badan Pengawas Obat dan Makanan (BPOM) Terkait Kasus Albothyl Menurut Undang-undang Perlindungan Konsumen, *Jurmal Ilmiah Advokasi*, 6 (1) : 70

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Department's efforts. The Health Department conducts monthly inspections of pharmacies in the city of Palu to ensure that no drugs are being distributed illegally or without proper authorization. A distribution permit is a form of approval for registration to be circulated within Indonesia (Article 1 paragraph (6) of BPOM Regulation No. 14 of 2022 concerning the Withdrawal and Destruction of Drugs that Do Not Meet Standards and/or Safety, Efficacy, Quality, and Labeling Requirements).

In the event of cases where drugs are circulated illegally or without proper authorization and are sold freely, the Health Department will withdraw these drugs and coordinate with BPOM to check the circulation of such drugs. Therefore, it becomes the responsibility and authority of BPOM, as a non-governmental agency responsible for drug distribution in the community. The process of drug withdrawal involves removing drugs that have been distributed but do not meet standards and/or safety, efficacy, quality, and labeling requirements.

The importance of a distribution permit is evident from the stringent and difficult process of obtaining such permits from BPOM. It is therefore suspected that drugs without distribution permits may contain harmful substances, lack clear producers, and do not guarantee consumer safety. If drugs without distribution permits are widely traded, the consumers are the ones who suffer. This situation is difficult to address if the consumed drugs contain hazardous substances.[6]

Several factors for the withdrawal of drugs can be carried out by BPOM as stipulated in Article 2 of BPOM Regulation No. 14 of 2022, as follows:

1. Drugs that do not meet the standards and/or requirements for safety, efficacy, quality, and/or labeling must be withdrawn.
2. Drugs referred to in paragraph (1) include:
    a) Drugs that already have a Distribution Permit, including Emergency Use Authorization (EUA); or
    b) Drugs that are imported into Indonesia through a special access scheme.
3. The standards and/or requirements for safety, efficacy, and quality referred to in paragraph (1) for drugs as mentioned in paragraph (2) letter a are based on:
    a) Parameters listed in the Indonesian Pharmacopeia, analytical methods, standards, and/or requirements for drugs and/or other pharmaceutical ingredients in accordance with the provisions of statutory regulations;
    b) Approved registration/approval documents; and
    c) Compliance with Good Manufacturing Practices (CPOB).
4. The standards and/or requirements for safety, efficacy, and quality referred to in paragraph (1) for drugs as mentioned in paragraph (2) letter b are based on the BPOM regulations that

[6] Alfan Muhammad Nur Zahaid, Bambang Eko Tresno, R. Suharto (2016), *Perlindungan Konsumen Terhadap Peredaran Obat Tanpa Izin Edar yang Dijual Secara Online di Indonesia*, Diponegoro Law Journal, 5(3), hlm 5

govern the importation of drugs and pharmaceutical ingredients through a special access scheme.

5. The standards and/or requirements for labeling referred to in paragraph (1) are based on the approved registration documents.

The withdrawal of drugs can involve either a single type of drug or multiple batches of drugs that are in circulation. This is in line with the information provided by Ms. Noviyanti from BPOM Kota Palu, who stated that if drugs sold freely or circulating in the community do not have a distribution permit, the appropriate action is to withdraw these drugs. The purpose of this is to protect consumers, namely the public, and to prevent any cases that could harm public health. Many drugs sold freely, whether online, at traditional markets, or in small shops, usually have distribution permits or have been registered with the pharmaceutical company at BPOM and are considered safe for over-the-counter sales. These drugs often include pain relievers, anti-pain, fever, or flu medications, which are generally generic and thus readily available without a prescription.

Interviews were also conducted with large pharmacies in Kota Palu. According to the Regulation of the Minister of Health No. 9 of 2017 on Pharmacies, a pharmacy is a facility for pharmaceutical services where pharmaceutical practices are carried out by pharmacists. Pharmacies are crucial for providing pharmaceutical needs to the community, managing pharmaceutical preparations, medical devices, and consumable medical supplies, and offering clinical pharmacy services, including those in the community.

According to Ms. Eka Ismiyanti (Pharmacist at Kimia Farma), regarding the free circulation of drugs, the responsibility for drugs at pharmacies lies with the distributor companies because pharmacies only receive drugs from pharmaceutical companies with official distributors. It is the responsibility of the pharmaceutical companies to ensure the distribution permit. Pharmacies only check the registration label and expiry date to ensure they match the registration number on the drug. If discrepancies are found, the pharmacy will return the drugs to the distributor. So far, Kimia Farma pharmacies do not accept drugs without registration numbers for sale, as this would not only pose risks to the public as consumers but also result in losses for the pharmacy itself, including the potential revocation of the pharmacy's practice license and business permit.

In a rapidly evolving economy with advancements in science and technology, the needs of human life, such as medications, are changing. Medications are a crucial aspect of supporting individual health. In healthcare services, including prevention, diagnosis, treatment, and recovery, drugs play a vital role in supporting consumer health. In this regard, consumers need clear and accurate information about the medications they consume. In daily life, medications are essential for maintaining life, protecting, and preserving health. Therefore, the safety of medications is very important for the public. Medication consumption should be tailored to individual needs.[7]

According to Mr. Reyhan, the owner of the Farmaindah pharmacy, they do not accept medications from distributors other than official pharmaceutical companies. If there are medications circulating outside the pharmacy, they are not the responsibility or concern of the pharmacy. Traditional

[7] Anisa Utami, Herwasoeti, (2022), *Perlindungan Hukum Terhadap Konsumen Atas Penjualan Obat-Obat Ilegal Secara Online, Klausula Jurnal Hukum Administrasi Negara dan Pidana* 1(2) Vol. 1 : 95-96

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medicines, such as ointments and diet drugs from China, will not be purchased by the pharmacy if they do not have official registration numbers or distribution permits from the National Agency of Drug and Food Control (BPOM). Many pharmacies, in pursuit of profit, sell medications without proper distribution permits, which necessitates that BPOM and related agencies intensify their oversight efforts.

It is important to note that consumers must be protected as stipulated by the Consumer Protection Law (UUPK), which aims to:

1. Increase consumer awareness, capability, and independence to protect themselves;
2. Enhance the dignity and status of consumers by protecting them from the negative consequences of using goods and/or services;
3. Empower consumers to choose, determine, and assert their rights as consumers;
4. Create a consumer protection system that includes legal certainty, information transparency, and access to information;
5. Foster awareness among business actors regarding the importance of consumer protection, leading to honest and responsible business practices;
6. Improve the quality of goods and/or services to ensure the continuity of business operations, and safeguard consumer health, comfort, safety, and security.

B. Legal Protection of Consumers Against the Free Circulation of Medications

Consumer issues affect everyone, making them a national concern that requires government attention and oversight. The objectives of organizing, developing, and regulating consumer protection are to enhance the dignity and awareness of consumers, and indirectly to encourage business actors to conduct their activities with a full sense of responsibility. However, many consumers are still unaware of the law, as well as their rights and obligations as consumers. This consumer protection also aims to impose penalties for any violations related to the provisions established in the Consumer Protection Law (UUPK). [8]

The Consumer Protection Law provides a definition of a consumer as any individual who uses goods and/or services available in the community, whether for personal, family, others, or other living beings' needs, and not for commercial purposes. Various countries have established consumer rights as a basis for consumer protection regulations. Consequently, the nation's broad policy framework always includes the necessity of consumer protection. As stated in MPR Decree Number II/MPR/1993, the importance of consumer protection is consistently emphasized. This reflects a commitment to continue advocating for consumer interests in Indonesia. The reasons for enacting specific legislation to regulate and protect consumer interests are as follows:

1. Consumers require distinct regulations because, in a legal relationship with sellers, consumers are users of goods and services for personal purposes and not for production or resale.

[8] Leli Juwanti, dkk, *Loc.cit*, hlm 168

2. Consumers need specific legal mechanisms or procedures, similar to those for criminal corruption cases, to protect their rights. From the understanding of consumers, a crucial requirement is that they need products that are safe for their health and well-being, and generally for the welfare of their families or households. Therefore, legal standards are needed to ensure the safety of consumer products for human consumption, accompanied by accurate, honest, and responsible information.[9]

With the enactment of the Consumer Protection Law Number 8 of 1999 concerning Consumer Protection (UUPK), consumers of traditional medicines have indeed gained more advantages. These include the explicit guarantee of fundamental consumer rights, the establishment of the Consumer Dispute Settlement Board (BPSK), and the National Consumer Protection Agency (BPKN). However, the regulation concerning consumer interests is still limited to merely prohibiting and sanctioning business actors. [10]

Every individual has the right to legal protection, particularly consumers or the public who purchase medications, whether online, from pharmacies, or licensed stores. Terminologically, legal protection can be understood as a combination of two definitions: "protection" and "law." The Indonesian Dictionary (KBBI) defines protection as an act or measure that shields. Law, on the other hand, is defined as regulations or customs officially considered binding, established by authorities or the government.Why is legal protection important? The significance of protection and law enforcement lies in ensuring that legal subjects receive all of their rights. Additionally, in the event of a violation of these rights, legal protection can provide full protection to the legal subject who becomes a victim. Simanjuntak has formulated four elements of legal protection.

The types of legal protection according to Philipus M. Hadjon, which emphasize government actions (bestuurshandeling or administrative actions), are divided into two categories:

a. Preventive Legal Protection
   This aims to prevent disputes by providing citizens with the opportunity to submit objections (inspraak) or opinions before a government decision is finalized. This is significant for government actions based on discretion, as it encourages the government to be cautious in decision-making.
b. Repressive Legal Protection
   This aims to resolve disputes in a broad sense, including handling legal protection for citizens through general and administrative courts in Indonesia.[11]

Furthermore, C.S.T. Kansil states that the objectives of legal protection should be reflected in the functioning of the law, the legal process, and the outcomes of its enforcement. This can be observed from the diversity of relationships that occur in society. Interactions among members of society

[9] Sejati Dieda Amanda, B. Rini Heryanti, Dharu Triasih (2021) , *Tanggung Jawab Badan Pengawas Obat dan Makanan RI Dalam Melindungi Konsumen Terhadap Beredarnya Obat-obat yang Dilarang Edar Studi kasus Obat Ranitidine*, Skripsi Fakultas Hukum Universitas Semarang, https://repository.usm.ac.id/detail-jurnalmahasiswa-894.html, hlm. 4

[10] Rif'ah Roihanah (2019), Analisis Yuridis Perlindungan Konsumen Terhadap Peredaran Obat Tradisional Berbahan Kimia Obat, *Kodifikasi : Jurnal Penelitian Islam*, 13(1) : 102

[11] Philipus M. Hadjon (1987), Perlindungan Hukum Bagi Rakyat Indonesia, *Bina Ilmu*, Surabaya, hlm. 2

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give rise to laws that regulate and protect the interests of each member. The diversity of legal relationships necessitates rules that ensure balance, preventing disorder within society.[12]

Given that the city of Palu has numerous pharmacies and drug stores, there are still many cases of medications being sold illegally or without distribution permits according to BPOM Indonesia standards. This situation makes it difficult for the public to be cautious when purchasing medications that are distributed illegally or not authorized, whether bought online or from licensed pharmacies or drug stores. This raises concerns for consumers, who need to be aware of their rights regarding the circulation of medications as stipulated in Article 4 of Law Number 8 of 1999 on Consumer Protection, which includes the following consumer rights:

a. The right to comfort, safety, and security in consuming goods and/or services;
b. The right to choose goods and/or services and to obtain those goods and/or services according to their exchange value, condition, and promised guarantees;
c. The right to accurate, clear, and honest information regarding the condition and guarantees of goods and/or services;
d. The right to have their opinions and complaints heard regarding the goods and/or services used;
e. The right to receive advocacy, protection, and appropriate dispute resolution in consumer protection matters;
f. The right to consumer guidance and education;
g. The right to be treated or served fairly, honestly, and without discrimination;
h. The right to compensation, reimbursement, and/or replacement if the goods and/or services received do not conform to the agreement or are not as expected;
i. Other rights as regulated by other legislative provisions.

Preventive legal protection measures regulated in the UUPK include prohibitions for business actors, including pharmacies, as outlined in Article 8 of the UUPK, which states:

1. Business actors are prohibited from producing and/or trading goods and/or services that:
   a. Do not meet or comply with the required standards and legal regulations;
   b. Do not conform to the net weight, net content, or quantity as stated on the label or packaging of the goods;
   c. Do not match the actual size, measure, weight, or quantity as specified;
   d. Do not align with the condition, guarantee, specialty, or efficacy as declared on the label, packaging, or description of the goods and/or services;
   e. Do not meet the quality, grade, composition, processing method, style, mode, or specific use as described on the label or description of the goods and/or services;
   f. Do not fulfill the promises made on the label, packaging, description, advertisement, or promotional materials of the goods and/or

[12] C.S.T. Kansil (2009), Pengantar Ilmu Hukum dan Tata Hukum Indonesia, *Balai Pustaka*, Jakarta, hlm. 40

services;
g. Fail to indicate the expiration date or the best use period of certain goods;
h. Do not adhere to halal production standards as indicated by the "halal" statement on the label;
i. Do not include labels or explanations that state the name of the goods, size, net weight/content, composition, usage instructions, production date, side effects, the name and address of the business actor, and other required information; j. Fail to provide information and/or usage instructions in Indonesian as required by applicable regulations.

2. Business actors are prohibited from trading damaged, defective, or used goods, or goods that are contaminated, without providing complete and accurate information about the goods.
3. Business actors are prohibited from trading pharmaceutical and food products that are damaged, defective, used, or contaminated, with or without providing complete and accurate information.
4. Business actors who violate the provisions of paragraphs (1) and (2) are prohibited from trading those goods and/or services and are required to withdraw them from circulation.

As explained in the above Article, the authority to conduct sampling testing of pharmaceutical preparations is granted to the National Agency of Drug and Food Control (BPOM), which is a non-ministerial government agency responsible for the supervision of drugs and food. This authority is regulated under Article 4 of Presidential Regulation No. 80/2017, which states In performing its duties related to the supervision of drugs and food, BPOM has the following authorities:

a. to issue distribution permits and certificates in accordance with standards and requirements concerning safety, efficacy/benefit, and quality, as well as the testing of drugs and food in compliance with statutory regulations;
b. to conduct intelligence and investigations in the field of drug and food supervision in accordance with statutory regulations; and
c. to impose administrative sanctions in accordance with statutory regulations.

Given the authority bestowed upon BPOM by the government, it is evident that the responsibility for the circulation of drugs rests with BPOM. Therefore, BPOM, as a non-ministerial government agency, must ensure the protection of the public from the unrestricted purchase or distribution of pharmaceuticals. To enhance its vigilance, BPOM must implement oversight over the circulation of drugs within the community.

If the holder of a distribution permit and/or a business entity engaged in the production and/or distribution of Pharmaceutical Preparations, Medical Devices, and/or Household Health Products (PKRT) discovers that such Pharmaceutical Preparations, Medical Devices, and/or PKRT do not comply with the standards and/or safety requirements, efficacy/benefit, and quality, as well as labeling requirements, the holder of the distribution permit and/or the business entity is obliged to withdraw the Pharmaceutical Preparations, Medical Devices, and/or PKRT from circulation (Article 411, Government Regulation No. 28 of 2024).

In addition, as a repressive measure, if BPOM encounters the circulation of drugs without a distribution permit or in violation of statutory regulations, BPOM may undertake the withdrawal of the pharmaceuticals from circulation and also

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conduct the destruction of such pharmaceutical preparations. This is regulated under Articles 411 and 412 of Government Regulation No. 28 of 2024 as follows:

Article 411

> *If the holder of a distribution permit and/or a business entity engaged in the production and/or distribution of Pharmaceutical Preparations, Medical Devices, and/or Household Health Products (PKRT) discovers that such Pharmaceutical Preparations, Medical Devices, and/or PKRT do not meet the standards and/or safety requirements, efficacy/benefit, and quality, as well as labeling requirements, the holder of the distribution permit and/or the business entity is required to withdraw the Pharmaceutical Preparations, Medical Devices, and/or PKRT from circulation.*

In this regulation, the term "Drug Withdrawal" refers to the process of withdrawing drugs that have been distributed and do not meet the standards and/or safety requirements, efficacy, quality, and labeling. "Destruction" refers to the act of destroying and eliminating drugs, drug materials, packaging, labels, and/or brochures that do not meet the standards and/or safety requirements, efficacy, quality, and labeling, rendering them unusable (Article 1, BPOM Regulation).

Supervision is also conducted on pharmacies that hold a Pharmacy License (SIA), as stipulated in Ministerial Regulation No. 9 of 2017 concerning Pharmacies. The oversight and development of pharmacies are carried out by the Minister, the head of the provincial health office, and the head of the district/city health office, in a hierarchical manner according to their authority, regarding all activities related to pharmaceutical services in pharmacies. Supervision of the implementation of this Ministerial Regulation is carried out by the Minister and the head of the provincial health office. In the event of violations of these regulations, which also breach the Health Law and BPOM Regulations concerning drug distribution in the community, the pharmacy may be subject to administrative sanctions, including written warnings, temporary cessation of activities, and revocation of the Pharmacy License (SIA).

Further measures for resolving disputes by consumers may be pursued through both litigation and non-litigation channels, including dispute resolution through the courts or outside the courts. Consumer dispute resolution is regulated as follows:

The Consumer Protection Law has granted authority to the Consumer Dispute Resolution Agency (BPSK) as the institution responsible for resolving consumer disputes outside of the courts. While out-of-court dispute resolution is not a mandatory step that consumers must take before resorting to judicial resolution, it serves as a means of reconciling disputes between producers and consumers. Additionally, according to Article 60, paragraph (1) of the UUPK, the Consumer Dispute Resolution Agency is authorized to impose administrative sanctions on business operators who violate the provisions of Article 19, paragraphs (2) and (3), Article 20, Article 25, and Article 26.[13]

[13] Zsalsabella Putri, *Loc.cit*¸2101

CONCLUSION

The Health Office is responsible for the oversight and regulation of standards and/or safety requirements, efficacy/benefit, and quality of business operators in the fields of Pharmaceutical Preparations, Medical Devices, and Household Health Products (PKRT). This oversight is supported by the National Agency of Drug and Food Control (BPOM), a non-ministerial institution that issues drug distribution permits. Pharmacies, as business operators distributing drugs in the community, are responsible for the distribution permits, pharmaceutical preparations, medical devices, and PKRT. Legal protection for consumers against the unrestricted circulation of drugs is provided through regulations in the Health Law related to the safeguarding and supervision of pharmaceutical preparations. In cases of violations, drugs are withdrawn from circulation and destroyed by the business operator (pharmacy) as a repressive measure, as regulated in the Consumer Protection Law (UUPK). Business operators are liable to provide compensation for damage, contamination, and/or consumer losses resulting from the consumption of goods and/or services produced or traded by them. Dispute resolution may be pursued through litigation or non-litigation channels.

BIBLIOGRAPHY

Book

A.Z. Nasution (1996), *Konsumen dan Hukum*, Penerbit Pustaka Sinar Harapan, Jakarta

C.S.T. Kansil (2009), Pengantar Ilmu Hukum dan Tata Hukum Indonesia, *Balai Pustaka*, Jakarta

Gunawan Widjaja dan Ahmad Yani (2001), Hukum Tentang Perlindungan Konsumen, Penerbit Gramedia Pustaka Utama, Jakarta

Philipus M. Hadjon (1987), Perlindungan Hukum Bagi Rakyat Indonesia, *Bina Ilmu*, Surabaya

Shidarta (2000), *Hukum Perlindungan Hukum Indonesia*, PT Grasindo, Jakarta

Statute/Law

Kitab Undang-Undang Hukum Perdata

Undang-Undang Nomor 8 tahun 1999

Undang-Undang Nomor 17 Tahun 2023 Tentang Kesehatan

Peraturan Presiden Republik Indonesia Nomor 80 Tahun 2017 Tentang Badan Pengawas Obat Dan Makanan

Peraturan Badan Pengawas Obat dan Makanan Nomor 14 Tahun 2022 tentang Penarikan dan Pemusnahan Obat yang Tidak Memenuhi Standar dan/atau Persyaratan Keamanan, Khasiat, Mutu, dan Label

Peraturan Menteri Kesehatan Nomor 9 Tahun 2017 tentang Apotek

Peraturan Pemerintah Nomor 28 Tahun 2024 Tentang Pelaksanaan Undang-Undang Kesehatan.

Journal

Alfan Muhammad Nur Zahaid, Bambang Eko Tresno, R. Suharto (2016), *Perlindungan Konsumen Terhadap Peredaran Obat Tanpa Izin Edar yang Dijual Secara Online di Indonesia*, Diponegoro Law Journal, 5(3) : 5

Anisa Utami, Herwasoeti, (2022), *Perlindungan Hukum Terhadap Konsumen Atas Penjualan Obat-Obat Ilegal Secara Online*, *Klausula Jurnal Hukum Administrasi Negara dan Pidana* 1(2) Vol. 1 : 95-96

Kurniasanti, Joko Setiyono (2020), Urgensi Pengaturan Pengawasan Dan Penegakan Hukum Oleh BPOM Terhadap Tindak Peredaran

TALREV

Volume 9 Issue 2 December 2024: pp 442-454

ISSN: 2527-2977 | e-ISSN: 2527-2985.
Open access at: http://jurnal.fakum.ac.id/index.php/TLR

Obat dan Makanan Ilegal, *Yuriska : Jurnal Ilmu Hukum*, 12(2) : 74

Leli Juwanti, Marta Tilov (2018), Perlindungan Hukum Terhadap Konsumen Atas Penjualan Obat-Obatan Ilegal Secara Online, Jurnal Niagawan, 7(3) : 167

Zsalsabella Putri Moudzie (2021), Peranan Badan Pengawas Obat dan Makanan dalam Perlindungan Konsumen Terhadap Obat Racikan apotek Tanpa Resep Dokter, *Jurist-Diction*, 4(5) : 2093

OTHER

Mangkuti Raksum (2023), Perlindungan Hukum Indonesia : Pengertian, Aspek, Unsur dan Contoh, https://fahum.umsu.ac.id/perlindungan-hukum-indonesia-pengertian-aspek-unsur-dan-contoh/ tanggal akses 9 April 2024

Merry Anggraini (2019), Perlindungan Konsumen Terhadap Peredaran Obat Tradisional Tanpa Izin di Indonesia, Skripsi Fakultas Hukum Universitas Sriwijaya Inderalaya, Sumatera Selatan

Sejati Dieda Amanda, B. Rini Heryanti, Dharu Triasih (2021) , *Tanggung Jawab Badan Pengawas Obat dan Makanan RI Dalam Melindungi Konsumen Terhadap Beredarnya Obat-obat yang Dilarang Edar Studi kasus Obat Ranitidine*, Skripsi Fakultas Hukum Universitas Semarang, https://repository.usm.ac.id/detail-jurnalmahasiswa-894.html