
LEGAL PROTECTION FOR CONSUMERS RELATED TO THE DISTRIBUTION OF HARD DRUGS BY UNLICENSED DRUG STORES IN INDONESIA

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ABSTRACT

One of the aspects of welfare that must be achieved in line with the national aspirations of Indonesia is public health, which is acknowledged as a fundamental right governed by the 1945 Constitution. However, there is a growing risk of hard drug misuse due to people's inclination to self-medicate without a prescription. Government Regulation Number 51 of 2009 and Law Number 17 of 2023 stipulate that only pharmacists with a prescription from a doctor are authorized to administer hard substances. Nonetheless, it is still common for illicit drug outlets to offer strong pharmaceuticals to customers without a prescription, which puts their health at risk. This study employs a normative juridical methodology combining case-based and statutory approaches. Despite the legal protections for consumers regulated in Law Number 8 of 1999 (henceforth UUPK), many consumers do not understand their rights and obligations, so they are vulnerable to fraud and health risks. The findings of this research indicate the need for increased public awareness and stricter law enforcement to protect consumers from the misuse of hard drugs as well as supervision by Badan Pemeriksa Obat dan Makanan (henceforth BPOM) and the Public Health Office as an effort to control the circulation of hard drugs without a doctor's prescription, which are sold in the drug stores that do not have a business license.

Keywords: *Hard Drugs, Consumer Protection, Drug Stores, BPOM.*

INTRODUCTION

Public health is the foundation of a nation's progress and one of the necessities of human life. It is imperative to conduct all attempts to improve public health in accordance with the principles of sustainability, non-discrimination, participation and protection. This is crucial to building the Indonesian workforce, strengthening its resilience and competitiveness, while promoting national development as a whole. The Constitution also governs the right to health for every individual, recognizing and guaranteeing this same right. The 1945 Constitution of the Republic of Indonesia, in Article 28 H, paragraph 1, provides as follows: "... Everyone has the right to live a prosperous life in birth and mind, to live, and to get a good and healthy living environment and the right to receive health services...".

This means that every person, family, and community has the right to health protection. Furthermore, it is the responsibility of the State to regulate the implementation of the right to a healthy life for its people, including the poor and disadvantaged.

Based on the data from Statistics Indonesia 2024, published by the Statistics Indonesia (Badan Pusat Statistik or BPS). BPS recorded that the ratio of people who have health complaints is

26.27% of the total population of Indonesia, which accounts for 281,603,800 people. This represents a very small proportion of the population with health issues, with 73.73% of the population not known to be in good health, or sick but never having it checked by the health services.¹

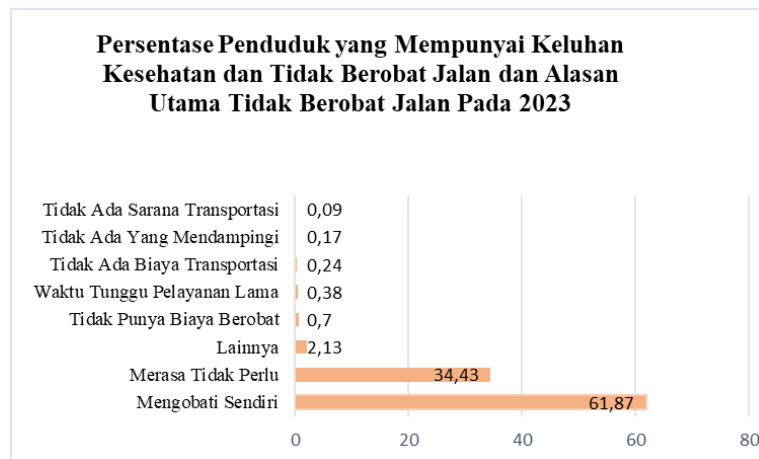


Chart 1. BPS Data

From the data published by BPS illustrates above, self-medication (or *mengobati sendiri*) is the reason of the majority of Indonesians do not do outpatient treatment even though they complaining for illness, which the percentage reaches 61.87%. This means that 6 out of 10 Indonesians does self-medicate their health issues by determining for themselves the type of medication to be taken without the advice or prescription from health workers. Coupled with the data from Survey Indonesian Health (Survey Kesehatan Indonesia/SKI) 2023, found that more than 60% of the public obtaining drugs without a prescription at pharmacies or drug stores.²

Therefore, many people do not go to the health service unit for check-ups, and choose to do self-medication by buying medicine at the drugstore without a prescription, and without thinking about the risks that can occur. In reality, to get the type of drug with a class of hard drugs requires a doctor's prescription. Because these drugs cannot be used carelessly, if hard drugs are used without a doctor's prescription, it is anticipated that it would be dangerous, and can trigger other diseases that can cause damage to organs in the body.³

Based on Article 320 Paragraph (2) of Law Number 17 of 2023 on Health, which states that "Prescription drugs are classified into a. Hard drugs; b. Narcotics; and c. Psychotropic drugs."⁴ The regulation on the distribution of hard drugs may only be carried out by pharmacists and only with a doctor's prescription, as stated in Article 24 Letter c of Government Regulation No. 51 of 2009 on Pharmaceutical Work, which states that "Within pharmaceutical institutions, pharmacists are responsible to administer soft drugs, narcotics, and psychotropic substances to the public on medical request, in compliance with legislative and regulatory regulations."⁵

¹Badan Pusat Statistik. (2024). *STATISTIK INDONESIA 2024 Statistical Yearbook of Indonesia 2024 Volume 52, 2024*. Indonesia: Badan Pusat Statistik.

²Humas BKPK. (2024). Potret Sehat Indonesia dari Kacamata SKI 2023. URL: <https://www.badankebijakan.kemkes.go.id/potret-sehat-indonesia-dari-kacamata-ski-2023/>. Diakses tanggal 14 September 2024.

³Jusela, F., & Achadi, A. (2024). Sanksi Pengedaran Obat-Obatan Keras daftar G pada Toko Obat Tanpa Keahlian dan Kewenangan Melakukan Praktik Kefarmasian: Studi Kasus. *Jurnal Cahaya Mandalika ISSN 2721-4796 (online)*. 5(1): Hlm 563-570.

⁴Pasal 320 Ayat (2) Undang-Undang Nomor 17 Tahun 2023 Tentang Kesehatan.

⁵Pasal 24 huruf c Peraturan Pemerintah Nomor 51 Tahun 2009 Tentang Pekerjaan Kefarmasian.

A pharmacy is a pharmaceutical facility operated by a pharmacist, which assists patients in selling and purchasing non-prescription drugs, limited non-prescription drugs, hard drugs, and traditional medicines. In difference with general drug stores in Indonesia, which do not require pharmacists but require pharmaceutical technical personnel and only sell over-the-counter drugs, limited over-the-counter medications, and traditional medicines that have a distribution permit.⁶

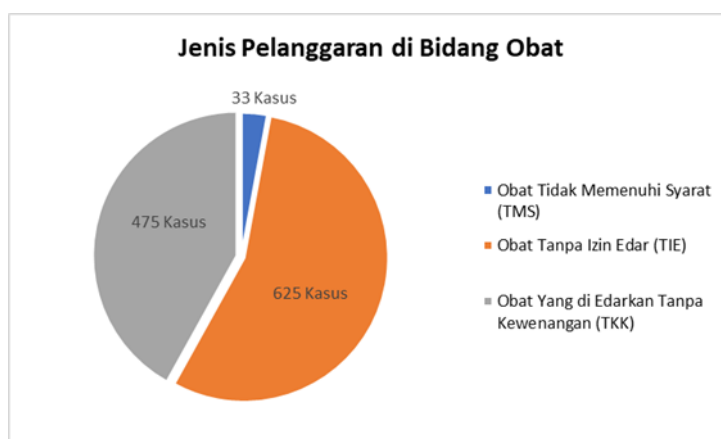


Chart 2. Types of Violations in the Field of Medicine

The Food and Drug Supervisory Agency (BPOM) found 1,133 cases of illegal drugs in Indonesia throughout 2022, consisting of cases drugs unqualified medicines (TMS), drugs without a Distribution Permit (TIE), and drugs distributed without expertise and authority (TKK). Based on the BPOM data, the number of cases of drugs distributed without expertise and authority (TKK) reached 475.⁷ This indicates that there are still many drug stores that sell drugs even though they do not have pharmaceutical technical personnel or do not have the expertise and authority to distribute these hard drugs. These traders often offer high-dose medicines without a doctor's prescription and lack the know-how and power to implement pharmaceutical procedures.

As is the case in several cities in Indonesia, one of which has happened in Jember, the Jember District Court based on Court Decision Number 145/Pid.Sus/2024/PN Jmr.⁸ A business actor named Awaludin Hasan, a person who does not have expertise and authority but carries out pharmaceutical practices related to pharmaceutical preparations in the form of hard drugs, as regulated in Article 145 Paragraph (1) of Law Number 17 of 2023 concerning Health, which reads "Pharmaceutical practices must be carried out by pharmaceutical personnel by the provisions of laws and regulations".⁹ Which is proven to trade hard drugs with the types of Trihexifenidil Y, DMP, and Tramadol.

Meanwhile, similar problems have also occurred in Palangkaraya, Central Kalimantan. A drug store was revoked by One Stop Investment and Integrated Services Office (DPMPSTP) by Number 503.3/04/DPM-PTSP/P1A/VI/2020. Because this drug store does not have pharmacists or pharmaceutical technical personnel. Other than license revocation by One Stop

⁶Gunawan, Y.I. dan Khoiruman, M. (2021). Analisa Consumer Trust Terhadap Partisipasi Konsumen Apotek Rakyat (Studi Kasus Maraknya Peredaran Obat Ilegal Di Surakarta). *Excellent : Jurnal Manajemen, Bisnis dan Pendidikan*. 8(1): Hlm 116-124.

⁷Pratiwi, F.S. (2023). *BPOM Temukan 1.133 Kasus Obat Ilegal di Indonesia pada 2022*. URL: <https://dataindonesia.id/varia/detail/bpom-temukan-1133-kasus-obat-ilegal-di-indonesia-pada-2022>. Diakses pada tanggal 5 Oktober 2024.

⁸Putusan Mahkamah Agung Republik Indonesia Nomor 145/Pid.Sus/2024/PN Jmr.

⁹*Ibid.*

Investment and Integrated Services Office (DPMPTSP) along with the Public Health Office, BPOM, dan Polresta Palangkaraya confiscated medicines in the store, including hard drugs to be secured.¹⁰

Also, we often encounter drugstores that run their business without a license from the Dinas Kesehatan or BPOM, an example of this is the drugstore located in Kalideres, West Jakarta. The store does not have an official license to sell drugs, even though this shop has been operating for decades. The types of hard drugs sold in this store include Amlodipine Besylate, Captopril, Voltadex, and others.¹¹ This contradicts article 145 paragraph 1 of Law no. 17 of 2023 on Health, which states that “Pharmaceutical professionals must practice their profession under the laws and regulations.”¹²

Every medicine has side effects that may arise if taken inappropriately. The use of hard drugs without a doctor’s prescription can have health consequences, with side effects felt in the form of dizziness, nausea, convulsions, and even kidney malfunction. Consumption of excessive doses of hard drugs can also result in resistance, and overdose and may cause death.¹³

This can cause concern for the people as consumers. The distribution of hard drug products carried out by sellers in drug stores who do not have the authority to practice pharmacy, it can threaten the safety and health of consumers and potentially cause harm to the public. Law no. 8 of 1999 defines consumer protection as “any action designed to ensure legal certainty to guarantee consumer protection”. A consumer is defined as any individual who makes use of goods or services offered by the community, whether for his or her account or for the benefit of others, , their families, or other living creatures. Trade does not fall under this definition.¹⁴

Indonesia already has regulations to protect the public from the circulation of hard drugs without a doctor’s prescription, but the public or consumers often do not pay attention to it. Therefore, to realize consumer protection against drug circulation by sellers in drug stores without authority to carry out pharmaceutical practices, the author will delve into the legal protection provided to consumers as a result of losses in the distribution of hard drugs by unlicensed drug stores (Based on Law Number 8 of 1999 concerning Consumer Protection), and the endeavor undertaken by BPOM in tackling the circulation of hard drugs in unlicensed drug stores.

METHOD

According to Soerjono Soekanto, the legal normative approach is based on legal research conducted using literature or secondary information as a basis for study. It involves examining regulations and literature relating to the problem under consideration.¹⁵ This study is a legal analysis, i.e. an examination of the implementation of the Consumer Protection Act in the context of hard drug trafficking. Through the approach of Statue Approach and Case Approach , by using primary legal sources, specifically the 1945 Constitution of the Republic of Indonesia, Law Number 8 Year 1999 on Consumer Protection (UUPK), and Law Number 17 Year 2023 on Health. Additionally, supplementary legal documents consist of publications about the law in the form of books on consumer protection, health, and food; Law Journal; Court Decisions;

¹⁰redaksikalteng.co. (2020). *Apotek Manjur Dipaksa Tutup Oleh Petugas*. URL: <https://kalteng.co/utama-headline-kalimantan-tengah/apotek-manjur-dipaksa-tutup-oleh-petugas/>. Diakses tanggal 15 September 2024.

¹¹Febrian, H.M. (2024). *Dinkes Jakbar Temukan Toko Tak Berizin Jual Obat Keras*. URL: <https://poskota.co.id/2024/08/12/dinkes-jakbar-temukan-toko-tak-berizin-jual-obat-keras>. Diakses tanggal 15 September 2024.

¹²*Ibid.*

¹³Sianipar, A.Y. and Thaib, C.M. (2020). *Penyuluhan Efek Samping Obat Tanpa Resep Dokter Yang Dapat Membahayakan Di Kelurahan Denai, Medan*. *Jurnal Abdimas Mutiara*. Vol 1(2). Hlm 86-89.

¹⁴Undang-Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen.

¹⁵Soerjono Soekanto & Sri Mamudja. (2001). *Penelitian Hukum Normatif (Suatu Tinjauan Singkat)*. Jakarta: Rajawali Pers. p. 13-14.

and the Internet. Then the data collection tools in this research are Library Research (searching for documents in the form of internet access, books, and research journals). The data obtained in library research is a source of information seen by experts in their fields so that it is relevant to the information under research.

ANALYSIS DAN DISCUSSION

Legal Protection for Consumers as a Result of Losses in the Circulation of Hard Drugs by Unlicensed Drug Stores (Based on Law Number 8 of 1999 on Consumer Protection)

Consumer problems are concern of everyone because consumer problems are national problems that should be protected and supervised by the government. The purpose of implementing, developing, and guaranteeing consumer protection is to increase consumer power and indirectly motivate businesses to engage in their business activities responsibly. However, at this time many people do not understand the law, their rights, and obligations as consumers.

With consumers' unfamiliarity, this is used as an opportunity for business actors to take advantage of the situation. As is the case with the selling of medications, where a large number of pharmacies continue to operate without the necessary authorization or license to engage in pharmaceutical activities. It is not uncommon for them to sell hard drugs without a doctor's prescription. This can lead to unwanted risks and other issues such as security, safety, and health for consumers.

Legally, there are many laws regarding the sale of medicines and the classification of medicines, but the regulations are still weak. Article 12 paragraph (1) of the Minister of Health Regulation Number 9 of 2017 concerning Pharmacies stipulates that the establishment of a Pharmacy must have a license from the Minister of Health. The Minister of Health is authorized to delegate the granting of this license to the district/city government.¹⁶

Secondly, the Minister of Health's regulation number 26 of 2018 on corporate licensing services that are electronically incorporated in the medical field. In Article 1 number 75, it is explained that a Drug Store is a means that has a permit to store limited non-prescription drugs and non-prescription drugs for retail sale. And in Article 31 paragraph (3), which explains the drug store permit with one of the conditions is to have a license to practice pharmaceutical technical personnel as the person in charge of the technical. Therefore, in the case of distribution of hard drugs by drug stores that do not have authority in pharmaceutical practice, they have violated Article 1 point 75 and Article 31 paragraph (3) in Permenkes No. 26/2018.¹⁷ Because the owner of the drug store does not have a license to practice pharmaceutical personnel and store and sell hard drugs, where the drug store should only be given a permit to store and sell non-prescription drugs and limited non-prescription drugs.

According to the guidelines for the use of over-the-counter medicines drawn up by the Community Pharmacy Development Directorate, the clinics of the Pharmaceutical Development Directorate, and the Medical Devices Directorate of the Ministry of Health, these can only be administered on medical prescription, and have a special mark in the form of a circle with a black circle with a red base with the letter "K" based on the Decree of the Minister of Health of

¹⁶Peraturan Menteri Kesehatan Nomor 9 Tahun 2017 Tentang Apotek.

¹⁷Peraturan Menteri Kesehatan Nomor 26 Tahun 2018 tentang Pelayanan Perizinan Berusaha Terintegrasi Secara Elektronik Sektor Kesehatan.

the Republic of Indonesia No. 02396/A/SK/V1986 concerning Special Signs for Hard Drugs.¹⁸ Drugs included in hard drugs are:¹⁹

1. All Injectable Drugs;
2. Antibiotic drugs, for example, Amoxicillin Chloramphenical, Penicillin, Tetracycline, and Ampicillin.
3. Antibacterial drugs, for example, Sulfadiazine (Elcosine), and Trisulfa.
4. Amphetamine (O.K.T)
5. Antazolinum/Antistin/Antihistamine Drugs.
6. Digitoxin, Lanatosid C/Cedalanid, Digitalis Folia (Heart Medicine).
7. Hydantoimun (Anti-epilepsy drug).
8. Reserpinum (Anti-intervention drug).
9. Duck. K (Anti-bleeding).
10. Meprobamatum (Sedative).
11. Tramadol, and Trihexyphenidyl.



Image 1. Signs of Hard Drugs

A medical prescription is required to acquire hard drugs and to dispense them through a licensed pharmaceutical employee. According to letter c, article 24, of government regulation no. 51 of 2009 concerning pharmaceutical work, “pharmacists have the power to administer hard drugs, narcotics, and psychotropic substances to the public on medical prescription, under applicable laws and regulations.”²⁰ Article 145, paragraph 1, of Law no. 17 of 2023 on health also specifies that “pharmaceutical personnel is required to carry out pharmaceutical practice in compliance with laws and regulations”.²¹

Regulations on the use of hard drugs are made to prevent abuse in the consumption of hard drugs. Because there are still many people who easily get hard drugs even without a doctor’s prescription sold in drug stores. The drug store should convey information about the hard drug, according to what is stated on the packaging. If hard drugs are used without a doctor’s prescription and in excessive doses, it can have an impact on the health of the body’s organs and can cause overdose and even death.²² Every drug has side effects in its use, for example, Amoxicillin is a hard antibiotic to treat bacterial infections-related illnesses, Amoxicillin’s

¹⁸Aryo Bogadenta. (2013). *Manajemen Pengelolaan Apotek*. Yogyakarta: D-Medika. p. 18.

¹⁹Muhid, H.K. (2022). *Apa Itu Obat Daftar G, Bagaimana Ciri-Cirinya? Ini Daftar Obat Keras Itu*. URL: <https://gaya.tempo.co/read/1617164/apa-itu-obat-daftar-g-bagaimana-ciri-cirinya-ini-daftar-obat-keras-itu>. Diakses pada tanggal 6 Oktober 2024.

²⁰*Ibid.*

²¹*Ibid.*

²²Pratama, I.K.D.D., Habibi, H. dan Suarna, I.N. (2022). Upaya Hukum Terhadap Penjualan Obat Keras Tanpa Resep Dokter (Kajian Undang-Undang Perlindungan Konsumen Dan Hukum Hindu). *Jurnal Hukum Agama Hindu Widya Kerta*. Vol 5(2): 138-150.

adverse effects include headaches, abdominal pain, dizziness and nausea, breathing problems, bloody bowel movements, jaundice, and even kidney failure.²³

The aim is therefore to raise awareness of the need to safeguard customers' rights in order to prevent any infringement and to prevent fraud perpetrated by commercial parties likely to cause harm to customers. Therefore, it is imperative to introduce protective measures for consumers, in line with the principles set out in Articles 2 and 4 of the Consumer Protection Act No. 8 of 1999. These govern safety and security standards designed to ensure the protection and safety of consumers when using goods or services offered by commercial parties.²⁴ Hence, regulations mentioned by the author above are a form of legal protection for consumers who are harmed in the case of the circulation of hard drugs by drug stores that do not have a license or who do not have the authority to carry out pharmaceutical practices.

The following are the specific rights of consumers as stated in Article 4 of Law Number 8 of 1999 concerning Consumer Protection:²⁵

- a. The right to guarantee safety, comfort, and well-being when consuming goods or services;
- b. The obligation to select and acquire goods under the exchange rate, conditions, and guarantees stipulated;
- c. The obligation to obtain accurate, clear, and authentic information on the condition and guarantee of goods or services.
- d. The ability to voice concerns on the products utilized;
- e. The ability to employ consumer dispute resolution, advocacy, and protection initiatives correctly;
- f. The entitlement to consumer guidance and instruction;
- g. The entitlement to impartial treatment devoid of bias;
- h. The right to substitute products or payment for damages in the event that the items are deemed unsuitable;
- i. Other rights as stipulated by other laws and regulations.

Consumers have recourse to legal proceedings if the distribution of hard drugs is carried out by unlicensed pharmacies, based on According to the UUPK Article 45, paragraph (2), parties may choose to resolve their disagreement amicably or amicably out of court. Dispute resolution through the courts: Under UUPK Article 46, paragraph (1), a lawsuit can be brought by:

- a. A disgruntled customer or heir is involved.
- b. A collection of customers with similar interests.
- c. Approved non-governmental organizations that promote consumer protection; can take the shape of foundations or legal entities that have explicitly stated in their articles of association that their mission is to advance consumer protection and that they have only conducted operations in compliance with these guidelines.
- d. The government and/or associated organizations if the products and/or services used or consumed cause substantial material losses and/or fatalities.

Out-of-court settlement of consumer disputes can be carried out by a special unit called a Badan Penyelesaian Sengketa Konsumen (BPSK) established and regulated by the Consumer Protection Law, whose main role is to resolve disputes between consumers and businesses.²⁶

²³Dr. Rizal F. (2024). *Amoxicillin Trihydrate*. URL: https://www.halodoc.com/kesehatan/amoxicillin-trihydrate?srslti-d=AfmBOorEFBVbjhYPvdRssjFFL-5lb6UKhBeZJCxKc-K_PjklP7FxbESL. Diakses pada tanggal 29 September 2024.

²⁴*Ibid.*

²⁵*Ibid.*

²⁶Putra, I.K.S. and Priyantini, G.A.P.N. (2021). Aspek Perlindungan Hukum Peredaran Obat Tanpa Izin Edar Lembaga Berwenang Menurut Undang-Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen (Studi Kasus: Putusan Pn Singaraja Nomor 80/Pid. Sus/2017/Pn Sgr). *Jurnal Media Komunikasi Pendidikan Pancasila Dan Kewarganegaraan*. Vol 3(2): 77-90.

Article 23 of the UUPK regulates this and gives BPSK the authority to administer administrative penalties to business actors who disobey specific rules that apply to business actors.

BPOM's Efforts to Tackle the Circulation of Hard Drugs in Unlicensed Drug Stores

In practice, we still find drug stores that do not have business licenses and do not have pharmaceutical technical personnel. An example that has happened in Kalideres, West Jakarta. Public Health Office found a drug store in Kalideres, which do not have a permit to distribute hard drugs. It is known that the store has been operating for decades, but does not have a business license to establish a drug store. The types of hard drugs sold at the store include Amlodipine Besilat, Captopril, dan Voltadex.²⁷ Cases like this do not only occur in West Jakarta, but also in several regions in Indonesia. Where there are still many drug stores that do not have a business license, but dare to continue to run their business, as well as store and distribute hard drugs without a doctor's prescription to consumers.

As for the case that has occurred in Jember, the Jember District Court based on Court Decision Number 145/Pid.Sus/2024/PN Jmr.²⁸ The business actor, named Awaludin Hasan, was found guilty of committing a criminal act “, According to Article 436, paragraph (2) of Law Number 17 of 2023 on Health, which states “Any individual lacking expertise and authority, but performing pharmaceutical acts in accordance with pharmaceutical preparations in the form of hard drugs is sentenced to a maximum fine of Rp 200,000,000 (two hundred million rupiah)”.²⁹ The defendant Awaludin was proven to have traded hard drugs with the types of Trihexifenidil Y, DMP, and Tramadol, so he was sentenced to 2 (two) years in prison.

In this problem, of course, consumers are very disadvantaged, because the use of hard drugs without a doctor's prescription can result in consumer health. The National Legal Development Agency stated that five factors weaken the position of consumers, namely:

1. There is still a weak level of consumer awareness of their rights;
2. The non-socialization of consumer protection laws explains the lack of conditioning in the consumer community;
3. There is no willingness of the consumer community to demand their rights if they are harmed;
4. The judicial process is complicated and time-consuming in resolving it;
5. Materially weak consumer processes.³⁰

This means that there is a need for stricter government supervision. Because drug abuse can result in losses, especially to consumers both material and immaterial, such as serious health problems for consumers or the community itself. Only pharmacies are permitted to offer hard drugs with a prescription from a doctor, per the laws.³¹ Drug stores are only permitted to supply and sell restricted over-the-counter medications; nonetheless, it is still common to find drug stores that sell hard narcotics without a prescription. Due to the lack of public knowledge about drug classes in Indonesia, it is very important to have an institution that has the expertise and knowledge to prevent and supervise the circulation of inappropriate and effective drugs in Indonesia, especially hard drugs.

Monitoring the circulation of non-prescription hard drugs sold by unlicensed drug stores is an important issue to avoid the misuse of hard drugs. Hard drugs that are easily obtained without a doctor's prescription can endanger the public because they can be used for illegal

²⁷Febrian, H.M. (2024). *Dinkes Jakbar Temukan Toko Tak Berizin Jual Obat Keras*. URL: <https://poskota.co.id/2024/08/12/dinkes-jakbar-temukan-toko-tak-berizin-jual-obat-keras>. Diakses tanggal 15 September 2024.

²⁸*Ibid.*

²⁹*Ibid.*

³⁰N.T.H Siahaan. (2005). *Perlindungan Konsumen dan Tanggung Jawab Produk*. Jakarta: Pantrei. p. 42.

³¹Hidayat, R. A. R. (2024). *Perlindungan Hukum Terhadap Konsumen Pengguna Obat Yang Beredar Luas Di Pasaran*. *Kultura: Jurnal Ilmu Hukum, Sosial, Dan Humaniora*. Vol 2(2): 247-274.

acts that will threaten safety and health. Therefore, the government has a responsibility to protect the circulation of drugs in the community, and strict supervision is needed to regulate the circulation of hard drugs sold by drug stores without a doctor's prescription.

In Indonesia, drugs and food are controlled by the National Drug and Food Control Agency (BPOM), spread across all provinces to enable supervision on a regional scale. BPOM aims to improve the role, effectiveness and efficiency of BPOM in carrying out its responsibilities and functions as an agency authorized to conduct drug and food supervision in Indonesia.³² Based on Presidential Regulation No. 8 concerning BPOM, legally it has the authority and position related to carrying out and forming regulations on drugs and food which aim to supervise products circulating throughout Indonesia.

Efforts made by BPOM in eradicating drug stores that sell hard drugs without a doctor's prescription include:

1. Educate drugstore and pharmacy business actors.

By conducting direct education by BPOM officers to pharmacies and drug stores as well as inspecting existing facilities. Implementation of Good Manufacturing Practices (GMP), administration, presence of pharmacy technicians when drug stores are opened, licensing, hygiene, and sanitation are indicators related to education and supervision conducted by BPOM.³³ As well as conducting counseling for business actors who want to establish a drug store, it is necessary to take care of the Drug Store License with one of the conditions, specifically adding a deed of collaboration between the pharmacy store facility's owner and the pharmacist assistant.³⁴ So, the drugstore has a pharmaceutical technician, to avoid the sale of hard drugs without a doctor's prescription among the public.

This is BPOM's effort to carry out a series of preventive measures aimed at protecting the public and preventing violations that can cause losses in the field of medicines, especially preventing losses caused by buying and selling hard drugs that are not in accordance with regulations.

2. Conduct supervision.

Although drug stores are not directly controlled by BPOM due to limited human resources, oversight is provided by a system that ensures that hard drugs are not distributed or sold in a manner that is against regulations. By monitoring distribution channels to ensure that they comply with standards, in a way BPOM is responsible for supervising Pharmaceutical Wholesalers (PBF), government pharmaceutical warehouses, and other distribution facilities to ensure compliance with regulations in the distribution of medicines.³⁵ It is very important to ensure that the drugs are not marketed on a large scale to unqualified individuals or companies.

Other than the BPOM, the Public Health Office also plays an important role in supervising and controlling the circulation of hard drugs among the public. In addition, the Public Health Office also grants distribution licenses to classes of hard drugs that meet predetermined safety and quality standards. The Public Health Office also has the authority to enforce regulations by applying administrative sanctions against business actors, namely drug stores that do not

³²Peraturan Badan Pengawas Obat dan Makanan Nomor 15 Tahun 2023 tentang Perubahan Keempat Atas Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor 24 Tahun 2017 tentang Kriteria dan Tata Laksana Registrasi Obat.

³³Siregar, A. S., & Darmawan, D. (2023). Jual Beli Obat Keras Tanpa Resep Dokter Dalam Perspektif Undang-Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen (Suatu Penelitian Di Kota Banda Aceh). *Jurnal Ilmiah Mahasiswa Bidang Hukum Keperdataan*. Vol 7(2): 214-222.

³⁴DPMPTSPTK. *Izin Pendirian Toko Obat*. URL: <https://dpmptsptk.landakkab.go.id/izin/detail/izin-pendirian-toko-obat>. Diakses pada tanggal 06 Oktober 2024.

³⁵Toyib, Linda, M., dan Agus, T. (2024). Analisis Pengaturan Penjualan Obat Bebas dan Obat Bebas Terbatas di Warung dan Toko Kelontong Berdasarkan Undang-Undang Kesehatan. *Jurnal Mahasiswa Humanis*. Vol 4(3).

have a license and distribute hard drugs without a doctor's prescription, so that business actors can comply with existing regulations.³⁶

3. Announcement of an investigation into unlicensed drug stores selling hard drugs.

BPOM announces to the public that the authorities investigate before proceeding to the stage of examining the case in court and announcing the judge's verdict for the crime.³⁷ The goal is to inform other pharmacy owners that selling hard drugs is punishable by law, to prevent them from doing so. The media can inform the public that the purchase of hard drugs in pharmacies is prohibited. This can discourage people from wanting to buy it.

4. Conducting an inspection directly to the drug store.

By routinely conducting sudden direct inspections to drug stores, which are unknown to drug store business actors, BPOM knows whether in practice many drug stores dare to sell hard drugs without a doctor's prescription, if they are not routinely monitored by BPOM.

External oversight from community institutions is required in addition to the efforts made by BPOM to eradicate unlicensed drug stores and distribute hard drugs without a prescription. This oversight can be provided by the Non-Governmental Consumer Protection Agency (LPKSM), a non-governmental organization that is actively involved in consumer protection and can help put consumer protection into practice.³⁸

The functions of guidance and supervision for consumer protection have been clearly defined by UUPK with guidance given as the duty of the government and other relevant institutions. The obligation to supervise lies not only with the government but also with the community via the LPKSM. If pharmacies are dispensing hard drugs without medical authorization, which could cause harm to consumers, the LPKSM is able to assist consumers in exercising their right to sue commercial players such as pharmacies. In this way, the LPKSM can support clients in defending their right to sue commercial players such as pharmacies.³⁹ LPKSM also provides further protection in the health sector by continuing to raise awareness of the importance of remaining vigilant about medicines circulating in the community. Business actors are also encouraged to comply with applicable regulations to avoid the application of penalties or sanctions for business actors who commit violations.

CONCLUSION

Legal protection for consumers in Indonesia, especially related to the sale of hard drugs without a doctor's prescription, is a very important issue. People are often unaware of their rights and obligations as consumers, making them vulnerable to illegal practices carried out by unlicensed drug stores. Despite regulations governing the sale of drugs, weak law enforcement and low consumer awareness are major challenges in protecting public health.

Under Article 45(2) of the UUPK, consumers have the right to take legal action in the event of losses arising from the supply of hard medicines by stores that are illegal or unlicensed to carry out pharmaceutical activities. The dispute resolution process may be judicial or extrajudicial, at the discretion of the parties concerned.

³⁶Amalina, R. A. (2024). Problematika Jual Beli Obat Keras Golongan Prekursor Oleh Apotek Di Samarinda. *DEDIKASI: Jurnal Ilmiah Sosial, Hukum, Budaya*. Vol 25(1): 33-48.

³⁷Suriangka, A. (2017). Perlindungan Konsumen Terhadap Penyaluran Obat Keras Daftar G Oleh Badan Pom Di Makassar. *Jurisprudentie : Jurusan Ilmu Hukum Fakultas Syariah Dan Hukum*, 4(2): 24-36.

³⁸Amelia, M., & Angraini, A. M. T. (2020). Peran pemerintah dalam mengawasi peredaran obat keras golongan G tanpa surat izin edar menurut Undang-Undang Nomor 8 Tahun 1999 tentang Perlindungan Konsumen (Studi kasus: Putusan Nomor 874/Pid. Sus/2018/PN. Sda). *Jurnal Hukum Adigama*. Vol 3(1): 269-295.

³⁹Ikhsa, M., Wahyati, E., & Wahab, S. (2022). Supervision of Drug Circulation and Protection of Health Rights for Consumers. *Soepra Jurnal Hukum Kesehatan*. Vol 8(1): 8-25.

The Food and Drug Supervisory Agency (BPOM) has a crucial role in supervising drug circulation and providing education to business actors. However, stronger collaboration is needed between the government, consumer protection agencies, and institutions in the health sector such as the Health Office and BPOM, as well as the public to raise awareness and prevent the circulation of hard drugs by unlicensed drug stores. With more decisive and educational measures, it is hoped that consumer protection can be improved so that public health can be maintained from the risk of hard drug abuse.

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