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LEGAL RESPONSIBILITIES OF PHARMACEUTICAL MANUFACTURERS IN VIETNAM: A COMPARATIVE STUDY OF INTERNATIONAL PRACTICES

RESPONSABILIDADES LEGAIS DOS FABRICANTES FARMACÊUTICOS NO VIETNÃ: UM ESTUDO COMPARATIVO DAS PRÁTICAS INTERNACIONAIS

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Abstract
This article provides a comprehensive analysis of Vietnam's legal framework governing the responsibilities of pharmaceutical manufacturing establishments, including those producing medicinal ingredients. It examines both the statutory provisions and the practical implementation of these regulations by enterprises operating within the sector. Through this dual lens, the study identifies key strengths in regulatory design, persistent challenges in enforcement, and systemic gaps that hinder compliance and operational efficiency. The research highlights the evolving nature of Vietnam's pharmaceutical legislation, particularly in light of recent amendments aimed at aligning domestic standards with international best practices. It also explores the implications of these legal developments for both domestic and foreign-invested enterprises, considering the broader context of Vietnam's ambition to become a regional hub for pharmaceutical innovation and production. Drawing on comparative insights from countries with mature pharmaceutical industries such as the United States, Japan, India, and member states of the European Union, the article proposes targeted legal and policy reforms. These recommendations are intended to enhance regulatory clarity, support sustainable industry growth, and foster a more competitive and

Resumo
Este artigo apresenta uma análise abrangente do arcabouço jurídico do Vietnã que rege as responsabilidades dos estabelecimentos de fabricação farmacêutica, incluindo aqueles que produzem ingredientes medicinais. Examina tanto as disposições legais quanto a implementação prática dessas regulamentações pelas empresas que atuam no setor. Por meio dessa abordagem dupla, o estudo identifica os principais pontos fortes do desenho regulatório, desafios persistentes na fiscalização e lacunas sistêmicas que dificultam a conformidade e a eficiência operacional. A pesquisa destaca a natureza evolutiva da legislação farmacêutica vietnamita, especialmente à luz de recentes emendas voltadas para alinhar os padrões nacionais às melhores práticas internacionais. Também explora as implicações dessas mudanças legais para empresas nacionais e com investimento estrangeiro, considerando o contexto mais amplo da ambição do Vietnã de se tornar um polo regional de inovação e produção farmacêutica. Com base em insights comparativos de países com indústrias farmacêuticas maduras, como Estados Unidos, Japão, Índia e Estados-membros da União Europeia, o artigo propõe reformas legais e políticas direcionadas. Essas recomendações visam aprimorar a clareza regulatória, apoiar o crescimento sustentável do setor e promover um

transparent pharmaceutical ecosystem in Vietnam.

Keywords: Pharmaceutical Law. Legal Compliance. Manufacturing Establishments. International Regulatory Comparison. Pharmaceutical Industry Development.

ecossistema farmacêutico mais competitivo e transparente no Vietnã.

Palavras-chave: *Legislação Farmacêutica. Conformidade Legal. Estabelecimentos de Fabricação. Comparação Regulatória Internacional. Desenvolvimento da Indústria Farmacêutica.*

1 INTRODUCTION

The pharmaceutical industry holds a vital position in safeguarding public health and has significantly contributed to the economic development of Vietnam, particularly in the aftermath of the COVID-19 pandemic. The crisis underscored the strategic importance of pharmaceutical capacity, further elevating the role and reputation of Vietnam's pharmaceutical sector. According to the World Health Organization (WHO), Vietnam's pharmaceutical industry is currently classified at level 3 out of 4, indicating its ability to proactively produce and export generic medicines. Domestically manufactured drugs account for approximately 70% of total consumption by volume and about 46% by value, reflecting both the scale and limitations of local production. The legal foundation for pharmaceutical governance in Vietnam is primarily established through the 2016 Pharmacy Law, which was amended and supplemented in 2024. This legislation, along with its accompanying regulatory documents, provides a framework for managing pharmaceutical enterprises. However, despite the existence of this legal infrastructure, the practical implementation of the law by manufacturing establishments reveals numerous deficiencies. These include inconsistencies in compliance, gaps in enforcement, and challenges in aligning domestic practices with international standards. This article aims to critically examine the current legal regulations governing pharmaceutical manufacturing in Vietnam, identify the shortcomings in their application, and propose targeted solutions for improvement. Drawing on comparative experiences from countries with advanced pharmaceutical industries, such as the United States, Japan, India, and members of the European Union, the study seeks to offer practical recommendations for enhancing Vietnam's legal and regulatory environment. Strengthening this framework is not only essential for ensuring public health and safety but also for fostering innovation, competitiveness, and sustainable growth in the pharmaceutical sector.

2 LITERATURE REVIEW

The legal framework governing pharmaceutical manufacturing in Vietnam has undergone significant development, particularly with the enactment of the Law on Pharmacy (2016) and its amendment in 2024. This legislation, along with supporting documents such as Decree No. 54/2017/ND-CP, Decree No. 155/2018/ND-CP, and Circular No. 35/2018/TT-BYT, has established a comprehensive regulatory structure for pharmaceutical production, circulation, and quality control. These legal instruments set forth conditions for infrastructure, personnel, and compliance with Good Manufacturing Practices (GMP), aligning Vietnam's pharmaceutical standards with international norms (Law on Pharmacy, 2016/2024; WHO GMP Guidelines).

Despite these advancements, practical implementation remains uneven. Studies and reports indicate persistent challenges in raw material dependency, administrative complexity, and enforcement inconsistency. Vietnam relies heavily on imported pharmaceutical ingredients, with over 80% sourced from China and India, creating vulnerability to global supply chain disruptions (Vietnambiz, 2018; Communist Review, 2022). Although the legal framework mandates strict control over raw materials, there is a lack of policy incentives to promote domestic production.

In terms of drug quality, Vietnam has made progress in reducing counterfeit and substandard products. The Ministry of Health reported a low rate of non-compliant samples in 2024, with only 0.53% failing quality tests and 0.06% suspected of being counterfeit (Health & Life, 2024). However, gaps in enforcement persist due to limited coordination among regulatory bodies and uneven compliance by enterprises (Do Xuan Tuyen, 2024).

International models offer valuable insights for legal reform. India's Pharma Parks initiative demonstrates how targeted financial and infrastructural support can reduce import dependency and stimulate domestic ingredient production (Government of India, 2020). The European Medicines Agency (EMA) provides a centralized and transparent regulatory model, while the U.S. Food and Drug Administration (FDA) employs expedited pathways for critical drug approvals. Japan's layered inspection system and use of digital technologies for supply chain monitoring further illustrate the benefits of integrated governance.

Vietnam's legal system also addresses criminal and civil liability. Article 194 of the Penal Code (2015/2025) imposes severe penalties for manufacturing and trading counterfeit drugs, including imprisonment, fines, and asset confiscation. Civil liability is governed by the Civil Code (2015), which outlines compensation mechanisms for contractual and non-contractual harm, supported by Resolution No. 02/2022/NQ-HDTP.

In summary, while Vietnam's legal framework for pharmaceutical manufacturing is structurally sound, its practical effectiveness requires enhancement through policy reform, technological integration, and international benchmarking.

3 METHODOLOGY

This study adopts a qualitative legal research methodology, combining doctrinal analysis with comparative legal evaluation. The doctrinal component involves a systematic examination of Vietnamese legal texts, including the Law on Pharmacy (2016, amended 2024), the Civil Code (2015), the Penal Code (2015, amended 2025), and relevant sub-law instruments such as decrees and circulars issued by the Ministry of Health. These documents are analyzed to identify the scope, structure, and enforcement mechanisms of legal responsibilities applicable to pharmaceutical manufacturing establishments.

In addition, the study incorporates empirical data from official reports, government publications, and media sources to assess the practical application of these laws. Sources include statistics from the Ministry of Health, inspection results from the Central Institute for Drug Control, and public statements by regulatory officials. These data provide insight into compliance levels, enforcement challenges, and industry responses.

The comparative dimension draws on international legal frameworks and policy models from jurisdictions with advanced pharmaceutical sectors, including India, the European Union, the United States, and Japan. These models are evaluated for their relevance and adaptability to the Vietnamese context, with particular attention to regulatory structure, approval processes, supply chain management, and technological integration.

4 VIETNAMESE LEGAL REGULATIONS ON THE LEGAL RESPONSIBILITIES OF PHARMACEUTICAL MANUFACTURING FACILITIES

4.1 Administrative responsibilities

Vietnam's legal framework governing pharmaceutical manufacturing facilities is primarily anchored in the Law on Pharmacy 2016, as amended and supplemented in 2024 (Luật Dược năm 2016). This statute serves as the highest legal authority regulating all business activities related to the production of drugs and pharmaceutical ingredients. Complementing this foundational law is Decree No. 117/2020/NĐ-CP, which provides detailed provisions on administrative sanctions applicable within the medical and pharmaceutical sectors.

Criteria for Drug and Pharmaceutical Ingredient Production

Pursuant to Article 33 of the Law on Pharmacy (as amended in 2024), pharmaceutical manufacturing establishments must satisfy stringent conditions relating to infrastructure, technical capacity, and human resources. Specifically, the law stipulates:

"1. Conditions on facilities, techniques and personnel are stipulated as follows: a) Establishments producing drugs and pharmaceutical ingredients must have a location, production workshop, testing room, warehouse for storing drugs and pharmaceutical ingredients, auxiliary systems, equipment, machinery for production, testing, and storage of drugs, a quality management system, technical documents and personnel that meet Good Manufacturing Practices for Drugs and Pharmaceutical Ingredients; b) Establishments importing drugs and pharmaceutical ingredients, establishments exporting drugs and pharmaceutical ingredients, establishments providing drug and pharmaceutical ingredient preservation services must have a location, warehouse for storing drugs, storage equipment, means of transport, a quality management system, technical documents and personnel that meet Good Manufacturing Practices for Drugs and Pharmaceutical Ingredients; c) Establishments wholesaling drugs and pharmaceutical ingredients must have a location, warehouse for storing drugs and pharmaceutical ingredients, drug management, storage equipment, means of transport, quality management system, technical documents and personnel that meet Good Distribution Practices for drugs and pharmaceutical ingredients…"

These provisions establish a mandatory threshold for operational eligibility. Enterprises may only commence pharmaceutical activities upon obtaining a Certificate of Eligibility for Pharmaceutical Business. This certificate functions not merely as an administrative formality but as a legal instrument for controlling the entry and operation of entities within the pharmaceutical supply chain.

Furthermore, Articles 33 and 34 of the Law on Pharmacy require that manufacturing facilities adhere to internationally recognized standards, including Good Manufacturing Practices (GMP) as issued by the World Health Organization (WHO) or equivalent standards approved by the Ministry of Health. These requirements ensure that infrastructure, equipment, and production processes meet rigorous safety and quality benchmarks.

Administrative Sanctions and Compliance Mechanisms

Decree No. 117/2020/NĐ-CP elaborates on the enforcement mechanisms applicable to pharmaceutical enterprises. Section 3 of the Decree outlines specific violations and corresponding penalties, including:

Article 52: Violations of regulations on pharmaceutical practice

Article 53: Violations concerning business establishment conditions

Article 54: Violations related to the Certificate of Eligibility for Pharmaceutical Business

Article 55: Breaches of rights and responsibilities of pharmaceutical business entities

Article 56: Violations in drug and ingredient registration

Article 57: Violations in drug and ingredient production

These provisions collectively aim to uphold public health by ensuring that all pharmaceutical products are manufactured under conditions that guarantee stability, safety, and efficacy. Importantly, the law emphasizes the role of human resources in maintaining drug quality, reflecting the State's regulatory philosophy that technological infrastructure must be complemented by qualified personnel.

Professional Responsibility of Key Personnel

Article 17 of the amended Law on Pharmacy delineates the qualifications required for individuals responsible for pharmaceutical expertise in establishments engaged in the import and export of drugs and ingredients. The law provides:

"1. The person responsible for pharmaceutical expertise of establishments exporting and importing drugs and pharmaceutical ingredients must have a professional degree specified in Point a, Clause 1, Article 13 of this Law and have 02 years of professional practice at a suitable pharmaceutical establishment…
2. The person responsible for pharmaceutical expertise of establishments exporting and importing vaccines and biological products must have one of the professional degrees specified in Point a, b or d, Clause 1, Article 13 of this Law and have 02 years of professional practice…
3. The person responsible for pharmaceutical expertise of establishments exporting and importing medicinal materials and traditional medicines must have a professional degree specified in Point a or Point c, Clause 1, Article 13 of this Law and have 02 years of professional practice…"

These provisions underscore the importance of professional qualifications in safeguarding the integrity of pharmaceutical operations. Article 13 further specifies that Vietnamese professionals must hold degrees in biology, chemistry, or related fields, while Article 14 sets forth criteria for foreign nationals practicing pharmacy in Vietnam. This regulatory structure ensures that individuals overseeing pharmaceutical activities possess the requisite expertise to manage risks associated with drug origin, quality, and safety.

Control of Raw Materials and Special Substances

Clause 26, Article 2 of the Law on Pharmacy introduces a classification system for substances subject to special control. These include:

Psychotropic drugs, addictive substances, precursors, and radioactive materials

Toxic drugs and toxic raw materials listed by the Ministry of Health

Substances banned in specific sectors as per Government regulations

Circular No. 20/2017/TT-BYT, issued on May 10, 2017, further mandates that such raw materials may only be imported or circulated if accompanied by documentation proving compliance with quality standards set by recognized pharmacopoeias or international benchmarks. As noted by the Ministry of Health:

"Strictly control the origin, quality and use of medicinal ingredients" (Ministry of Health, June 3, 2025)

Given Vietnam's reliance on imported raw materials, these regulations are essential to prevent the infiltration of counterfeit or substandard substances into the domestic market. Enterprises are required to implement robust systems for storage,

testing, and monitoring throughout the lifecycle of raw materials—from warehousing to production and distribution.

Regulation of Drug and Ingredient Distribution

Articles 57 and 59 of the Law on Pharmacy stipulate that all pharmaceutical products and ingredients must obtain a Circulation Registration Certificate from the Ministry of Health prior to public release. This process involves:

Review of technical documentation

Evaluation of quality standards

Assessment of safety and efficacy

Only upon satisfying these criteria may a product be legally circulated. Moreover, the legal framework provides for post-marketing surveillance, including inspection, sampling, and testing, to ensure continued compliance and protect patient safety.

4.2 Criminal liability of pharmaceutical manufacturing facilities

The Vietnamese legal system imposes strict criminal sanctions on individuals and entities involved in the unlawful production and distribution of counterfeit medicines and disease prevention drugs. These sanctions are codified in Article 194 of the Penal Code of 2015, as amended and supplemented in 2025. This provision reflects the State's determination to safeguard public health and maintain the integrity of the pharmaceutical supply chain through punitive measures that correspond to the severity of the offense.

Clause 1 of Article 194 stipulates that any individual who manufactures or trades counterfeit medicines or disease prevention drugs shall be subject to imprisonment ranging from two to seven years. This baseline penalty applies to general violations without aggravating circumstances. However, Clause 2 of the same article prescribes enhanced penalties, ranging from five to twelve years of imprisonment, for offenses committed under specific aggravating conditions. These include cases involving organized criminal activity, professional offending, repeat violations deemed dangerous, abuse of official position or authority, misuse of institutional identity, cross-border trafficking, and offenses involving counterfeit goods or illegal profits valued between one hundred and fifty million Vietnamese dong and five hundred million Vietnamese dong. Additional aggravating factors include causing bodily harm to others with an injury rate

between thirty-one percent and sixty percent, or causing property damage within the same monetary range.

Clause 3 escalates the severity of punishment to a range of twelve to twenty years of imprisonment for offenses involving counterfeit goods or illegal profits valued at five hundred million Vietnamese dong or more, or where the consequences include death, serious bodily injury exceeding sixty percent, harm to multiple individuals with a combined injury rate between sixty-one percent and one hundred twenty-one percent, or property damage valued between five hundred million and one billion five hundred million Vietnamese dong.

Clause 4 provides for the most severe penalties, including twenty years of imprisonment, life imprisonment, or the death penalty. These apply to cases involving illegal profits of two billion Vietnamese dong or more, the death of two or more individuals, cumulative bodily injury to multiple victims exceeding one hundred twenty-two percent, or property damage exceeding one billion five hundred million Vietnamese dong.

In addition to custodial sentences, Clause 5 authorizes supplementary penalties. Offenders may be fined between twenty million and one hundred million Vietnamese dong, prohibited from holding professional positions or practicing certain occupations for a period of one to five years, and may be subject to partial or total confiscation of assets.

Clause 6 extends criminal liability to commercial legal entities. Entities found guilty under Clause 1 may be fined between one billion and four billion Vietnamese dong. Those committing offenses under the aggravating circumstances listed in Clause 2 may face fines ranging from four billion to nine billion Vietnamese dong. For violations under Clause 3, the fine may range from nine billion to fifteen billion Vietnamese dong. Entities involved in offenses under Clause 4 may be fined between fifteen billion and twenty billion Vietnamese dong or may have their operations suspended for a period of one to three years. In cases involving violations of Article 79 of the Penal Code, permanent suspension of operations may be imposed. Furthermore, commercial entities may be fined between one hundred million and three hundred million Vietnamese dong and prohibited from conducting business, operating in specific sectors, or raising capital for a period of one to three years.

These provisions establish a robust legal framework for prosecuting and penalizing pharmaceutical manufacturing facilities and their representatives who engage

in criminal conduct. The severity of the sanctions reflects the gravity of the harm caused to public health, consumer safety, and economic integrity. The law thereby serves both a deterrent and corrective function, reinforcing the ethical and legal obligations of pharmaceutical enterprises operating in Vietnam.

4.3 Civil liability of pharmaceutical manufacturing facilities

In addition to criminal sanctions, pharmaceutical manufacturing establishments may be held civilly liable for damages caused to consumers. This liability arises under both contractual and non-contractual obligations, as provided for in the Civil Code of 2015. The legal framework governing civil liability is designed to ensure that victims of harm resulting from pharmaceutical activities are adequately compensated and that enterprises are held accountable for breaches of duty, whether arising from contractual relationships or independent tortious conduct.

Contractual liability is triggered when a pharmaceutical manufacturer fails to perform its obligations as agreed upon in a contract, resulting in material harm to the counterparty. This may include failure to deliver products that meet agreed-upon quality standards, delays in delivery, or other breaches that cause financial or physical harm.

Non-contractual liability, or tort liability, applies when a manufacturing establishment engages in conduct that infringes upon the health, life, honor, dignity, reputation, property, or other lawful interests of individuals, regardless of whether a contractual relationship exists. Article 584 of the Civil Code provides the foundational basis for such liability. It states that any person who causes damage through unlawful conduct shall be liable for compensation, except in cases where the law provides otherwise. Clause 2 of the same article exempts liability in situations involving force majeure or where the damage is entirely attributable to the fault of the injured party, unless otherwise agreed or provided by law. Clause 3 extends liability to owners or possessors of property that causes damage, subject to the same exceptions.

Resolution No. 02/2022/NQ-HDTP offers interpretive guidance on the application of these provisions, particularly in cases involving non-contractual liability. Article 585 of the Civil Code outlines the principles of compensation, which are further elaborated in Article 3 of the Resolution. The types of compensable damages include property damage as defined in Article 589, damage resulting from health infringement under Article 590,

damage caused by loss of life under Article 591, and damage to honor, dignity, and reputation under Article 592. These categories are detailed in Articles 6 through 9 of the Resolution, providing a comprehensive framework for assessing and awarding compensation.

Article 608 of the Civil Code imposes liability on individuals and legal entities that produce or trade goods or services without ensuring their quality, thereby causing harm to consumers. This provision is particularly relevant to pharmaceutical manufacturing, where the consequences of substandard or unsafe products can be severe. Clause 1 of Article 2 of the Law on Pharmacy defines pharmaceuticals as including both drugs and pharmaceutical ingredients. Accordingly, these products are considered commodities subject to the general rules of consumer protection and product liability.

The legal system thus establishes a multi-layered structure of accountability for pharmaceutical manufacturing establishments. In addition to the Law on Pharmacy, several subordinate legal instruments provide detailed regulatory guidance. These include Decree No. 54/2017/ND-CP, which elaborates on the requirements for facilities, equipment, documentation, and procedures necessary for obtaining a certificate of eligibility for pharmaceutical business. Decree No. 155/2018/ND-CP introduces amendments aimed at streamlining administrative procedures and facilitating business operations. Circular No. 35/2018/TT-BYT issued by the Ministry of Health sets forth specific regulations on drug quality inspection and the supervision of raw material production and importation.

Beyond these sector-specific regulations, broader legal instruments such as the Penal Code, Civil Code, Law on Administrative Violations, Law on Product and Goods Quality, Law on Consumer Protection, and Law on Food Safety collectively reinforce the legal responsibilities of pharmaceutical enterprises. These statutes are supplemented by a range of decrees, circulars, and resolutions that provide operational clarity and enforcement mechanisms.

In conclusion, the Vietnamese legal framework governing the responsibilities of pharmaceutical manufacturing establishments is extensive and multifaceted. While the system is generally comprehensive, its practical implementation reveals areas that require further refinement. Enhancing regulatory coherence, strengthening enforcement capacity, and aligning domestic standards with international best practices are essential steps

toward ensuring public health safety and fostering sustainable development in the pharmaceutical sector amid the challenges of global integration.

5 PRACTICAL APPLICATION OF THE LAW ON LEGAL LIABILITY OF PHARMACEUTICAL MANUFACTURING ESTABLISHMENTS

In recent years, Vietnam's pharmaceutical sector has demonstrated notable growth in both scale and quality, reflecting the increasing maturity of the domestic industry. According to data published by the Ministry of Health, as of 2024, there are 238 pharmaceutical factories in Vietnam that meet the standards of Good Manufacturing Practice as recognized by the World Health Organization. A number of these facilities have further advanced to comply with more stringent international standards, including those of the European Union, Japan, and the Pharmaceutical Inspection Co-operation Scheme. These achievements have enabled Vietnamese pharmaceutical enterprises to access and compete in demanding international markets. For instance, SaVinpharm Company has been certified under both Japanese and European GMP standards, affirming its capacity to produce high-quality pharmaceutical products and positioning it as a potential leader in global pharmaceutical exports.

These developments suggest that the legal framework established by the 2016 Law on Pharmacy and its implementing instruments has had a positive impact on the industry. The law has compelled enterprises to enhance their production capabilities, improve quality control systems, and align their operations with international norms. However, despite these advancements, the practical enforcement and application of legal provisions in the pharmaceutical manufacturing sector continue to encounter significant challenges.

One of the most pressing issues is the overwhelming dependence on imported raw materials. Vietnam currently sources more than eighty percent of its pharmaceutical ingredients from foreign suppliers, primarily China and India. This reliance renders domestic manufacturers vulnerable to fluctuations in global supply chains and pricing. During the COVID-19 pandemic, disruptions in international logistics led to acute shortages of raw materials, severely affecting drug production and availability. Although the legal framework contains provisions for raw material management, there remains a lack of robust policy incentives to stimulate domestic investment in pharmaceutical

ingredient production. Without strategic intervention, this dependency poses long-term risks to national pharmaceutical security.

Another area of concern is the enforcement of drug quality standards. While the regulatory system governing GMP compliance and drug circulation has contributed to a reduction in the prevalence of substandard products, implementation gaps persist. According to Deputy Minister of Health Do Xuan Tuyen, Vietnam maintains a relatively low rate of counterfeit drugs compared to global averages. Nonetheless, data from the Central Institute for Drug Control in 2024 revealed that out of 43,197 samples tested, approximately 0.53 percent failed to meet quality standards, and 0.06 percent were suspected of being counterfeit or of dubious origin. These figures, though modest, underscore the persistent disconnect between legal mandates and enforcement outcomes. The causes of this gap include limited legal awareness among certain enterprises and a lack of coordination among regulatory bodies responsible for inspection and oversight.

Administrative procedures also present a significant barrier to effective legal compliance. Despite the reforms introduced by Decree No. 155/2018/ND-CP, which aimed to streamline licensing processes, the procedures for obtaining a certificate of eligibility for pharmaceutical business or registering drug circulation remain complex and time-consuming. Enterprises are required to compile extensive documentation and often face prolonged appraisal periods. These delays hinder operational efficiency and impede the timely introduction of new pharmaceutical products to the market, thereby affecting public access to essential medicines.

Furthermore, disparities in business capacity and legal compliance are evident across the industry. While some large enterprises have invested in advanced technologies and research and development, many small and medium-sized pharmaceutical companies struggle to meet legal requirements, particularly those related to GMP standards. The financial burden of constructing compliant facilities, acquiring modern equipment, and recruiting qualified personnel exceeds the capacity of many smaller firms. This imbalance contributes to uneven competitiveness and undermines the sustainability of the domestic pharmaceutical market.

In summary, although Vietnam’s legal framework for pharmaceutical manufacturing is relatively comprehensive and well-structured, its practical application reveals several systemic weaknesses. These include overreliance on imported raw materials, inconsistent enforcement of quality standards, burdensome administrative

procedures, and unequal capacity among industry participants. Addressing these challenges requires targeted legal and policy reforms informed by international best practices.

6 RECOMMENDATIONS FOR LEGAL IMPROVEMENT BASED ON INTERNATIONAL EXPERIENCE

While the 2016 Law on Pharmacy, as amended in 2024, and its accompanying legal instruments have laid a foundational framework for regulating pharmaceutical production, further refinement is necessary to address persistent shortcomings and enhance the effectiveness of legal enforcement. Drawing on comparative experiences from countries with advanced pharmaceutical sectors, several recommendations can be proposed.

First, Vietnam should prioritize the development of domestic pharmaceutical ingredient production. Current legal and policy efforts have focused primarily on promoting the cultivation and processing of medicinal herbs and basic active ingredients. In contrast, countries such as India have established specialized pharmaceutical industrial zones, known as Pharma Parks, supported by preferential tax regimes and credit facilities. These initiatives have enabled India to reduce its dependence on imports and emerge as a global pharmaceutical hub. Vietnam could adopt similar strategies by offering financial incentives, allocating land for industrial development, and facilitating access to technology, thereby fostering a self-sufficient pharmaceutical ingredient industry.

Second, although Vietnam's legal provisions on drug quality management and circulation are relatively comprehensive, their implementation remains suboptimal. The European Union offers a model of centralized and transparent pharmaceutical governance through the European Medicines Agency. The EMA oversees drug approval processes with input from independent scientific bodies and mandates the public disclosure of clinical trial data. Adopting elements of this model could enhance transparency, strengthen public trust, and improve regulatory oversight in Vietnam.

Third, the drug registration process in Vietnam is often criticized for its complexity and inefficiency. In contrast, the United States Food and Drug Administration has implemented expedited pathways such as Fast Track and Priority Review for drugs addressing serious medical conditions or public health emergencies. These mechanisms

balance the need for rigorous safety and efficacy standards with the imperative of timely access to innovative treatments. Vietnam should consider integrating similar procedures to encourage pharmaceutical innovation while maintaining regulatory integrity.

Fourth, the inspection and enforcement mechanisms in Vietnam require greater consistency and technological integration. Despite existing legal provisions, counterfeit and smuggled drugs continue to pose risks to public health. Japan's layered pharmaceutical management system offers valuable lessons in this regard. Local agencies collaborate closely with the national Ministry of Health and utilize digital technologies to monitor the pharmaceutical supply chain. Vietnam could enhance its enforcement capacity by promoting inter-agency cooperation and adopting advanced technologies such as blockchain and artificial intelligence to track drug origin, monitor transportation, and verify quality.

7 CONCLUSION

The current legal framework governing the responsibilities of pharmaceutical manufacturing establishments in Vietnam has laid a foundational and relatively comprehensive structure for regulating this critical sector. These regulations have played a significant role in enhancing the quality and safety of pharmaceutical products, thereby contributing to the overall development of the industry and the protection of public health. The 2016 Law on Pharmacy, along with its amendments and implementing instruments, has established essential standards for infrastructure, personnel, production processes, and quality control.

However, the practical application of these legal provisions continues to face notable challenges. Among the most pressing issues are the heavy reliance on imported raw materials, which exposes the industry to global supply chain vulnerabilities; the complexity and duration of administrative procedures, which hinder operational efficiency and innovation; and the limited effectiveness of inspection and supervisory mechanisms, which compromise regulatory enforcement and public trust.

International experience demonstrates that a robust support system is essential for the pharmaceutical industry to thrive under legal regulation. This includes streamlining administrative processes, enhancing transparency in regulatory decisions, and integrating scientific and technological advancements into management and oversight functions.

Countries with advanced pharmaceutical sectors have successfully implemented centralized regulatory bodies, digital monitoring systems, and incentive-based policies to foster innovation and ensure compliance.

To address the existing gaps and strengthen the legal infrastructure, continued research and legislative refinement are imperative. Improving the coherence, efficiency, and enforceability of pharmaceutical laws will not only provide manufacturing establishments with a stable and predictable legal environment but also reinforce consumer protection mechanisms. A well-developed legal corridor will serve as both a regulatory safeguard and a catalyst for sustainable growth, enabling Vietnam's pharmaceutical industry to meet domestic needs and compete effectively in the global market.

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Authors' Contribution

Both authors contributed equally to the development of this article.

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