

Increasing Criminal Threats for Illegal Pharmaceutical Trade: A Critical Review of Health Law Reform in Indonesia

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Abstract. *The illegal trade in pharmaceutical preparations poses a public health risk and challenges the effectiveness of the criminal justice system. Reforms through Law No. 17 of 2023 concerning Health increase the criminal penalty for violating quality standards to 12 years in prison and a fine of 5 billion rupiah, but simultaneously remove the explicit provisions regarding criminal penalties for distribution without a distribution permit, as previously stipulated in Article 197 of Law No. 36 of 2009. This article normatively and critically analyzes the implications of these reforms for legal certainty and deterrent effects, by linking empirical findings from several regional studies (Tarakan, Gorontalo, and North Bolaang Mongondow) and enforcement practices in the e-commerce realm. The results of the study indicate a strengthening of quality sanctions, but also a potential gap in norms for distribution without a permit, which encourages the dominance of administrative sanctions (takedown) over criminal penalties. Implementation obstacles also stem from inter-institutional coordination, limited infrastructure, and low public participation. Recommendations are directed at harmonizing derivative regulations, strengthening coordination between BPOM, the Police, the Prosecutor's Office, and the Courts, as well as arranging proportional and consistent administrative-criminal sanction schemes.*

Keywords: *Criminal; Health; Sanctions; Illegal; Pharmaceutical.*

1. Introduction

Health is right basic human and one of element welfare that must be realized in accordance with ideals the Indonesian nation as intended in Pancasila and the Preamble The 1945 Constitution of the Republic of Indonesia. In order to realize degrees health the highest level of society, the government has organize various effort integrated and comprehensive health in form effort health individual and effort health society One of the component important in system health national is availability stock safe, quality, affordable and reliable pharmaceuticals clear legality.

Preparation pharmacy according to Article 1 number 12 of the Law No. 17 of 2023 concerning Health is medicine, ingredients medicine, drugs material nature, cosmetics, supplements health and medicine quasi. In practice, the preparation pharmacy must fulfil standard safety, efficacy or benefits, and quality that have been determined by the government through the Food and Drug Monitoring Agency However Thus, the circulation stock pharmacy illegal Still become problem serious threat health Indonesian society to moment this circulation stock pharmacy illegal No only violate provision applicable law, but also very dangerous Because no guaranteed quality, safety, and efficacy. Products pharmacy illegal substances circulating in society can cause risk health Serious start from effect the side that is not desired, failure treatment, until death. This is caused by Because stock pharmacy illegal No through a strict monitoring and evaluation process from authority health, so that content, dosage and quality No can confirmed

The circulation of illegal pharmaceuticals continues to increase year after year, particularly with the development of information technology and e-commerce platforms. Data from the Semarang Food and Drug Monitoring Agency (BPOM) shows that between June and August 2023 alone, 2,472 cases of illegal online pharmaceutical distribution were discovered through cyber patrols. This figure demonstrates the widespread circulation of illegal drugs through digital platforms, which are difficult to monitor.

Previous studies have emphasized the need for a multidisciplinary approach and community participation, but have generally relied on the framework of Law 36/2009 and have not systematically examined the impact of the removal of Article 197 on the criminalization of unauthorized distribution under Law 17/2023. Furthermore, field research has revealed a disparity between criminal threats and actual sanctions (predominantly administrative), but has not yet developed a regulatory engineering design to close the normative gap post-reform. This article fills this gap by linking normative comparisons, regional empirical findings, and policy recommendations based on legal effectiveness.

2. Research Methods

This article used method study juridical normative, namely study law that studies or analyze material primary and material law secondary with understand law as a set regulation or positive norms within system legislation that regulates about life man The approach used is approach statute approach and legal approach conceptual approach. legislation done with examine all relevant laws and regulations related with issue current law handled, especially Constitution Number 17 of 2023 concerning Health, Law No. 36 of 2009 concerning Health, Law No. 8 of 1999 concerning Protection Consumers, as well as regulation implementer related Whereas approach conceptual done with analyze developing views and doctrines in knowledge law, in particular theory effectiveness laws and theories enforcement law Type of data used in study This is secondary data consisting from

material primary law in the form of regulation legislation related stock pharmaceuticals, materials law secondary in the form of books, journals scientific, results research, and relevant articles with topic research, as well as material law tertiary in the form of dictionary law and encyclopedia. Data collection techniques are carried out through studies library research with method study and learn literature, regulations legislation, journal scientific, and documents law other related matters with circulation stock pharmacy illegal and enforcement the law.

3. Results and Discussion

3.1. Comparison of Criminal Regimes: Health Law No. 36 of 2009 and Health Law No. 17 of 2023

The criminal regime in Law No. 36 of 2009 and Law No. 17 of 2023 demonstrates a shift in approach that has a direct impact on the certainty of criminal penalties for cases of illegal pharmaceutical distribution. Under Law 36/2009, the criminal offense is structured in layers: Article 197 explicitly criminalizes anyone who intentionally distributes pharmaceutical preparations without a distribution permit, with a maximum penalty of 15 years' imprisonment and a fine of up to 1.5 billion rupiah, while Article 196 targets violations of quality standards. This configuration provides a relatively clear criminal corridor for licensed violations: when the element of "without a distribution permit" is proven, the reference to the article is explicitly available without the need to reinterpret the normative bridge from administrative violations to criminal offenses. In the practice of socialization and enforcement, these provisions are also frequently referenced by local authorities when taking action against cosmetics and drugs distributed without legal status, providing law enforcement with a clear textual basis for proceeding from the investigation stage to criminal prosecution.

The reforms through Law 17/2023 strengthened sanctions on the quality aspect—the criminal penalty was increased to 12 years in prison and a fine of 5 billion rupiah—but simultaneously removed the explicit provision regarding criminalization for distribution without a distribution permit, which previously resided in Article 197. As a result, for cases where the violation essentially lies in the “absence of a permit” (business permit), authorities lost the reference article that clearly criminalized the act. This vacuum created a normative gap: permit violations could potentially be dragged into the quality violation regime or transferred to other legal instruments not specifically designed for illegal pharmaceutical cases, thus opening up room for inconsistent implementation, including the option to stop at administrative sanctions alone. Theoretically, this shift shifts the burden of proof from a formal reading of the permit status to proving product quality—which is not always the primary issue in illegal distribution cases—and in turn weakens the criminalization pathway for violations that are essentially administrative but pose health risks. This picture is confirmed

in field findings which show a preference for administrative handling, rather than criminal prosecution, when the quality element is not the focus of the evidence.

The practical implications of the regime change are most evident in the realm of e-commerce. Patrols and enforcement of hundreds of illegal drug seller accounts on online platforms have predominantly resulted in "takedowns" without escalating to criminal proceedings. Functionally, this enforcement model is temporary: perpetrators can quickly migrate by opening new accounts, thus weakening deterrence and failing to establish a deterrent effect. This pattern demonstrates how the absence of specific criminal provisions for permit violations encourages law enforcement to remain confined to the administrative realm, despite the scale of violations being massive and repeated. The imbalance between the severity of criminal threats on paper and the low intensity of actual punishments indicates a gap between norms and implementation.

The consistency of sentencing at the judicial level also reflects the effectiveness of the overall system. Several decisions indicate sentences that fall far below the maximum threshold stipulated by law, even when the elements of the offense are met. In some rulings, the courts have emphasized the destruction of evidence and the confiscation of the means of crime as part of a deterrent strategy. While these measures are important for breaking the chain of distribution, the disparity between the threat and the actual punishment raises questions about the resulting deterrent. For perpetrators with strong economic motives and low substitution costs, the perceived risk remains small if the probability of prosecution is low and the threat of punishment imposed in practice is insignificant. Therefore, without restructuring the normative pathway for permit violations, strengthening evidentiary capacity, and establishing prosecution guidelines that encourage consistent sentencing, increased punishment risks remaining merely a symbolic policy.

Comparative Table of Sanctions in the Health Law Related to the Distribution of Illegal Pharmaceutical Preparations

Aspect	Law No. 36 of 2009 concerning Health	Law No. 17 of 2023 concerning Health
Provisions for Violation of Distribution Permit	Explicitly regulated in Article 197: prohibiting the distribution of pharmaceutical preparations without a distribution permit	Does not explicitly regulate the prohibition of distribution without a permit; the term is replaced with "business permit" (Article 143), but there are no criminal sanctions.
Criminal Threats for Violating Distribution Permits	Maximum 15 years in prison & a fine of up to 1.5 billion rupiah (Article 197)	There are no specific provisions regarding criminal sanctions for violations of business licensing; potential legal vacuum

Provisions for Violation of Quality Standards	Article 196: distribution of pharmaceutical preparations that do not meet quality standards	Article 435: violation of safety, quality or efficacy standards for pharmaceutical preparations
Criminal Penalties for Quality Violations	Maximum 10 years in prison & a fine of 1 billion rupiah (Article 196)	Increased penalties: max. 12 years in prison & a fine of 5 billion rupiah (Article 435)
Permit Terminology	"Distribution Permit"	Changed to "Business Licensing" in accordance with the Job Creation Law (Article 143 paragraph 1)
Effectiveness in Court Decisions	Many cases refer to Article 197 to ensnare distributors without a permit, e.g. decision Number: 351/ Pid.Sus /2018/PN Smn (4 months in prison)	Court decisions began referring to Article 435 for violations of quality standards, but could not enforce criminal penalties for permit violations due to the lack of regulations.

From the Table Above, the Comparative Narrative of Sanctions in Law 36/2009 and Law 17/2023 Regarding the Circulation of Illegal Pharmaceutical Preparations A comparison of the criminal sanction regime in Law No. 36 of 2009 and Law No. 17 of 2023 shows a significant change in the legal approach to violations in the field of distribution of pharmaceutical preparations. In Law No. 36 of 2009, the regulation of sanctions for the distribution of pharmaceutical preparations without a distribution permit is explicitly regulated through Article 197. This provision prohibits anyone from distributing pharmaceutical preparations without a distribution permit and threatens the perpetrator with imprisonment of up to 15 years and a maximum fine of 1.5 billion rupiah. The existence of this article provides certainty of norms in taking action against violations of distribution permits and serves as a strong basis for law enforcement in the field.

However, Law No. 17 of 2023 introduces drastic changes. The article explicitly criminalizing the distribution of pharmaceuticals without a distribution permit is no longer included. The term "distribution permit" is replaced with "business permit" as stipulated in Article 143, but without specific criminal sanctions. This change has the potential to create a legal vacuum, particularly in the context of criminalizing distribution permit violations, as there is no longer an article explicitly prohibiting the distribution of pharmaceuticals without a permit. Thus, the provisions in Law No. 17/2023 tend to focus more on administrative aspects rather than criminal repression.

On the other hand, regulations regarding violations of quality standards continue to receive attention in both laws, albeit with adjustments to the magnitude of the criminal penalties. In Law No. 36 of 2009, violations of the quality of pharmaceutical preparations are regulated through Article 196 and carry a maximum penalty of 10 years' imprisonment and a fine of up to 1 billion rupiah. Law No. 17 of 2023 reformulates this provision by strengthening this provision

through Article 435, which regulates violations of safety, quality, or efficacy standards and increases the penalty to a maximum of 12 years' imprisonment and a fine of 5 billion rupiah. This increase reflects an intensified legal approach to crimes that directly endanger consumer safety.

However, despite the strengthening of sanctions for quality violations, the absence of explicit criminal provisions regarding violations of distribution permits leaves a gap that impacts law enforcement practices. In several court decisions, such as Decision Number 351/ Pid.Sus /2018/PN Smn, judges applied Article 197 of Law No. 36 of 2009 to impose four months' imprisonment on perpetrators of drug distribution without a distribution permit. Under Law No. 17 of 2023, judges began referring to Article 435 in cases of quality standard violations, but could no longer prosecute perpetrators who merely violated distribution permits due to the lack of legal basis. As a result, violations of distribution permits that are not accompanied by quality violations are difficult to prosecute and are generally only subject to administrative sanctions such as permit revocation or removal of goods from circulation.

This situation indicates a shift in approach in the latest Health Law, which places greater emphasis on protecting product quality while weakening enforcement against distribution permit violations. This regulatory gap has crucial implications for the effectiveness of law enforcement, particularly in preventing the distribution of illegal pharmaceutical products, which is now rampant through online platforms. To ensure that criminal law remains an effective instrument of social control, harmonization of implementing regulations is necessary to address this gap in criminal penalties for distribution permit violations.

3.2. Regulatory Reform Regarding the Update of Law No. 36 of 2009 and Law No. 17 of 2023

The Direction of Regulatory Engineering Post-Health Law Reform: Normative Analysis Health law reform through the enactment of Law No. 17 of 2023 reflects the intention of lawmakers to increase public protection from health risks posed by the circulation of illegal pharmaceutical preparations. The increase in criminal threats for violations of quality standards, from 10 years imprisonment and a fine of 1 billion rupiah in Law No. 36/2009 to 12 years imprisonment and a fine of up to 5 billion rupiah in Law No. 17/2023, indicates a stronger repressive approach against perpetrators of crimes that endanger public security and safety. However, amid the strengthening of quality sanctions, there was the elimination of Article 197 in Law No. 36/2009 which explicitly addressed the crime of distributing pharmaceuticals without a distribution permit. This normative vacuum results in violations of distribution permits no longer being directly punishable by specific criminal provisions in the latest Health Law, which then has the potential to impact the effectiveness of law enforcement, particularly in the digital/e- commerce realm, where permit violations are more common than quality violations.

This situation requires concrete regulatory intervention to ensure that the criminalization regime for the distribution of illegal pharmaceutical products remains effective. Several normative and institutional strategies can be considered, as follows:

- a. Drafting derivative regulations: The government needs to issue a Government Regulation or Ministerial Regulation that explicitly criminalizes the distribution of pharmaceutical products without a business license. These regulations must contain clear elements of the offense, including a mechanism for proving digital distribution and criminal provisions for corporations.
- b. Preparation of inter-agency coordination protocols: Especially between the POM Center, the Police, the Public Prosecutor, and the Court, through a clear case handling pipeline system starting from cyber patrols, confiscation, forensic testing, to criminal action, not just administrative.
- c. Strengthening law enforcement capacity: Including human resource training in digital evidence-based illegal pharmaceutical investigations, procurement of forensic laboratory facilities, and cyber-intelligence tools to monitor and prosecute illegal dealers on online platforms.
- d. Responsive socio-legal-based interventions: For example, health literacy campaigns for consumers and integrated online reporting features between e-commerce platforms and law enforcement agencies to encourage specific action against repeat illegal seller accounts.

Table of Recommendations for Regulatory Engineering Post-Health Law Reform

Aspect	Law No. 36 of 2009	Law No. 17 of 2023	Regulatory Recommendations	Engineering
Criminal Violation of Distribution Permit	Explicitly regulated through Article 197	Deleted, no explicit articles	Derivative regulations (PP/Permenkes) which regulate prohibitions and penalties for distribution without a business permit	
Pharmaceutical Product Quality Sanctions	Maximum 10 years in prison, fine of 1 billion	Max 12 years in prison, 5 billion fine	clear implementation guidelines for proving pharmaceutical quality at the investigation and trial levels	
Law Enforcement Coordination	Not yet systematically arranged in norms	Does not specifically regulate technical coordination between institutions	Preparation of SOP for BPOM Police Prosecutor's Office coordination regarding the flow of action from cyber patrols, confiscations, investigations, and prosecutions.	

Digital Proof (e Commerce)	-	Not regulated	Not yet formulated	Inclusion of digital evidence provisions in derivative regulations, including electronic transaction documents, digital wallets, account history, and log records
Corporations Actors	as	Not explicitly regulated	Not described as a criminal subject	Derivative regulations need to formulate criminal and administrative sanctions against corporations, including revocation of business permits and freezing of servers/domains.
Consumer Approach	Social	Not yet integrated	Does not emphasize public literacy	Collaboration between Ministry of Health BPOM Kominfo e-commerce platform in public campaigns and illegal product reporting schemes

From the Narrative Above Comparison of Post-Reform Regulatory Engineering Narratives of Law No. 36 of 2009 and Law No. 17 of 2023 The amendment of Law No. 36 of 2009 to Law No. 17 of 2023 brings important consequences in law enforcement against violations in the field of distribution of illegal pharmaceutical preparations. Although the reform strengthens the aspect of criminal sanctions in terms of quality violations, there are strategic areas that now experience regulatory gaps, so that further normative intervention is needed through derivative regulations.

First, regarding the criminal aspect of violating distribution permits, Law No. 36 of 2009 previously explicitly regulated Article 197 regarding the prohibition of pharmaceutical distribution without a distribution permit. However, in Law No. 17 of 2023, this provision was removed without a replacement article explicitly regulating similar penalties. This legal vacuum hampers effective law enforcement, particularly in cases of distribution that violates permits but is not directly related to product quality. To address this, it is urgent to formulate derivative regulations such as Government Regulations or Minister of Health Regulations that criminalize the distribution of pharmaceutical preparations without a business permit, complete with elements of the articles and the potential penalties.

Second, regarding quality sanctions, Law No. 17 of 2023 has increased the criminal penalty for violating safety and quality standards from 10 years' imprisonment and a fine of 1 billion rupiah to 12 years' imprisonment and a fine of 5 billion rupiah. However, to strengthen the implementation of this provision, implementing guidelines are needed that explain the procedures for proving quality elements from the investigation stage through to trial, to avoid confusion among law

enforcement officials in handling violations involving substandard pharmaceutical substances or products.

Third, regarding law enforcement coordination, both laws fail to detail the technical relationships between law enforcement agencies such as the Food and Drug Monitoring Agency (BPOM), the police, the prosecutor's office, and the courts. In practice, the absence of joint working guidelines often results in administrative actions being more dominant than criminal prosecution. Therefore, it is necessary to develop a cross-agency standard operating procedure (SOP) that outlines the process for handling cases, from cyber patrols, evidence seizure, laboratory examination, and the transfer of case files to prosecutors.

Fourth, the method of proving criminal acts in the digital distribution realm is not explicitly regulated in either law. However, cases of illegal pharmaceutical distribution through e-commerce platforms are increasingly prevalent and require legally valid electronic evidence. Therefore, derivative regulations need to include adequate provisions regarding the use of electronic documents, digital transaction data, digital wallet records, and account activity history as valid evidence in the proving process.

Fifth, regarding legal subjects, there are no explicit provisions governing corporations as perpetrators in health crimes, even though the distribution of illegal pharmaceutical products often involves large-scale businesses, both as distributors and digital service providers. Therefore, derivative regulations need to include criminal and administrative provisions that can be imposed on corporations, including sanctions such as revocation of business licenses, freezing of website domains, or blocking of digital transactions.

Finally, a consumer-focused approach has not yet been incorporated into the regulations in either law. Public awareness of the dangers of consuming illegal pharmaceuticals is a crucial factor in curbing their distribution. Therefore, collaboration between the government, the Food and Drug Monitoring Agency (BPOM), the Ministry of Health, the Ministry of Communication and Information Technology (Kominfo), and e-commerce platforms is needed in the form of public campaigns and the provision of effective reporting channels to eradicate the circulation of illegal products with public participation.

4. Conclusion

Based on the entire explanation presented, it can be concluded that although the reform of the Health Law through Law No. 17 of 2023 brought a significant increase in criminal threats for violations of pharmaceutical quality standards, these changes do not fully guarantee the effectiveness of law enforcement. The elimination of explicit provisions regarding criminal penalties for distribution without a distribution permit, previously regulated in Article 197 of Law No. 36 of 2009, creates a normative vacuum that has the potential to weaken legal

protection against the distribution of illegal pharmaceutical preparations, especially for violations related to distribution permits but not directly related to quality. Analysis of law enforcement practices and court decisions shows that criminal sentences are often far lower than the threat of legal action, indicating a weak deterrent effect. This is exacerbated by technical challenges such as a lack of digital evidence and forensics, inadequate coordination between law enforcement agencies, and low public awareness of the dangers of illegal pharmaceuticals. Thus, concrete efforts are needed in the form of drafting derivative regulations that strictly regulate criminal penalties for the distribution of unlicensed pharmaceuticals, establishing coordination protocols between law enforcement agencies, strengthening investigative capacity and digital evidence, and implementing socio-preventive strategies through consumer education. These steps are necessary to ensure that the criminal system in the Health Law not only functions normatively but also effectively suppresses and prevents violations in the real world, particularly in the digital era that facilitates the distribution of illegal pharmaceuticals.

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