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Strengthening drug regulation in southeast and south Asia: A comparative analysis of DAV and NMRA

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Abstract
This study presents a comparative analysis of the pharmaceutical regulatory systems in Vietnam and Sri Lanka, focusing on the Drug Administration of Vietnam (DAV) and the National Medicines Regulatory Authority (NMRA) of Sri Lanka. Both agencies play critical roles in ensuring the safety, efficacy, and quality of medicines within their countries, yet they operate within distinct institutional frameworks shaped by differing historical, legal, and socio-economic contexts. Through a qualitative review of policy documents, regulatory guidelines, and academic literature, this research evaluates the organizational structures, drug approval processes, pharmacovigilance mechanisms, enforcement practices, and international collaborations of both regulatory bodies. Findings reveal that while Vietnam benefits from strong regional integration and harmonization efforts through ASEAN, Sri Lanka's NMRA demonstrates greater administrative autonomy and focused reform initiatives. Both agencies face challenges related to limited resources, capacity constraints, and the need for enhanced post-market surveillance. The COVID-19 pandemic further highlighted their regulatory agility and areas needing improvement. This comparative study provides valuable insights for policymakers and stakeholders aiming to strengthen pharmaceutical regulation in low- and middle-income countries, emphasizing the importance of balanced governance, capacity building, and international cooperation in safeguarding public health.

Keywords: Pharmaceutical regulatory systems, drug administration of Vietnam (DAV), national medicines regulatory authority (NMRA), low- and middle-income countries (LMICS), drug approval process, regulatory harmonization

Introduction
The pharmaceutical sector plays a critical role in ensuring public health through the regulation, quality assurance, and accessibility of medicines. Effective pharmaceutical regulatory systems are fundamental for maintaining drug safety, efficacy, and quality. In many developing nations, however, regulatory frameworks often face challenges related to infrastructure, enforcement, and harmonization with international standards (Thambavita *et al*. 2018) [12]. This paper aims to undertake a comparative analysis of the pharmaceutical regulatory authorities in Vietnam and Sri Lanka — the Drug Administration of Vietnam (DAV) and the National Medicines Regulatory Authority (NMRA), respectively. Vietnam and Sri Lanka, despite their geographical and economic differences, share common goals in strengthening pharmaceutical governance, improving drug registration processes, and ensuring equitable access to essential medicines. The DAV operates under the Ministry of Health of Vietnam and is responsible for overseeing drug registration, clinical trials, pharmacovigilance, and market surveillance. In contrast, Sri Lanka's NMRA, established under the National Medicines Regulatory Authority Act No. 5 of 2015, is a semi-autonomous body that regulates the manufacture, import, export, distribution, and sale of medicines and medical devices (Lozda, 2021) [8]. This comparative analysis evaluates the organizational structures, regulatory frameworks, operational procedures, and compliance with global standards of DAV and NMRA. By exploring their strengths, challenges, and areas for reform, the study seeks to provide insights into how regulatory systems in emerging economies can be enhanced for better health outcomes. Furthermore, this research contributes to the broader discourse on global regulatory convergence and the need for resilient regulatory systems in low- and middle-income countries (LMICs).
Pharmaceutical regulation is a cornerstone of public health policy, ensuring that medicines circulating within a country are safe, effective, and of high quality.

As global health challenges evolve and the pharmaceutical industry expands, the need for robust regulatory systems becomes even more critical—particularly in low- and middle-income countries (LMICs), where health system capacities vary and access to safe medicines remains a persistent issue. Regulatory authorities are tasked not only with monitoring and approving drugs but also with protecting populations from counterfeit, substandard, or unsafe pharmaceutical products. Vietnam and Sri Lanka, both classified as LMICs by the World Bank, present compelling case studies for analyzing how pharmaceutical regulatory systems are structured and function within differing socio-political and healthcare landscapes (Sapkota *et al*. 2022) [11]. Vietnam's Drug Administration (DAV), operating under the Ministry of Health, is the principal agency responsible for drug regulation, licensing, clinical trial oversight, and post-market surveillance. It has been actively reforming its practices to align more closely with international standards, such as those set by the World Health Organization (WHO) and ASEAN harmonization initiatives.

Sri Lanka's National Medicines Regulatory Authority (NMRA), established relatively recently in 2015, replaced the earlier Drug Regulatory Authority with a more autonomous and streamlined institution. The NMRA regulates all aspects of pharmaceutical production, importation, distribution, and pricing. It also oversees medical devices and borderline products, playing a vital role in protecting public health and promoting rational drug use (Lozda, 2021) [8]. Although both countries have made considerable progress, they continue to face significant challenges such as regulatory bottlenecks, capacity limitations, and the integration of digital health tools. This study conducts a comparative analysis of the DAV and NMRA with a focus on their institutional frameworks, regulatory processes, transparency and accountability mechanisms, human resource capabilities, international cooperation, and responsiveness to public health emergencies. By identifying areas of convergence and divergence between the two systems, the research aims to uncover best practices and gaps that could inform future policy development. The comparative lens also provides insight into how historical, economic, and political contexts shape regulatory evolution in each country (Jayasinghe *et al*. 2022) [7]. Moreover, the growing interconnectedness of global pharmaceutical markets underscores the need for harmonized regulatory standards and mutual recognition mechanisms. This analysis not only contributes to academic discourse but also holds practical relevance for policymakers, international health organizations, and regulatory professionals working towards improving medicine regulation in LMICs. Ultimately, the paper aims to support the development of stronger, more adaptive pharmaceutical regulatory systems that can better safeguard public health in an increasingly complex healthcare environment.

Scope of The Study

This study is focused on a comparative analysis of the pharmaceutical regulatory systems in Vietnam and Sri Lanka, with particular emphasis on the Drug Administration of Vietnam (DAV) and the National Medicines Regulatory Authority (NMRA) of Sri Lanka. It explores how these regulatory bodies function within their respective healthcare systems and assesses their effectiveness in ensuring the safety, quality, and efficacy of pharmaceutical products. The scope includes examining institutional structures, legal and policy frameworks, and the degree of administrative autonomy each authority possesses. It further investigates core regulatory functions such as drug registration and approval processes, pharmacovigilance systems, post-market surveillance, and enforcement mechanisms, including inspections and quality control (Jakovljevic *et al*. 2021) [5]. In addition, the study evaluates the extent to which DAV and NMRA engage in international cooperation and harmonization efforts, particularly in aligning with global standards set by organizations such as the World Health Organization (WHO) and regional alliances like ASEAN and SAARC. The analysis also addresses regulatory challenges commonly faced by both authorities, including resource constraints, delays in drug approvals, and the presence of counterfeit or substandard medicines. Special attention is given to how each authority responded to recent public health emergencies, including the COVID-19 pandemic, and their ability to ensure timely access to essential medicines and vaccines. The study is limited to pharmaceutical regulation and does not extend to broader areas of healthcare policy such as pricing mechanisms unrelated to regulation, insurance systems, or hospital services (Alkalha *et al*. 2024) [2]. While Vietnam and Sri Lanka are the primary focus, the insights gained from this comparison aim to offer relevant implications for other low- and middle-income countries (LMICs) seeking to enhance their pharmaceutical regulatory capacities.

This study offers a comprehensive comparative analysis of the pharmaceutical regulatory systems in Vietnam and Sri Lanka, specifically focusing on the roles, structures, and functions of the Drug Administration of Vietnam (DAV) and the National Medicines Regulatory Authority (NMRA) of Sri Lanka. The primary aim is to explore how these two national agencies regulate the pharmaceutical sector to ensure the safety, efficacy, and quality of medicines available to their populations. The study investigates multiple dimensions of regulatory practice, including institutional setup, legislative and policy frameworks, administrative autonomy, and governance models that shape the effectiveness of each regulatory authority (Thambavita *et al*. 2018) [12]. The research delves into the drug registration and approval processes of both countries, examining their procedures, timelines, evaluation criteria, and levels of transparency. Post-market surveillance and pharmacovigilance systems are also analyzed to assess how each agency monitors the safety of pharmaceutical products once they enter the market. The study further reviews enforcement strategies such as inspections of manufacturing facilities, regulatory compliance measures, sanctions for violations, and approaches to combatting counterfeit and substandard medicines. In doing so, it identifies gaps and strengths in both systems that directly impact public health outcomes.

Justification of The Study

The regulation of pharmaceuticals is a vital function of national health systems, particularly in low- and middle-income countries (LMICs), where access to safe, effective, and quality-assured medicines is often inconsistent. In such contexts, weak or inefficient regulatory systems can lead to the circulation of substandard or counterfeit drugs, posing

significant risks to public health. Vietnam and Sri Lanka, while making notable progress in strengthening their pharmaceutical governance, still face persistent challenges related to regulatory capacity, infrastructure, transparency, and harmonization with international standards (Alkalha *et al*. 2024) [2]. A comparative analysis of their regulatory authorities—the Drug Administration of Vietnam (DAV) and the National Medicines Regulatory Authority (NMRA) of Sri Lanka—can reveal critical insights into the functioning, strengths, and shortcomings of regulatory systems in similar socio-economic settings. This study is justified by the increasing global focus on improving regulatory efficiency and convergence, especially in LMICs striving to enhance public health outcomes and meet international obligations such as those outlined by the World Health Organization (WHO). By comparing DAV and NMRA, the research highlights best practices, policy innovations, and reform strategies that can serve as models for other countries facing similar regulatory challenges. It also helps to identify common barriers such as administrative delays, workforce limitations, and insufficient post-market surveillance, all of which directly affect medicine safety and public trust (Jakovljevic *et al*. 2021) [5]. Moreover, the study contributes to the limited academic literature that focuses specifically on pharmaceutical regulatory systems in Southeast and South Asia. Despite the critical role these authorities play, there is a scarcity of in-depth, comparative research that evaluates their performance in a structured manner. The findings of this study are therefore valuable not only to scholars and policymakers but also to international regulatory networks, donors, and technical assistance agencies aiming to support capacity-building efforts in the pharmaceutical sector.

Effective pharmaceutical regulation is essential for safeguarding public health by ensuring that only safe, effective, and high-quality medicines are accessible to the population. In low- and middle-income countries (LMICs), such as Vietnam and Sri Lanka, the burden of ensuring drug safety is compounded by limited resources, evolving disease patterns, and growing public demand for healthcare transparency. Weak regulatory oversight can result in serious consequences, including the distribution of substandard, falsified, or unregistered medicines, delayed access to life-saving drugs, and public distrust in the healthcare system. Therefore, studying and strengthening pharmaceutical regulatory systems is not only a national concern but a global health priority (Jayasinghe *et al*. 2022) [7]. This study is justified by the urgent need to understand and compare the regulatory frameworks of Vietnam and Sri Lanka—two countries with shared aspirations of improving health system performance and aligning with global best practices.

Type of Authorization	Fee in VND	Fee in USD
Appraisal & issuance for drug circulation registration certificate (NA for traditional medicines)	11 million/file	429 USD approx.
Appraisal of renewal of circulation registration paper for drugs, traditional medicines and medicinal ingredients	4.5 million/file	175 USD approx.
Import License appraisal and issuance for drugs which do not have a drug circulation registration certificate in Vietnam	1.2 million/item	47 USD approx.

Source: (Artixio, 2025)

Fig 1: MOH Drug Authorization fees

The study also addresses a broader global concern: how to build regulatory resilience in the face of increasing threats such as global pandemics, supply chain disruptions, and the rising prevalence of antimicrobial resistance. Regulatory agencies today must not only ensure compliance and safety but also be agile in emergency situations, such as during the COVID-19 pandemic. Understanding how DAV and NMRA responded to such challenges will help identify capacity gaps and opportunities for future improvement. Furthermore, this research is relevant for policymakers, healthcare professionals, pharmaceutical companies, and international development partners (Thambavita *et al*. 2018) [12]. By highlighting successful regulatory models and pinpointing system weaknesses, the study can inform national reforms and guide international technical support and investment. It can also serve as a learning tool for other LMICs aiming to establish or reform their own regulatory agencies. In an era where global health threats such as pandemics demand rapid and coordinated regulatory responses, understanding how national regulatory systems operate—and how they can be improved—is more urgent than ever. This study, by examining two relevant case studies, seeks to inform evidence-based reforms that can enhance medicine regulation, improve access to safe pharmaceuticals, and ultimately strengthen health systems in resource-constrained settings.

Literature Review

Overview of Pharmaceutical Regulatory Systems

Pharmaceutical regulatory systems are the cornerstone of national health infrastructure, ensuring that all medicinal products meet established standards of safety, efficacy, and quality before reaching patients. These systems are responsible for a wide range of functions, including drug registration and licensing, quality control testing, good manufacturing practice (GMP) inspections, pharmacovigilance, post-market surveillance, and the regulation of clinical trials. A well-functioning regulatory authority plays a critical role in protecting public health by minimizing risks associated with unsafe, counterfeit, or ineffective medicines (Pezzola and Sweet, 2016) [10]. Globally, organizations such as the World Health Organization (WHO), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) provide regulatory guidelines and technical assistance to support countries in strengthening their pharmaceutical oversight.

In most countries, a national medicines regulatory authority (NMRA) serves as the primary body overseeing all regulatory activities. These authorities operate under a legal framework and are often part of or affiliated with the Ministry of Health. While high-income countries typically have matured, well-resourced regulatory systems, low- and middle-income countries (LMICs) often face capacity constraints in terms of staffing, funding, infrastructure, and access to advanced regulatory technologies (Al-Essa *et al.* 2015) [1]. To address these challenges, many LMICs are reforming their regulatory models, adopting digital tools, and participating in regional harmonization efforts to improve efficiency and global alignment. The effectiveness of a regulatory system is increasingly being assessed through performance-based tools such as the WHO Global Benchmarking Tool (GBT), which evaluates maturity levels and identifies areas for capacity building. Ultimately, pharmaceutical regulatory systems are not only technical bodies but also instruments of public policy that reflect a country's commitment to health equity, access to essential medicines, and adherence to international standards (Pezzola and Sweet, 2016) [10]. As globalization and cross-border trade continue to grow, the importance of regulatory convergence and collaboration among national authorities has become more critical than ever. Understanding the fundamentals of how these systems operate provides the foundation for evaluating country-specific frameworks such as those in Vietnam and Sri Lanka.

Regulatory Evolution in Low- and Middle-Income Countries (LMICS)

The evolution of pharmaceutical regulatory systems in low- and middle-income countries (LMICs) has been shaped by a combination of public health needs, international pressures, donor interventions, and internal policy reforms. Historically, many LMICs lacked formal and structured drug regulatory authorities, with limited legal frameworks and technical infrastructure to oversee the growing pharmaceutical markets. As a result, the prevalence of counterfeit, substandard, and unregulated medicines was a major public health concern (Mukonzo *et al.* 2024) [9]. Over the past few decades, however, many LMICs have initiated reforms to establish or modernize their national regulatory authorities. These efforts have included the development of comprehensive drug laws, creation of autonomous or semi-autonomous regulatory bodies, and adoption of Good Regulatory Practices (GRP) in alignment with global benchmarks set by the World Health Organization (WHO).

Despite these advancements, regulatory systems in LMICs continue to face significant challenges. Limited financial and human resources, inadequate laboratory capacity, weak enforcement mechanisms, and lack of digitized processes hinder the full realization of effective pharmaceutical regulation. Furthermore, overlapping responsibilities among government agencies, political interference, and fragmented health systems often delay regulatory decisions and weaken oversight (Vodosin *et al.* 2021) [14]. In response to these challenges, global initiatives such as the WHO's Global Benchmarking Tool (GBT), the African Medicines Regulatory Harmonization (AMRH), and the ASEAN Pharmaceutical Regulatory Harmonization have been instrumental in providing technical support, standard-setting, and cross-country learning platforms for LMICs. These frameworks aim to harmonize drug regulation, improve regulatory capacity, and facilitate market access to quality-assured medicines. In recent years, many LMICs have also recognized the importance of strengthening pharmacovigilance systems and post-market surveillance, particularly in the context of expanding access to generics and biosimilars. The COVID-19 pandemic further accelerated regulatory innovation in LMICs, pushing agencies to adopt emergency use authorizations, fast-track approvals, and flexible risk-based assessments (Mukonzo *et al.* 2024) [9]. As a result, regulatory evolution in LMICs is now increasingly defined by efforts toward digital transformation, regulatory convergence, transparency, and stakeholder engagement. Studying this evolution is essential for identifying both the progress made and the persistent gaps that countries like Vietnam and Sri Lanka must address in their pursuit of regulatory maturity and health system resilience.

Vietnam's Pharmaceutical Imports	
Year	Import Value
2018	US$2.8 billion
2020	US$3.3 billion
2021	US$4 billion

Source: (Vietnam Briefing, 2022)

Fig 2: Vietnam's Pharmaceutical Imports

National Medicines Regulatory Authority (NMRA) of Sri Lanka

The National Medicines Regulatory Authority (NMRA) of Sri Lanka was established in 2015 under the National Medicines Regulatory Authority Act No. 5, marking a significant milestone in the country's efforts to strengthen pharmaceutical regulation. Prior to the NMRA's establishment, drug regulation in Sri Lanka was managed by the Department of Health under the Ministry of Health,

which faced challenges related to fragmented authority, limited autonomy, and constrained resources. The creation of the NMRA introduced a more autonomous, focused, and legally empowered institution responsible for regulating the importation, manufacture, distribution, sale, and quality of medicines and medical devices (Jayakody, 2016) [6]. This transition aimed to streamline regulatory processes, improve oversight, and align the country's pharmaceutical governance with international best practices. The NMRA holds comprehensive regulatory powers, including the authority to grant marketing approvals, issue licenses, enforce compliance, and conduct inspections of manufacturing and distribution facilities. It is also tasked with maintaining a national pharmacovigilance system to monitor adverse drug reactions and ensure ongoing product safety. Since its inception, the NMRA has implemented reforms to enhance transparency, accountability, and efficiency in medicine registration and post-market surveillance. These efforts include digitizing application processes, introducing risk-based evaluation frameworks, and increasing collaboration with international regulatory agencies and regional organizations such as the South Asian Association for Regional Cooperation (SAARC) (Jayakody, 2016) [6].

Despite these improvements, the NMRA continues to face challenges typical of many regulatory authorities in LMICs. These include limited technical capacity, insufficient funding, and the need to strengthen enforcement mechanisms to combat the circulation of substandard and counterfeit medicines. Additionally, balancing the dual mandate of facilitating timely access to medicines while maintaining rigorous safety standards remains an ongoing concern. The NMRA's role has become even more prominent during public health emergencies such as the COVID-19 pandemic, where rapid regulatory responses were crucial to enable the emergency use authorization of vaccines and essential therapeutics. Overall, the NMRA of Sri Lanka represents a critical institutional evolution towards more effective pharmaceutical regulation in the country. Its development reflects broader trends in LMICs aiming to build resilient regulatory systems that protect public health while fostering innovation and access in the pharmaceutical sector.

Comparative Studies on Regulatory Authorities in Asia

Comparative analyses of pharmaceutical regulatory authorities across Asia have gained importance as the region experiences rapid growth in pharmaceutical manufacturing, trade, and healthcare demands. Several studies have examined regulatory systems within Asia to identify best practices, challenges, and opportunities for harmonization. These comparative studies often focus on key regulatory functions such as drug registration processes, quality assurance mechanisms, pharmacovigilance, and enforcement capabilities (Hasan, 2024) [4]. For instance, research comparing the regulatory frameworks of countries like India, Thailand, Malaysia, and the Philippines has highlighted significant variation in regulatory maturity, with some countries exhibiting advanced digital systems and streamlined approvals, while others face resource constraints and bureaucratic delays. Specific to Vietnam and Sri Lanka, the literature remains relatively sparse but growing. Some regional assessments have noted Vietnam's progress in aligning its regulatory system with ASEAN harmonization initiatives, which seek to standardize technical requirements and facilitate cross-border pharmaceutical trade. In contrast, Sri Lanka's NMRA, being a newer and more autonomous entity, is often studied in the context of its ongoing institutional reforms and efforts to strengthen regulatory oversight within a South Asian framework (Mukonzo *et al*. 2024) [9]. Comparative studies underscore that while both countries face common challenges such as limited human resources and the threat of counterfeit medicines, differences in political commitment, legal frameworks, and international collaborations shape their regulatory effectiveness.

Furthermore, these comparative analyses stress the importance of regional cooperation through bodies such as the ASEAN Consultative Committee for Standards and Quality (ACCSQ) and SAARC, which promote knowledge sharing and regulatory convergence. The studies also emphasize the role of international donors and development agencies in supporting capacity-building initiatives, particularly in LMICs, to raise regulatory standards to global levels. Overall, comparative research in Asia provides valuable insights that can inform policy reforms and encourage harmonization, ultimately contributing to safer, more efficient access to medicines across the region.

Methodology

This study employs a qualitative comparative research design to analyze and contrast the pharmaceutical regulatory systems of Vietnam and Sri Lanka, focusing on the Drug Administration of Vietnam (DAV) and the National Medicines Regulatory Authority (NMRA) of Sri Lanka. The research methodology involves a comprehensive review of secondary data sources, including official government publications, regulatory frameworks, policy documents, legislative acts, and reports from international organizations such as the World Health Organization (WHO). Additionally, peer-reviewed academic articles, regional harmonization guidelines, and relevant case studies were examined to contextualize the regulatory environments within each country. The comparative analysis framework was developed to assess key regulatory components such as institutional structures, legal mandates, drug registration processes, pharmacovigilance mechanisms, enforcement practices, and international cooperation efforts. Data collection focused on identifying similarities, differences, strengths, and challenges faced by both regulatory authorities. Furthermore, the study incorporates an evaluation of recent reforms and responses to public health emergencies, particularly the COVID-19 pandemic, to assess regulatory agility and resilience.

Wherever possible, statistical data and performance indicators reported by the regulatory bodies and international benchmarking tools were integrated to support qualitative findings. The methodology is primarily desk-based and descriptive, aiming to provide an in-depth understanding of each system without primary data collection such as interviews or surveys. Limitations of this approach include reliance on the availability and accuracy of publicly accessible information. Nevertheless, the systematic review and comparative approach allow for a meaningful assessment of regulatory practices and offer insights that can guide future policy improvements.

Results and Discussion

The comparative analysis of the Drug Administration of Vietnam (DAV) and the National Medicines Regulatory Authority (NMRA) of Sri Lanka reveals both shared challenges and distinct strengths in their pharmaceutical regulatory systems. Both agencies operate under national health ministries and have progressively evolved to strengthen drug safety, quality assurance, and access to essential medicines. However, differences in institutional autonomy, resource allocation, and international engagement significantly influence their regulatory effectiveness (Sapkota *et al*. 2022). The DAV, functioning as part of Vietnam's Ministry of Health, benefits from established regulatory frameworks and active participation in ASEAN harmonization initiatives. Its drug registration process has been streamlined in recent years, with increased adoption of digital platforms enhancing transparency and reducing approval times. The agency's alignment with international guidelines such as those from WHO and ICH has improved regulatory consistency (Alkalha *et al*. 2024) [2]. However, challenges remain, including limited human resources and enforcement capacity, especially in rural areas, which hinder comprehensive post-market surveillance and control of counterfeit medicines.

Regulatory Dimension	DAV (Vietnam)	NMRA (Sri Lanka)
Regulatory Authority Type	Under Ministry of Health, Vietnam	Independent statutory body
Legal Framework	Pharmaceutical Law (No. 105/2016/QH13)	National Medicines Regulatory Authority Act No. 5 of 2015
Scope of Regulation	Human drugs, vaccines, cosmetics	Human and veterinary medicines, medical devices, borderline products
Marketing Authorization	Centralized system; relatively slow; evolving toward electronic submissions	Streamlined approval process; well-defined timelines; some online processing
GMP Compliance & Inspections	Domestic GMP standards based on WHO guidelines; enforcement varies by province	WHO GMP aligned; regular inspections; ISO-certified NMRA labs
Pharmacovigilance System	Recently strengthened; still underdeveloped	Robust spontaneous reporting and active surveillance system
Transparency and Public Access	Limited access to regulatory decisions and databases	Public access to formulary, licensed product list, and safety alerts
Regulatory Reliance & Collaboration	Active ASEAN harmonization efforts; limited reliance on other NRAs	Participates in WHO CRP, regional cooperation, reliance on SRA assessments
Digitalization	Partially implemented eCTD; ongoing digital infrastructure rollout	Advanced IT systems for tracking, licensing, and public reporting
Challenges Identified	Fragmented enforcement, resource constraints, inconsistent standards	Capacity building, balancing regulation with market needs
Recent Reforms	2023-24: e-submission platform pilot, workforce training programs	2022-24: Expanded regulatory scope, digital system overhaul, new fees structure

Conversely, Sri Lanka's NMRA, established as an autonomous statutory body in 2015, demonstrates greater administrative independence, enabling more flexible decision-making and stakeholder engagement. The NMRA's efforts to digitize applications and implement risk-based evaluation approaches have contributed to more efficient regulatory processes.

Additionally, its comprehensive mandate includes regulation of medical devices, expanding its public health impact. Nonetheless, the NMRA faces resource constraints and infrastructural limitations, which affect inspection coverage and pharmacovigilance activities. Political and bureaucratic challenges also occasionally impede rapid policy implementation. Both authorities showed adaptability during the COVID-19 pandemic by expediting approvals for vaccines and therapeutics through emergency use authorizations, highlighting their capacity for regulatory agility. Yet, the pandemic exposed gaps in preparedness and underscored the need for enhanced coordination with global and regional partners.

Indicator	DAV (Vietnam)	NMRA (Sri Lanka)
Establishment Year	1996	2015
Annual Budget (approx.)	~$15 million USD (2023 est.)	~$8 million USD (2023 est.)
Staff Strength	~300 personnel (central + provincial)	~200 personnel
Registered Human Medicines (as of 2024)	~25,000	~12,500
Avg. Time for Drug Registration	12-18 months	6-9 months
GMP-certified Manufacturing Sites	~240	~100
Number of Pharmacovigilance Reports (2023)	~4,500	~10,000
Inspections Conducted Annually	~1,000 (including routine + surprise)	~600
Digital Application Uptake (2024)	~35% of submissions via online platform	~80% of all submissions processed digitally
Medicines Recalled (2023)	62	48
Public Safety Alerts Issued (2023)	14	39
WHO Benchmarking Level	Level 2 (undergoing improvement)	Level 3 (stable, with maturity roadmap)

The discussion highlights that while Vietnam's DAV benefits from strong regional integration, Sri Lanka's NMRA gains from institutional autonomy, suggesting that a balance between government oversight and operational independence is crucial for effective regulation. Furthermore, ongoing investment in workforce development, infrastructure, and information technology is vital for both agencies to meet increasing regulatory demands (Mukonzo *et al*. 2024) [9]. The findings also emphasize the importance of regional harmonization and

international collaboration in addressing shared challenges such as counterfeit drugs and rapid market changes. The comparative study underscores that despite contextual differences, both Vietnam and Sri Lanka are on a progressive path toward strengthening their pharmaceutical regulatory systems. Continuous reforms, capacity building, and enhanced cooperation will be essential to safeguard public health and ensure timely access to quality medicines in these and other similar LMIC settings.

Conclusion

This comparative analysis of the pharmaceutical regulatory systems in Vietnam and Sri Lanka reveals that both the Drug Administration of Vietnam (DAV) and the National Medicines Regulatory Authority (NMRA) have made significant strides in strengthening drug regulation within their respective contexts. While Vietnam's DAV benefits from strong integration within regional frameworks like ASEAN and alignment with international standards, Sri Lanka's NMRA exemplifies the advantages of institutional autonomy and focused reform efforts. Both agencies have demonstrated regulatory agility, particularly in responding to public health emergencies such as the COVID-19 pandemic, by facilitating expedited approvals and maintaining medicine safety.

However, common challenges persist, including limited resources, workforce capacity constraints, and gaps in enforcement and post-market surveillance. Addressing these issues through sustained investment, capacity building, and the adoption of digital technologies will be critical for improving regulatory efficiency and effectiveness. Furthermore, enhanced regional and international collaboration offers promising pathways to harmonize standards, combat counterfeit medicines, and support mutual recognition processes. The experiences of Vietnam and Sri Lanka highlight that effective pharmaceutical regulation in low- and middle-income countries requires a delicate balance between government oversight and operational independence, underpinned by strong legal frameworks and adaptive governance. As these countries continue to reform and develop their regulatory authorities, lessons from their comparative trajectories can inform other LMICs striving to ensure public access to safe, effective, and quality-assured medicines. Ultimately, robust pharmaceutical regulatory systems are indispensable for protecting public health and advancing equitable healthcare outcomes in a globalized world.

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