

PRACTICE AND SOLUTIONS TO ENHANCE THE EFFECTIVENESS OF APPLYING CRIMINAL LAW PROVISIONS ON THE OFFENSE OF PRODUCING AND TRADING COUNTERFEIT MEDICINES FOR TREATMENT AND PREVENTION IN VIETNAM IN THE COMING PERIOD

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ABSTRACT

This article examines the practice of applying criminal law provisions on the offense of producing and trading counterfeit medicines for treatment and prevention in Vietnam in recent years. It identifies difficulties and obstacles in the application of criminal law to this type of offense, as well as the causes and limitations. On that basis, the paper proposes solutions to improve the effectiveness of applying criminal law provisions on the offense of producing and trading counterfeit medicines for treatment and prevention in Vietnam in the coming period.

Keyword: *Solutions; counterfeit goods; producing and trading counterfeit goods; medicines for treatment; medicines for prevention.*

1. INTRODUCTION

Since the 6th National Congress of the Communist Party of Vietnam, the Party and State have consistently pursued the policy of transitioning the economic management mechanism from a centrally planned and bureaucratic subsidy system to a socialist-oriented market economy. This transition has involved the diversification of economic sectors and a more liberalized regime of imports and exports. Moreover, after Vietnam officially became a member of the World Trade Organization (WTO), the socialist-oriented market economy of our country has achieved strong growth with a highly dynamic commodity market supplied not only by domestic production but also through imports from abroad.

However, alongside these positive developments, it is impossible to overlook the shortcomings and limitations stemming from the influx of products into Vietnam, including medicines for treatment and prevention. One of the notable shortcomings lies in the legal framework governing the production and trade of medicines, which has revealed many limitations, while criminal activities in this field have become increasingly sophisticated and dangerous. This category of crime has caused significant harm to the national

economy and society with negative impacts on public health, human life and consumer trust. Therefore, studying and evaluating the practical application of criminal law provisions on the offense of producing and trading counterfeit medicines for treatment and prevention is essential to identifying the advantages and obstacles in implementation. This, in turn, provides the basis for proposing solutions to improve the effectiveness of applying criminal law in addressing this offense in Vietnam in the coming period.

This article presents the results of the institutional-level scientific research project “Research on Criminal Law Provisions on the Offense of Producing and Trading Counterfeit Medicines for Treatment and Prevention” conducted at Hanoi University of Natural Resources and Environment, Project Code: 2025.TDHHN.07.02. The findings presented herein constitute an important part of the project outcomes.

2. RESEARCH CONTENT

2.1. The Situation of the Crime of Producing and Trading Counterfeit Medicines for Treatment and Prevention in Vietnam in Recent Years

Prior to 2018, although the production and trade of counterfeit medicines had already been considered a highly dangerous act, the legal framework remained insufficiently detailed and such violations were predominantly dealt with through administrative sanctions, which limited their deterrent effect. Data from this period were not clearly published; however, according to reports from 2022 - 2023, the competent authorities handled more than 28,000 cases of smuggling, trade fraud and counterfeit goods with recovered fines amounting to VND 3,387 billion. Within these, although the exact proportion related to counterfeit medicines was not specified, public opinion indicated that such acts frequently escaped criminal prosecution due to the lack of clear legal distinction on which behaviors constituted criminal offenses subject to criminal liability.

Since the Penal Code of 2015 (amended and supplemented in 2017) officially came into effect, the handling of acts of producing and trading counterfeit medicines within the scope of criminal law has received more emphasis. For example, in 2023 alone, more than 160 cases related to counterfeit medicine production and trade were detected, many of which were subject to criminal proceedings. By 2024 and early 2025, violations continued to evolve in complexity: the competent agencies in Ho Chi Minh City detected and handled 178 violations related to pharmaceuticals, seizing 262,158 infringing products valued at over VND 15.4 billion with 4 cases transferred for criminal investigation.

With the increasing frequency of medicine use, especially during epidemic periods, offenders exploited the situation to introduce counterfeit drugs into the market through sophisticated methods such as counterfeiting packaging, labels and inspection certificates, as well as selling through social media platforms or informal retail channels. Strengthened enforcement measures were also implemented effectively: a concentrated campaign from mid-May to mid-June 2025 recorded over 3,100 violations related to smuggling and counterfeit goods, resulting in administrative penalties of more than VND 63 billion.

Several typical criminal cases of producing and trading counterfeit medicines for treatment and prevention can be cited, including:

- The case of Pham Ngoc Tien and his wife, Doan Thi Nguyet, in Hanoi, who manufactured 100 tons of counterfeit goods consisting of dietary supplements and medical equipment (involving more than 100 different product codes).
- The case of 500 boxes of counterfeit Viagra labeled under Pfizer Australia with a total value exceeding VND 390 million.
- The case of a criminal network in Thanh Hoa producing and trading 21 types of counterfeit pharmaceutical products for musculoskeletal treatment with illicit profits amounting to nearly VND 200 billion.
- The case of counterfeit production of Cefuroxime 500mg, Cefixime 200mg and Panadol Extra in Thanh Hoa.
- In Ho Chi Minh City, police confiscated 1,164 boxes of finished pharmaceutical products and raw materials, including 56,255 finished counterfeit medicine units; more than 1,600 kg of raw powder for counterfeit tablet production; and five complete machinery systems for capsule filling, blister packaging, bottle sealing and hot-press packaging.
- In Ha Nam province, police seized over 4,000 bottles of traditional medicine for sinusitis and gynecological treatment, more than 2,000 boxes of traditional medicine for pharyngitis and insomnia, over 1,500 herbal packages for hemorrhoids and musculoskeletal disorders, as well as medicines for rhinitis, weight loss and diabetes treatment.

2.2. Assessment of Advantages and Challenges in the Application of Criminal Law on the Offense of Producing and Trading Counterfeit Medicines for Treatment and Prevention

2.2.1. Achievements

First, in recent years, the competent authorities have achieved significant results in combating and handling the crime of producing and trading counterfeit medicines for treatment and prevention. The police, market management, customs and health authorities have closely coordinated, regularly conducting inspections and audits, thereby detecting and dismantling numerous large-scale, transnational networks involved in the production and trade of

counterfeit medicines. For instance, the case in Thanh Hoa involved more than 10 tons of counterfeit medicines with illicit profits of nearly VND 200 billion; other major cases have been prosecuted in Gia Lai, Ha Nam, Ho Chi Minh City and Hanoi. These cases were brought to trial, demonstrating the State's firm stance in protecting public health and deterring crime. Alongside criminal prosecution, administrative measures have also been strictly enforced, such as monetary fines, confiscation of goods, temporary or permanent suspension of operations and revocation of licenses for organizations and individuals in violation.

Second, awareness-raising campaigns on the dangers of counterfeit medicines have been intensified through mass media, social networks and direct communication programs in hospitals, pharmacies and health facilities. Citizens have been provided with basic knowledge to distinguish genuine from counterfeit medicines, check labeling, expiration dates and anti-counterfeit seals. This has contributed to raising public vigilance, encouraging people to report violations and gradually bringing the circulation of counterfeit medicines under control, while strengthening social trust in the rule of law and the effectiveness of state governance in the health sector.

Third, the authorities have made public information about criminal cases and networks involving the production and trade of counterfeit medicines for treatment and prevention through mass media. This has created a strong deterrent effect while reinforcing public confidence in the strictness of the law. In many instances, citizens who became aware of such information proactively reported suspicious activities to the authorities, thereby facilitating further investigations and timely detection of additional cases.

2.2.2. Limitations and Obstacles

In recent years, the application of criminal law provisions on the offense of producing and trading counterfeit medicines for treatment and prevention has contributed significantly to maintaining political security, public order and safety, while protecting the interests of the State and the lawful rights and interests of organizations and citizens. However, given the increasingly complex nature of this crime, certain

legal provisions have revealed shortcomings and are no longer adequate for current realities. The enforcement of criminal law provisions in this area has also encountered several limitations and obstacles:

First, confusion remains in the determination of charges between the offense of producing and trading counterfeit medicines for treatment and prevention and other crimes. In practice, courts at various levels have, on occasion, confused this offense with others, such as smuggling.

Second, there are still cases in which the courts inaccurately determine the appropriate charge for the defendant's conduct. Specifically, if the offender engages in "production," they should be prosecuted for producing counterfeit medicines for treatment and prevention; if they engage in "trade," they should be prosecuted for trading counterfeit medicines for treatment and prevention. Only when the offender commits both acts should they be prosecuted for the combined offense of producing and trading counterfeit medicines for treatment and prevention.

Third, in sentencing, adjudicating panels often focus primarily on the defendant's personal circumstances and aggravating or mitigating factors without sufficiently analyzing the nature and degree of social danger posed by the conduct. Judgments frequently use the generalized expression that "the defendant's conduct is dangerous to society," which fails to specify the actual degree of danger. As a result, in some cases, although the aggravating and mitigating circumstances were adequately considered, the punishment imposed was disproportionately lenient or severe relative to the social harm caused.

Fourth, it remains extremely difficult to impose criminal liability on commercial legal entities engaged in the production and trade of counterfeit medicines. The issue of fault attributable to the legal entity, as distinct from the individuals who act on its behalf, is critical. In practice, proving the culpability of a commercial legal entity requires demonstrating the fault of its representative at the time of the offense. However, the Penal Code of 2015 (amended and supplemented in 2025) only establishes principles of liability for individuals, not for legal entities. Consequently, proving the culpability of commercial legal entities in this offense is highly challenging.

Fifth, legal dissemination, education and awareness-raising remain limited. Current efforts against counterfeit crimes in general and the production and trade of counterfeit medicines in particular, have focused primarily on detection and punishment rather than prevention. Public legal education remains weak and irregular. Knowledge of counterfeit medicines is still relatively new for most citizens and even for some officials working in law enforcement agencies.

Sixth, the rapid development of social networks has turned them into a major channel for marketing and distributing counterfeit and substandard medicines. Offenders exploit public fascination with foreign goods or so-called “miracle cures,” posting exaggerated and false advertisements promising treatment for all diseases, weight loss or improved health. Due to the lack of strict content moderation, such advertisements can reach tens of thousands, even hundreds of thousands of people in a short time.

In practice, the phenomenon of livestream sales of counterfeit medicines has become increasingly widespread, especially on TikTok and Facebook. Many individuals with no pharmaceutical expertise present themselves as “online doctors” or “nutrition experts,” giving unfounded advice that misleads consumers. This not only deceives the public but also erodes trust in official healthcare information channels. Moreover, it is extremely difficult for consumers to verify the origin of products sold online. Consumers are often provided only with images or promotional clips without invoices or circulation permits. Offenders further complicate matters by using sophisticated counterfeit packaging and labels, making it difficult even for knowledgeable individuals to detect the fraud.

2.2.3. Causes of Limitations and Obstacles

First, judicial activities of the People’s Courts: Detecting and handling crime is a crucial component of criminal justice. Early detection of criminal signs facilitates faster prosecution and enhances deterrence. In reality, counterfeit medicine production and trade are often detected late with some facilities operating for extended periods before being exposed. Delayed detection fosters offenders’ disregard for the law, contributing to the increasing number of cases in recent years. Moreover, sentences imposed by the courts are sometimes disproportionate to the

severity of the offenses. Some judges lack a comprehensive understanding of the grave consequences caused by counterfeit medicines, leading to leniency. In addition, the professional competence of certain judges does not yet meet the requirements of the task, resulting in judicial errors.

Second, inter-agency coordination: Coordination among the police, market management, customs and health agencies is sometimes ineffective. Overlapping jurisdiction or delays in information sharing hinder the efficiency of investigations and prosecutions. Human resources remain limited in both quantity and expertise. Officials tasked with enforcement often lack specialized pharmaceutical knowledge, making it difficult to identify criminal acts. Furthermore, heavy workloads and broad areas of responsibility reduce the effectiveness of monitoring and supervision. Instances of negligence or lax management have also been observed with counterfeit medicines remaining on the market for extended periods before discovery, reflecting weaknesses in routine inspections and circulation licensing.

Third, dissemination of legal knowledge on the offense of producing and trading counterfeit medicines remains limited. The methods and content of communication are neither systematic nor sufficiently widespread, often confined to mass media or short-term campaigns without consistent long-term implementation. This reduces effectiveness, as many citizens quickly lose vigilance once campaigns end. Outreach efforts have also been concentrated mainly in urban areas, while rural and remote regions—where residents have less access to official information—remain neglected. Offenders exploit these gaps by distributing counterfeit medicines via street vendors, informal markets or uncontrolled online sales. Moreover, communication campaigns often lack depth, focusing on general warnings rather than practical guidance. Citizens are seldom taught concrete skills such as how to verify medicine registration numbers, check anti-counterfeit seals or confirm the legitimacy of manufacturers. As a result, public participation in self-protection and crime reporting remains limited.

Fourth, regulatory gaps in social media management: Platforms such as Facebook, TikTok and YouTube largely rely on user reports and lack

effective filters to automatically block counterfeit medicine advertisements. Consequently, removal of violating content is slow and even when accounts are deleted, offenders can easily create new ones to continue operations. Moreover, online advertising regulations have not kept pace with reality. While Vietnamese law provides for pharmaceutical advertising regulation, its enforcement in cyberspace remains weak with insufficient cooperation between regulators and technology platforms. As a result, counterfeit medicine advertisements continue to proliferate unchecked.

3. SOLUTIONS TO ENHANCE THE EFFECTIVENESS OF CRIMINAL LAW ENFORCEMENT ON THE CRIME OF MANUFACTURING AND TRADING COUNTERFEIT MEDICINES IN VIETNAM IN THE COMING PERIOD

3.1. Solutions for Improving Criminal Law on the Crime of Manufacturing and Trading Counterfeit Medicines

First, separating Article 194 of the 2015 Penal Code (amended and supplemented in 2025) into two distinct offenses. Currently, Article 194 of the Penal Code (2015, amended in 2025), entitled “The Crime of Manufacturing and Trading Counterfeit Medicines”, stipulates two different acts within the same provision. As analyzed above, in practice, there have been many cases where law enforcement and judicial bodies became confused: when an offender committed only “manufacturing” or only “trading,” the conviction still cited the entire article “The Crime of Manufacturing and Trading Counterfeit Medicines.” The author argues that such a legislative design is unreasonable because combining two distinct acts under one provision easily leads to confusion in judicial practice. Therefore, to accurately reflect the nature of the offense and minimize errors in adjudication, it is proposed to split Article 194 into two separate provisions: The Crime of Manufacturing Counterfeit Medicines and The Crime of Trading Counterfeit Medicines.

Second, improving legal provisions on the criminal liability of commercial legal entities for manufacturing and trading counterfeit medicines. Regarding the conditions for holding commercial legal entities criminally liable, to ensure a more effective legal framework, it is suggested to merge

two conditions “the criminal act is committed in the name of the commercial legal entity” and “the criminal act is committed under the direction, management or approval of the commercial legal entity” into a single unified condition. This would serve as the legal basis for criminal liability. In cases where an individual, though acting under the approval of the commercial legal entity, only performed one or several stages in the process of manufacturing or trading counterfeit medicines, it is necessary to carefully determine their subjective awareness and criminal intent through objective indicators such as contracts, negotiations or communications before attributing criminal liability to the legal entity.

In addition, the law must be supplemented regarding the principle of fault of commercial legal entities. To guarantee the requirement of culpability in proving criminal acts committed by commercial legal entities, lawmakers need to incorporate provisions on fault as well as complicity to provide competent authorities with clear legal grounds for criminal prosecution. This would help improve the effectiveness and consistency of criminal justice while avoiding impunity.

Third, establishing separate penalties for the crime of manufacturing and trading counterfeit functional foods. Besides counterfeit medicines, counterfeit functional foods pose a grave danger because of their widespread daily use and potential risk to human life and health. Thus, it is proposed that separate criminal provisions and sanctioning guidelines be established for this offense with specific deterrent measures, including the retention of the death penalty for perpetrators of especially dangerous acts.

3.2. Solutions for Adjudication and Guidance on the Application of Criminal Law

It is necessary to strengthen the review and summarization of adjudication practices and provide guidance on the application of criminal law regarding the crime of manufacturing and trading counterfeit medicines. The Supreme People’s Court should regularly organize thematic conferences and issue judicial guidelines on counterfeit goods offenses, particularly counterfeit medicines, based on the synthesis of nationwide case reports. These conferences should focus on issues such as the determination of charges, sentencing and grounds for sentencing.

This would ensure accurate adjudication in terms of person, offense and applicable law.

3.3. Solutions for Enhancing the Professional Competence of Judges

The capacity and expertise of judicial officers must be continuously improved because judges play a decisive role in trials. Alongside People's Jurors, presiding judges bear ultimate responsibility for court rulings. Therefore, it is necessary to regularly organize advanced training courses on criminal law, adjudication techniques, political theory and professional ethics.

In recent years, the Supreme People's Court has already implemented mandatory annual training programs, professional workshops and online seminars. However, practical knowledge and legal interpretation cannot be acquired effectively through a few sessions. Moreover, scheduling conflicts between work and training reduce the effectiveness of such programs. Therefore, intensive and specialized training is urgently needed, especially in areas such as criminal psychology and courtroom management, to ensure judges are equipped with both theoretical and practical skills.

3.4. Solutions for Legal Dissemination and Public Education

Public participation plays a crucial role in combating counterfeit medicine crimes. Hence, efforts to disseminate legal knowledge must be strengthened so that citizens actively engage in prevention and reporting. Legal education on counterfeit goods should be included in extracurricular activities within the national education system, reinforced through contests, awareness campaigns in enterprises and social organizations and mass media dissemination. This would help foster social awareness, civic responsibility and collective vigilance.

3.5. Solutions for Inter-agency Coordination and International Cooperation

Closer coordination among law enforcement agencies investigating authorities, the People's Procuracy and courts is required with each body fulfilling its statutory functions to maximize efficiency in crime prevention. Additionally, the analysis of past cases should inform strategies for combating future offenses. International cooperation must also be expanded, as counterfeit

medicine crimes increasingly involve cross-border networks. Strengthened collaboration with foreign law enforcement is necessary to dismantle transnational supply chains, whether counterfeit medicines are produced abroad and smuggled into Vietnam or vice versa. This crime undermines not only national interests but also the global health system, thus international legal cooperation is imperative.

3.6. Solutions for the Application of Information Technology

Applying information technology (IT) in counterfeit medicine prevention offers groundbreaking opportunities. Electronic traceability systems using QR codes, barcodes or RFID chips allow authorities, pharmacies and consumers to verify product origins and quickly identify counterfeits. A centralized pharmaceutical database should be developed to link the Ministry of Health, pharmaceutical enterprises, hospitals and pharmacies, thus strengthening control over medicine distribution. Advanced technologies such as Artificial Intelligence (AI) and Big Data analytics can detect abnormal patterns in distribution networks, e-prescriptions and import activities, while Blockchain ensures transparency and immutability in supply chain management. IT tools can also monitor e-commerce platforms and social media, enabling early detection of illicit sales channels. In practice, the Ministry of Health has deployed QR code scanning systems, while major companies such as Traphaco and DHG Pharma have adopted smart anti-counterfeit labels. Market surveillance forces, customs and police also use digital monitoring systems to detect counterfeit networks. Some domestic enterprises have even piloted Blockchain-based supply chain management. These developments demonstrate that IT not only enhances state management but also mobilizes private sector and community involvement, creating a transparent digital ecosystem to safeguard public health and effectively prevent counterfeit medicine crimes.

4. CONCLUSION

The crime of manufacturing and trading counterfeit medicines both therapeutic and preventive poses not only a grave threat to human health and life but also destabilizes social order, erodes public trust in the healthcare system and undermines the integrity of the pharmaceutical business environment. Enhancing the practical

effectiveness of combating this crime requires a comprehensive approach that integrates legal reform, strengthened enforcement capacity, the application of modern information technology and heightened community awareness. Only when a robust legal framework is in place, coupled with transparent monitoring mechanisms and the active participation of both enterprises and citizens, can the prevention, detection and prosecution of such crimes achieve sustainable effectiveness. Therefore, comprehensive solutions must not be limited to imposing strict sanctions on violations, but should also aim at building a safe and transparent pharmaceutical management ecosystem that is human-centered, thereby ensuring every citizen's legitimate right to health care.

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REFERENCES

- [1]. Penal Code 2015 (as amended and supplemented in 2025);
- [2]. Law on Pharmacy 2016;
- [3]. Hanoi Law University (2020), Textbook on Vietnamese Criminal Law, Part on Criminal Offenses, Volume 1, People's Public Security Publishing House, Hanoi;
- [4]. Hanoi Law University (2020), Textbook on Vietnamese Criminal Law, Part on Criminal Offenses, Volume 2, People's Public Security Publishing House, Hanoi;
- [5]. Le Dang Doanh (2010), "The Need for Guidance on Characteristic Elements of Crimes Infringing upon Industrial Property Rights and Crimes of Manufacturing Counterfeit Goods," Kiem Sat Journal, No. 21/2010;
- [6]. Hoang Hai (2020), "Some Issues Concerning Criminal Liability of Commercial Legal Entities Committing the

Crime of Manufacturing and Trading Counterfeit Goods," Legal Profession Journal;

- [7]. Nguyen Dinh Hung (2019), "Some Difficulties in Handling the Crime of Manufacturing and Trading Counterfeit Goods and Several Recommendations," Legal Profession Journal, No. 6/2019;
- [8]. Nguyen Thu Thuong (2017), The Crime of Manufacturing and Trading Counterfeit Goods under Vietnamese Criminal Law, Master's Thesis in Law, Hanoi Law University