

ISRG Journal of Arts, Humanities and Social Sciences (ISRGJAHSS)



ISRG PUBLISHERS

Abbreviated Key Title: ISRG J Arts Humanit Soc Sci

ISSN: 2583-7672 (Online)

Journal homepage: <https://isrgpublishers.com/isrgjahss>

Volume – IV Issue - IV (July – August) 2026

Frequency: Bimonthly



The Role of the Food and Drug Monitoring Agency in Supervising the Distribution of Free-Prescription Hard Drugs: An Empirical Legal Study in Surabaya

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| **Received:** 10.07.2026 | **Accepted:** 14.07.2026 | **Published:** 16.07.2026

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Abstract

The distribution of drugs without a doctor's prescription remains a problem that threatens public health since the distribution is carried out illegally and does not comply with statutory provisions. This study aims to analyze the role of the Surabaya's Food and Drug Monitoring Agency (FDMA) in tackling the distribution of free-prescription drugs, identifying obstacles, and formulating criminal law policy reforms. This study employs an empirical legal research method with a sociological approach. Data were obtained through interviews and observation at Surabaya, then analyzed descriptively qualitatively. The results of the study show that FDMA in Surabaya has implemented investigative authority in accordance with Law Number 17 of 2023 concerning Health through supervision, investigation, coordination with the Regional Police and the prosecutor, along with education to the public. However, several obstacles are still found in the implementation, such as a limited number of investigators, uncooperative suspects, the existence of parties protecting illegal business actors, intervention by legal counsel, and low public awareness. Based on the findings, this article urges an update on criminal law policy in the form of regulating criminal liability for parties who intentionally purchase free-prescription hard drugs in unreasonable quantities for the purpose of illegal re-distribution in order to break the chain of distribution of drugs while still adhering to the principles of legality, fault, and proof in criminal law.

Keywords: Criminal law, distribution, illegal drugs.

Introduction

Health is one of the fundamental rights of every citizen, guaranteed by the state as part of human rights. To achieve the highest level of public health, the government is obligated to ensure the availability of safe, high-quality, and accessible health services. One of the ways to realize this idea is through the supervision of pharmaceutical preparations. As a key component of health services, drugs play a vital role in the prevention, treatment, and

recovery of disease. Therefore, every stage of drug production, distribution, and delivery to the public must be carried out in accordance with statutory provisions to achieve the ideal state of public health protection (Notoatmodjo, 2010).

In the Indonesian pharmaceutical system, not all types of drugs are freely available to the public. One category that receives special supervision is prescription drugs. This type of drug can only be

used with a doctor's prescription because they contain substances that have the potential to cause side effects, dependency, or abuse if used without medical supervision (Subing, 2025). Multiple regulations have been enacted to ensure the rational use of drugs while protecting the public from health risks arising from the use of drugs that are not medically indicated. Therefore, giving away prescription drugs without a doctor's prescription is a violation of the pharmaceutical supervision system established by the state.

Despite strict regulations, the practice of distributing prescription drugs without a doctor's prescription remains prevalent in various regions, including Surabaya. Medications such as Tramadol, Trihexyphenidyl (Double L pills), and Amoxicillin can still be obtained through pharmacies, drug stores, and even illegal distribution channels without prior medical examination (Faradilla et al., 2024). This phenomenon demonstrates that prescription drugs, which should be under the supervision of healthcare professionals, are circulating freely in society. This situation not only increases the risk of drug abuse but also has the potential to lead to dependency, antibiotic resistance, and even death due to inappropriate use.

Normatively speaking, the prohibition on the distribution of prescription drugs without a doctor's prescription is regulated in Law Number 17 of 2023 concerning Health. Article 138 stipulates that everyone is prohibited from distributing pharmaceutical goods that do not meet safety, efficacy, and quality standards, while criminal provisions are regulated in Article 435. This supervision is further strengthened through Regulation of the Food and Drug Monitoring Agency Number 12 of 2025 concerning Certain Drugs that are Often Abused, which stipulates Tramadol and Trihexyphenidyl as drugs that require special supervision due to their high level of abuse. The existence of these various regulations demonstrates that the state has provided a sufficiently strong legal basis for controlling the distribution of prescription drugs (Widowati & Zamroni, 2023).

In implementing these provisions, the Indonesian Food and Drug Monitoring Agency (FDMA) holds a strategic position as a government agency responsible for drug and food oversight. In addition to inspecting drug production and distribution facilities, the agency also employs investigators authorized to investigate drug and food crimes, as stipulated in the Criminal Procedure Code and Law Number 17 of 2023 concerning Health. Therefore, the FDMA not only perform administrative functions but also act as law enforcement officers in the criminal justice system (Aristawidya & Zuhrotun, 2025). This role is crucial given that pharmaceutical crimes have characteristics that directly impact public safety. The urgency of this research is reinforced by empirical data regarding law enforcement against the crime of distributing hard drugs.

Table 1. Data on Criminal Decisions Related to the Distribution of Hard Drugs at District Courts in the Surabaya FDMA Work Area of 2023–2025

District Court	Year	Register	Decided	Uploaded
Surabaya Class I A, Arjuno No.16-18, Sawahan, Sawahan, Surabaya City, East Java, 60251.	2023	90	89	93
	2024	93	72	70
	2025	69	76	75
Malang Class I A	2023	11	14	14

North Jenderal Ahmad Yani No. 198, Malang, East Java, 65126	2024	24	13	23
	2025	15	22	24
Madiun City, Raden Ajeng Kartini No.7, East Java, 6312	2023	20	23	22
	2024	6	5	15
	2025	5	6	7
Kediri, Jaksa Agung Suprpto No. 14. Mojoroto, Kediri City, East Java	2023	24	24	22
	2024	25	23	31
	2025	18	14	14
Blitar, Imam Bonjol Nomor 68, Sananwetan, Blitar City, East Java,66137.	2023	197	194	213
	2024	78	82	86
	2025	87	87	87

Source: Processed by the author based on data from the Directory of Decisions of the Supreme Court of the Republic of Indonesia.

Based on data from the Supreme Court of the Republic of Indonesia's Decision Directory, cases related to the distribution of hard drugs were consistently found in several district courts in the Surabaya's FDMA working area during the 2023–2025 period. The Blitar District Court recorded the highest number of case registers, namely 197 cases in 2023, 78 cases in 2024, and 87 cases in 2025. Meanwhile, the Surabaya District Court also recorded 90 cases in 2023, 93 cases in 2024, and 69 cases in 2025. These findings indicate that the crime of distributing hard drugs remains a real problem in the Surabaya's FDMA working area.

In 2024, there were 2,433 cases of drug abuse recorded. This number increased to 2,685 cases in 2025. As of June 27, 2026, the number of cases had reached 1,557, indicating that the illegal distribution of hard drugs is still widespread. This data indicates that law enforcement efforts have not been able to fully suppress the circulation of hard drugs without a doctor's prescription.

This phenomenon is also reflected in the Indonesian National Police's Criminal Statistics data regarding the crime of selling or distributing hard drugs without a permit.

Table 2. Crime Statistics for the Crime of Selling or Distributing Hard Drugs/Restricted Over-the-Counter Drugs Without a Permit 2024–2026

Year	Period	Case Number
2024	January 1 – Desember 31 of 2024	2.433
2025	January 1 – Desember 31 of 2025	2.685
2026	January 1 – June 27 of 2026	1.557

Source: Processed by the author based on the Indonesian National Police Crime Statistics Dashboard of 2024–2026.

In 2024, 2,433 cases were recorded, increasing to 2,685 cases in 2025. As of June 27, 2026, the number of cases had reached 1,557, indicating that the illegal distribution of hard drugs is still widespread. This data indicates that law enforcement efforts have

not been able to fully suppress the circulation of free-prescription hard drugs.

The rampant circulation of illegal drugs has also raised public concern. One case that has gained massive public attention is the action carried out by the social media account of @badanperwakilannetizen, which went viral after uploading a video of people throwing firecrackers at several shops suspected of selling drugs illegally. According to Tempo, the action was carried out as a form of protest against the continued rampant sale of hard drugs without permits and the suboptimal enforcement of business actors who trade these drugs illegally. This phenomenon shows that the circulation of illegal drugs is no longer just a pharmaceutical administration issue, but has developed into a social problem that affects the public's sense of security.

Several previous studies have examined the supervision and criminal liability for the distribution of prescription drugs. Damayanti and Tanudjaja examined criminal liability for the misuse of pharmaceutical goods following the enactment of Law Number 17 of 2023 concerning Health (Damayanti & Tanudjaja, 2025). Furthermore, a research by Heriyanto et al., also discussed the concept of criminalizing active buyers of illegal prescription drugs as part of an effort to break the distribution chain (Heriyanto et al., 2020). These studies contribute to the development of health law, but have not specifically examined the role of the FDMA in the law enforcement process based on empirical data from investigations in Surabaya City.

Based on previous research mentioned above, there is a significant research gap regarding how the investigative authority of the National Agency for Drug and Food Control is implemented in practice, the obstacles faced by investigators, and the efforts made to combat the distribution of prescription drugs. Most previous research focuses on normative aspects of supervision and criminal accountability, while empirical studies on the implementation of investigations by the National Agency for Drug and Food Control are relatively limited. This empirical aspect is crucial for understanding the effectiveness of law enforcement in the field and the factors influencing its success. Therefore, this study is novel because it combines normative analysis with empirical findings obtained through direct interviews with the FDMA of Surabaya.

This study aims to analyze the role of the Food and Drug Monitoring Agency (FDMA) in enforcing the law against the distribution of prescription drugs without a doctor's prescription in Surabaya City, while also analyzing the obstacles faced and the efforts made to overcome them. This study is expected to provide theoretical contributions to the development of health law and criminal law, as well as to be evaluation material for the government and the FDMA in strengthening the supervision and law enforcement system in the field of pharmaceutical preparations. In addition, the results of this study are also expected to serve as a reference in the formulation of more effective policies to suppress the illegal distribution of prescription drugs and improve the protection of public health.

Research Method

This article employs an empirical legal research method with a statutory and sociological approach. This approach is used to examine how legal provisions regarding the supervision and investigation of criminal acts of distributing prescription drugs without a doctor's prescription are applied in practice (Fuady, 2018). Empirical legal research was chosen because it examines

not only law as a norm but also as actual behavior in the exercise of authority of the FDMA at Surabaya.

Data of this article consists of primary and secondary data. Primary data were obtained through in-depth interviews with a member of FDMA in Surabaya, who directly handle investigations relating to drugs and food crimes. Secondary data were obtained through a literature review, which included primary legal materials in the form of laws and regulations; secondary legal materials in the form of books, relevant articles, and other related legal documents; and tertiary legal materials in the form of legal dictionaries and other supporting literature. These data were collected through interviews and documentation studies. The interviews were conducted in a structured manner using interview guidelines to obtain information regarding the role of investigators, obstacles in the investigation process, and efforts to combat the circulation of illegal drugs. In addition, documentation studies were also conducted at the Surabaya Food and Drug Administration to get annual reports, court ruling data, crime statistics, and other documents related to the research object to strengthen the interview results.

The data obtained through the interview and documentation were then analyzed descriptively and qualitatively through the stages of data reduction, data presentation, and conclusion drawing. The analysis was conducted by linking empirical findings in the field with the provisions of laws and regulations and the theories used in the research. This resulted in a picture of the implementation of the authority of the FDMA in enforcing the law against the distribution of prescription drugs without a doctor's prescription in the city of Surabaya.

Results and Discussion

1. The Role of the Food and Drug Monitoring Agency in Enforcing the Distribution of Prescription-Free Hard Drugs in Surabaya City

1.1. The Role of the Food and Drug Monitoring Agency as Law Enforcer

Based on the results of empirical research conducted at the Surabaya through interviews with Herni Sri Sundari, as a Junior Expert of Pharmaceutical and Food Supervisor, it was discovered that FDMA already has a strategic position in enforcing regulations in the field of drugs and food. This role is not only limited to carrying out investigations into health crimes, but also includes the functions of supervision, prevention, guidance, and education for the public. Thus, the prevention of the circulation of prescription drugs without a doctor's prescription can be carried out through a preventive and repressive approach.

As a preventative measure, the FDMA conducts several actions to prevent the circulation of prescription-free hard drugs, such as inspecting drug distribution facilities, taking product samples, monitoring distribution channels, and providing public education on rational drug use. This oversight is conducted both before the drug is distributed (pre-market control) and after the drug is distributed to the public (post-market control). Furthermore, public education is provided through social media, direct outreach, and various public

communication programs to ensure the public understands that prescription drugs can only be obtained with a doctor's prescription.

In addition, the agency can also make repressive measure to exercise their investigative authority as stipulated in Article 424 paragraph (3) of Law Number 17 of 2023 concerning Health. Based on the interview results, the investigative action began with receiving public reports and the results of internal supervision, then continued with initial verification, witness examination, confiscation of evidence, requesting expert testimony if necessary, carrying out a case title, coordinating with the Supervisory Corps of the East Java Regional Police, until the transfer of case files to the Public Prosecutor.

The research also shows that the majority of cases handled by the FDMA originate from active supervision, making sufficient evidence even before investigation began. This situation results in relatively rare terminations of investigations because the elements of a crime can be proven from the initial stages of the examination. This finding indicates that the investigation process is conducted based on the prudential principle, so only cases that meet the evidentiary requirements proceed to the prosecution stage.

These empirical findings are supported by data on drug trafficking cases within the jurisdiction of Surabaya FDMA. Based on data from the Supreme Court of Indonesia's Decision Directory for the 2023–2025 period, the Surabaya District Court recorded 90 cases in 2023, 93 cases in 2024, and 69 cases through 2025. Compared to other jurisdiction, the Blitar District Court recorded the highest number of cases, with 197 cases in 2023, 78 cases in 2024, and 87 cases in 2025. The Malang, Kediri, and Madiun District Courts also consistently handled cases related to the distribution of prescription-free drugs. These data indicate that pharmaceutical crimes continue to occur repeatedly within the Surabaya jurisdiction, which necessitate ongoing monitoring.

In addition to court ruling data, the high rate of drug trafficking is also reflected in the Indonesian National Police's Criminal Statistics. A total of 2,433 cases were recorded in 2024, increasing to 2,685 cases in 2025, and 1,557 cases as of June 27, 2026. This data demonstrates that despite law enforcement has been done by various agencies, the practice of distributing prescription-free hard drugs remains a serious problem that requires strengthening coordination among agencies.

Judging from Satjipto Rahardjo's Law Enforcement Theory, the role of the FDMA in Surabaya reflects a progressive legal concept that views law as an instrument for public protection, not merely the formal application of norms. Law enforcement does not stop at punishing perpetrators but is also

realized through monitoring drug distribution, educating the public, and fostering the development of pharmaceutical businesses (Herlindah, 2022).

Thus, the legal objectives of justice, benefit, and legal certainty can be realized in a more balanced manner.

However, research indicates that effective law enforcement still faces various challenges, including the vast scope of the Surabaya's FDMA work area, which covers 27 districts/cities, limited number of investigators, and low public legal awareness regarding the use of prescription drugs. These conditions result in supervision not being able to optimally reach all drug distribution facilities, resulting in the continued practice of selling prescription-free drugs.

1.2. Theoretical Analysis of Food and Drug Monitoring Agency in Enforcing the Distribution of Prescription-Free Hard Drugs

The investigation act conducted by the FDMA is essentially an implementation of the authority granted directly by Law Number 17 of 2023 concerning Health. Based on research results, this authority includes receiving reports, examining witnesses and suspects, confiscating evidence, requesting expert testimony, conducting case conferences, and submitting case files to the public prosecutor. All of these actions are carried out in accordance with criminal procedural law mechanisms.

According to Philipus M. Hadjon, government authority can be obtained through attribution, delegation, and mandate (Turnip, 2025). Based on this theory, the authority of the FDMA is attributional authority because the authority is granted directly by the law, not through delegation from another official. Therefore, all investigative actions carried out by the FDMA have strong legal legitimacy and meet the principle of legality.

This research indicates that each stage of the investigation is always preceded by an initial verification process and culminates in a case conference before the case file is submitted to the prosecutor. Furthermore, the FDMA may also coordinates with other agencies, such as the Special Criminal Investigation Directorate of the East Java Regional Police to supervise the investigation. This mechanism demonstrates that the use of investigative authority remains within the oversight system, thus minimizing the potential for abuse of authority.

This coordination does not constitute a form of delegation of authority as defined in Hadjon's theory, but rather an implementation of the Integrated Criminal Justice System principle, which places each law enforcers in a complementary role. The FDMA continues to exercise its authority independently, while the Regional Police and the Public Prosecutor carry out supervisory and control

functions in accordance with their respective authorities.

Thus, the research results indicate that the implementation of investigative authority by FDMA in Surabaya has been in accordance with the attribution concept of Philipus M. Hadjon. All investigative actions are carried out based on the authority granted directly by law, implemented in accordance with criminal procedural law procedures, and supported by a coordination mechanism between law enforcement agencies to ensure legal certainty, accountability, and the effectiveness of law enforcement against the distribution of prescription-free drugs.

2. Obstacles Faced by the FDMA and Efforts to Combat the Circulation of Prescription-Free Hard Drugs in Surabaya

2.1. Obstacles Faced by the FDMA in Surabaya in Tackling the Circulation of Prescription-Free Hard Drugs

Based on an interview conducted on June 24, 2026, with Herni Sri Sundari, it was found that investigations relating to the crime of distributing prescription-free drugs still face various obstacles. These obstacles not only originate from the perpetrators of the crime but are also influenced by institutional conditions and community characteristics. Based on Sundari's view, these obstacles directly affect the effectiveness of investigations and overall prevention efforts. There needs to be a new strategy to overcome these obstacles in a sustainable manner.

Sundari explained that the first obstacle stems from the suspect's uncooperative behavior during the investigation. In several cases, the suspect attempted to demolish any evidence, hide related-documents, or erase traces of transactions related to the distribution of prescription-free drugs. Furthermore, there were attempts to influence witnesses to provide testimony favorable to the suspect's interests. This situation resulted in the evidentiary process taking longer than in cases where the suspect was cooperative.

Another obstacle is that there are several allegation relating to the protection provided by certain parties to the people or corporates who sell hard drugs illegally. Sundari added that this practice is known as "security," meaning that certain parties allegedly provide protection to businesses, making the prosecution process more complex. Nevertheless, investigators continue to carry out their duties based on evidence and applicable legal provisions. This situation requires investigators to be more careful in every investigative action. Furthermore, Sundari also explained that in some cases, the investigation process is also influenced by the legal steps taken by the suspect's legal counsel. This form of assistance is a right of every suspect, as stipulated

by the law. However, in practice, filing objections or pretrial motions can lead to lengthy case resolution. As a result, investigators must adjust the investigation stages to accommodate the ongoing legal process.

Another obstacle faced by the FDMA in Surabaya relates to the limited number of investigators. Interview results revealed that the FDMA in Surabaya has eleven investigators, but only seven are actively carrying out investigative duties. Meanwhile, the work area of FDMA in Surabaya encompasses several regencies and cities in East Java Province, with a relatively large number of cases. This situation results in a relatively high workload for investigators.

In addition to internal factors, Sundari also explained that low public legal awareness remains a significant obstacle. Some people still purchase hard drugs without a doctor's prescription because they consider the procedure for obtaining a prescription too complicated or because they don't understand the regulations regarding the classification of prescription drugs. This high demand indirectly encourages businesses to continue selling prescription drugs illegally. According to Sundari, this situation demonstrates that law enforcement alone is not sufficient in addressing the problem; it also requires a high-level of public awareness.

2.2. Obstacles Related to Legal Vacuum for Hard Drugs Buyers in Unreasonable Amounts for the Purpose of Redistribution

One of the obstacles identified in this research is the lack of clear regulations regarding criminal liability for those who purchase large quantities of prescription-free drugs for the purpose of re-distributing them. The paradigm of provisions in Law Number 17 of 2023 concerning Health are still oriented towards prosecuting perpetrators who produce, store, distribute, or trade pharmaceutical goods illegally. As a result, investigators do not yet have an adequate legal basis to prosecute buyers who are in fact part of the illegal drug distribution chain, despite strong indications that the purchases were made for re-trading purposes.

The absence of such regulations results in more repressive law enforcement once hard drugs are circulating in the community, so that efforts to break the distribution chain at an early stage cannot be carried out optimally. Therefore, this study proposes an update to criminal law policy through regulations regarding criminal liability for buyers who intentionally obtain hard drugs without a doctor's prescription in unreasonable quantities for the purpose of re-distributing them. These regulations need to be formulated in a limited manner while still adhering to the principles of legality, fault, and proof of the existence of an intention to re-distribute them, so as not to criminalize consumers who purchase drugs for legitimate medical purposes.

2.3. FDMA's Efforts to Combat the Circulation of Prescription-Free Drugs in Surabaya

Based on the interview, Sundari explained that the Surabaya Food and Drug Monitoring Agency (FDMA) not only carries out investigations but also implements various preventive measures against the distribution of prescription-free drugs. These efforts are carried out through the Information and Communications, an agency tasked with providing education to the public. According to Sundari, a preventive approach is crucial to reducing public demand for illegal prescription drugs. Therefore, educational activities are being carried out continuously.

One form of preventive activity is counseling through Radio Klik FM Surabaya, held every Wednesday at 12:00 p.m. The activity is also broadcast live on the official Instagram account of the Surabaya Food and Drug Monitoring Agency, thus reaching a wider audience. The material presented covers drug safety, how to obtain medication correctly, the dangers of using prescription-free drugs, and the importance of purchasing drugs from licensed pharmaceutical facilities. Through this activity, FDMA hopes that the public will become more aware of the risks of inappropriate use of prescription drugs.

In addition to providing information through mass media, the FDMA in Surabaya also provides an Online Consultation Center (*Warung Konsultasi Online (Warkop)*). This service is available through the Zoom Meeting app, Monday through Friday, from 8:00 a.m. to 4:00 p.m. Through this service, the public and businesses can consult regarding permits, regulations, and various issues related to drug and food supervision. According to Sundari, this service provides convenience for the public without having to visit the FDMA office in person.

Another effort is through direct Information, Education and Communication (IEC) activities for the community. These activities are held periodically in schools, sub-districts, government agencies, MSMEs, and other community groups within the work area of Surabaya's FDMA. These activities educate the public on the importance of purchasing medication from licensed pharmacies or pharmaceutical facilities. They are also informed about the dangers of using prescription drugs without a doctor's prescription.

In addition to these preventive activities, the FDMA continues to implement repressive measures through investigations into any suspected criminal acts that meet the elements of a crime. Investigations begin with receiving reports, examining witnesses, confiscating evidence, conducting case conferences, coordinating with the East Java Regional Police's Supervisory Unit, and transferring case files to the Prosecutor's Office. The combination of preventive and repressive measures is the strategy used by the FDMA to gain a more effective way to combat the

circulation of prescription-free hard drugs. Thus, countermeasures are not only oriented towards prosecution, but also on preventing violations from recurring.

Conclusion

The research conclude that the role of the Food and Drug Monitoring Agency (FDMA) in tackling the circulation of prescription drugs has been implemented through an integrated repressive and preventive approach. The repressive role is realized through the implementation of investigations in accordance with the authority granted in Article 424 paragraph (3) of Law Number 17 of 2023 concerning Health, starting from receiving reports, initial verification, examination of witnesses and suspects, confiscation of evidence, case titles, coordination with the Regional Police, to the transfer of case files to the Prosecutor's Office. In addition, the FDMA also carries out preventive functions through supervision of drug distribution facilities, inspections, sampling, and public education regarding the correct use of drugs.

However, there are still several obstacles faced by the FDMA in Surabaya in tackling the circulation of prescription-free drugs that come from both internal and external factors, namely the limited number of active investigators, uncooperative suspects, the existence of parties providing protection to illegal business actors, intervention through legal efforts, low public legal awareness, and the absence of clear regulations regarding criminal liability for parties who purchase prescription-free drugs in unreasonable quantities for the purpose of illegal re-distribution. This study recommends an update to criminal law policy through regulations regarding criminal liability for buyers who intentionally obtain prescription-free drugs in large quantities for the purpose of re-distribution, while still being guided by the principles of legality, the principle of fault, and proof of the existence of an intention to re-distribute.

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