

## The Danger of Illegal Drugs to Public Health from A Criminological and Regulatory Perspective

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### ABSTRACT

The circulation of unlicensed drugs remains a significant public health concern in Indonesia, particularly among lower-income populations who often purchase medications from unregulated sources such as street vendors and informal shops. These drugs frequently lack verified safety standards, increasing the risk of harmful side effects. The inability to distinguish between genuine and counterfeit drugs, compounded by a lack of consumer knowledge and weak enforcement, contributes to the persistent distribution of unauthorized pharmaceutical products. This study aims to examine the legal regulations governing the distribution of drugs without a license and analyze the enforcement mechanisms applied to offenders. Employing normative juridical research methods, the study reviews and interprets existing legal frameworks including Law No. 17 of 2023 on Health, Regulation of the Minister of Health No. 10101/MENKES/PER/XI/2008 on Drug Registration, Presidential Regulation No. 80 of 2017 concerning the National Food and Drug Authority (BPOM), and BPOM Regulation No. 24 of 2021. The findings indicate that strict legal provisions prohibit the production, storage, promotion, or distribution of pharmaceutical products that do not meet safety, efficacy, and quality standards, with severe sanctions outlined in Article 435 of the Health Law. This study highlights the critical need for enhanced public awareness, stricter enforcement, and strengthened coordination among regulatory bodies to protect consumers from unsafe drug distribution and uphold public health standards.

### INTRODUCTION

In Indonesia's positive law, there is a regulation that specifically regulates health, namely in Law No. 17 of 2023 concerning Health, hereinafter referred to as the Health Law, the definition of health is a person's state of health, both physically, mentally, and socially and not just being free from disease to enable him to live a productive life (Daeng et al., 2023; Satria Indra Kesuma, 2023a, 2023b, 2024; Widjaja, 2023). So health is one of the basic human needs that must be met. Health is one of the parameters to measure the success of human development. Without health, human beings will not be productive to live economically viable and undergo good education".

One of the fulfillments carried out by the Government in order to support public health is to ensure the availability of medicines. Based on article 1 number 15 of the Health Law, "drugs are

materials, guidance materials that include biological products, which are used to affect physiological systems or pathological states in the context of determining diagnosis, prevention, cure, recovery, health improvement, and contraception for humans". Being healthy is something to be proud of, while when sick what can be proud of, because of course humans cannot do various activities and may be able to make family or other people anxious and worried (Borraccino et al., 2019; Iwano et al., 2022; Lorenzetti et al., 2022; Pronk et al., 2021; Traina et al., 2019).

Health is an important factor in human survival, this is because with a healthy body, humans can carry out daily activities and can carry out their role in society well. Everyone wants to have a healthy life, so various efforts are made to maintain health but it does not rule out the possibility for everyone to be affected by a disease, ranging from mild to severe diseases (Etim et al., 2020; Hsieh, 2019; Hsu & Chiang, 2020; Skallevoid et al., 2023). If they are in an unhealthy condition, there is no other option but to do treatment. In various types of treatment for the healing process of the disease suffered, medicine is not always curative. In fact, it is not uncommon to use drugs that are not suitable to cause new or even more severe diseases.

People are vulnerable to consuming drugs that do not meet safety standards and requirements and the absence of a prescription from a doctor because of the difficulty of distinguishing between real and fake drugs. Lower class people usually consume drugs sold in stalls and shops outside pharmacies without first ensuring whether they are safe for consumption and will not add side effects that are harmful to health if consumed. There are factors that affect the circulation of unlicensed drugs is increasing among the public, namely: Internal factors, namely from the consumers themselves, where they lack knowledge about the products to be consumed, especially the problem of drugs that are safe for consumption by consumers, this happens because some consumers choose drugs at cheaper prices and are easy to obtain. People basically really want the safety of medicinal products that do not result in health disturbances both for themselves and others.

External factors are the lack of concern and knowledge from drug traders for drug products that do not meet the applicable regulations, in this case there are traders who do not know the dangers that will be caused by the use of drugs without a license, there are also drug traders who already know the dangers of drugs without a distribution permit, but these drugs are still sold and bought because they want to make a big profit (Ambaw et al., 2020).

Based on Presidential Decree No. 166 of 2000 and Presidential Decree No. 103 of 2001, the Food and Drug Supervisory Agency (BPOM) was established, which in the implementation of government duties in the field of drug and food supervision in accordance with the provisions of applicable laws, with its authority, among others, granting permits and supervision of drug circulation as well as supervising the pharmaceutical industry and testing the efficacy and safety of drug products before being distributed to consumers or community. This is based on the interests of consumers in order to avoid the circulation of medicinal products that can cause harmful side effects to health if consumed. The Food and Drug Control Agency (BPOM) has also prepared a Consumer Complaint Service Unit (ULPK). The public or business actors can commit crimes by selling drugs without permission to consumers who have minimal knowledge, so that the writer wants to know the problems of the rules that apply to the perpetrators.

Previous studies have examined the legal frameworks and enforcement challenges related to the distribution of unlicensed drugs in Indonesia. Faradilla et al. (2022) highlighted that despite existing regulations, the circulation of drugs without distribution permits persists due to factors such as lack of public awareness, inadequate supervision, and the pursuit of profit by unscrupulous traders.

Similarly, Lazuardi and Handayati (2023) emphasized the need for stricter enforcement and public education to combat the proliferation of unlicensed drug distribution.

The novelty of this research lies in its focused analysis of the legal arrangements and sanctions specifically targeting individuals who distribute drugs without a license in Indonesia. By examining the effectiveness of existing laws and identifying gaps in enforcement, this study aims to provide comprehensive insights into the legal mechanisms addressing unlicensed drug distribution, which has not been extensively explored in previous literature. Based on the description above, The objectives of this research are to: (1) analyze the legal provisions governing the distribution of unlicensed drugs in Indonesia, and (2) examine the legal sanctions imposed on individuals who distribute drugs without a license.

## **METHOD**

This study employs a normative juridical legal research method, which is used to examine legal norms, principles, and rules applicable to the circulation of unlicensed drugs in Indonesia. The normative approach is descriptive in nature, aiming to systematically analyze legal materials relevant to the problem under investigation. The research is based on the interpretation of positive law, particularly statutory regulations, legal doctrines, and legal theories concerning pharmaceutical distribution and consumer protection.

The research process involves several key steps. First, the researcher conducts legal inventorying and identification, collecting primary legal materials such as Law No. 17 of 2023 on Health, Presidential Regulation No. 80 of 2017, Minister of Health Regulation No. 10101/MENKES/PER/XI/2008, and BPOM Regulation No. 24 of 2021. Second, the study utilizes legal interpretation techniques (statutory, systematic, and teleological interpretation) to understand the intent, scope, and applicability of these legal norms. Third, a legal comparison is conducted to evaluate consistency across various regulatory instruments and identify normative gaps.

Secondary legal materials such as journal articles, legal commentaries, and expert opinions are used to support doctrinal analysis. Actual cases, policy papers, and BPOM reports are also referenced to link legal norms with their practical application in society. The method ensures that the legal findings are grounded in both formal law and real-world context, thus enabling a critical assessment of existing legal protections and enforcement mechanisms against the unauthorized distribution of drugs.

## **RESULT AND DISCUSSION**

### **Legal Regulations for Unlicensed Drug Dealers**

The legal regulation regarding the prohibition of producing or distributing drugs without a license is contained in Article 138 paragraph (2) of Law No. 17 of 2023 concerning Health which reads "Every Person is prohibited from holding, producing, storing, promoting, and/or distributing Pharmaceutical Preparations that do not meet the standards and/or requirements for safety, efficacy/usefulness, and quality."

Equipped with sanctions contained in Article 435 which reads "Every Person who produces or distributes pharmaceutical preparations or medical devices that do not meet the standards and/or requirements of safety, efficacy/usefulness, and quality as referred to in Article 138 paragraph (2) and paragraph (3) shall be sentenced to imprisonment for a maximum of 12 (twelve) years or a maximum fine of Rp5,000,000,000, 00 (five billion rupiah)." According to the applicable legal provisions in Indonesia, the circulation of drugs without a distribution permit is regulated by various

laws and regulations, including those issued by the Ministry of Health. Drugs circulating in the community must have a distribution permit starting from domestically produced drugs and drugs from abroad. The drug permit is issued by the Food and Drug Supervisory Agency (BPOM).

Based on article 143 Paragraph (1) of the Health Law and the Regulation of the Minister of Health No. 28 of 2022 concerning Changes in Classification, Restrictions, and Categories of Drugs, it is stipulated that "Pharmaceutical preparations and medical devices can only be circulated after obtaining a distribution permit" While distribution permits are according to the Regulation of the Food and Drug Supervisory Agency Number 13 of 2021 concerning Criteria and Procedures for Drug Registration, Article 1 number 7 stipulates that "Distribution permit is a form of registration approval to be circulated in Indonesian territory" further regarding regulations related to distribution permits, also regulated in Article 3 of BPOM Regulation Number 8 of 2020, stipulates that "Drugs that are circulated must have a distribution permit and meet the requirements for good manufacturing and distribution of drugs in accordance with the provisions of laws and regulations" With a distribution permit from the Food and Drug Supervisory Agency, it shows that The drug is suitable for consumption and meets the requirements for safety, efficacy/benefits, and quality if there is a drug that is not registered first, the drug is an illegal drug as regulated in Article 1 number 1 of the BPOM Regulation concerning Criteria and Procedures for Drug Registration, stipulating that "Drug registration, hereinafter referred to as registration, is a procedure for drug registration and evaluation to obtain approval" The drug being circulated must meet the requirements contained in Article (2) in the Regulation of the Head of the Food Drug Supervisory Agency Number 24 of 2017 concerning Drug Registration Procedures, among others;

1. Drugs to be distributed in Indonesian territory are required to have a distribution permit
2. To obtain a distribution permit as intended in Paragraph (1), registration must be carried out
3. Registration as intended in Paragraph (2) is submitted by the registrant to the Authorized Agency".

The crime of distributing pharmaceutical preparations without a permit is an activity carried out by a person or individual or a group who deliberately makes or distributes pharmaceutical preparations without the attachment of laboratory test results and distribution permits from the Food and Drug Supervisory Agency.

Based on the Regulation of the Minister of Health of the Republic of Indonesia Number 8 of 2022, determining the criteria and requirements for drugs that must meet the distribution permit are as follows:

1. **Drugs Must Be Registered:** Drugs must have a distribution permit number issued by the Food and Drug Supervisory Agency (BPOM) or an authorized institution.
2. **Drugs Must Meet Technical Requirements:** Drugs must meet established technical requirements, including quality, safety, and efficacy standards
3. **Information and Labels:** Medications should be accompanied by appropriate information and labels, which contain important information such as indications, dosage, how to use, and side effects.
4. **Documentation and Evidence:** Drug manufacturers or importers must include documentation and evidence supporting the safety, efficacy, and quality of the drug.
5. **Supervision and Evaluation:** Drugs must go through a monitoring and evaluation process conducted by BPOM to ensure that they are safe and effective to use.

The government provides an institution that functions to ensure the safety of food and drugs in the market. This institution functions to issue licenses to companies that have passed the test that the products they release will not have adverse effects on the human body, the institution in question is the Food and Drug Supervisory Agency. that way no person or company dares to release products for

consumption that are illegal, meaning without BPOM permission. The purpose of monitoring drugs and food is to ensure that all products to be distributed are safe and do not harm consumers.

Government Regulation of the Republic of Indonesia Number 72 of 1998 concerning the Security of Pharmaceutical Preparations and Medical Devices in Article 9 of the Regulation reads:

1. Pharmaceutical preparations and medical devices can only be distributed after obtaining a distribution permit from the Minister.
2. Exempt from the provisions as intended in paragraph (1) for pharmaceutical preparations in the form of traditional medicines produced by individuals.

Article 1 paragraph (1) of the Regulation of the Head of the Food and Drug Supervisory Agency of the Republic of Indonesia Number 24 of 2017 explains that "a distribution permit is a form of approval for registration for medicinal products, traditional medicines, cosmetics, food supplements and food issued by the Food and Drug Supervisory Agency of the Republic of Indonesia so that the product can be legally distributed in Indonesian territory". In this case, namely the Regulation of the Head of BPOM in Law Number 17 of 2023 article 143 paragraph (1) also explains that pharmaceutical preparations and medical devices can only be circulated after obtaining a distribution permit, so that if someone distributes pharmaceutical preparations without a distribution permit, they will get the sanctions that have been determined, namely in Law Number 17 of 2023 concerning health In Article 139, 143, 435, and 436 of Law No. 17 of 2023 concerning Health discuss illegal drugs as follows: Article 139 of Law No. 17 of 2023 concerning Health reads:

1. Pharmaceutical preparations and medical devices must be safe, efficacious/useful, quality, and affordable.
2. Everyone who does not have expertise and authority is prohibited from procuring, storing, processing, promoting, and distributing drugs and materials that have medicinal properties.
3. Provisions regarding the procurement, storage, processing, promotion, and distribution of pharmaceutical preparations and medical devices must meet the quality standards of pharmaceutical services set by Government Regulations.

Article 143 of Law No. 17 of 2023 concerning Health reads:

1. Pharmaceutical preparations and medical devices can only be distributed after obtaining a distribution permit.
2. The marking and information of pharmaceutical preparations and medical devices must meet the requirements of objectivity and completeness and are not misleading.
3. The government is authorized to revoke distribution permits and order the withdrawal from circulation of pharmaceutical preparations and medical devices that have obtained distribution permits, which are then proven to not meet the requirements of quality and/or safety and/or usefulness, can be confiscated and destroyed in accordance with the provisions of laws and regulations.

The circulation of illegal drugs that is increasingly rampant among the public makes law enforcers carry out their duties in accordance with applicable laws and regulations such as Article 8 of Law Number 8 of 1999 concerning Consumer Protection.

### **Legal Sanctions Against Drug Dealers Without Permission**

One of the criminal acts in the health sector is in the pharmaceutical sector. Pharmacy is a profession related to health that is closely related to health sciences and chemistry. Pharmacy is a profession in the health sector that includes various activities in the fields of: discovery, development, production, processing, compounding, and distribution of drugs.

The Food and Drug Supervisory Agency (BPOM) in Article 1 number 11 of the Regulation of the Head of the Food and Drug Supervisory Agency (Per KBPOM) Number 24 of 2017 concerning the Supervision of the Entry of Drugs and Food into Indonesian territory states that a distribution permit is a form of approval for drug registration to be distributed in Indonesian territory. Every pharmaceutical preparation to be distributed must first have a distribution permit, as contained in Article 143 paragraph (1) and paragraph (2) of Law Number 17 of 2023 concerning Health, namely, (1) Every Person who produces and/or distributes Pharmaceutical Preparations, Medical Devices, and PKRT (Household Health Supplies) must comply with a business license from the Central Government or Regional Government in accordance with their authority based on norms, standards, procedures, and criteria in accordance with the provisions of laws and regulations. (2) Every Person who produces and/or distributes Pharmaceutical Preparations, Medical Devices, and PKRT (Household Health Supplies) that has obtained a business license, which is proven to not meet the requirements of safety, efficacy/usefulness, and quality shall be subject to administrative sanctions in accordance with the provisions of laws and regulations in the field of business licensing.

Criminal acts in the health sector are all acts in the field of health services related to health services that are prohibited by law accompanied by certain criminal threats against anyone who violates the prohibition. Thus, the object of a criminal act in the health sector is health services or everything related to or related to health services.

The explanation of the regulation of drug trafficking crimes contained in Law Number 17 of 2023 concerning Health is as follows: 1. Article 435 of Law Number 17 of 2023 concerning Health "Any person who produces or distributes pharmaceutical preparations or medical devices that do not meet the standards and/or requirements for safety, efficacy / usefulness, and quality as referred to in article 138 paragraph (2) and paragraph (3) shall be sentenced to imprisonment a maximum of 12 (twelve) years or a maximum fine of Rp5,000,000,000.00 (five billion rupiah).

The elements contained in Article 435 of Law Number 17 of 2023 concerning Health are as follows:

- a. Everyone here means who is a legal subject, that is, every person or individual can be responsible and capable of law in accordance with laws and regulations and legal entities that are legal entities in accordance with laws and regulations.
- b. Producing or distributing pharmaceutical preparations and/or medical devices Producing is an act that is a process to produce results, while the word circulating means an act of carrying something from one hand to another or from one place to another.
- c. Which does not meet the standards and/or requirements of safety, efficacy or usefulness, and quality as referred to in Article 138 paragraph (2) and paragraph (3).

Article 436 paragraph (1) of Law Number 17 of 2023 concerning Health "Every person who does not have expertise and authority but carries out pharmaceutical practices as referred to in article 145 paragraph (1) shall be punished with a maximum fine of Rp200,000,000.00 (two hundred million rupiah) 3. Article 436 paragraph (2) of Law Number 17 of 2023 concerning Health "In the event that there is a pharmaceutical practice as referred to in paragraph (1) related to pharmaceutical preparations in the form of hard drugs, it shall be punished with imprisonment for a maximum of 5 (five) years or a maximum fine of IDR 500,000,000.00 (five hundred million rupiah).

Article 62 of Law No. 8 of 1999 concerning Consumer Protection explains criminal sanctions, namely:

1. Business actors who violate the provisions as referred to in Article 8, Article 9, Article 10, Article 13 paragraph (2), Article 15, Article 17 paragraph (1) letter a, b, letter c, letter e,

- paragraph (2), and Article 18 shall be sentenced to a maximum prison sentence of 5 (five) years or a maximum fine of Rp 2,000,000,000.00 (two billion rupiah).
2. Business actors who violate the provisions as referred to in Article 11, Article 12, Article 13 paragraph (1), Article 14, Article 16, and Article 17 paragraph (1) letters d and f are sentenced to a maximum prison sentence of 2 (two) years or a maximum fine of Rp 500,000,000.00 (five hundred million rupiah).
  3. Violations that result in serious injury, serious illness, permanent disability or death are subject to applicable criminal provisions.

Article 386 paragraph (1) of the Criminal Code also regulates the criminalization of food and drug circulation where the article reads: Whoever sells, offers or delivers food, beverages, or medicines that he knows to be fake, and conceals them, is threatened with imprisonment for a maximum of 4 (four) years.<sup>32</sup> Law Number 17 of 2023 concerning Health regulates criminal sanctions against perpetrators of distributors of preparations pharmaceutical without a license, namely in Article 435 states "Every person who produces or distributes pharmaceutical preparations and/or medical devices that do not meet the standards and/or requirements of safety, efficacy/usefulness, and quality as referred to in Article 138 paragraph (2) and paragraph (3) shall be sentenced to imprisonment for a maximum of 12 (twelve) years or a maximum fine of Rp5,000,000,000, 00 (five billion rupiah)."

Furthermore, Article 436 Every person who does not have expertise and authority but carries out pharmaceutical practices as referred to in Article 145 paragraph (1) shall be punished with a maximum fine of Rp200,000,000.00 (two hundred million rupiah). Sanctions are urgently needed to support the regulations imposed on criminal acts, in the hope that the person concerned will not repeat the act. Without the support of sanctions that accompany prohibitions or orders, people cannot expect much for the creation of a just and prosperous life in accordance with the mandate of the law. In the implementation of law enforcement, there are several aspects that can affect law enforcement itself so that law enforcement can be realized.

The following factors affect law enforcement include:<sup>33</sup>

1. The Law is inseparable from law enforcement because the Law that regulates a rule in the form of in this case a drug that does not have a distribution permit regarding the Law has several principles whose purpose is for the law to have a positive impact on its implementation, it means that the law must be effective and achieve its purpose.
2. Law enforcement Law enforcement is part of the behavior carried out by law enforcement officials. In Indonesia itself, law enforcement is carried out by law enforcers such as police, prosecutors, judges and lawyers, these law enforcers are tasked with maintaining the law so that it is still obeyed by the community, as a law enforcer the government is obliged to maintain and maintain order in the community by enforcing the law to the community who commit violations of the law, if law enforcement is unable to carry out their duties as mandated in the The law will have a negative impact on law enforcement, if the role of law enforcement goes well, law enforcement can run well as well.
3. The community plays an important role in law enforcement efforts, because the higher the level of legal awareness of the community, the more good law enforcement will be possible. Law enforcement exists for the community to create order, justice, certainty, and benefits in society. So the community itself is a factor that can affect the law enforcement process.

In eradicating the circulation of drugs that do not have a permit, law enforcement represented by BPOM and other related parties, must supervise the makers or sellers of drugs and conduct raids if there are reports or information related to the circulation of illegal drugs found by the public. As

has been found to be one of the drug trafficking that does not have a permit which occurred on August 27, 2023 where, the Public Relations of the Jabart Police – the Cirebon Police Narcotics Task Force revealed the alleged criminal act of distributing pharmaceutical preparations without a distribution permit. In the disclosure, the officers secured several drugs as evidence.

Based on public information, the police conducted an investigation and uncovered the criminal act of distributing pharmaceutical preparations without a distribution permit at one of the cosmetic stores in the jurisdiction of the Cirebon Police. The female suspect with the initials JA, a resident of Tengah Tani Village, was secured with evidence of hard drugs of the type Tramadol HCL 8 grains, psychotropic type Alprazolam type 5 grains.<sup>34</sup> . In addition to criminal sanctions, administrative sanctions that can also be imposed on drug dealers without a license are

1. Temporary ban on the distribution of medicines and food;
2. An order to withdraw medicinal products and food from circulation if there is a risk of contamination of medicines and food or medicines and food that are not safe for human safety;
3. Destruction if proven to endanger human health and soul;
4. Imposition of fines.

## CONCLUSION

The legal framework governing the circulation of pharmaceutical products in Indonesia demonstrates a strong commitment to consumer protection through a combination of statutory regulations and regulatory agency oversight. Laws such as Law No. 17 of 2023 on Health, the Minister of Health Regulation No. 28 of 2022, and BPOM regulations explicitly prohibit the production and distribution of drugs that do not meet established standards for safety, efficacy, and quality. However, while these legal instruments provide a solid foundation, their effectiveness remains contingent upon consistent enforcement, public awareness, and ethical compliance from drug traders. The persistence of unlicensed drug distribution in informal markets indicates a gap between normative regulation and practical application. Therefore, beyond legal sanctions, there is a need for multi-stakeholder collaboration, including stricter market surveillance by BPOM, targeted legal education for consumers, and stiffer penalties for repeat offenders. The government must also prioritize proactive measures such as community-based health literacy campaigns and accessible reporting mechanisms to empower citizens against harmful pharmaceutical practices. Strengthening institutional synergy between law enforcement, regulatory agencies, and health practitioners is essential to ensure that the public's right to safe and lawful medication is not only protected in theory but realized in everyday practice.

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