



# REVIEW OF THE CRIMINAL LAW ON THE DISTRIBUTION OF PHARMACEUTICAL SEDATIVES ACCORDING TO LAW NO. 17 OF 2023 CONCERNING SELECTIVE HEALTH

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| Keywords  | Abstract   |
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| <i>Criminal Acts, Circulation of Pharmaceutical Preparations, Law No. 17 of 2023, Health, Law Enforcement</i> | <i>This study aims to analyze the crime of illegal pharmaceutical preparation circulation according to Law No. 17 of 2023 concerning Health. The circulation of unlicensed pharmaceutical preparations is a serious threat to public health and has the potential to cause significant health impacts. In this study, a normative approach is used to review relevant laws and regulations, especially the provisions in Law No. 17 of 2023 which regulates criminal sanctions for these violations. The study also discusses the role of law enforcement in eradicating the circulation of illegal pharmaceutical preparations and the challenges faced in law enforcement. The results of the study show that although regulations have been tightened, implementation in the field still encounters various obstacles, such as weak coordination between institutions and limited resources. This study recommends increased supervision, more effective law enforcement, and education to the public about the dangers of using illegal pharmaceutical preparations.</i> |

## 1. INTRODUCTION

The pharmaceutical industry has experienced rapid development in line with the increasing public need for safe and quality pharmaceutical products. Innovations in the pharmaceutical field have resulted in various types of drugs, supplements, and medical devices that are increasingly sophisticated to support human health (Taylor 2020.). Factors such as population growth, increased life expectancy, and awareness of the importance of health have made the demand for pharmaceutical preparations continue to increase. In addition, technological advances and in-depth research in the medical world have also enabled the development of new drugs for diseases that were previously difficult to treat. Pharmaceutical companies are competing in conducting research and development to meet this need, both at the national and global levels (Rodrigues et al. 2023).

In Indonesia, the public's need for pharmaceutical preparations is increasing along with the development of various types of diseases, including infectious and non-communicable diseases (Albals et al., 2021). The availability of easily accessible medicines is very important, especially for those who live in remote areas. However, the high demand for pharmaceutical products also presents its own challenges, such as the emergence of the circulation of illegal pharmaceutical preparations that do not have a distribution permit. These illegal pharmaceutical preparations often do not meet safety standards and have the potential to endanger consumer health (Adejoh, Bello, and Shotunde 2024). Therefore, strict regulation and effective supervision from the government are urgently needed to ensure that pharmaceutical preparations circulating in the community meet the established health standards.

The phenomenon of the circulation of illegal pharmaceutical preparations in Indonesia has become a serious concern in recent years. The increasing demand for medicines and health products, especially those that can be accessed quickly and cheaply, is driving the growth of the black market for illegal pharmaceutical preparations (Sattler et al. 2024). These products often do not have a distribution permit from the Food and Drug Supervisory Agency (BPOM) and are produced without adequate supervision, so their quality, safety, and effectiveness are not guaranteed. Some of the factors that cause the rampant circulation of illegal pharmaceuticals include weak supervision at the distribution level, ease of access through online platforms, and lack of public awareness about the dangers of using drugs without medical supervision (Al-Taie, Büyük, and Sardas 2022)

This increase in the circulation of illegal pharmaceutical preparations poses a serious threat to public health. Illegally sold drugs have the potential to contain dangerous ingredients or improper dosages, which can cause dangerous side effects, worsening health conditions, or even death (Eikelenboom-Schieveld and Fogleman 2023). In addition, the circulation of counterfeit drugs also harms the legitimate pharmaceutical industry and weakens public trust in pharmaceutical products. To address this problem, the government has implemented various efforts, including increased surveillance, stricter law enforcement, and public education campaigns about the risks of using illegal pharmaceutical preparations. However, the circulation of illegal pharmaceuticals continues to increase, demonstrating the need for more intensive collaboration between various parties in combating this problem (Stacciarini 2023).

The use of illegal pharmaceutical preparations carries serious health risks to the public because the products often do not meet the established safety and quality standards. Illegal drugs can contain dangerous ingredients, inappropriate doses, or even do not contain the active substances they should. This condition can result in various adverse effects, ranging from ineffective treatment to the appearance of dangerous side effects. Some users may experience severe allergies, organ damage, or fatal drug reactions as a result of consuming illegal pharmaceutical products. In addition, because illegal pharmaceutical preparations are not clinically tested, the long-term risks for users are also unpredictable (Szerman et al. 2023).

Another danger of using illegal pharmaceutical preparations is increased resistance to drugs, especially antibiotics. Improper use of illegal drugs can result in bacteria becoming resistant to treatment, making the disease more difficult to treat in the future (Rossi and Conti 2023). In addition, users who rely on illegal pharmaceutical preparations for treatment may experience delays in obtaining appropriate medical care, which ultimately worsens their health conditions. These health impacts are not only detrimental to individuals but also burden the national health system, as there will be more cases of medical complications that require intensive care due to uncontrolled drug use.

The government has an important role in regulating the circulation of pharmaceutical preparations to protect public health from illegal and unsafe products. Through strict regulations, the government seeks to ensure that only pharmaceutical products that meet the standards of quality, safety, and effectiveness are allowed to circulate on the market. One significant step in this effort is the ratification of Law No. 17 of 2023 concerning Health, which provides a more comprehensive legal framework related to the supervision, production, distribution, and sale of pharmaceutical preparations in Indonesia. This law emphasizes the importance of distribution permits issued by the Food and Drug Supervisory Agency (BPOM) for every pharmaceutical product in circulation, as well as providing strict sanctions for violators of the rules.

In addition, Law No. 17 of 2023 also strengthens supervision of pharmaceutical preparation distribution activities, including online sales, which is one of the main channels for the circulation of illegal pharmaceutical products. The government through BPOM and related institutions also has the

authority to conduct inspections and take action against violations involving the production and sale of drugs without a license. In addition to law enforcement, this law underlines the importance of educating the public about the dangers of using illegal pharmaceutical preparations and the importance of buying drugs only from trusted sources. With this regulation, it is hoped that the circulation of illegal pharmaceutical preparations can be significantly reduced, so that public health is more guaranteed.

Legal studies on the implementation and effectiveness of regulations related to the crime of circulating illegal pharmaceutical preparations are very important to assess the extent to which existing laws have been properly implemented in combating the circulation of illegal pharmaceutical products. Although regulations such as Law No. 17 of 2023 have provided a strong legal foundation, further research is needed to evaluate whether law enforcement in the field has been effective and in accordance with the expected objectives. In many cases, the circulation of illegal pharmaceutical preparations is still on the rise despite tightening regulations (Rossi and Conti 2023). This indicates that there are possible gaps in the implementation of the law, such as weak supervision, lack of law enforcement resources, or lack of coordination between related institutions.

Through legal studies, various obstacles faced in enforcing these rules can also be identified, including technical and social challenges, such as a lack of public awareness of the dangers of illegal drugs and difficulties in controlling online sales. The results of this study not only provide an overview of the effectiveness of existing policies, but can also be input for future regulatory improvements. In-depth research will help the government formulate a better strategy to eradicate the circulation of illegal pharmaceutical preparations, both through strengthening the law, increasing supervision, and more intensive public education.

Research by Mahendra (2020) found that weak supervision and low public awareness are the main factors that encourage the rampant circulation of illegal drugs in Indonesia. The study also highlights the role of technology in facilitating the sale of illegal pharmaceutical products through online platforms, which is difficult for relevant authorities to effectively supervise. The study recommends strengthening coordination between the government, internet service providers, and the public to suppress the spread of illegal pharmaceutical products through online channels.

Another study by Suryani (2019) examines aspects of law enforcement related to the criminal act of illegal pharmaceutical preparation circulation in Indonesia. The results of the study show that although regulations have been tightened with various laws, including the Health Law and BPOM Regulations, their implementation is still less effective. The study also noted that sanctions imposed often do not have a deterrent effect on perpetrators, especially due to slow law enforcement processes and limited resources. The study recommends increasing law enforcement capacity as well as the use of technology in monitoring and reporting violations, which is expected to speed up legal processes and improve regulatory compliance.

## **2. RESEARCH METHODS**

This research uses a normative juridical approach, which focuses on the study of laws and regulations and legal documents related to the crime of illegal pharmaceutical preparations. The main data sources used in this study are Law No. 17 of 2023 concerning Health, its implementing regulations, and other relevant legal provisions, such as the Regulation of the Food and Drug Supervisory Agency (BPOM). This normative approach aims to deeply understand how existing legal rules are implemented and their effectiveness in suppressing the circulation of illegal pharmaceutical preparations in Indonesia. This study also analyzes various legal literature, scientific journals, and court decisions related to criminal cases of illegal pharmaceutical drug preparations.

Data collection is carried out through literature studies that include studies of various secondary sources, such as books, scientific articles, and previous research reports that discuss the problem of illegal pharmaceutical circulation. The data collected were analyzed qualitatively by descriptive-analytical methods to identify problems in the implementation of regulations and obstacles in law enforcement. In addition, this study will also conduct a comparative analysis of cases that have been handled by the courts to see how sanctions are applied to illegal pharmaceutical preparations and measure the effectiveness of these legal actions.

### **3. RESULTS AND DISCUSSION**

#### **Overview of Law No. 17 of 2023 concerning Health**

Law No. 17 of 2023 concerning Health is an important regulation that aims to regulate and supervise the circulation of pharmaceutical preparations in Indonesia. This law is designed to protect the public from the risks posed by pharmaceutical preparations that do not meet safety, quality, and effectiveness standards. By prioritizing the principles of prudence and consumer protection, this law provides a clear legal framework regarding distribution permits, supervision, and sanctions for violations (Szerman et al. 2023). One of the main focuses of this law is strict regulation of pharmaceutical preparations circulating in the market, both prescription drugs and over-the-counter drugs. In Law No. 17 of 2023, pharmaceutical preparations are comprehensively defined to include various types of medical products, including medicines, health supplements, and medical devices. This law stipulates that every pharmaceutical preparation to be marketed must obtain a distribution permit from the Food and Drug Supervisory Agency (BPOM). This licensing process involves a thorough evaluation of the safety, efficacy, and quality of the product before it can be distributed to consumers. This aims to prevent the circulation of products that can endanger public health (Christophersen et al. 2020).

Law No. 17 of 2023 also regulates criminal sanctions for violators involved in the circulation of illegal pharmaceutical preparations. Perpetrators who are proven to produce, distribute, or sell pharmaceutical preparations without a distribution permit will be subject to penalties that can be in the form of fines, imprisonment, or imprisonment. This sanction aims to provide a deterrent effect and prevent similar violations in the future. This law authorizes BPOM and law enforcement officials to take legal action against violations found, as well as stipulate legal procedures that must be followed.

In its implementation, Law No. 17 of 2023 requires strict supervision of the entire pharmaceutical preparation distribution chain. BPOM as the main supervisory institution has the responsibility to conduct routine inspections of production facilities, distribution warehouses, and pharmacies. In addition, this law also regulates the need for cooperation between BPOM, the police, and other authorities in conducting law enforcement operations against violations related to illegal pharmaceutical preparations (Christophersen et al. 2020).

Although Law No. 17 of 2023 has provided a strong legal framework, challenges in its implementation remain. Issues such as lack of coordination between agencies, limited resources, and the emergence of new distribution channels such as online sales can hinder the effectiveness of these regulations. Therefore, it is important to continue to evaluate and improve the implementation process so that this law can run optimally in protecting the public from the dangers of illegal pharmaceutical preparations.

Overall, Law No. 17 of 2023 concerning Health is a step forward in efforts to maintain public safety and health through regulating the circulation of pharmaceutical preparations. However, the success of these regulations depends heavily on effective implementation and a shared commitment from all relevant parties to enforce the law consistently. With continuous monitoring and strict law enforcement, it is hoped that the circulation of illegal pharmaceutical preparations can be controlled and the public can be protected from the health risks caused.

### **Analysis of Criminal Cases of Illegal Pharmaceutical Preparations Circulation**

An analysis of criminal cases of illicit pharmaceutical preparations reveals significant challenges in law enforcement and community protection. These cases often involve serious violations of regulations set by the Food and Drug Supervisory Agency (BPOM) and Law No. 17 of 2023 concerning Health. One of the prominent cases is the control operation carried out against factories that produce drugs without a distribution permit. In such cases, it was found that many illegal pharmaceutical products contain dangerous or unregistered active ingredients, which can cause serious side effects for consumers (Rossi and Conti 2023).

In further analysis, criminal cases of illegal pharmaceutical preparations often show the involvement of complex distribution networks, including actors from various levels, ranging from manufacturers to distributors and retailers. For example, some cases involve the use of online sales networks to distribute illegal products widely. This shows that the circulation of illegal pharmaceutical preparations not only occurs at the local level, but also has a national and international dimension, requiring more coordinated handling from the authorities.

The application of criminal sanctions against violators of the law in cases of circulation of illegal pharmaceutical preparations varies. In some cases, perpetrators are sentenced to prison and significant fines as a form of punishment and deterrent effect (Stacciarini 2023). However, law enforcement often faces obstacles, such as insufficient evidence and difficulty in tracing the distribution chain. This shows the need to strengthen the judicial system and improve the ability of law enforcement officials to handle cases involving illegal pharmaceutical products.

Case studies also show that although the sanctions imposed can reduce the frequency of circulation of illegal pharmaceutical preparations, their effectiveness is still limited by several factors. For example, many perpetrators violate the law in clever ways, such as disguising products or using fake addresses to distribute goods. In addition, perpetrators often take advantage of legal loopholes or shortcomings in regulations to avoid legal action.

In some cases, legal analysis shows that law enforcement faces major challenges in terms of coordination between agencies. These cases often involve cooperation between BPOM, the police, and other institutions, but there are often obstacles in terms of communication and information exchange. To improve the effectiveness of law enforcement, there needs to be a better mechanism in terms of coordination and data exchange between the agencies involved.

Overall, the analysis of criminal cases related to the circulation of illegal pharmaceutical preparations shows the need for a more holistic approach in law enforcement. This research underscores the importance of strengthening regulations, increasing the capacity of law enforcement, and improving the coordination system between institutions (Rodrigues et al. 2023). With a more effective and comprehensive strategy, it is hoped that the circulation of illegal pharmaceutical preparations can be significantly reduced, protecting the public from the potential dangers posed by these illegal products.

### **Constraints on Law Enforcement of Illegal Pharmaceutical Sales and providing an effective deterrent effect.**

The constraints of law enforcement on the circulation of illegal pharmaceutical preparations in Indonesia involve various complex challenges. One of the main problems is

weak supervision and enforcement in the field. Despite strict regulations, implementation at the distribution and sales level is often ineffective. Supervision of production and distribution facilities, especially in remote areas, is often inadequate. This provides an opportunity for perpetrators to circulate illegal pharmaceutical products undetected (Rossi and Conti 2023).

Another obstacle is the use of sophisticated technology by perpetrators to disguise their illegal activities. The sale of illegal pharmaceutical preparations through online platforms is increasingly difficult to monitor, as products can be sold anonymously and delivered through various logistics channels. The use of fake names, vague addresses and frequently changing websites makes it difficult for law enforcement to track and stop the circulation of these illegal goods. This points to the need for improved technological capabilities and resources to combat illicit pharmaceutical trafficking in cyberspace (Pereira 2021).

In addition, there are coordination issues between various law enforcement and regulatory agencies. Illegal pharmaceutical supply cases often involve various parties, including BPOM, the police, and other agencies (Rodrigues et al. 2023). However, the lack of communication and integration between agencies can hinder the law enforcement process. Without effective coordination, efforts to combat the circulation of illegal pharmaceutical preparations are not optimised and affect the success of legal actions taken (Anon 2022).

Law enforcement is limited by human and financial resources. Law enforcement often faces challenges in terms of the number of personnel and budget available to conduct surveillance and investigations. Lack of training and resources can also affect the quality and effectiveness of law enforcement. To address this, adequate budget allocations and training programmes are needed to increase the capacity of law enforcement in handling cases of illicit pharmaceutical supply circulation (Sattler et al. 2024). Constraints in law enforcement are also caused by a lack of public awareness regarding the dangers of illicit pharmaceutical supplies. Many consumers are unaware of the risks associated with using unlicensed pharmaceutical products. This lack of knowledge makes them more vulnerable to illegal sales practices and less cautious in choosing health products. Therefore, public education and awareness campaigns need to be improved to help the public understand and avoid the dangers of illegal pharmaceutical preparations (Corkery et al. 2022).

Lastly, existing regulations and sanctions are often not enough to deter perpetrators. Some perpetrators may only face small fines or penalties that are disproportionate to their profits (Ricci et al. 2022). To address this issue, law enforcement needs to be improved by setting tougher sanctions and ensuring that legal proceedings take place quickly and efficiently. Adjustments to policies and regulations may be needed to ensure that offences in this area receive appropriate action and provide an effective deterrent (Wibowo 2024).

## Conclusion

From the results of this study, it can be concluded that although regulations have been tightened, implementation in the field still encounters various obstacles, such as weak coordination between institutions and limited resources. This study recommends increased supervision, more effective law enforcement, and education to the public about the dangers of using illegal pharmaceutical preparations. Law No. 17 of 2023 concerning Health provides a comprehensive legal framework to regulate the circulation of pharmaceutical preparations, its implementation still faces various significant obstacles. Major issues include weak oversight on the ground, challenges in tracking the circulation of illegal products through online channels, and a lack of coordination between law enforcement agencies. In addition, limited human and

financial resources and low public awareness of the dangers of illegal pharmaceutical preparations have also worsened the effectiveness of law enforcement

To improve the effectiveness of regulation and law enforcement, improvements are needed that include improved coordination between agencies, the use of technology to monitor online distribution, and adequate allocation of resources for law enforcement. Public education must also be strengthened to increase public awareness about the risks of illegal pharmaceutical preparations. By overcoming these obstacles, it is hoped that law enforcement related to illegal pharmaceutical preparations can become more effective, so that the protection of public health can be significantly improved.

## REFERENCE

- Adejoh, Sunday, Bashir Bello, and Biola Shotunde. 2024. *National Drug Law Enforcement Agency and National Security: Perspectives on Drug, Crime and Human Security*.
- Albals, Dima, Alaa Yehya, and Mayyada Wazaify. 2021. "Psychoactive Substances Use in Jordan: Descriptive Study of Data from Anti-Narcotic Department (AND), 2014-2018." *Journal of Substance Use* 27:1–6. doi: 10.1080/14659891.2021.1941354.
- Al-Taie, Anmar, Ayşe Şeyma Büyük, and Semra Sardas. 2022. "A Scoping Systematic Assessment for Post-Marketing Abuse Drug Withdrawal." *Journal of Pharmaceutical Health Services Research* 13:115–23. doi: 10.1093/jphsr/rmac010.
- Anon. n.d. "2023000002785.Pdf."
- Christophersen, Asbjørg S., Ritva Karinen, Jørg Mørland, and Hallvard Gjerde. 2020. "The Implementation of Per-Se Limits for Driving under the Influence of Benzodiazepines and Related Drugs: No Increased Risk for Arrest during Therapeutic Use in Norway." *Traffic Injury Prevention* 21(2):122–26. doi: 10.1080/15389588.2020.1724977.
- Corkery, John Martin, Amira Guirguis, Stefania Chiappini, Giovanni Martinotti, and Fabrizio Schifano. 2022. "Alprazolam-Related Deaths in Scotland, 2004–2020." *Journal of Psychopharmacology* 36(9):1020–35. doi: 10.1177/02698811221104065.
- Eikelenboom-Schieveld, Selma, and James Fogleman. 2023. "Violence Caused by Prescription Medication." Pp. 215–41 in.
- Pereira, Paulo. 2021. "Drug Control, Violence and Capitalism in an International Perspective: An Analytical Framework." *Critical Military Studies* 10:1–16. doi: 10.1080/23337486.2020.1868060.
- Ricci, Giovanna, Francesco Busardò, Filippo Gibelli, Ascanio Sirignano, and Pietro Brunetti. 2022. "Evaluating the Risk of Toxicity and Adverse Drug Interactions Involving Recreational GHB Use and Prescribed Drugs." *Expert Opinion on Drug Metabolism & Toxicology* 17. doi: 10.1080/17425255.2021.2029404.
- Rodrigues, Caio H. P., Lívia S. Mariotto, Jade S. Castro, Paulo H. Peruquetti, Newton C. Silva-Junior, and Aline T. Bruni. 2023. "Acute, Chronic, and Post-Mortem Toxicity: A Review Focused on Three Different Classes of New Psychoactive Substances." *Forensic Toxicology* 41(2):187–212. doi: 10.1007/s11419-022-00657-3.
- Rossi, Carla, and Susanna Conti, eds. 2023. *Evaluating the Impact of Laws Regulating Illicit Drugs on Health and Society*. BENTHAM SCIENCE PUBLISHERS.
- Sattler, Sebastian, Floris Van Veen, Fabian Hasselhorn, Lobna El Tabei, Uwe Fuhr, and Guido Mehlkop. 2024. "Prevalence of Legal, Prescription, and Illegal Drugs Aiming at Cognitive

- Enhancement across Sociodemographic Groups in Germany.” *Deviant Behavior* 1–35. doi: 10.1080/01639625.2024.2334274.
- Stacciarini, João. 2023. “The Consolidation of the Pharmaceutical Sector in the Global Economy: Growth, Influence, Deviations, and Marketing.”
- Szerman, Nestor, Pedro Ruiz, Icro Maremmani, Caroline Salom, Yatan Balhara, Ruben Baler, Javier Didia, Leo Sher, Marta Torrens, Jun Chen, Rafael Maldonado, Maurice Dematteis, Jibrán Khokha, Christian Schutz, Rodrigo Marin, Katherine Mills, Elena Martin Garcia, Min Zhao, Yifrah Kaminer, Lars Lien, Mercedes Lovrecic, Barbara Lovrecic, Rok Tavcar, Mojca Zvezdana Dernovšek, Mirjana Radovanovic, and Maja Rus Makovec. 2023. “World Association on Dual Disorders VII World Congress Portoroz, Slovenia April 28-30, 2023.”
- Taylor, Michael D. n.d. “WHITHER THE REGULATOR: FOOD AND DRUG LAW, THE NATURAL HEALTH PRODUCT REGULATIONS AND THE EROSION OF SAFETY, EFFICACY AND QUALITY.”
- Wibowo, David Rudy. 2024. “Analisis Peraturan Perundang-Undangan Mengenai Kesehatan Kerja Pasca Terbitnya Undang-Undang Nomor 17 Tahun 2023 Tentang Kesehatan.” *SOEPRA* 10(1):176–96. doi: 10.24167/sjhc.v10i1.11962.