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LEGAL FRAMEWORK FOR DRUG OPTIMIZATION IN VIETNAM: ALIGNING WITH INTERNATIONAL BEST PRACTICES

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Abstract This study investigates legal and policy reforms to strengthen Vietnam's drug control system through a holistic approach integrating public health, legal foundations, political will, and international cooperation. Using mixed-methods, legal analysis, literature review, and comparative case studies, it assesses Vietnam's laws against global frameworks, identifying key areas for reform. Insights from Germany and Singapore offer practical governance models. Grounded in empirical data and legal scholarship, the study proposes context-sensitive recommendations tailored to Vietnam's institutional landscape. It contributes to global discourse on drug policy and urges policymakers to adopt integrated, adaptive strategies that reduce harm and align with international standards.

Keywords
adaptive policy strategies, drug control policies, international drug policies, evidence-based policies, public health policy, legal compliance

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1 Introduction

Managing and administering drugs in Vietnam is the responsibility of the Ministry of Health (MOH) and the Drug Administration of Vietnam (DAV). In contrast, the Department of Medical Equipment and Health Works (DMEHW) regulates medical devices (Nguyen & Scannapieco, 2008). According to Luong (2021), the responsibility for administering drugs is considered crucial, especially given the increasing number of drug-related violations in recent years. The DAV and the MOH oversee the drug management system, regulating both medicinal and illicit drug products. Their responsibilities include developing policies to standardize medical products, licensing, and to establish drug mitigation procedures. Within this framework, the DAV is critical in analyzing, verifying, and approving pharmaceutical information before processing and distributing drugs. Once a drug is reviewed and meets the necessary standards, the DAV issues an approval statement for its distribution.

However, if a drug already on the market fails to comply with set consumption or content requirements, the institution issues a warning and withdraws the product. Effective drug management remains a primary responsibility of the DAV, ensuring that medicinal products meet key criteria. A qualified drug must demonstrate effectiveness in disease prevention and treatment, have minimal or no harmful side effects, maintain stable quality throughout its shelf life, and be practical for use and storage.[1] Achieving these objectives requires rigorous control and oversight by competent state agencies, emphasizing the importance of regulatory enforcement in safeguarding public health. One of the biggest challenges exposed is the weak supply chain management, which has led to the distribution of substandard medication and shortages in necessary medical supplies. According to a study by Do (2024), the COVID-19 pandemic posed the biggest challenge encountered by the MOH, especially given the fast spread of the disease and the limited medical resources within the country. Consequently, the pandemic imposed numerous threats to the healthcare system, bringing to light the necessity to develop a holistic and more diverse healthcare system, especially regarding drug management. During the pandemic, the role of the DAV came to light as the institution was tasked with drug

[1]Drug Administration of Vietnam, *Function & Assignment*. Retrieved from https://dav.gov.vn/function-amp;-assignment-ce1.html (July 29, 2025).

registration, receiving drug information, and declaring drug prices. These responsibilities allowed the institution to analyze the drugs developed and distributed in the country to curb the spread of the pandemic. Additionally, it is necessary to overcome existing shortcomings to improve Vietnam's law on drug management and fulfill the goal of protecting and caring for people's health (Do, 2024). This current study examines methods to optimize drug regulation in Vietnam by analyzing its national legal framework considering international best practices. Furthermore, the author approaches the terminology of drugs and analyzes the shortcomings in managing medications for human use within the scope of the Law on Pharmacy 2016.

2 Conceptual Framework

This study's conceptual framework is grounded in the principle of optimizing drug regulation in Vietnam through the alignment of its national legal framework with international best practices. Drawing from a wide variety of studies, the conceptual framework for the current study is anchored on the premise that effective drug regulation necessitates a comprehensive approach encompassing legal structures, enforcement mechanisms (Duc, 2020), public health considerations, and international cooperation (Feng et al., 2024). The framework is built upon several interconnected concepts.

First, International Drug Control Standards, articulated by the World Trade Organization,[2] form a crucial pillar. This encompasses the body of treaties, conventions, and guidelines developed by international organizations, notably the United Nations (UN) and the World Health Organization (WHO). These standards provide a blueprint for national drug control laws, striving to balance the imperative of preventing drug abuse and trafficking with ensuring access to essential medicines. Second, the National Legal Framework of Vietnam, which encompasses the country's domestic laws, regulations, and policies about drug control, is a key component. The framework analyzes the existing legal instruments, who they are implemented, and their effectiveness in achieving desired outcomes. It critically

[2] World Trade Organization, *International export regulations and controls: Navigating the global framework beyond WTO rules*. Retrieved from https://www.wto.org/english/res_e/booksp_e/int_exp_regs_part2_1_e.pdf (July 29, 2025).

examines the strengths and weaknesses of the current system, pinpointing areas ripe for reform.

Third, the "Best Practices" concept is central to this study. This refers to the most effective and efficient approaches to drug regulation, identified through rigorous research, practical experience, and thorough evaluation. The study investigated best practices in other countries, focusing on Germany and Singapore. These nations were selected for comparative analysis due to their divergent approaches, Germany with a harm reduction emphasis in certain areas, and Singapore with a stricter, zero-tolerance stance, offering a spectrum of perspectives on drug control. Fourth, policy optimization is the dynamic process of adopting and implementing best practices within the specific context of Vietnam (Feng et al., 2024). It acknowledges that a universally applicable solution is unrealistic and that effective drug regulation requires tailoring policies to the country's unique social, cultural, and economic realities. The framework underscores the importance of evidence-based policymaking, meaningful stakeholder engagement, and continuous evaluation to ensure policy effectiveness.

Finally, "public health and safety" constitute the overarching goal of effective drug regulation (Luong, 2024). The framework recognizes that drug control policies should aim to minimize the harms associated with drug abuse and trafficking while simultaneously ensuring access to necessary medications and promoting public health. It considers the wide-ranging impact of drug policies on individuals, families, and communities. This framework proposes that by systematically comparing Vietnam's national legal framework with international standards and best practices in other countries, and through careful consideration of public health and safety, pathways for optimizing drug regulation in Vietnam can be identified. This optimization involved developing and implementing evidence-based policies tailored to the specific needs and context of the country while adhering to international obligations.

3 Materials and Methods

This study adopted a mixed-methods approach, integrating legal research, a systematic literature review, and comparative analysis. The legal literature review comprehensively examined relevant legal documents within Vietnam and

internationally. This review encompassed Vietnamese drug laws and regulations, including an analysis of the existing legal framework for drug control in Vietnam, encompassing relevant statutes, regulations, and policies. It also examined international drug control treaties and conventions to which Vietnam is a signatory to identify Vietnam's international obligations and commitments. Finally, relevant academic articles, books, and drug law and policy reports were reviewed to provide context and inform the analysis.

The systematic literature review involved a rigorous search of scientific journals to identify evidence-based best practices in drug regulation. This entailed searching relevant databases such as PubMed, Scopus, and Google Scholar using keywords related to drug policy, drug regulation, and international best practices in Vietnam. Studies were screened based on pre-defined inclusion criteria, focusing on research that evaluated the effectiveness of different drug control policies affecting Vietnam. Relevant data from included studies were extracted and synthesized to identify key findings and best practices.

The comparative analysis involved a detailed comparison of Vietnam's drug regulatory framework with those of Germany and Singapore. These countries were selected for their diverse approaches to drug control. The analysis focused on legal frameworks, comparing the legal frameworks for drug control in the three countries, including relevant legislation, regulations, and enforcement mechanisms. It also examined policy approaches, analyzing the different policy approaches adopted by the three countries, including harm reduction strategies, law enforcement approaches, and public health initiatives. Finally, it compared the outcomes and effectiveness of drug control policies in the three countries, considering indicators such as drug use prevalence, drug-related crime rates, and public health outcomes. The legal literature review, systematic review, and comparative analysis findings were synthesized to develop a framework to optimize drug regulation in Vietnam. This framework included specific recommendations for legal and policy reforms, considering the unique context of Vietnam and its international obligations.

4 Findings and Discussion

4.1 Legal Provisions of Vietnam on Drug Management

4.1.1 The Concept of Drug - an Object of Regulation by the Law on Pharmacy 2016

According to the provisions of Clause 2, Article 2 of the Law on Pharmacy 2016, "Drug means a preparation containing a pharmaceutical ingredient or medicinal materials for prevention, diagnosis, cure, treatment or mitigation of human diseases or modification of physiological functions of the human body. Drugs include pharmacochemical drugs, drugs made from medicinal materials, traditional drugs, vaccines, and biological products." Thereby, some of the following characteristics can be drawn:

First, a drug is a preparation containing pharmaceutical or medicinal ingredients. Specifically, the pharmaceutical or active ingredient may consist of a single substance or a mixture of substances, while medicinal materials are derived from plant, animal, or mineral sources.[3] The Law on Pharmacy (2005) defined drugs as substances or mixtures, implying that drugs encompass only pharmaceutical substances. At that time, two distinct concepts of drugs existed: material medical and traditional medicaments (Clauses 8 and 9, Article 2 of the 2005 Law on Pharmacy) and the general concept of drugs. Consequently, the definition of drugs primarily referred to Western medicine products, excluding traditional medical products.

Second, a drug is intended for the prevention, diagnosis, treatment, or mitigation of human diseases and for modifying physiological functions within the human body. In this context, drugs are strictly for human use. They are distinct from veterinary medicines, regulated under the Law on Veterinary Medicine (2015),[4] and pesticides, which fall under the Law on Plant Protection and Quarantine (2013).[5] This distinction ensures that pharmaceutical regulations and safety standards are

[3]National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 4, Article 2.
[4] National Assembly of the Socialist Republic of Vietnam. (2015). *Law on Veterinary Medicine (No. 79/2015/QH13), dated June 19, 2015*.
[5] National Assembly of the Socialist Republic of Vietnam. (2013). *Law on Plant Protection and Quarantine (No. 41/2013/QH13), dated November 25, 2013*.

appropriately tailored to human health needs, separate from those governing animal or agricultural treatments.

Third, a drug must fall into one of five specific categories: pharmacochemical drugs, drugs derived from medicinal materials, traditional drugs, vaccines, or biological products. While current regulations no longer explicitly exclude functional foods, as was the case under the Law on Pharmacy (2005), it is essential to note that certain products with drug-like properties, such as cosmetics (regulated under Circular 06/2011/TT-BYT, issued on January 25, 2011, by the Minister of Health) and functional foods (governed by the Law on Food Safety (2010)), are not classified as drugs. This distinction ensures that only substances meeting strict pharmacological criteria are subject to drug-specific regulatory oversight, maintaining the integrity of drug safety and efficacy standards.

In addition, the Law on Pharmacy 2016 and related legal documents only regulate issues related to pharmaceutical products such as drugs and drug materials in the context of human beings.[6] On September 5, 2022, the Government of Vietnam, through the MO H, issued Circular No. 08/2022/TT-BYT, introducing new guidelines for the registration of drugs and drug materials. This Circular, which took effect in October 2022, replaced Circular No. 32/2018 and introduced significant amendments aimed at streamlining the drug registration process.[7] One of the key changes involved modifying the requirements for granting a Certificate of Pharmaceutical Products (CPP), making the criteria less restrictive to facilitate access to essential medicines. Additionally, the revised regulation allowed manufacturers to submit legal documents demonstrating compliance with Good Manufacturing Practice (GMP) standards before obtaining a license to operate or manufacture pharmaceuticals. The current study acknowledges that such drug regulation updates reflect the government's commitment to enhancing regulatory efficiency while ensuring the quality and safety of pharmaceutical products.

[6] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 1, Article 2.
[7] Ministry of Health of the Socialist Republic of Vietnam. (2022). *Circular No. 08/2022/TT-BYT dated September 5, 2022, on marketing authorization of drugs and medicinal materials.*

4.1.2 Regulations on the Registration of Free Sale of Drugs

One form of drug registration, known as drug circulation registration, involves issuing a certificate of free sale. Rama Kishore et al. (2022) observes that this certificate is granted for drugs that either lack or possess an existing certificate that has changed various aspects. These changes may include alterations in pharmaceutical ingredients or medicinal materials, variations in the content, concentration, or quantity of active pharmaceutical ingredients, modifications to the form of preparation, changes in the route of administration, or a shift in the manufacturer. However, changes related to secondary packaging establishments or manufacturing locations do not necessitate a new certificate. According to regulatory requirements, establishments engaged in the manufacturing, wholesaling, exporting, or importing of drugs or drug materials, whether located in Vietnam or foreign entities with representative offices in Vietnam, must register their drugs with the appropriate state management agencies before their circulation within the Socialist Republic of Vietnam.[8]

Drugs may be allowed for circulation in Vietnam without prior registration under specific exclusive circumstances, ensuring essential medicines remain accessible for urgent medical needs while maintaining regulatory oversight.[9] One such case involves prescription drugs prepared at drugstores, where retail, and pharmaceutical establishments produce medications on-site using approved drug materials. These preparations are permitted exclusively within the same establishment where they are produced.[10]

Another exception applies to drugs manufactured and prepared within medical examination and treatment facilities. These drugs are produced to meet the facility's internal treatment needs. However, an exception exists for radioactive drugs,[11] which may be supplied to other healthcare institutions if the quantity produced

[8] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Points a and b, Clause 2, Article 55.
[9] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 1, Article 54.
[10]National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Point b, Clause 1, Article 47.
[11] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 2, Article 85.

exceeds the facility's actual treatment demand[12] and if the MOH, specifically the Drug Administration, grants written approval.[13]

Additionally, certain imported drugs that lack certificates of free sale in Vietnam may be imported in restricted quantities based on import permits. This applies to drugs containing pharmaceutical ingredients that are not yet registered for free sale in Vietnam or are registered but in insufficient supply to meet treatment demands. It also includes drugs containing pharmaceutical ingredients introduced in Vietnam or those previously available but now in limited supply. Medications required for urgent national defense, security needs, epidemic control, disaster response, or exceptional treatment cases also fall under this exemption. Furthermore, rare drugs, which are not commonly available but are essential for treating specific medical conditions, may be imported without prior registration.

In cases where drugs are identical to brand-name pharmaceuticals already registered in Vietnam, including those with the same trade name, active ingredient, concentration, or dosage form, they may be imported if they are manufactured either by the original producer or an authorized manufacturer and are priced lower than the brand-name equivalent. The MOH must request such importation. Additionally, medications designated for national health programs are permitted to ensure widespread public health initiatives are met. Drugs provided as aid or humanitarian donations also qualify under these exemptions, as they support healthcare initiatives and disaster relief efforts. Another category includes drugs imported for non-commercial purposes, such as those used for clinical trials, bioequivalence and bioavailability studies, scientific research, exhibitions, registration samples, or testing.[14] These exemptions reflect the Vietnamese government's commitment to balancing drug accessibility, public health needs, and regulatory control. By allowing unregistered drugs in exceptional cases, the system seeks to meet urgent and critical medical needs while upholding safety and quality standards.

[12] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 3, Article 85.
[13] Article 9 of Circular No. 20/2017/TT-BYT dated May 10, 2017 of the Minister of Health detailing a number of articles of the Law on Pharmacy and Decree No. 54/2017/ND-CP dated May 8, 2017 of the Government on drugs and drug materials subject to special control.
[14] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 2, Article 60.

Traditional drugs refer to medicinal products processed, prepared, and dispensed based on traditional medical prescriptions or formulations. These drugs are produced within medical examination and treatment establishments that apply traditional medicine and are used internally within the facility or sold under prescription at the same establishment.[15] Additionally, traditional drugs prepared by hospitals at the provincial level or higher, incorporating traditional medicine practices, may be distributed to other medical facilities specializing in traditional medicine within the same province or centrally governed city.[16] This distribution ensures that patients receiving treatment at these facilities have access to standardized traditional medicinal products.

The authority to grant a certificate of free sale (CFS) for drugs rests with the MOH. This certification is issued following an appraisal and consultation process conducted by the Advisory Council for the Grant of Certificates of Free Sale of Drugs and Drug Materials. The certificate of free sale serves as an official approval for drug circulation, affirming that the product meets safety, efficacy, and quality standards. A certificate of free sale for drugs remains valid for five years from the date of issuance. However, suppose a drug is subject to continued safety and efficacy monitoring. In that case, the certificate's validity is limited to three years from the date of issuance, as stipulated in Clause 6, Article 56 of the Law on Pharmacy 2016.[17] This regulatory framework ensures that traditional drugs adhere to national safety and efficacy requirements while supporting the integration of traditional medicine into Vietnam's healthcare system.

Under the Law on Pharmacy 2005, the only option for maintaining the validity of a certificate of free sale (CFS) for drugs was re-granting rather than extending the certificate. This process was unnecessarily costly and imposed administrative burdens on businesses, negatively impacting their operations.[18] Although regulatory changes have since been introduced, the extension of a CFS remains a form of drug registration rather than a streamlined renewal process. To apply for an extension,

[15] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 1, Article 70.
[16] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 1, Article 70.
[17] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 1, Article 56.
[18] Report No. 562/TTr-CP dated October 22, 2015 of the Government on the Pharmaceutical Law Project (amended).

the submitted dossier must remain unchanged from the originally approved application and be filed within 12 months before the certificate's expiration. Additional procedures must be followed if there are any modifications to the drug at the time of extension registration. In cases where significant changes occur, a new CFS or supplementary registration must be obtained rather than a simple extension.[19]

The authority and procedures for extending a CFS mirror those required for its initial issuance. Once expanded, the certificate remains valid for five years from the extension date, ensuring continuous authorization for drug circulation.[20] The standard five-year validity period and mandatory extensions were temporarily adjusted in response to the urgent medical needs during the COVID-19 pandemic.[21] Specifically, certificates set to expire between December 30, 2021, and December 31, 2024, have been automatically extended until December 31, 2024. This measure was implemented to prevent drug availability disruptions and support public health efforts during the pandemic.[22]

4.1.3 The issues of Counterfeit Drugs, Substandard Drugs

The current legal framework no longer considers "fraudulent intent," [23] or the subjective will of the drug manufacturer or distributor, as determining factors in identifying counterfeit drugs. Instead, a drug is classified as counterfeit if it meets specific criteria outlined in Clause 33, Article 2 of the Law on Pharmacy. These criteria fall into two main categories: content and form. From a content perspective, a drug is deemed counterfeit if it lacks the declared pharmaceutical ingredients or medicinal materials, contains pharmaceutical ingredients different from those

[19] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Point b, Clause 1, Article 55.
[20] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 4, Article 55.
[21] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 6, Article 56.
[22]See Resolution No. 12/2021/UBTVQH15 dated December 30, 2021 of the National Assembly Standing Committee on allowing the implementation of a number of mechanisms and policies in the health sector to serve the prevention and control of the COVID-19 epidemic and Resolution No. 80/2023/QH15 dated January 9, 2023 of the National Assembly on continuing to implement a number of policies in the prevention and control of the COVID-19 epidemic and the use of certificates of free sale of drugs and drug materials expiring from January 1, 2023 to December 31, 2024.
[23] National Assembly of the Socialist Republic of Vietnam. (2005). *Law on Pharmacy (No. 34/2005/QH11), dated June 14, 2005*. Clause 24, Article 2.

indicated on its label, or fails to meet the quality standards registered for circulation or stated in its import permit. Additionally, a drug is classified as counterfeit if it contains pharmaceutical ingredients or medicinal materials in concentrations, quantities, or amounts inconsistent with those registered for circulation, except in cases where the quality has degraded due to storage or distribution conditions.

Regarding form and appearance, a drug is considered counterfeit if it is manufactured, presented, or labeled in a way that imitates a genuine manufacturer, misrepresents the country of manufacture, or falsely claims a different country of origin. Since drugs are classified as goods, the production and distribution of counterfeit drugs fall under the broader category of counterfeit goods manufacturing and trading. As such, these activities may be subject to administrative penalties under Decree No. 98/2020/ND-CP, issued on August 26, 2020, which governs sanctions for violations in commercial activities, counterfeit goods production, and consumer protection. In more severe cases, those involved in producing and selling counterfeit drugs may face criminal prosecution under Article 192 of the 2015 Criminal Code, as amended in 2017, for the crime of manufacturing and trading counterfeit goods.

However, different legal provisions apply depending on the counterfeit drug's intended use. For drugs intended for diagnosing, treating, mitigating diseases, or regulating physiological functions, administrative sanctions or criminal liability under Article 192 apply. In contrast, counterfeit drugs specifically meant for disease prevention and treatment are subject to stricter legal consequences, bypassing administrative penalties and directly falling under Article 194 of the Criminal Code, which governs the manufacturing and trading of counterfeit medicines intended for disease prevention or treatment.

"Poor quality drug" is replaced by "substandard drug" with the same meaning. They refer to drugs not satisfying the quality standards registered with competent state agencies.[24] In addition, drugs with pharmaceutical ingredients and medicinal materials are not following registered quality standards, but they are counterfeit drugs if they have not met the standards right before and during registration, and

[24] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 32, Article 2.

drugs that do not meet quality standards are unintended to be changed during storage and circulation.[25]

4.1.4 Regulations on Illicit Drugs

Vietnam's drug enforcement framework, governed by the 2015 Criminal Law[3], is stringent yet nuanced, balancing punitive measures with harm reduction. Vietnam legally defines illicit drugs as narcotic substances with addictive or psychotropic properties, as outlined in Article 2, Clause 1 of the Law on Drug Prevention and Control (No. 73/2021/QH14).[26] These include substances like opium, heroin, cocaine, and amphetamine-type stimulants listed in Annexes I to IV, prohibited for unauthorized use, production, or distribution, except for regulated medical or scientific purposes.[27] This definition underpins the country's regulatory approach, balancing enforcement with harm reduction.

The Penal Code safeguards national security, human rights, and public order while addressing criminal acts, including illicit drug use and trafficking. Over recent decades, Vietnam's drug landscape has evolved due to technological advancements and the emergence of new substances like amphetamine-type stimulants.[28] In 2009, Vietnam decriminalized personal drug use, reclassifying it as an administrative violation rather than a criminal offense (Vuong et al., 2012). This shift aimed to reduce penalties for users while maintaining strict enforcement against trafficking, though it has sparked challenges in balancing decriminalization with effective control.

The United Nations Office on Drugs and Crime reports a global rise in illicit drug use, particularly among youth, driven by low costs and increased availability. Vietnam, with its historical ties to opium production, faces persistent challenges (Windle, 2015). The government has adopted multifaceted strategies, including supply reduction, demand suppression, and harm reduction, such as establishing

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[25] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Point c, Clause 33, Article 2.
[26] National Assembly of Vietnam. (2021). Law on Drug Prevention and Control No. 73/2021/QH14, Article 2, Clause 1. Hanoi: National Assembly.
[27] National Assembly of the Socialist Republic of Vietnam. (2021). *Law on Drug Prevention and Control (No. 73/2021/QH14), dated March 30, 2021.*
[28] United Nations Office on Drugs and Crime (UNODC), *Viet Nam Office*. Retrieved from https://www.unodc.org/roseap/en/vietnam/overview.html (July 29, 2025).

detox clinics and promoting rehabilitation over punishment (Hieu et al., 2021). However, distinguishing between recreational and habitual users remains problematic, undermining efforts to curb demand (Nguyen, 2008). Critics argue that lenient policies for users, coupled with harsh penalties for traffickers, create enforcement inconsistencies (Hue et al., 2024).

Vietnam's "open door" economic policy, implemented in the late 1980s, has inadvertently facilitated drug trafficking by enhancing cross-border trade.[29] Despite this, the government has reduced domestic poppy cultivation, contributing to a decline in internal drug supply.[30] Vietnam's commitment to international cooperation, including membership in the Greater Mekong Sub-Region Memorandum of Understanding on Drug Control and adherence to UN conventions such as the UN Convention against Illicit Trafficking of Narcotic Drugs of 1988, has strengthened its legal framework (Buddenberg et al., 2003). However, challenges persist, particularly in distinguishing between users, suppliers, and financiers, which complicates enforcement efforts (Reid & Higgs, 2011).

4.2 Comparative Analysis with Singapore and Germany

A comparative analysis of Vietnam's drug regulation landscape alongside those of Singapore and Germany reveals divergent policy architectures, each shaped by distinct legal traditions, public health priorities, and socio-political contexts. While Singapore's drug policy is anchored in a zero-tolerance paradigm, characterized by stringent enforcement, mandatory sentencing, and capital punishment for certain offenses, it has achieved low prevalence rates of drug use through aggressive supply-side interventions such as border surveillance and deterrent policing (Koman, 2019). However, this model has drawn sustained criticism from international human rights bodies for its limited incorporation of harm reduction and its punitive stance toward drug users (Miao & Lai, 2023).

[29] United Nations Office on Drugs and Crime (UNODC), *Viet Nam Office*. Retrieved from https://www.unodc.org/roseap/en/vietnam/overview.html (July 29, 2025).
[30] United Nations Office on Drugs and Crime (UNODC), *World Drug Report 2020*. Retrieved from https://wdr.unodc.org/wdr2020/index2020.html (July 29, 2025)

Germany, by contrast, has adopted a public health-oriented framework that integrates harm reduction, treatment, and social reintegration. Its decentralized governance structure allows for regional tailoring of drug programs, including supervised consumption sites, opioid substitution therapy, and community-based rehabilitation (Savaskan et al., 2024). The German model reflects a normative shift toward recognizing substance use disorders as health conditions rather than criminal infractions, aligning with WHO and UNODC guidelines on drug policy reform.

Vietnam's regulatory regime occupies a transitional space. Historically rooted in enforcement-heavy strategies, the country has begun to incorporate public health considerations, particularly through methadone maintenance programs and pilot harm reduction initiatives. Nonetheless, enforcement challenges persist, exacerbated by porous borders, fragmented inter-agency coordination, and limited institutional capacity (Thanh-Luong, 2022). Moreover, Vietnam's regulatory scope remains narrowly focused on illicit substances, with limited attention to pharmaceutical governance, access to controlled medicines, and pharmacovigilance, areas where Germany has developed robust oversight mechanisms (Shinde et al., 2025).

Three key insights emerge from this comparative exercise. First, Vietnam's drug policy reform would benefit from adopting a more evidence-based and multi-sectoral approach, integrating epidemiological data, health economics, and legal analysis to inform policy design. Second, the dichotomy between enforcement and public health should be re-framed as a continuum, where strategic integration, rather than substitution, of approaches yields more sustainable outcomes. Third, international collaboration must extend beyond bilateral exchanges to include participation in global monitoring platforms such as the Global Drug Policy Index, which benchmarks national performance across dimensions including access to medicines, proportionality of criminal justice responses, and development-linked drug policy.[31]

While neither Singapore nor Germany offers a universally transferable model, each provides instructive contrasts. Singapore's supply-side efficacy is tempered by ethical concerns and limited scalability, whereas Germany's harm reduction success is

[31] International Drug Policy Consortium (IDPC), *The Global Drug Policy Index 2021: Analytical Report*. Retrieved from https://idpc.net/publications/2021/11/the-global-drug-policy-index-2021-analytical-report (July 29, 2025).

contingent on strong institutional infrastructure and public trust. Vietnam's path forward lies in synthesizing these lessons into a context-sensitive framework that balances enforcement with health imperatives, aligns with international obligations, and reflects the country's evolving socio-legal landscape.

4.3 Inadequacies and Recommendations for Improvement

Vietnam's Law on Pharmacy 2016 faces definitional and procedural challenges that hinder effective drug regulation, necessitating amendments to align with international best practices. The definition of "drugs" in Clause 2, Article 2, while describing characteristics and uses, is undermined by specifying only five substances, creating ambiguity that enables manufacturers to evade registration obligations (Nguyen, 2015). This restrictive approach renders broader definitional elements redundant, complicating enforcement. France's Public Health Code, in contrast, offers a useful alternative model that employs a precautionary principle, classifying ambiguous products as drugs if they meet both drug and other product definitions (Legifrance, 2023). Following the French model, Vietnam could redefine drugs as preparations containing pharmaceutical ingredients or medicinal materials for prevention, diagnosis, treatment, or physiological modification, adopting this principle to ensure public health protection.[32] The absence of cosmetics from the Law on Pharmacy creates a regulatory gap,[33] despite their health impacts and oversight by the Drug Administration under Circular 06/2011/TT-BYT.[34] Codifying cosmetics as substances for external human use to cleanse or enhance appearance, as in Canada's Food and Drugs Act 1985,[35] would streamline governance. The certificate of free sale (CFS) extension process burdens the system, requiring full dossiers even for safe drugs, causing supply disruptions, with 12,896 registrations expiring between 2021 and 2022 (Minh, 2022). Adopting the European Union's model[36] of indefinite renewals after five years with post-market surveillance

[32] European Medicines Agency (EMA), *Medicinal Product Definitions*. Retrieved from https://www.ema.europa.eu/en/human-regulatory/overview/medicinal-products (July 29, 2025)
[33] Report No. 4360/BC-UBVĐXH13 of the Committee on Social Affairs verifying the Pharmaceutical Law Project (amended).
[34] Clause 1, Article 2 of Circular 06/2011/TT-BYT dated January 25, 2011 of the Minister of Health regulating the management of cosmetics.
[35] *Food and Drugs Act*, R.S.C., 1985, c. F-27 (Canada). Retrieved from https://laws-lois.justice.gc.ca/eng/acts/f-27/ (accessed May 9, 2025).
[36] Full text: "*Lorsque, eu égard à l 'invemble de ses caractéristiques, un produit est susceptible de répondre à la fois à la définition du médicament prévue au premier alinéa du I et au II et à celle d 'autres catégories de produits régies par le droit européen ou national, il*

or China's manufacturer-led safety approach would enhance efficiency (Feng and Li, 2021). Vietnam's limited processing capacity, 500 applications monthly against 14,000 annual extensions, underscores this need (Minh, 2022). The definition of "counterfeit drugs" in Clause 33, Article 2, incorrectly labels them as drugs lacking pharmaceutical ingredients, leading to misapplied criminal convictions, such as smuggling (Nguyen, 2019). Aligning with the World Health Organization's[37] definition of counterfeit drugs as fraudulently mislabeled products and adopting Singapore's[38] stringent penalties would clarify enforcement. These reforms, rooted in global practices, would strengthen Vietnam's pharmaceutical framework, enhancing public health and regulatory efficiency.

5 Conclusion

In conclusion, the Law on Pharmacy ensures that individuals can access quality, safe, and affordable medications. This law must establish a robust framework for regulating drug manufacturing, distribution, and pricing, focusing on consumer protection and patient safety. The COVID-19 pandemic has underscored the need for Vietnam to reevaluate its legal and policy frameworks for drug management. By reflecting on the lessons learned during the pandemic, Vietnam has the opportunity to strengthen its legal provisions and improve drug regulation. This study emphasizes the importance of looking at international models from countries like Germany and Singapore, and Canada, France and the EU, to identify best practices that can be adapted to Vietnam's context. Moreover, it is critical to address the inconsistencies in Vietnam's policies related to counterfeit drugs, aligning them with international standards, especially given the challenges posed by porous borders. Closing these gaps through stronger regulations and fostering international cooperation will enhance Vietnam's drug regulatory framework, help improve public health and safety while meeting global obligations. This research contributes to the ongoing discussion on effective drug control by providing evidence-based recommendations for legal reforms that are contextually relevant and in line with

est, en cas de doute, considéré comme un médicament", Article L5111-1 Code de la santé publique*, see https://www.legifrance.gouv.fr/codes/texte_lc/LEGITEXT000006072665/* (May 10, 2023).

[37] World Health Organization, *Guidelines for the development of measures to combat counterfeit drugs*, pp. 7–8. Retrieved from https://apps.who.int/iris/handle/10665/65892 (May 8, 2025).

[38] *Misuse of Drugs (Amendment) Act 2023*, No. 12 of 2023, Republic of Singapore Government Gazette, Acts Supplement, April 28, 2023. Retrieved from https://sso.agc.gov.sg/Acts-Supp/12-2023/Published/20230424 (July 29, 2025).

international best practices, paving the way for a more resilient and efficient drug regulation system in Vietnam.

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Povzetek v slovenskem jeziku

Ta študija preučuje pravne in politične reforme za krepitev vietnamskega sistema nadzora nad drogami s celostnim pristopom, ki vključuje javno zdravje, pravne temelje, politično voljo in mednarodno sodelovanje. Z uporabo mešanih metod, pravne analize, pregleda literature in primerjalnih študij primerov ocenjuje vietnamsko zakonodajo glede na globalne okvire ter opredeljuje ključna področja za reformo. Spodbudni primeri iz Nemčije in Singapurja ponujajo praktične modele upravljanja. Na podlagi empiričnih podatkov in pravne znanosti študija predlaga kontekstualno občutljiva priporočila, prilagojena institucionalnemu okolju Vietnama. Prispeva k globalni razpravi o politiki glede drog ter poziva oblikovalce politik k sprejemanju integriranih in prilagodljivih strategij, ki zmanjšujejo škodo in se usklajujejo z mednarodnimi standardi.