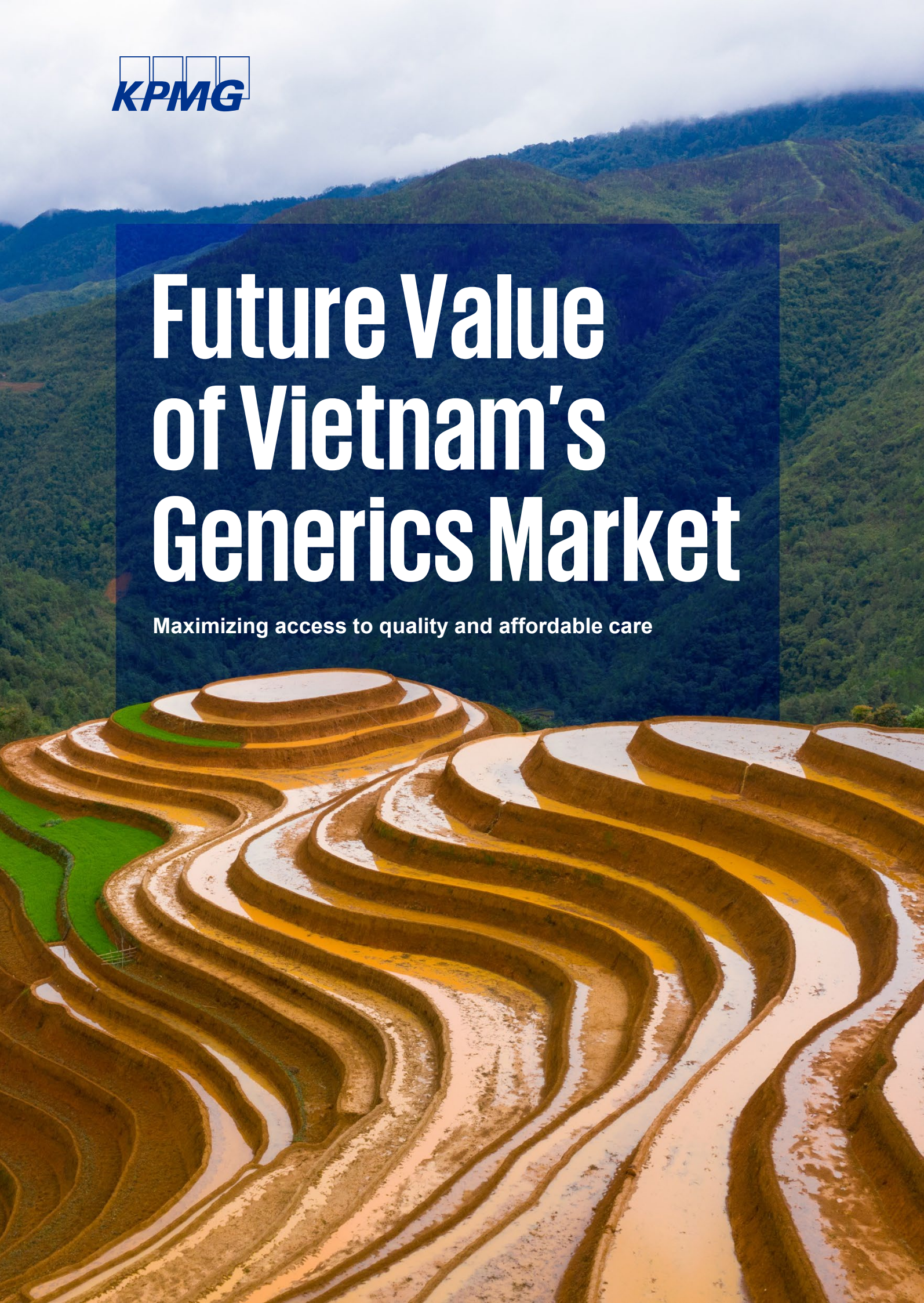
KPMG

Future Value of Vietnam's Generics Market

Maximizing access to quality and affordable care



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Glossary

AMA	American Medical Association
API	Active pharmaceutical ingredient
ARTG	Australian Register of Therapeutic Goods
BE studies	Bioequivalence studies
CAD	Canadian Dollar
CADTH	Canadian Agency for Drugs and Technologies in Health
CAGR	Compound Annual Growth Rate
CBE	The Centre for Biopharmaceutical Excellence
CIT	Corporate Income Tax
CMO	Contract manufacturing organizations
CMSS	Central Medical Services Society
COPD	Chronic Obstructive Pulmonary Disease
COR	Comparable Overseas Regulator
CPD	Continuing Professional Development
DAV	Drug Administration of Vietnam
DERP	Drug Effectiveness Review Project
EBRD	The European Bank for Reconstruction and Development
EC	EU Commission
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
ERAs	Environmental Risk Assessments
ESG	Environmental, Social, and Governance
EU	European Union
EU-GMP	European Union Good Manufacturing Practice
EuroCham	European Chamber of Commerce
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
GDP	Gross Domestic Product
GMAP	Generic Medicines Awareness Programme
GMBA	Generic Medicines and Biosimilars Association
GMiA	Generic Medicines Industry Association
GMP	Good Manufacturing Practice
GMWG	Generic Medicines Working Group
HSA	Health Services Authority
HTA	Health technology assessment
IGH	Infrastructure, Government and Healthcare
IQGx	International Quality Generics Group
MAPS	Malaysian Association of Pharmaceutical Suppliers
MCDA	Multiple Criteria Decision Analysis
MOH	Ministry of Health
MOPI	Malaysian Organization of Pharmaceutical Industries
MPS	Malaysian Pharmaceutical Society
MRA	Mutual recognition agreement
NCA	National Competent Authority
NCDs	Non-Communicate Diseases
NGO	Nongovernmental Organizations
NHS	National Health Service
NPRA	National Pharmaceutical Regulatory Agency
NPS	National Prescribing Service
OECD	Organization for Economic Co-operation and Development
OTC	Over the Counter
P/TD	Price per Treatment Day
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PMDA	Pharmaceuticals and Medical Devices Agency
PPP	Public-Private Partnerships
R&D	Research and Development
RPS	Reference Pricing System
SEZ	Special economic zone
SMEs	Small and medium-sized enterprises
TGA	Therapeutic Goods Administration
UNDP	United Nations Development Programme
WHO	World Health Organization
WIPO	World Intellectual Property Organization

Foreword

Vietnam stands at a pivotal moment in the evolution of its healthcare sector. As the country undergoes rapid economic transformation, ensuring access to high-quality, affordable medicines remains a critical priority. The generic pharmaceutical industry has a vital role to play in meeting this need by offering cost-effective alternatives that maintain the highest standards of safety and efficacy.

The European Chamber of Commerce in Vietnam is committed to supporting the government in strengthening its pharmaceutical landscape. Through this report, we aim to highlight the immense potential of Vietnam's generic drugs market and provide a roadmap for reform that will benefit both the public health system and the broader economy. By learning from global best practices and addressing existing barriers, Vietnam can accelerate its journey toward becoming a regional hub for pharmaceutical innovation and production.

This report presents a detailed analysis of the current state of Vietnam's generics market, identifying key regulatory and investment challenges while showcasing lessons from peer markets. The findings reinforce the fact that strategic policy changes such as regulatory streamlining, investment incentives, and greater public awareness can unlock substantial economic and social benefits.

We encourage policymakers, industry stakeholders, and healthcare professionals to collaborate in fostering an environment that promotes the growth of the generics sector. With the right reforms, Vietnam can improve access to essential medicines, enhance its pharmaceutical manufacturing capabilities, and attract greater investment, all while ensuring long-term sustainability in its healthcare system.

We extend our gratitude to all contributors and experts who have provided valuable insights for this report. It is our hope that these findings and recommendations will serve as a catalyst for meaningful change, positioning Vietnam as a leader in the regional pharmaceutical industry.

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Head of Infrastructure,
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KPMG in Vietnam and Cambodia

Executive Summary

Vietnam's pharmaceutical sector stands at a critical turning point. Rising healthcare costs and an aging population are driving demand for affordable medicines, making generic drugs a proven solution to improve access, reduce costs, and support economic growth. Regulatory inefficiencies, limited investment incentives, and low stakeholder awareness have slowed the development of Vietnam's generics market. Overcoming these challenges will unlock significant opportunities to strengthen the industry and create a more sustainable healthcare system.

This report, prepared for the European Chamber of Commerce in Vietnam, outlines the key barriers preventing market expansion and provides a roadmap for policy reforms that can unlock the sector's full potential. Vietnam stands to benefit from significant economic and social gains, including improved healthcare access, increased investment, and stronger integration into global pharmaceutical supply chains, if it takes decisive action.

01

Key highlights of our analysis

Rising Healthcare Costs & Economic Strain

- Vietnam's healthcare spending is projected to increase from USD 24.7 billion in 2024 to USD 57.1 billion by 2029.
- Healthcare expenditure is increasingly shifting toward the private care sector, surpassing the growth of public spending.
- Healthcare expenditure per capita is growing at a rate that exceeds disposable income growth, making affordability a major concern.

The Generics Market Opportunity

- Generic drugs currently dominate 58.8% of Vietnam's pharmaceutical market but remain underutilized compared to regional peers.
- EU-quality generics have the potential to reduce treatment costs by up to 40% while maintaining high safety and efficacy standards.
- Expanding generic drug adoption can ease the financial burden on the healthcare system and improve patient access to essential medicines.

Regulatory & Investment Barriers

- Drug registration in Vietnam can take up to 24 - 36 months, significantly longer than in peer markets like Singapore (6-9 months).
- Limited investment incentives discourage pharmaceutical manufacturers from entering the market, despite Vietnam's strategic advantages.
- Compliance with EU-GMP (European Union Good Manufacturing Practice) standards is costly and complex, making it difficult for local manufacturers to compete globally.

02

Lessons from Peer Markets

Australia, Singapore, New Zealand, Malaysia, and Poland have successfully expanded their generics markets through:

- Streamlined regulatory approvals that reduce delays and improve market access.
- Public-private partnerships to enhance domestic production capacity.
- Educational campaigns to increase awareness and trust in generics among doctors and patients.

03

Projected Economic & Social Benefits

- Market Growth: Vietnam's generics market could expand to USD 29-55 billion by 2039 with targeted reforms.
- GDP Contribution: The sector could add USD 20.1 billion to GDP under a high-growth scenario.
- Job Creation: Up to 945,000 jobs could be generated annually by 2039.
- Export Potential: Vietnam could emerge as a regional hub for pharmaceutical production, reducing dependence on imports. By 2029, total export turnover is projected to reach USD 454.42 million, with a remarkable 28% CAGR.

04

Policy Recommendations

To unlock the full potential of Vietnam's generics market, policymakers should prioritize:

Regulatory Efficiency & Fast-Track Approvals

- Implement reliance pathways for EU-approved generics to shorten approval times.
- Expand the use of Electronic Common Technical Document (eCTD) to standardize and digitalize approvals.

Investment Incentives

- Provide tax benefits, grants, and low-interest loans for generic drug manufacturers.
- Encourage public-private partnerships to support domestic production.

Awareness & Trust Building

- Launch education campaigns targeting healthcare professionals and consumers to dispel misconceptions about generics.
- Strengthen quality control and transparency measures to enhance trust in domestic production.

EU-GMP Compliance Support

- Introduce financial assistance programs for manufacturers upgrading to EU-GMP standards.
- Foster technology transfer partnerships between Vietnamese and European pharmaceutical firms.

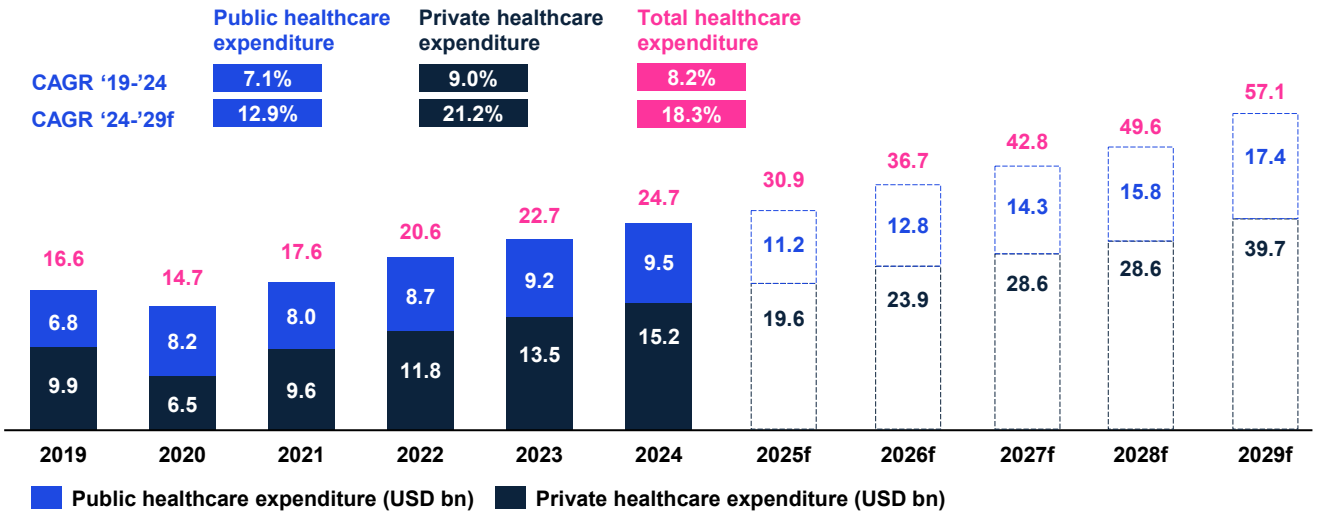
1. Current state of Vietnam's healthcare system

1.1 Overview

1.1.1 Macroeconomics factors

Rising Healthcare Expenditure: A Shift Towards Private Care

Figure 1.1: Public and private healthcare expenditure in Vietnam from 2019 to 2029f (USD billion)



Source: BMI Fitch Solutions

Vietnam's healthcare spending has been on a steady rise since its dip in 2020 and is set to grow substantially over the next five years. Total expenditure is projected to jump from USD 24.7 billion in 2024 to USD 57.1 billion by 2029, reflecting a high compound annual growth rate (CAGR) of 18.3%, more than double the 8.2% CAGR seen from 2019 to 2024.

Key drivers of this surge include:

- **Rising incomes** and a growing middle class willing to invest in better healthcare.
- **Increased public awareness** of healthcare options and preventive care.
- **Higher domestic demand** for pharmaceuticals and medical services.

Private Healthcare Growth Outpacing Public Spending

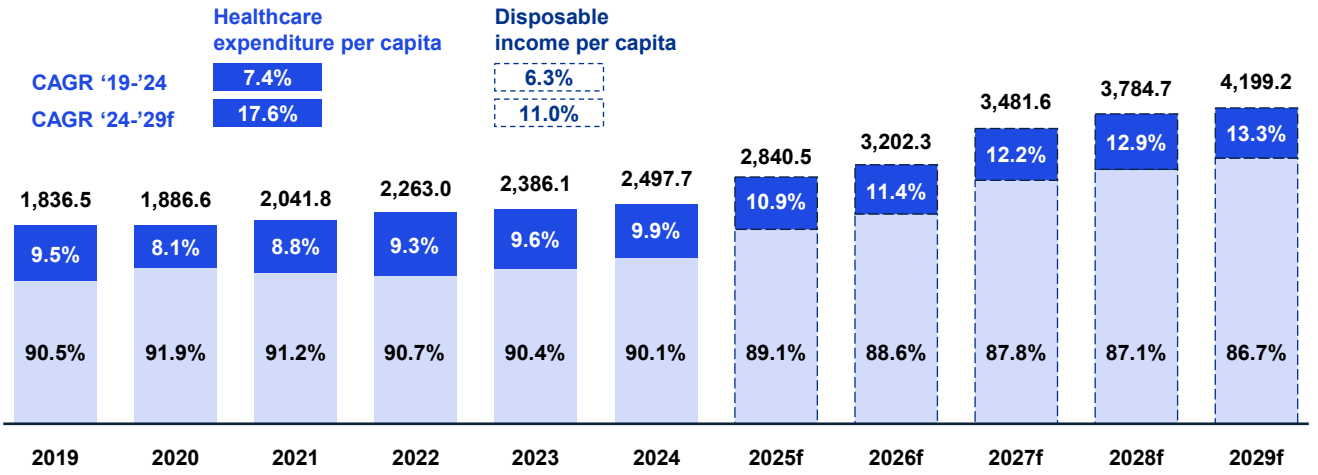
A major trend shaping Vietnam's healthcare landscape is the rapid expansion of private healthcare spending:

- Over the past five years, public healthcare grew at 7.1% CAGR, while private healthcare increased at 9.0% CAGR.
- From 2024 to 2029, the gap will widen significantly, with public spending expected to grow at 12.9% CAGR, while private healthcare surges at 21.2% CAGR.

This shift toward private healthcare services signals growing consumer expectations for higher-quality care, but also raises concerns about affordability and access, particularly for lower-income groups. Without strategic interventions, Vietnam risks creating a two-tiered healthcare system, where only those with higher incomes can afford premium medical services.

Rising Healthcare Costs outpacing Income growth, Increasing Financial Strain

Figure 1.2: Disposable income and Healthcare expenditure per capita in Vietnam from 2019 to 2029f (USD)



Source: BMI Fitch Solutions

Between 2024 and 2029, healthcare expenditure per capita is projected to grow at a CAGR of 17.6%, significantly outpacing the 11.0% CAGR for disposable income per capita. This widening gap is expected to place a growing financial strain on individuals, making essential healthcare services increasingly difficult to afford.

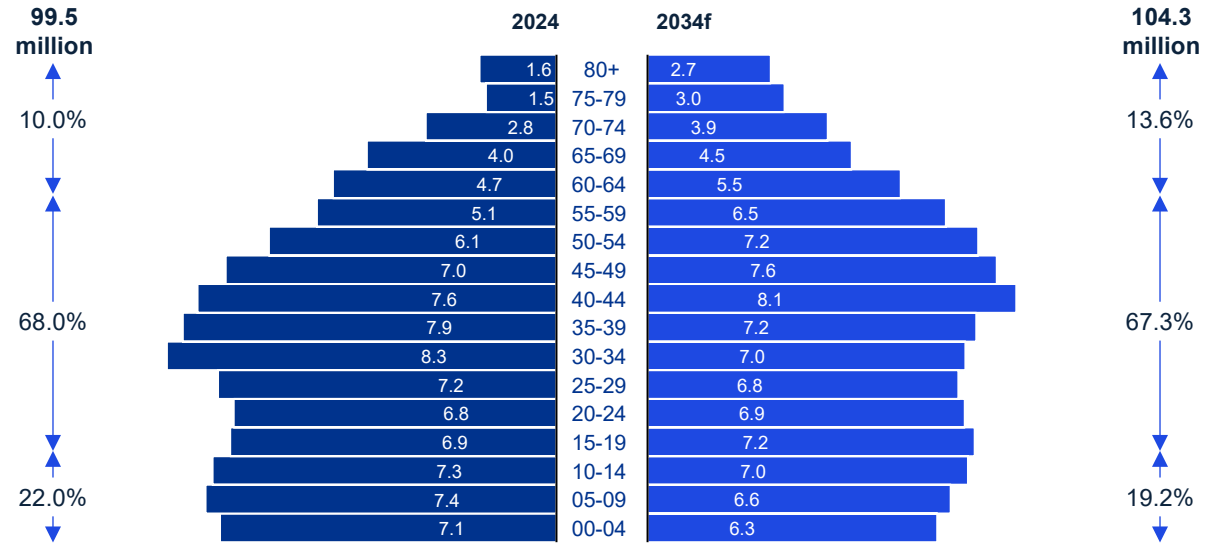
The proportion of healthcare spending to disposable income has been steadily rising:

- 2020: **8.1%**
- 2024: **9.9%**
- 2029f: **13.3%**

This surge is driven by higher demand for healthcare services and rising treatment costs. As consumers allocate a larger share of their income to medical expenses, high-quality generic medicines present a viable, cost-effective solution to maintain accessibility and affordability in Vietnam's healthcare system.

Vietnam's Demographic Shift: From a Young Workforce to an Aging Society

Figure 1.3: Population in Vietnam from 2024 to 2034f (million people)



Source: GSO; BMI Fitch Solutions

Figure 1.4: Regional population benchmarking from 2024 to 2029f

	Median age			Life expectancy at birth			Live births per 1,000 of population		
	2024	2029f	Δ	2024	2029f	Δ	2024	2029f	Δ
Singapore	43.3	45.3	+2.0	84.4	85.0	+0.6	7.1	6.9	-0.2
Thailand	40.7	42.5	+1.8	80.1	85.0	+4.9	8.6	8.3	-0.3
Vietnam	39.5	41.6	+2.1	74.9	75.7	+0.8	14.0	12.9	-1.1
Malaysia	31.2	32.9	+1.7	76.6	77.4	+0.8	14.6	13.5	-1.1
Indonesia	30.1	31.2	+1.1	71.2	71.9	+0.7	15.8	15.0	-0.8
Philippines	25.2	26.3	+1.1	72.4	72.9	+0.5	21.1	19.8	-1.3
China	39.5	41.6	+2.1	79.0	80.0	+1.0	7.4	7.1	-0.3

Source: GSO; BMI Fitch Solutions

As of 2024, Vietnam's population has reached 99.5 million, making it the 16th most populous country in the world. For years, the country benefited from a "golden population structure", where a large working-age demographic fueled economic growth. This advantage is now fading, with the working-age population share declining to 68.0% in 2024.

The Rise of an Aging Population

Vietnam is undergoing a rapid demographic shift, with aging trends expected to accelerate over the next decade:

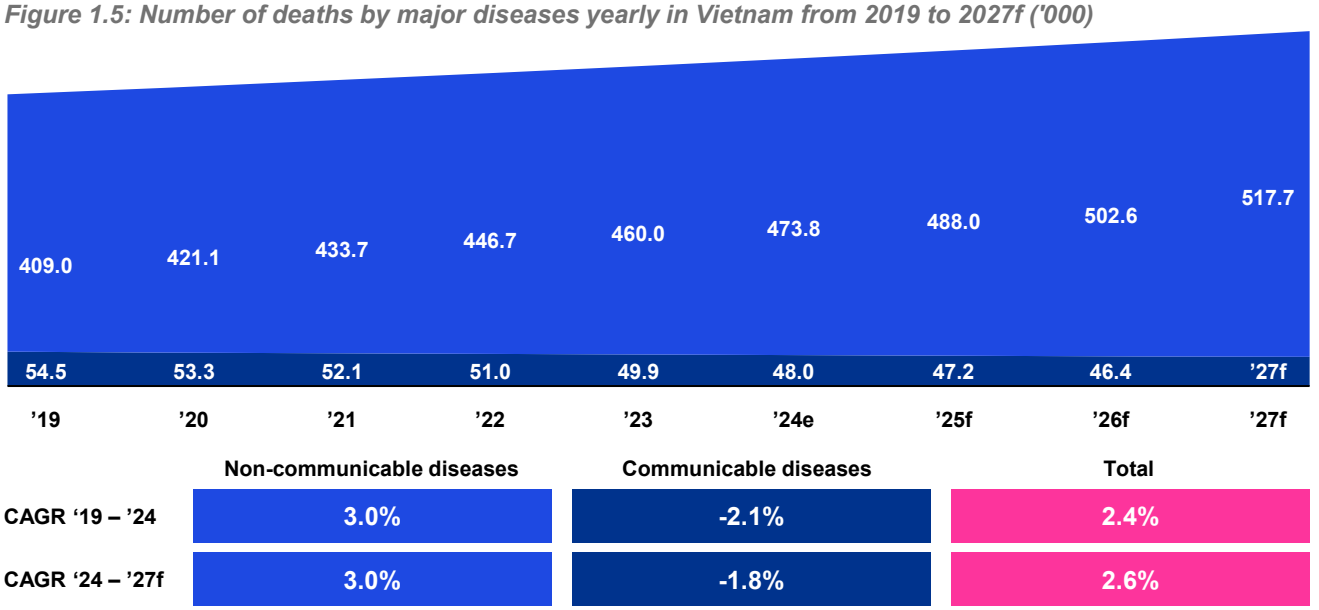
- By 2034, the proportion of elderly citizens is projected to increase by 3.6%, reshaping the country's demographic structure.
- Life expectancy is forecasted to rise by 0.8 years, while birth rates are expected to decline by 1.1%.
- Over the next decade, the median age will rise by 2.1 years, outpacing demographic shifts in many regional peers.

Healthcare Demand and the Role of Generic Medicines

As Vietnam's population ages, the demand for healthcare services and medications will surge. Managing these rising costs will be essential to maintaining healthcare accessibility. Generic drugs present a cost-effective alternative, ensuring affordability while meeting the growing needs of an elderly population. Strengthening Vietnam's generics market will be critical to sustaining a resilient and inclusive healthcare system in the years ahead.

Rising Mortality Rates and the Burden of Non-Communicable Diseases

Figure 1.5: Number of deaths by major diseases yearly in Vietnam from 2019 to 2027f ('000)



Source: BMI Fitch Solutions

Mortality rates in Vietnam continue to climb, driven by an aging population and the rise of chronic diseases. Between 2019 and 2024, the number of deaths grew at a CAGR of 2.4%, with projections indicating a slight increase to 2.6% CAGR between 2024 and 2027.

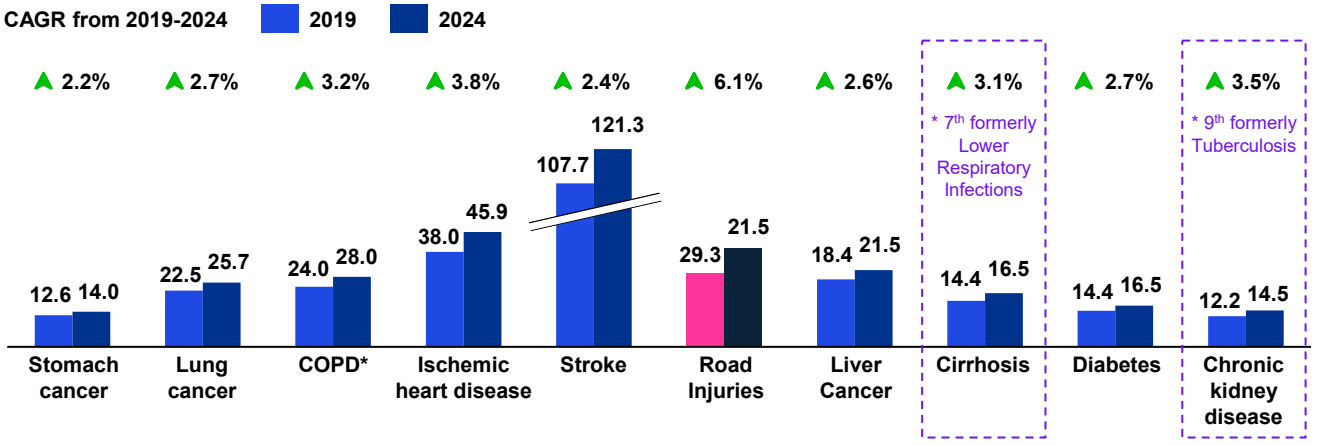
Shifting Causes of Mortality

- **Declining Communicable Disease Deaths:** Advances in healthcare and disease prevention have reduced mortality from infectious diseases.
- **Rising Non-Communicable Diseases (NCDs):** Deaths from heart disease, diabetes, cancer, and respiratory conditions have been consistently increasing.

The Impact on Vietnam's Healthcare System

This trend is largely driven by unhealthy diets, sedentary lifestyles, and rising stress levels, leading to a growing burden of chronic illnesses that require long-term, costly treatments. As healthcare demand surges, affordable and effective solutions including greater access to generic medicines, will be essential in ensuring sustainable and equitable healthcare for all.

Figure 1.6: Top causes of death in Vietnam from 2019 to 2024 ('000)



Source: GSO; BMI Fitch Solutions

Note: COPD-Chronic Obstructive Pulmonary Disease, Road Injuries*-marked with a different color because deaths from road injuries are not classified as NCDs*

Chronic Diseases Dominate Mortality Trends

Over the past five years, nine of the top ten causes of death in Vietnam have been non-communicable diseases (NCDs), all growing at a CAGR above 2.2%. Among them, ischemic heart disease, chronic kidney disease, and COPD experienced the sharpest increases, with CAGRs of 3.2% to 3.8% between 2019 and 2024.

The Growing Healthcare Burden

This rise in chronic illnesses is primarily driven by lifestyle factors and an aging population, placing increasing strain on Vietnam's healthcare system. Without effective intervention, the economic and social costs of managing these conditions will continue to escalate.

The Role of Generic Medicines in Addressing NCDs

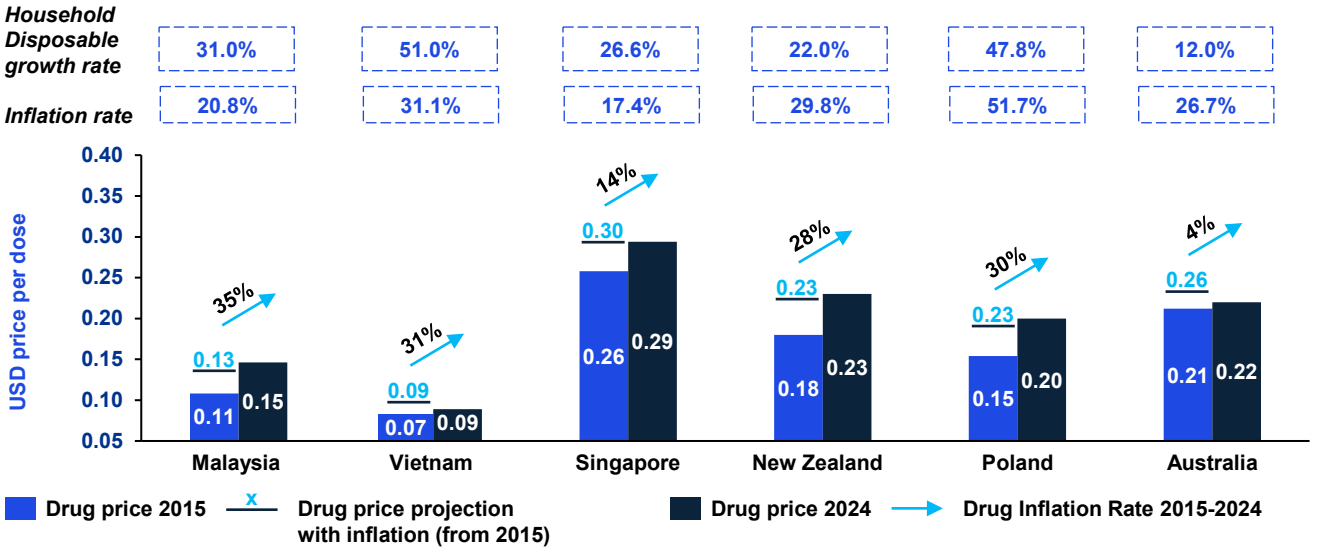
High-quality generic drugs present a cost-effective solution to managing chronic diseases:

- Affordable alternatives to patented drugs, ensuring wider accessibility.
- Comparable efficacy, allowing patients to receive the same standard of care at a lower cost.
- Greater treatment adherence, as lower costs reduce financial barriers to medication.

Expanding access to high-quality generics will be essential to improving health outcomes in Vietnam while alleviating the financial burden on both individuals and the healthcare system.

Drug prices in Vietnam have increased more slowly than overall inflation and disposable income, making domestic drugs more affordable over time

Figure 1.7: Affordability of the top 5 best-selling EU-GMP generic drugs in Vietnam compared to other markets from 2015 to 2024



Source: KPMG Research and Analysis, In-country pharmacy references.

Note: Prices are the average of the 5 most popular generic drugs: Amlodipine, Metformin, Amoxicillin, Paracetamol, and Omeprazole

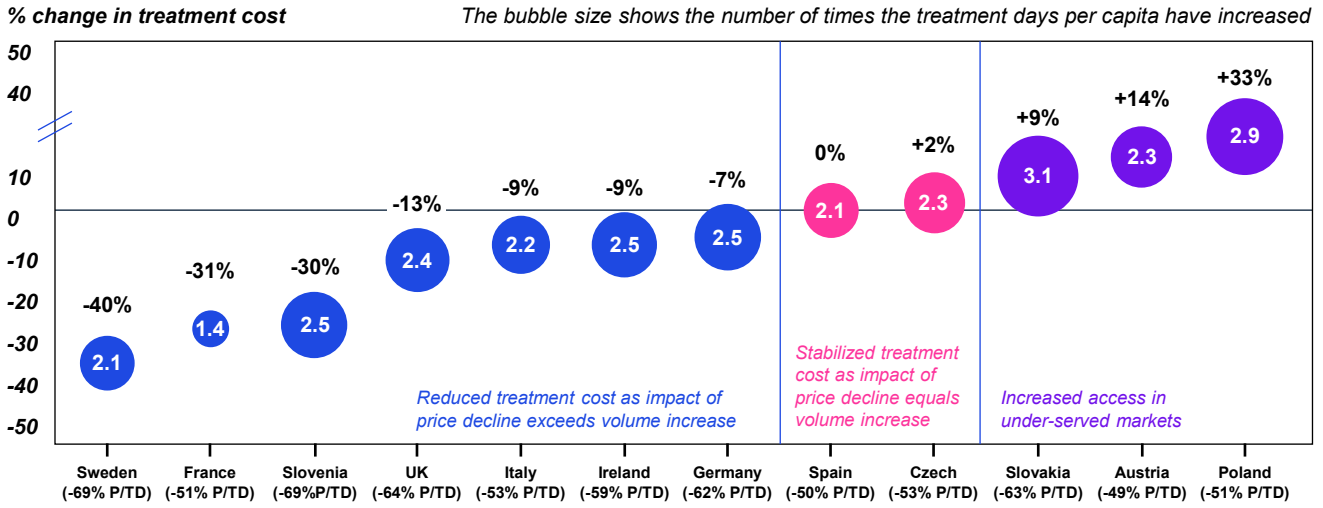
Vietnam's commonly sold generics have become more affordable over time

This increased affordability is evident based on the average prices, in USD, of top five most sold EU-GMP generic drugs in Vietnam: Amlodipine, Metformin, Amoxicillin, Paracetamol, and Omeprazole in 2015 and 2024. During this period, drug prices in Vietnam have increased by 0.02% less than general inflation.

- Vietnam's generic drug prices have remained stable, with 2024 prices lower than inflation-adjusted projections. Over the past decade, minimal price increases reflect strong price control measures.
- Rising disposable incomes have made medications more affordable in real terms, enhancing accessibility for consumers.
- Vietnam's generic drug prices are lower than the ASEAN average, driven by competitive bidding packages that are 1.5-2 times cheaper than in other regional markets.

EU generics offer Vietnam an affordable solution, improving access and reducing costs

Figure 1.8: Impact of Generic Drug Adoption on Price, Volume, and Treatment Costs across 12 European countries



Source: IQVIA

Note: P/TD-price per treatment day

A study by IQVIA found that the adoption of generic drugs led to a 49%-69% reduction in treatment costs per day across 12 European countries, significantly improving healthcare access. As a result:

- Treatment days per capita increased, with France seeing the smallest rise (1.4x) and underserved markets like Poland (2.9x) and Slovakia (3.1x) experiencing the largest gains.
- 7 out of 12 countries reduced treatment costs between 2005 and 2014, with Sweden, France, and Slovenia achieving savings of up to 40%.
- In some markets, increased treatment demand outweighed cost reductions, leading to stable or slightly higher overall spending.

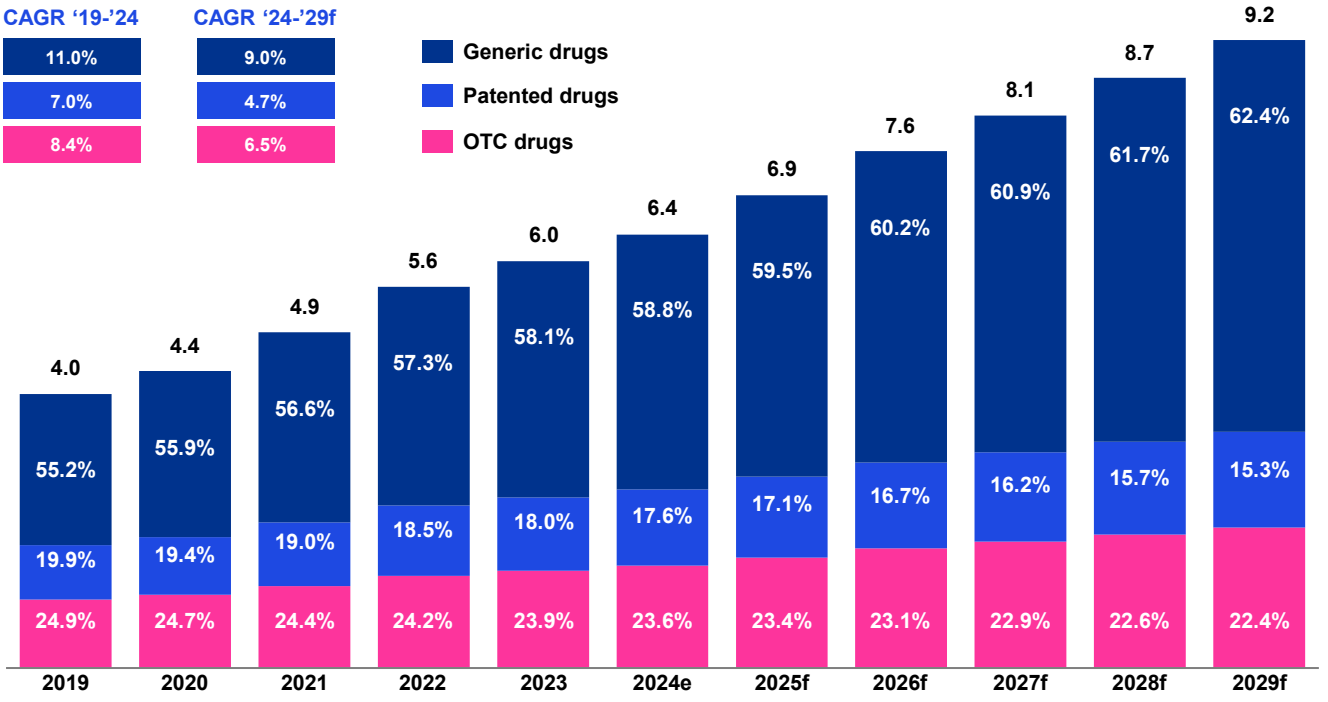
Implications for Vietnam

The European experience shows that high-quality EU generics can play a critical role in lowering healthcare costs while expanding treatment access. If applied in Vietnam, these cost-effective medicines could enhance health outcomes and ease financial pressures on both patients and the healthcare system.

1.1.2 Vietnam's generic drugs industry overview

Vietnam's pharmaceutical market is growing sustainably, dominated by generic drugs, but there is still room for further expansion

Figure 1.9: Market value of pharmaceutical industry in Vietnam from 2019 to 2029f (USD billion)



Source: BMI Fitch Solutions

Vietnam's pharmaceutical market value has surged from USD 4.0 billion in 2019 to a projected USD 9.2 billion by 2029, with generic drugs dominating and expanding their market share.

- Generics share has increased from 55.2% in 2019 to 62.4% by 2029, growing at a CAGR of 11.0% (2019-2024).
- Patented drugs are expanding more slowly, with a 7.0% CAGR in the same period, reaching USD 1.4 billion by 2029.

Vietnam's shift toward generic medicines reflects a strong focus on affordability, positioning them as the fastest-growing segment in the industry and a key driver of future market expansion.

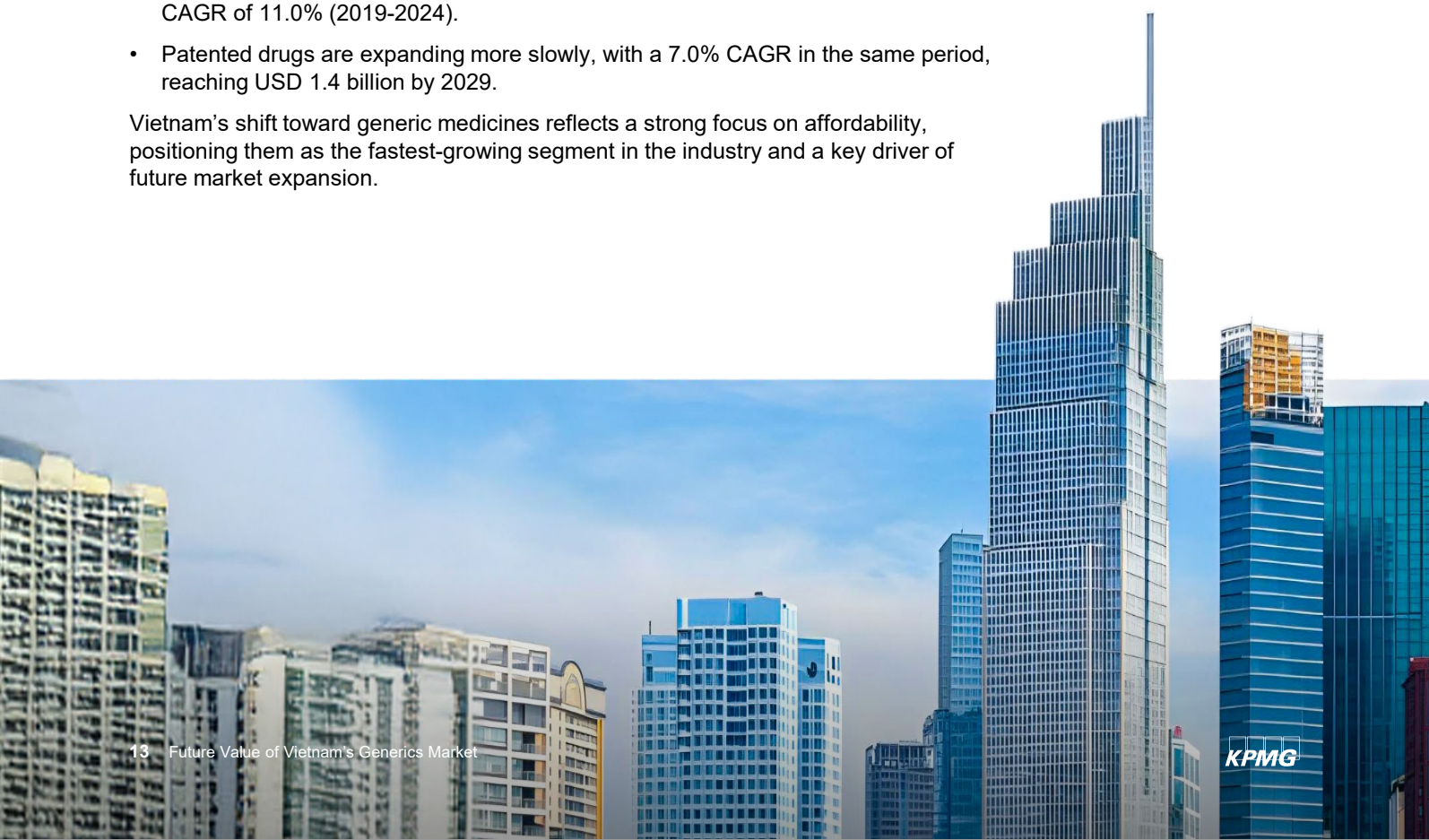
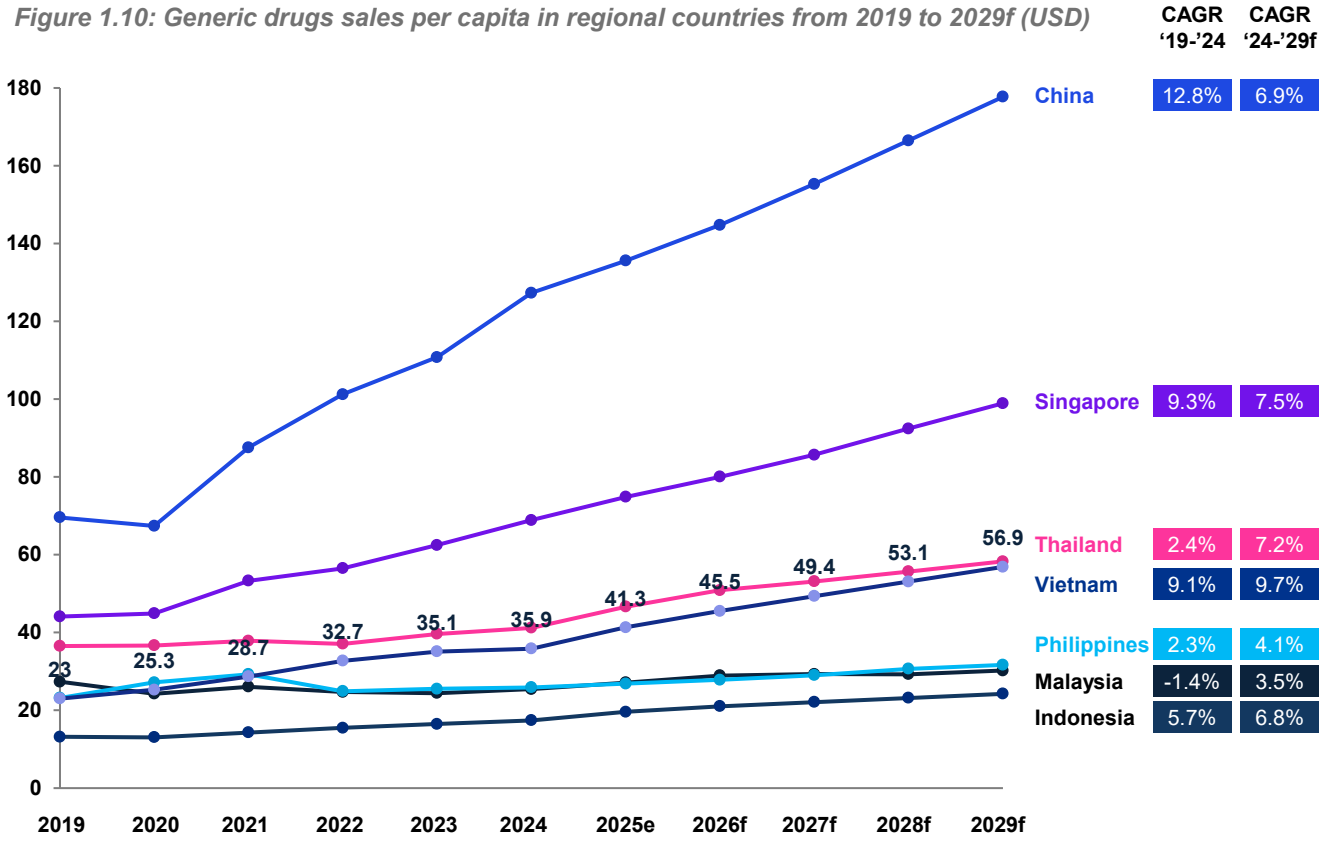


Figure 1.10: Generic drugs sales per capita in regional countries from 2019 to 2029f (USD)

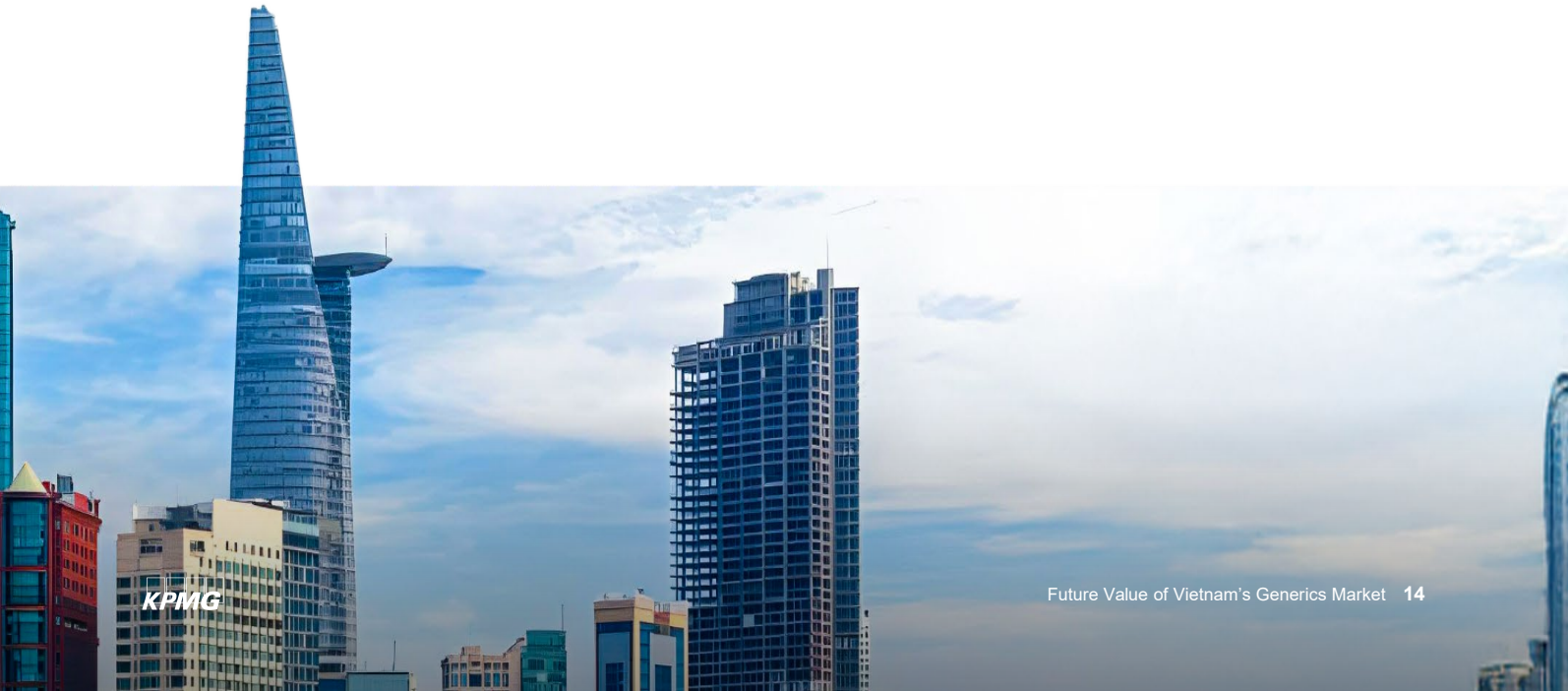


Source: BMI Fitch Solutions

Between 2019 and 2024, Vietnam's generic drug market experienced strong growth, with per capita sales rising at a CAGR of 9.1%, the third highest in the region after China (12.8%) and Singapore (9.3%).

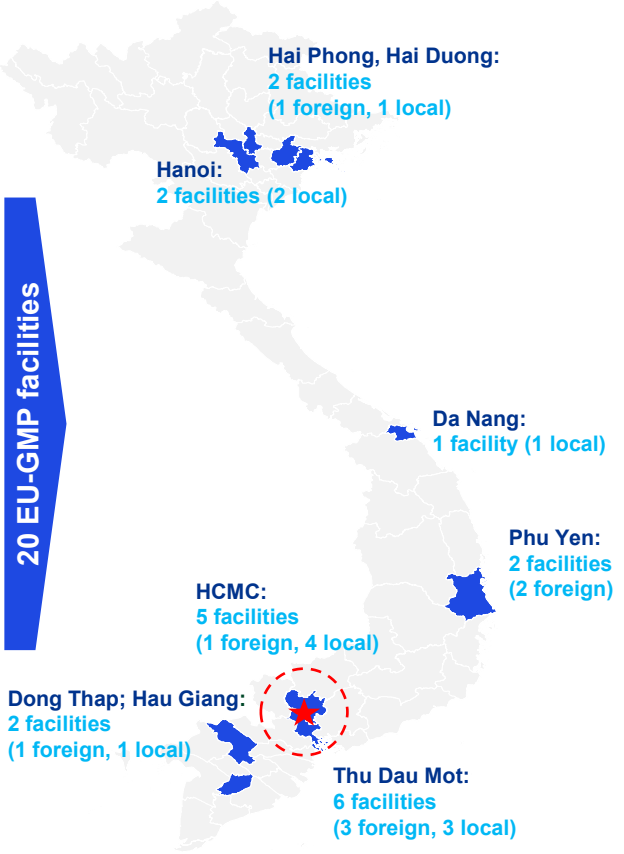
- Growth is expected to accelerate to 9.7% CAGR (2024-2029f), making Vietnam the fastest-growing generic drug market in the region.
- Despite this, per capita spending on generics remains low, at USD 35.9 in 2024, ranking fourth in the region.
- In comparison, China's spending is three times higher, and Singapore's is twice as much.

While still underpenetrated, Vietnam's generic drug sector is set for rapid expansion, offering significant growth potential in the coming years.



To further enhance the quality of generic drugs in Vietnam, greater emphasis should be placed on EU-GMP-certified facilities

Figure 1.11: EU-GMP-certified facilities in Vietnam



★ *Locations with the most concentrated EU-GMP certified facility*

	Foreign	Local
North	1 facilities • Nipro Pharma	3 facilities • HD Pharma • Mediplantex • Armephaco
Central	2 facilities • STADA • Pymepharco	1 facilities • Danapha
South	5 facilities • Sanofi • Imexpharm • Medochemie • Rohto Mentholatu • Phil Inter Pharma	8 facilities • Savipharm • Tenamyd • Nadyphar • Davipharm • DHG Pharma • Imexpharm • Blood Transfusion Haematology Hospital • Hasan-Dermapharm

Source: GMP-Vietnam

As of 2024, Vietnam has 288 pharmaceutical manufacturing facilities, but only 20 have achieved EU-GMP certification. These facilities are strategically concentrated in major industrial and economic hubs, optimizing production and distribution efficiency.

- Binh Duong has the highest number of EU-GMP-certified facilities, while the Northern region lags behind in achieving certification.
- The low penetration rate of EU-GMP-certified facilities highlights an opportunity to enhance medicine quality and attract investment.

Bridging Vietnam's Pharmaceutical Supply Gap: Ensuring Quality, Safety, and Growth

Vietnam's pharmaceutical industry faces a growing supply-demand imbalance, with USD 3.8 billion worth of medicines imported in 2024, while locally produced generic drugs meet only 40% of domestic demand. Addressing this gap requires not just increased production but a focus on quality and safety. Expanding access to EU-GMP-certified generic drugs, whether through domestic manufacturing or faster import pathways, ensures Vietnam meets rising healthcare needs without compromising patient safety.

EU-GMP manufacturing standards are globally recognized for their stringent safety, efficacy, and quality controls. To safeguard public health, Vietnam should prioritize either importing EU-GMP-manufactured generic drugs or producing them domestically at EU-GMP standards. Filling the supply gap with lower-quality alternatives could put patients at risk, undermining trust in generics and creating long-term healthcare challenges. A dual approach, strengthening domestic production while streamlining market access for high-quality European pharmaceuticals, will enable Vietnam to reduce import dependency, ensure drug safety, and position itself as a leading generics manufacturer for Southeast Asia.

With the right policies in place, Vietnam can not only meet domestic demand but also establish itself as a trusted hub for high-quality, export-ready generics, setting a benchmark for safety and affordability in the region.

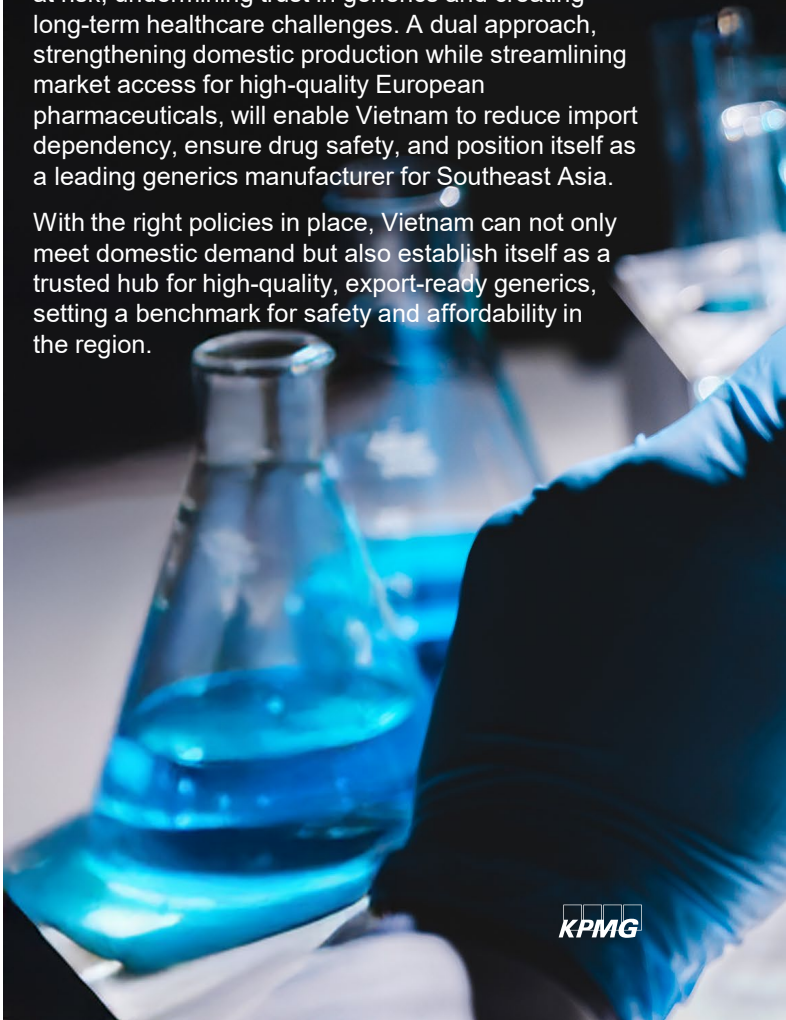


Table 1.1: Policies and Initiatives of Vietnam to support generic drugs

Year	Policy	Description	Impact on the Generic Drug Market
2014	Approving the National Strategy on Development of the Vietnam Pharmaceutical Industry up to 2020, with a vision toward 2030 - Decision No. 68/QĐ-TTg	Aimed to increase domestic production of generics to 40%, requiring bioequivalence and bioavailability evaluations.	Built public trust in locally manufactured medicines, offering cost-effective treatments and optimizing public healthcare spending.
2021	Approving Development Program for Pharmaceutical Industry and Domestically Produced Herbal Ingredient until 2030 and vision to 2045 - Decision No. 376/QĐ-TTg	Focused on attracting foreign investment for patented innovative drugs, high-tech generics, vaccines, and biologics.	Increased international partnerships, enhanced availability of advanced generics, and accelerated market growth.
2023	Approving National Strategy for Vietnam's Pharmaceutical industry Development by 2020 with a vision towards 2045-Decision No. 1165/QD-TTg	Required 30% of generics to be produced domestically or imported with valid bioequivalence registration and set a target for 20% of manufacturing facilities to achieve EU-GMP certification by 2030.	Expanded local manufacturing capacity, strengthened industry competitiveness, and improved access to affordable generics.
2024	Amendment to Certain Articles of the Law on Pharmacy - Decision No. 44/2024/QH15	Implemented investment incentives for R&D, technology transfer, and production of generic drugs.	Created financial and non-financial incentives to boost local production, reducing import dependence while ensuring affordable medication access.

Source: Thuvienphapluat, KPMG Research and Analysis

1.2 Key barriers of generic drugs in Vietnam

The generic drug market in Vietnam holds potential for improving healthcare affordability and access. There are challenges that need to be addressed to fully realize this potential. These challenges include **regulatory**, and **issues related to awareness** & trust among stakeholders. Addressing these barriers through collaborative effort can help Vietnam's pharmaceutical industry grow while ensuring alignment with international standards and public health priorities.

Focus areas

Barriers

Regulatory

Complex registration process: A lengthy, costly approval process and lack of transparency in criteria and pricing data increase costs, delay market entry, and limit competition, driving higher generic drug prices and procurement inefficiencies.

Limited regulatory capacity: Insufficient human resources and lack of inter-department coordination delay clinical data evaluation and approvals.

Limited Incentives for Investors and Manufacturers: Absence of incentives, subsidies, or guidance discourages investment in high-quality generic manufacturing and R&D in Vietnam.

High cost of compliance with EU Standards: Meeting stringent EU requirements for sanitization, quality testing, and documentation increases costs for manufacturers.

Challenges from low generic drug prices: Tightly controlled low generic drug prices, may deter high-quality foreign manufacturers and challenge the industry's quality in long-term.

Import

Manufacture locally

Awareness & Trust

Low awareness of total benefits among doctors and pharmacists: in generic quality delays prescription and adoption at the early stages, which leads to Doctors and pharmacists may favor branded drugs.

Lack of awareness in self-care among patients: Persistent concerns about the safety and reliability of generics hinder widespread use and patients lack understanding that high-quality generics are identical to originator drugs in efficacy and materials.

In need of awareness/attention from the Government: Insufficient awareness at governmental to highlight cost and efficacy benefits of generics.

1.2.1 Regulatory

Complex registration process

Vietnam's drug registration system, managed by the Drug Administration of Vietnam (DAV) under the Ministry of Health (MOH), remains complex and time-consuming, creating significant barriers for generic drug manufacturers. The approval process for new medicine is 12 months from the date of dossier submission under Circular No. 03/VBHN-BYT,[1] but in practice, it often takes up to 24 - 36 months, exceeding timelines in other ASEAN (Association of Southeast Asian Nations) countries. In contrast, Singapore offers a more efficient system, with drug registration taking up to 270 working days, and priority reviews completed within 180 days. These delays limit the availability of generic medicines, increase costs for manufacturers, and slow down patient access to affordable treatments.

Lengthy Approval Timelines:

- Registering a new medicine in Vietnam can take up to 24 - 36 months.
- Singapore's process is significantly faster, with approvals in 6-9 months for standard cases and <180 days for priority reviews.

Bureaucratic Inefficiencies:

- Manufacturer imposters must comply with duplicative documentation requirements.
- Inter-departmental coordination challenges further slow approvals.
- High administrative burdens increase costs and limit timely market entry.

Current reforms help, but need more:

- The Amended Law on Pharmacy (effective July 2025) introduces a reliance pathway for drugs approved by trusted authorities.
- This reform aims to reduce timelines from 12 months to 9 months[2], but in reality, current approval times extend to 24 - 36 months.
- The new law does not fully address the complexity of registering locally manufactured generics.

Lack of Standardization and Digitalization:

- Vietnam lacks a centralized digital platform or standardized templates for streamlined approvals.
- Paper-based processes lead to higher costs and inefficiencies.
- Competitor markets benefit from faster, digitalized regulatory frameworks, making Vietnam less attractive for pharmaceutical investment.

Lack of Transparency in Registration Process:

- Opaque approval criteria increase corruption risks, favoring larger manufacturers.
- Non-transparent processes limit competition, slowing generics market growth.
- Hidden costs from unclear procedures could raise generic drug prices.

Limited regulatory capacity

Vietnam's pharmaceutical regulation faces challenges due to limited inter-departmental coordination and staffing shortages, leading to delays in drug approvals and quality control oversight.

- High Volume of Pending Dossiers: The Drug Administration of Vietnam (DAV) had over 14,000 backlogged dossiers as of 2020. This challenge has been exacerbated by manpower shortages, with key personnel resigning or transferring between 2018 and 2021, further extending approval timelines.[3]
- Strengthening Quality Oversight: The Law on Pharmacy No. 105/2016/QH13 provides a framework for drug quality and manufacturing facility inspections. As demand for regulatory approvals increases, ensuring timely and consistent enforcement remains an area for continued focus. Expanding resources and capacity for inspections will be essential to maintaining high standards.
- Impact of the Amended Law: The Amended Law on Pharmacy (effective July 2025) introduces measures to streamline drug regulation and enhance Good Manufacturing Practice (GMP) compliance. While these changes are positive, ensuring sufficient staffing and regulatory resources will be key to maximizing their effectiveness.

Enhancing regulatory capacity, improving coordination, and ensuring adequate resources will help accelerate drug approvals, strengthen quality oversight, and support the continued growth of Vietnam's pharmaceutical sector.

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[1] Ministry of Health (2025), Circular No 03/VBHN-BYT on "Regulations on registration of drugs and medicinal ingredients", thuvienphapluat.vn, Available at Link

[2] Thai Binh (2024), "Thời gian cấp Giấy đăng ký lưu hành thuốc mới sẽ giảm từ 12 tháng xuống 9 tháng", Suckhoedoisong.vn, Available at Link

[3] Phuong Anh (2024) " Còn nhiều hồ sơ tồn đọng, Cục Quản lý Dược nói gì?", Thanhtra.com.vn, Available at Link

Limited incentives for investors and manufacturers

Vietnam's pharmaceutical reforms are making strides toward attracting investment and expanding domestic production. In 2023, the Prime Minister's Decision No. 1165/QD-TTg outlined a vision for the development of the pharmaceutical sector through 2030, with a long-term outlook to 2045. This policy highlights generic medicine production as a key priority, presenting an opportunity to further enhance industry growth with targeted incentives.

Enhancing Support for Generic Drug Manufacturing

While Vietnam has introduced several measures to promote pharmaceutical investment, there is room to strengthen incentives for high-quality generic drug production:

- Current policies focus heavily on innovative medicines, leaving an opportunity to expand support for cost-effective generics that can improve public health access.
- The most recent Amended Law on Pharmacy advances the sector, but additional incentives for generic drug manufacturers could increase affordability and availability of essential medicines.
- Ministry of Health proposals, including tax benefits, land leasing support, and favorable borrowing terms, provide a strong foundation for investment. Expanding these incentives to cover generic drug production would further stimulate industry development.
- There is no distinction between tender groups to acknowledge the quality improvements made by manufacturers focused on export-driven production.

Positioning Vietnam as a Competitive FDI Destination

Vietnam has made progress in attracting foreign investment, with 159 foreign companies investing approximately USD 1.8 billion in the pharmaceutical sector.[4] There is significant potential to expand this further by simplifying regulatory processes and supporting local raw material production, following the successful models of Malaysia and Singapore.

High cost of compliance with EU-GMP standards: The high cost of EU-GMP compliance remains a major challenge for domestic manufacturers. Upgrading facilities, implementing advanced quality controls, and maintaining certification require significant investment, making it difficult for many local producers to compete. Without financial support or incentives, smaller firms may struggle to justify the expense, slowing industry-wide adoption.

High regulatory complexity: Regulatory complexity further complicates compliance. The Amended Law on Pharmacy (effective July 2025) introduces a reliance pathway for drug approvals, the process for certifying EU-GMP facilities remains resource-intensive and time-consuming. Circular No. 07/2022/TT-BYT provides guidelines for Good Manufacturing Practices (GMP) assessments and sets requirements for bioequivalence (BE) studies. Only 26 molecules are currently required to submit BE study data, a small fraction of the over 1,500 registered molecules in Vietnam.[5] This limited scope of enforcement means that many drugs on the market lack full bioequivalence verification, creating inconsistencies in quality control. Expanding these requirements could help ensure greater standardization and alignment with global pharmaceutical regulations.

Challenges from low generic drug prices: Low generic drug prices in Vietnam may discourage EU-GMP manufacturers from maintaining high-quality standards, increasing the risk of substandard drugs. Additionally, limited profit margins could deter investment in innovation and production expansion, slowing industry growth.

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[4] Thanh Van (2024), "Legal reform could woo foreign investment to pharmaceuticals", Vietnam Investment Review, Available at Link

[5] Zaheer-Ud-Din Babar (2017) 'Pharmaceutical Policy in Vietnam' Available at Link

1.2.2 Awareness and Trust

Low awareness of total benefits among doctors and pharmacists: Healthcare professionals, including doctors and pharmacists, play a pivotal role in promoting the adoption of generic medicines. High-quality generics are bio-equivalent to their branded counterparts, meeting the same safety, efficacy, and regulatory standards while offering a more cost-effective alternative. This may not be universally known. A 2018 study indicated that only 47.3% of pharmacists believed that products approved as generic equivalence can be considered therapeutically equivalent to the innovator drug, and 25.5% believed generic medicines are of an inferior quality to branded medicines.[6] Building trust among healthcare professionals through education and transparent communication about quality standards is crucial.

In need of awareness/attention from the Government: Awareness among key stakeholders, including policymakers and public health officials, remains limited regarding the role of generic medicines in Vietnam's pharmaceutical strategy. Recent policies, such as Decision No. 1165/QĐ-TTg (Vietnam's National Strategy for Pharmaceutical Industry Development, 2024) and the Amended Law on Pharmacy (2024), prioritize the development of innovative drugs, signaling a shift away from generics. While fostering innovation is important, the current policy framework lacks balance, with insufficient focus on the cost savings and public health benefits that generics provide. Greater government attention to generics as a complement to innovation could strengthen Vietnam's healthcare affordability and accessibility while supporting broader pharmaceutical industry growth.

Lack of awareness in self-care among patients: Patients' lack of knowledge about self-care and reliance on healthcare professionals limit the adoption of generic drugs. While campaigns like "Chăm sóc Sức khỏe Việt Nam" (2019 -2025) promoted health awareness, they did not emphasize generics or their benefits. Many patients still perceive brand-name drugs as superior, influenced by cultural preferences and concerns about counterfeit medicines. Limited public education and physician prescribing habits further reinforce these perceptions. Expanding educational campaigns and strengthening healthcare communication will be key to improving confidence in generics.

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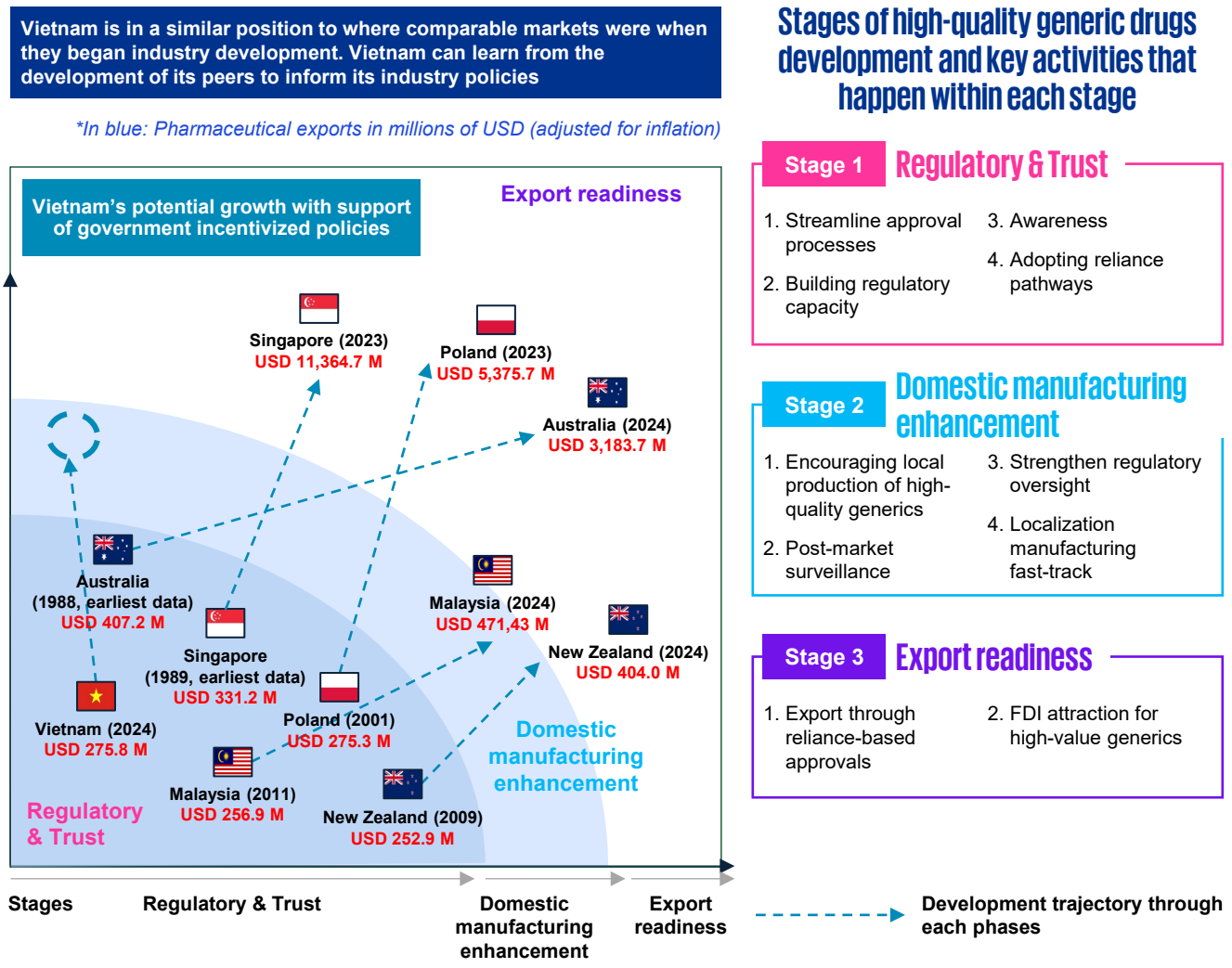
[6] Journal of Pharmacy & Pharmacognosy Research (2018) 'Acceptance and perceptions of generic substitution among pharmacists: A preliminary study in Vietnam', Available at Link

2. Lesson from other markets: Country benchmarking

Figure 2.1: How Other Countries Have Advanced in High-Quality Generic Drug Development



Source: KPMG Research and Analysis

The generic drug industry has evolved significantly over the past two decades, with countries strengthening regulatory frameworks, domestic manufacturing capabilities, and export readiness. A study of five markets at different stages of development reveals three key phases in the growth of a high-quality generics industry:

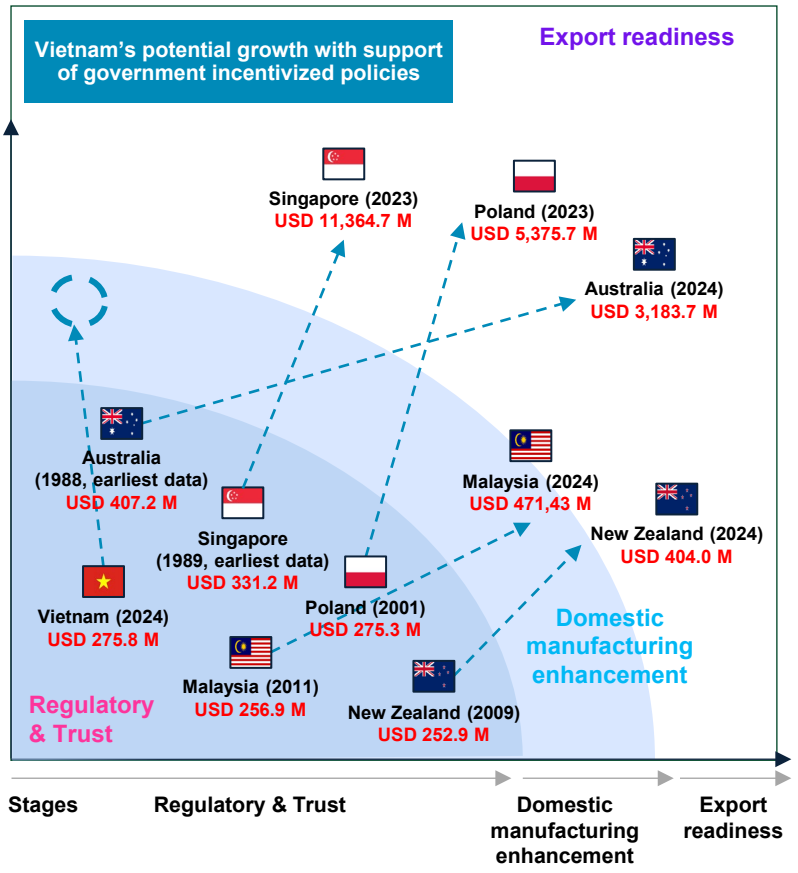
- **Stage 1: Regulatory & Trust:** A strong generics market begins with stricter regulations, streamlined approvals, and alignment with international standards. Governments prioritize building confidence among healthcare professionals and consumers while ensuring quality compliance and attracting investment.
- **Stage 2: Domestic Manufacturing Enhancement:** A robust regulatory framework allows governments to shift focus to strengthening local production. Technology transfer programs, regulatory oversight improvements, and targeted incentives help domestic manufacturers expand operations, improve supply chains, and reduce reliance on imports.
- **Stage 3: Export Readiness:** A well-established domestic industry paves the way for global expansion. Countries at this stage leverage reliance-based approvals, foreign direct investment (FDI) incentives, and international partnerships to increase exports of high-value generics and biosimilars.

Vietnam remains in the **Regulatory & Trust phase**, similar to the early stages of generics industry growth in many developed markets. Strengthening regulatory frameworks, accelerating approval processes, and increasing trust in local manufacturers will support the country's transition toward domestic manufacturing enhancement and eventual export readiness.

Figure 2.2: Economic and Social Benefits Achieved at Each Stage of Development

Vietnam is in a similar position to where comparable markets were when they began industry development. Vietnam can learn from the development of its peers to inform its industry policies

**In blue: Pharmaceutical exports in millions of USD (adjusted for inflation)*



Stages of generic drugs development

Stage 1 Regulatory & Trust

- Faster access to medicines
- Improve access to chronic disease medication
- Enhance public health outcomes
- Lower administrative costs
- Strengthening local production

Stage 2 Domestic manufacturing enhancement

- Attract FDI investment
- Encouragement of local innovation
- Jobs creation & increase in productivity
- Universal access to essential medicines

Stage 3 Export readiness

- Increase confidence in generic medications
- Market expansion for generics
- Innovative driven industry
- Export growth opportunities

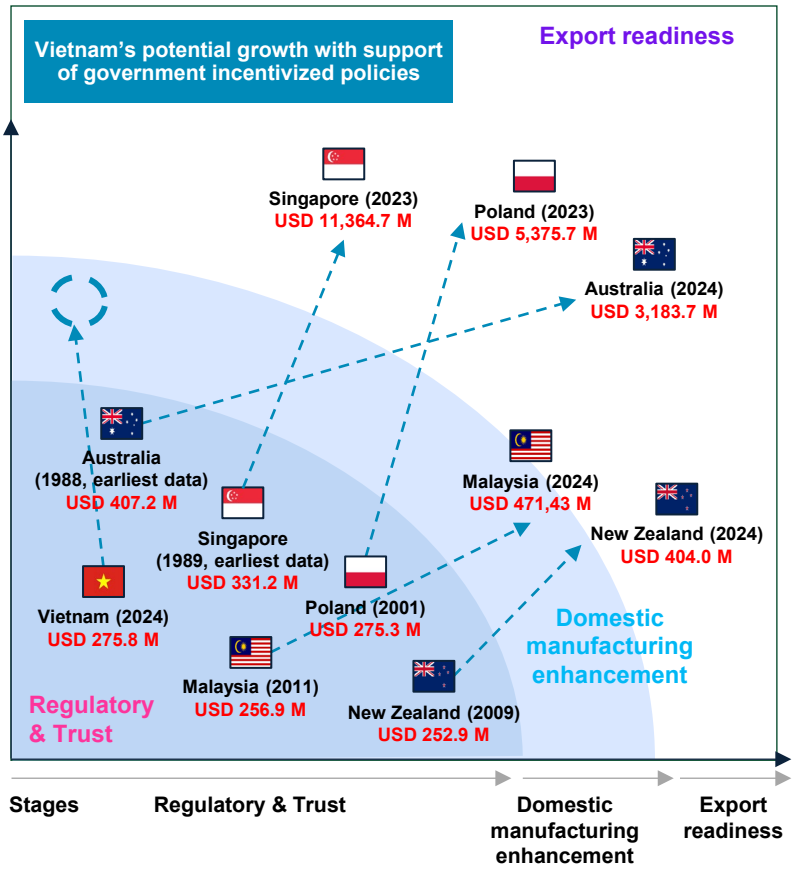
Source: Economist Intelligence Unit, KPMG Research and Analysis

Analysis of these five markets offers key insights to guide Vietnam's policy and generic drug development.

Figure 2.3: Challenges faced by five countries when developing their generic drug industry (similar to Vietnam's current situation)

Vietnam is in a similar position to where comparable markets were when they began industry development. Vietnam can learn from the development of its peers to inform its industry policies

**In blue: Pharmaceutical exports in millions of USD (adjusted for inflation)*



Common barriers faced by other countries during the development of their generic drugs market (by level of priority of the barriers that Vietnam is facing)

- **Complex registration process & Limited regulatory capacity**
- **Limited incentives for investors and manufacturers**
- **High cost of compliance with EU Standards**
- **Low awareness of total benefits among doctors and pharmacists**
- **Lack of awareness in self-care among patient**
- **In need of awareness/attention from the Government**

Development trajectory through each phases

Source: Economist Intelligence Unit, KPMG Research and Analysis

**Note:*

- *Typical barriers faced in Regulatory & trust phase*
- *Typical barriers faced in Domestic manufacturing enhancement phase*

Figure 2.4: 5 countries in the Shortlist

Australia

Barriers

1. Low awareness of total benefits among doctors and pharmacists
2. Complex registration process
3. Lack of awareness in self-care among patients

Solution

1. **Pharmaceutical Benefits Scheme (PBS) Policy**: Allows and promotes generic substitution, making pharmacists more familiar with cost-effective alternatives and increasing doctors' awareness of the financial and accessibility benefits for patients.
2. **Streamlining and fast tracking**: Reducing the Therapeutic Goods Administration (TGA) registration process to 11 months and introducing reliance pathways, like the Comparable Overseas Regulator (COR) pathway, reduces approval times for generic drugs. This makes the process faster and less complex by leveraging approvals from trusted overseas regulators.
3. **National Prescribing Service (NPS) education campaigns**, funded by the government, increased consumer awareness about generic medicines and their effectiveness. By promoting informed decision-making through TV campaigns and other initiatives, patients became more confident in managing their own medication choices.

Malaysia

Barriers

1. Low awareness of total benefits among doctors and pharmacists
2. Lack of awareness in self-care among patients

Solution

1. **Pharmaceutical Association of Malaysia** provide educational programs, such as workshops, CPD courses, and seminars, tackle the lack of awareness about generics. These initiatives provide doctors and pharmacists with critical information on the safety, efficacy, and cost advantages of generics, sharing up-to-date research, case studies, and regulatory guidelines to encourage informed prescribing and dispensing.
2. **Implementing Generic Medicine Awareness Program** enhanced stakeholder education and removing potential barriers such as low awareness and misconceptions in generic drugs. This focuses on increasing acceptance and confidence in cost-effective alternatives through internal training and education for both physicians and patients.
3. **The Ministry of Health (MOH) has reassured the public that generic medicines in Malaysia are safe and effective**, highlighting that all generics adhere to strict standards. All generic drugs must undergo testing to verify they deliver the same therapeutic effects as their brand-name counterparts.

New Zealand

Barriers

1. Low awareness of total benefits among doctors and pharmacists
2. Complex registration process

Solution

1. **Pharmac established in** 1993 raises awareness among doctors and pharmacists by emphasizing the cost-saving benefits of generic medicines. Through evaluations and community campaigns, it educates healthcare professionals on the financial and clinical advantages of generics.
2. **Generic approval process revised in 2010:** streamlined registration by prioritizing generic medicines with significant benefits. Medsafe's 28-day response mandate accelerates approvals, reducing delays and making the process more efficient.
3. **Electronic Common Technical Document (eCTD) made mandatory** in May 2023 streamlined the registration process by aligning New Zealand with global standards. This reduces duplication, speeds up approvals, and enables reliance on trusted international regulators, making generic drug registration more efficient.

Singapore

Barriers

1. Low awareness of total benefits among doctors and pharmacists
2. Lack of awareness in self-care among patient

Solution

1. **Cost-effective generic alternatives** are guided Singapore's Ministry of Health, doctors, and pharmacists which ensures healthcare professionals have clear guidance for patient prescription decisions while promoting evidence-based generic drug adoption across the healthcare system
2. **Singapore's Ministry of Health has established affordability** as a key national healthcare goal, implementing strategic encouragement of generic drug usage with comprehensive subsidy listings, creating a systematic approach to financial assistance that ensures broader patient access to affordable treatment options

Poland

Barriers

1. Limited Incentives for Investors and Manufacturers
2. Complex registration process

Solution

1. **The reference pricing system (RPS)** in Poland promotes generics by grouping medicines with the same active ingredients and setting reimbursement limits, encouraging cost-effective generic use and boosting manufacturer and investment. Besides, the legal framework established by the Act of 27 August 2004 and the Pricing Law strengthened these incentives by providing clear guidelines for pricing and reimbursement. By requiring pharmacists to inform patients about cheaper generic alternatives, the system creates guaranteed market demand, making investment in generic manufacturing more attractive.
2. **The registration process has been streamlined through the European Commission Directive 2001/83/EC and the Amendment of Implementation of Reimbursement Lists**. This creates a fast-track procedure that eliminates extra evaluation needs by the HTA Agency, enables generic drugs to be approved based on bioequivalence without full clinical data, and requires prices to be at least 25% lower than the original product. Additionally, if a drug is approved in any EU Member State or by the EMA, it is automatically authorized in Poland, significantly reducing both time and costs.

2.1 Overview of Case Study Countries

Rising healthcare costs have prompted many countries to integrate generic drugs into their health systems, leveraging their cost-saving potential to improve access and health outcomes. Expanding the use of generics has proven effective in reducing overall healthcare expenditures while ensuring broader patient access to essential medicines. Countries that once faced barriers similar to Vietnam in scaling their generic drug supply have taken different policy approaches to overcome these challenges. The selected case study countries highlight unique strategies in regulation, domestic manufacturing, and market expansion, offering valuable lessons for Vietnam's pharmaceutical development.

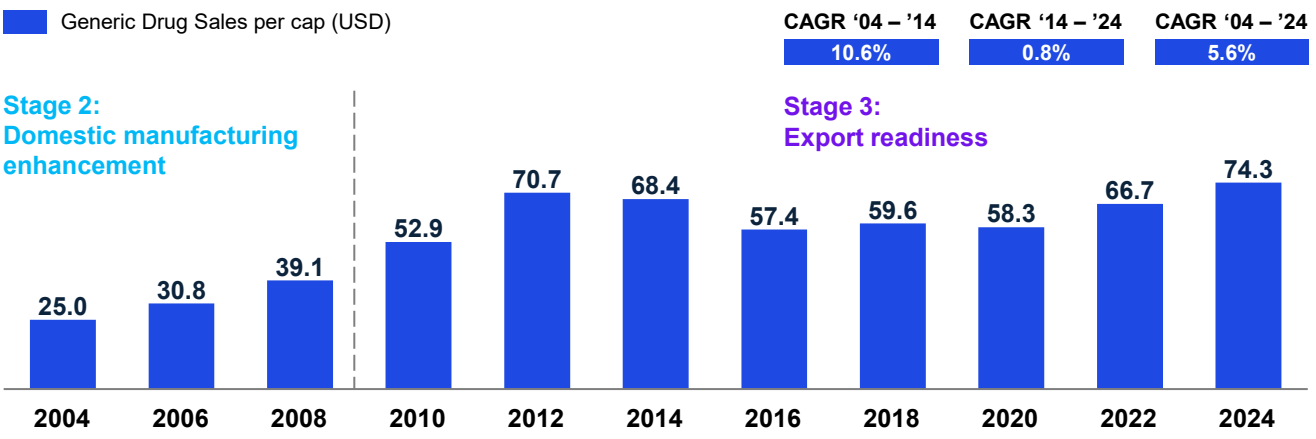
2.2 Case Study

Australia

2.2.1 Overview

Policy reforms and education initiatives have driven steady growth in Australia's generic drug market

Figure 2.5: Australia Generic drugs sales per capita (2004-2024)



Source: BMI Fitch Solutions

Australia's generic drug market experienced its fastest growth between 2004 and 2014, with a CAGR of 10.6%. For the past 15 years, the country has been in the export readiness phase, establishing itself as a key player in global pharmaceutical trade. In 2024, pharmaceutical exports reached USD 2.73 billion. 4F At the same time, the domestic market continues to expand, with per capita sales reaching USD 74.3 in 2024.[7] This sustained growth aligns with the government's commitment to ensuring affordable, high-quality medicines for its population while maintaining a competitive position in global markets.

Industry collaboration has played a vital role in shaping Australia's generic drug policies. The Generic Medicines Industry Association (GMiA), established in 2001, has worked closely with the government to refine the drug registration process and promote generics. In 2021, now operating as the Generic Medicines and Biosimilars Association (GMBA), the organization signed a renewed five-year strategic agreement with the government to further strengthen the sector.

Public confidence in generics has increased alongside consistent growth in per capita sales volume. Government-backed educational campaigns, facilitated by the National Prescribing Service (NPS), have played a key role in raising awareness and trust in generic medicines. Pharmacists have also gained greater confidence in dispensing generics, further driving adoption and ensuring broader public access to cost-effective treatments.

2.2.2 Key policies and initiatives to overcome the barriers

Table 2.3: Key policies and initiatives in Australia

Year	Policy	Impact
1994	Generic Substitution[8]	Allowed pharmacists to substitute brand-name drugs with generics, increasing affordability and access.
2001	Establishment of GMiA	Advocated for policy reforms, boosting market acceptance of generics.
2008	Drug Registration Reforms	Streamlined approval processes, accelerating access to generics.
2010	Government-Funded Awareness Campaigns	Increased consumer confidence in generic medicines.
2015	Strategic Agreement (GMiA & Government)	Strengthened public-private collaboration, expanding generic drug access.
2019	Active Ingredient Prescribing	Reduced brand-name bias, promoting cost-effective prescribing.
2021	New Strategic Agreement (GMBA & Government)	Enhanced market stability and affordability of generics.

Source: Australian Government

2.2.3 Key actions taken to develop its generic drug market

Streamlining the registration process enhanced the efficiency of Australia's drug approval process

In 2008, Australia faced a surge in generic drug applications due to expiring patents and increased interest from international generics manufacturers. The Therapeutic Goods Administration (TGA), responsible for drug approvals, struggled to process the rising volume of submissions, leading to delays. Recognizing the need for reform, the Generic Medicines Industry Association (GMiA) worked with the TGA to implement a streamlined registration system with clear timelines and structured steps. The new process introduced an eight-step electronic submission system, requiring manufacturers to provide data on quality, safety, and efficacy. Applications undergo two rounds of review, and upon approval, the drug is registered with the Australian Register of Therapeutic Goods (ARTG).[9]

These reforms significantly improved approval efficiency, allowing Australia to accommodate rapid industry growth. Today, registering a generic drug in Australia takes 11 months,[10] compared to 24 - 36 months in Vietnam, highlighting the benefits of a structured and well-resourced system.

To further accelerate approvals, Australia introduced reliance pathways, such as the Comparable Overseas Regulator (COR) pathway and Access Consortium, which fast-tracks generics already approved by trusted regulators, including those in the USA, Canada, Japan, and EU member states. By creating a more efficient and predictable approval system, these reforms have expanded patient access to affordable generics and strengthened Australia's position as a leader in the global generics market.

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[8] Generic Medicines Industry Association (2010), 'Applicants response to issues raised in the public consultation process concerning Applications for Authorisation of the Generic Medicines Industry Association Code of Practice' Available at Link

[9] Therapeutic Goods Administration (2022) 'Prescription medicines: registration of new chemical entities in Australia', Available at Link

[10] Therapeutic Goods Administration (2021) 'Prescription medicines registration process' Available at Link

Public and private cooperation through strategic agreements boosted generic medicine access

Public and private sector agreements have played a key role in strengthening Australia's generic medicines industry. The Generic Medicines Industry Association (GMiA), established in 2001, worked closely with the government to advocate for policy reforms and raise awareness of generic medicines. In 2015, the association signed Australia's first strategic agreement between generic medicine suppliers and policymakers, ensuring a stable and affordable medicine supply. As part of this agreement, the Generic Medicines Working Group (GMWG) was created, bringing together public and private stakeholders to develop policies that support the generics sector and increase adoption. This initiative contributed to greater patient access to affordable medicines and cost savings for the Pharmaceutical Benefits Scheme (PBS), Australia's subsidized prescription drug program. Today, GMiA members supply over 90% of medicines dispensed through the PBS, reinforcing the impact of this agreement.

In 2021, the renamed Generic Medicines and Biosimilars Association (GMBA) signed a new five-year strategic agreement with the Australian Government. This agreement expanded on the 2015 framework, introducing the Medicines Supply Security Guarantee to ensure a stable supply of essential medicines. Additionally, the government reinforced its commitment to public investment in the pharmaceutical sector, further embedding public-private collaboration as a driver of industry stability and growth.

Australia's experience highlights how strategic partnerships between industry and government can create a more efficient, resilient, and accessible pharmaceutical market.

Government-funded educational campaigns increase patient awareness of the benefits of generic medicines

Pharmacist and consumer confidence in generic medicines has improved significantly, largely due to government-backed educational campaigns led by the National Prescribing Service (NPS). By the early 2010s, the Australian government strongly supported generics, recognizing their role in improving accessibility and reducing healthcare costs. Public perception lagged, and uptake remained slow despite government confidence in their safety and effectiveness.

To address this gap, the 2010 Commonwealth Budget allocated USD 6.2 million over four years to fund NPS-led awareness campaigns.[11] One of the most impactful initiatives was a six-week television campaign emphasizing the message: "Generic medicines are an equal choice."These efforts helped shift consumer attitudes, increasing trust in generics and encouraging greater patient participation in self-care.

Australia's experience underscores an important lesson: increasing the supply of generics is only part of the solution. Governments must also focus on demand-side factors, such as public awareness and education, to ensure generics gain widespread acceptance and adoption.

[11] Parliament of Australia (2012), 'PHARMACEUTICAL BENEFITS SCHEME BILL'. Available at Link

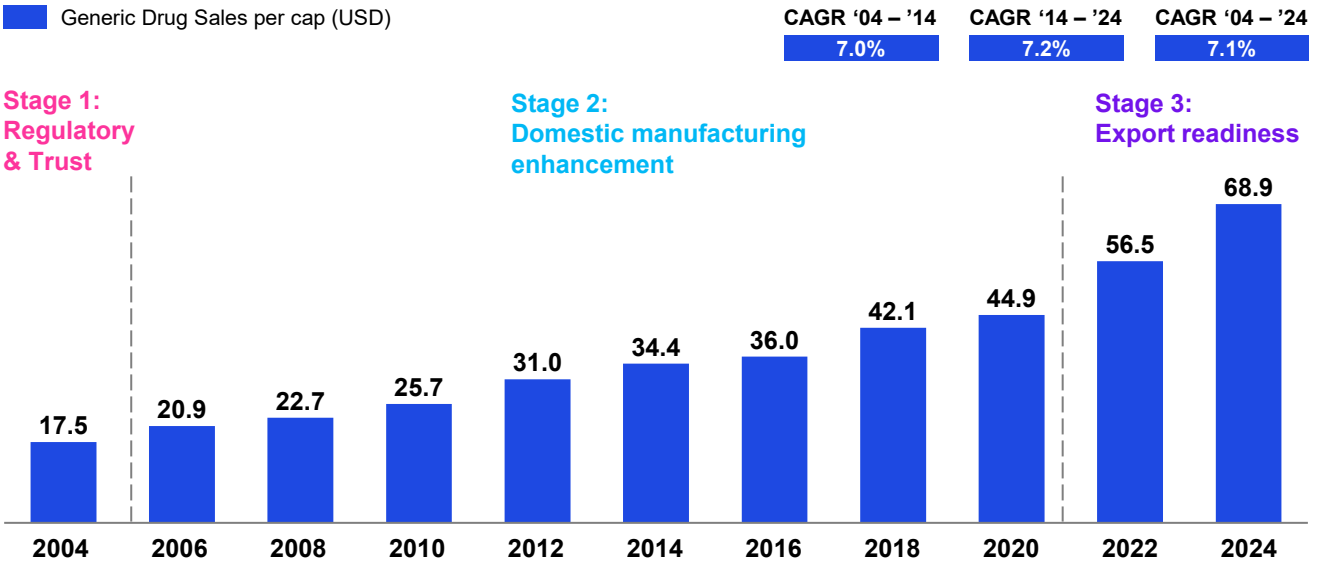
2.3 Case Study

Singapore

2.3.1 Overview

Singapore has seen a consistent rise in per capita generic drug sales, progressing through three stages of development over the past 20 years

Figure 2.6: Singapore Generic drugs sales per capita (2004-2024)



Source: BMI Fitch Solutions

Singapore's generic drug market has expanded significantly, with per capita sales increasing nearly fourfold over two decades. A structured approach to pharmaceutical industry development has driven steady growth, ensuring a smooth transition through key industry stages.

Market expansion accelerated in 2006, when Singapore shifted into the Domestic Manufacturing Enhancement phase. Investments in local production and regulatory improvements led to per capita sales rising from USD 17.5 in 2006 to USD 20.9 in 2008. Continued growth pushed sales to USD 44.9 per capita by 2020, reinforcing Singapore's position as a leading pharmaceutical hub. By 2022, the country entered the Export Readiness stage, further strengthening its role in regional trade.

Sustained growth has resulted in a CAGR of 7.0% (2004-2014), 7.2% (2014-2024), and 7.1% (2004-2024). Singapore now accounts for a large share of Southeast Asia's generic drug exports, demonstrating how a structured strategy enhances cost-effective healthcare while driving economic growth through pharmaceutical exports.

2.3.2 Key policies and initiatives to overcome the barriers

Table 2.4: Key policies and initiatives of Singapore to overcome the barriers

Year	Policy	Impact
2017	Clinical Practice Guidelines	The Ministry of Health encouraged doctors to prescribe generics to improve affordability.
2019	Generic Drug Prescription Guide	A collaborative effort by the Ministry of Health, doctors, and pharmacists established a list of cost-effective generics to guide prescriptions.
2022	"Access, Affordability, Availability" as a National Objective	The Ministry of Health set affordability as a priority, promoting generic drug use and expanding financial assistance through subsidies.

Source: Singapore's Health Sciences Authority

2.3.3 Key actions taken to develop its generic drug market

Prescription guidelines have improved awareness and increased the adoption of generic medicines

In 2017,[12] Singapore's Ministry of Health (MOH) collaborated with doctors and pharmacists from public healthcare institutions to promote the appropriate use of generic medicines. To support this effort, MOH introduced a selection of clinically effective and cost-efficient generics as alternatives to the more expensive branded drugs.

To guide practitioners, MOH implemented the Medication Safety Practice Guidelines and Tools, which emphasized prescribing medications using generic names instead of brand names. The guidelines also required ongoing education for physicians, pharmacists, and nurses to ensure clear communication with patients about generic medicines. Additionally, the Electronic Communication of Medical Orders system was enhanced with a search function linking all medications to their default generic name, reinforcing standardization and reducing prescription errors.

These measures aimed to reduce confusion, improve prescription rates, and increase patient acceptance of generics. With a more efficient medication management system, the Singapore MOH reported a steady rise in generic drug adoption, contributing to a more cost-effective and sustainable healthcare system.

Setting National objective to prioritize the development of generic medicine market

Singapore's National Medicines Policy (2022)[13] outlines key objectives to shape the country's pharmaceutical landscape, with a strong focus on generic drug accessibility and quality assurance.

The first objective, "Access, Affordability and Availability," promotes the use of generics by reducing market entry barriers and integrating them into national healthcare financing schemes, particularly subsidy listings. By encouraging generic adoption, the Ministry of Health (MOH) ensures that essential medicines remain affordable while maintaining a sustainable healthcare system.

The second objective, "Quality, Safety, and Efficacy," reinforces strict regulatory oversight across the entire medicine lifecycle. Best practices in governance and rapid response to safety concerns enhance trust among healthcare professionals and patients, fostering greater acceptance of generics.

Financial incentives and strict regulatory standards are set to drive growth in assured quality generics, strengthening domestic production and supporting a resilient, cost-effective healthcare system in Singapore.

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[12] Measures in place to promote use of generic drugs, 2017, Link

[13] SINGAPORE'S NATIONAL MEDICINES POLICY, Available at Link

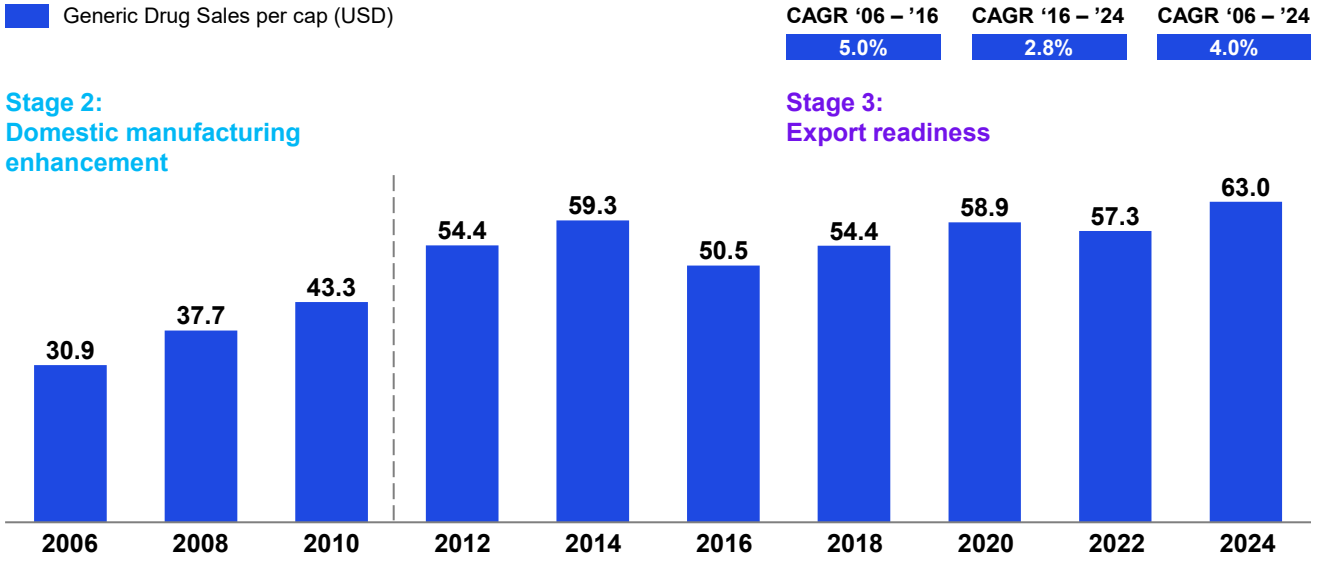
2.4 Case Study

New Zealand

2.4.1 Overview

New Zealand has experienced consistent growth in generic drug sales over time

Figure 2.7: New Zealand Generic drugs sales per capita (2006-2024)



Source: BMI Fitch Solutions

New Zealand's generic drug market has experienced steady growth, with per capita sales increasing at a CAGR of 5% from 2006 to 2016. This growth was largely influenced by the 2010 generic drug registration reforms, which shortened approval timelines and improved market access.

Following these reforms, New Zealand transitioned from domestic manufacturing enhancement to export readiness, reaching a more mature stage of development. By 2024, pharmaceutical exports totaled USD 233.9 million, reflecting the industry's expansion into international markets.[14]

To support long-term growth, New Zealand has focused on streamlining its drug registration process through globally harmonized documentation and reliance pathways, allowing faster approvals. At the same time, Medsafe, the country's regulatory authority, ensures that the public remains well informed about the safety and efficacy of generic medicines, fostering greater confidence and adoption.

[14] SINGAPORE'S NATIONAL MEDICINES POLICY, Available at Link

2.4.2 Key policies and initiatives to overcome the barriers

Table 2.5: Key policies and initiatives of New Zealand to overcome the barriers

Year	Policy	Impact
1993	Establishment of Pharmac[15]	Balanced drug cost and quality considerations, favoring generics and reducing healthcare expenditure.
2010	Revised Generic Drug Approval Process	Accelerated approvals for priority generics, improving availability and patient health outcomes.
2020	Medsafe Public Awareness Initiative[16]	Addressed public concerns about generics, reinforcing trust and supporting market growth.
2023	Adoption of Electronic Common Technical Document (eCTD)[17]	Streamlined and globally harmonized drug registration, enabling faster market access.

Source: BMI Fitch Solutions

2.4.3 Key actions taken to develop its generic drug market

Pharmac's integrated approach, combining financial management with scientific recommendations, optimized cost-effectiveness in the healthcare system.

New Zealand’s Pharmac provides a strong example of efficient healthcare management. Established in 1993, Pharmac determines which medicines receive public subsidies, ensuring a balance between clinical effectiveness and cost. Unlike many other health systems, Pharmac evaluates scientific and financial factors together, preventing misalignment between drug recommendations and funding decisions.

In Australia, for example, the Pharmaceutical Benefits Advisory Committee (PBAC) makes scientific recommendations, while a separate body manages funding. This separation can lead to financial strain, as funders may approve medicines without considering affordability. Pharmac eliminates this issue by integrating cost and clinical evaluation, allowing New Zealand’s healthcare system to maximize value within its budget. Generic medicines play a key role in this strategy, driving cost savings and broader healthcare access.

EuroCham has partnered with Vietnam’s Ministry of Health and the IQGx (now the ESM Sector Committee) to develop a comparable system in Vietnam, proposing a Multiple Criteria Decision Analysis (MCDA) framework to enhance procurement and decision-making for off-patent drugs. Like Pharmac, MCDA would assess pricing and drug formulas simultaneously, ensuring a balanced approach to medicine selection. Progress on this initiative has stalled in recent years. If Vietnam adopts a system that evaluates cost and clinical factors in parallel, the country could improve public access to essential medicines while reducing healthcare expenditures.[18]

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[15] Pharmac (2024), ‘History of Pharmac’, Available at Link

[16] MEDSAFE (2020), ‘Q&A on generic medicines’. Available at Link

[17] International Journal of Pharmaceutical Investigation (2023). ‘How Generic Drugs are Registered in Europe, United Kingdom, Australia and New Zealand? -A Drug Regulatory Perspective’. Available at Link

[18] EuroCham (2017) ‘Development of Multiple Criteria Decision Analysis Framework for Off-patent Pharmaceuticals Decision Making in Vietnam’ Available at Link

Efficient pathways for drug registration led to faster market access

New Zealand has established one of the most efficient generic drug registration systems globally, with approval timelines averaging under 200 days[19]. In comparison, similar processes take over 12 months in both the USA and the UK. Several key reforms, including strict approval timelines, the implementation of eCTDs, direct communication with manufacturers, and prioritization of key generics, have significantly improved efficiency.

In 2010, the government introduced a revised approval process for priority generic medicines, allowing fast-tracking for drugs with significant clinical benefits or cost-saving advantages. Medsafe now requires priority applications to respond within 28 days, ensuring a streamlined process and quicker market access for generic medicines.

Further strengthening this system, New Zealand made eCTDs mandatory in May 2023, aligning with global regulatory standards used by the USA, EU, UK, and Japan. This harmonization facilitates mutual recognition of approvals, supported by reliance pathways for generic drugs entering the market. As a result, New Zealand has reduced administrative costs, accelerated market penetration for generics, and ensured faster patient access to essential medicines.

Medsafe serves as a trusted public resource for therapeutic goods, providing New Zealanders with reliable information to support informed health decisions

Public awareness of the safety and efficacy of generic medicines in New Zealand has improved over time, largely due to Medsafe's active role in public education. As the Ministry of Health's regulatory unit for therapeutic goods, Medsafe plays a key role in disseminating accurate information and addressing public concerns about medicines.

Medsafe has been highly responsive to misinformation surrounding generic drugs. In 2020, a podcast on Radio New Zealand spread misleading claims about generic drug safety, raising unnecessary concerns among the public. In response, Medsafe quickly issued a press release to clarify the facts and reinforce confidence in the regulatory standards ensuring generic drug quality.

Through proactive communication and public engagement, Medsafe has strengthened consumer trust in generics, preventing potential declines in sales and ensuring New Zealanders remain well-informed and confident in managing their own healthcare choices.

[19] International Journal of Environmental Research and Public Health (2013) 'New Zealand's Drug Development Industry'. Available at Link

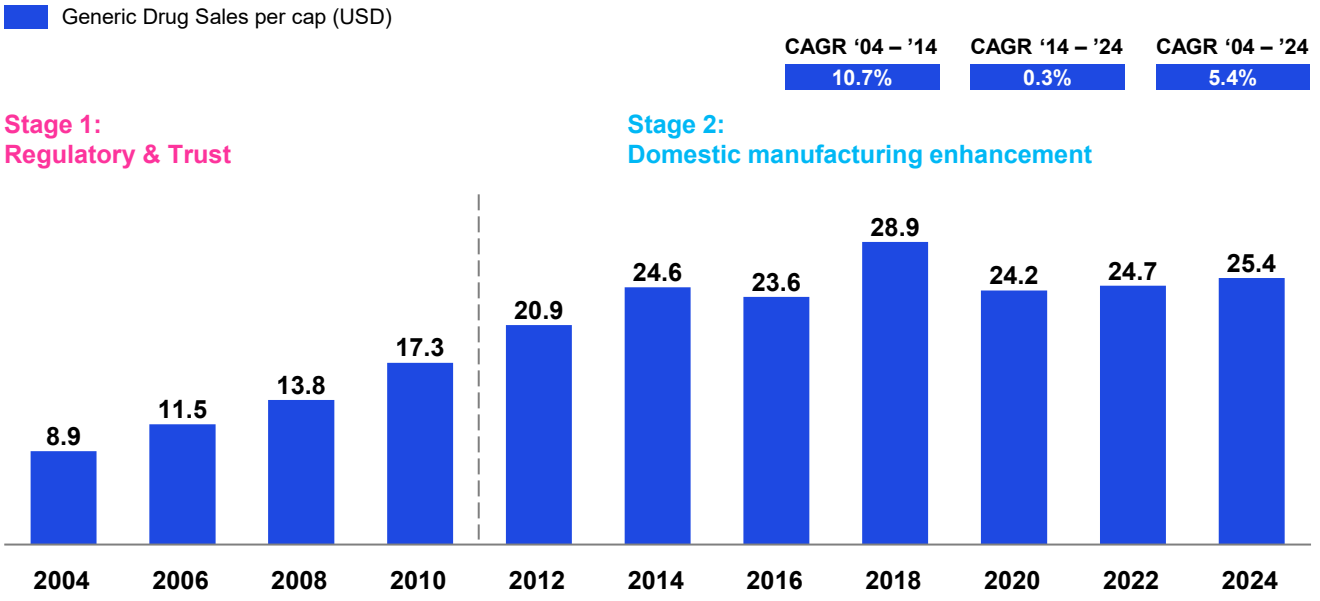
2.5 Case Study

Malaysia

2.5.1 Overview

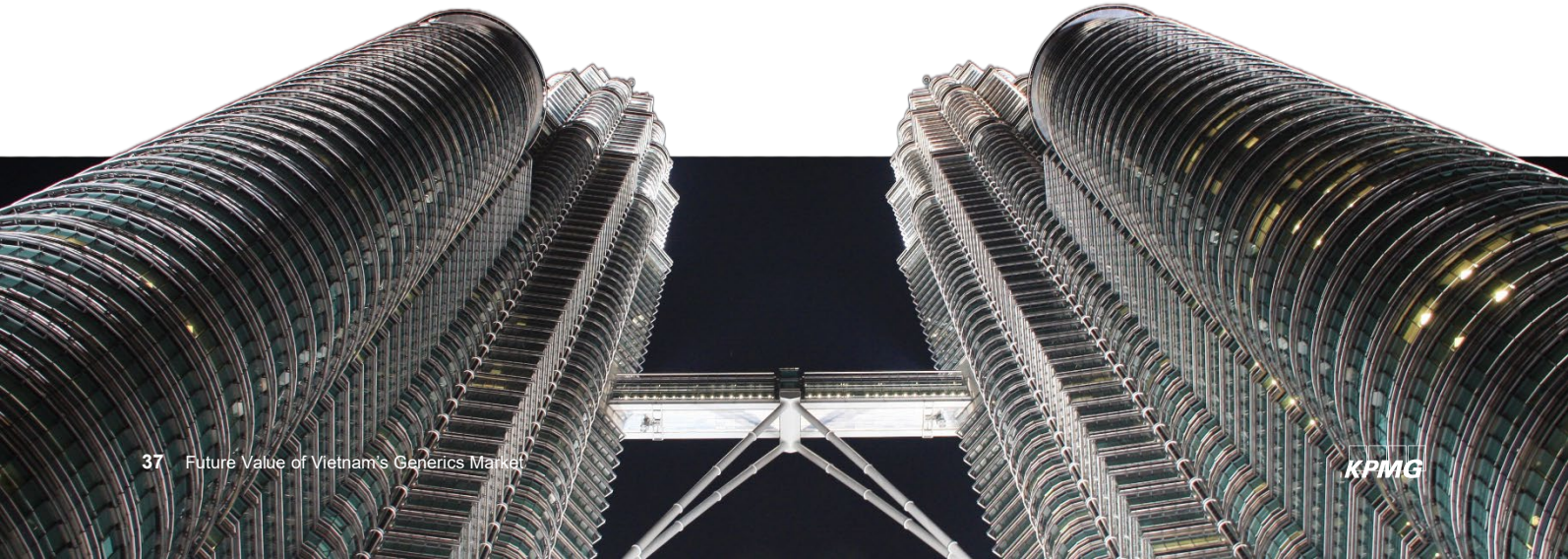
Malaysia's generic drug market has experienced steady growth since 2004, with sales reaching their highest point in 2018

Figure 2.8: Malaysia Generic drugs sales per capita (2004-2024)



Source: BMI Fitch Solutions

Malaysia's generic drug market has reached a mature stage, supported by a well-developed infrastructure for production and distribution. The market experienced significant growth, with a peak CAGR of 10.7% from 2004 to 2014, driven by increasing demand for affordable healthcare solutions. From 2014 to 2024, growth stabilized as generics became firmly established in the healthcare system. Government initiatives, such as the National Medicines Policy, played a key role in promoting generics, particularly in the early stages. Over time, generics have expanded across various therapeutic areas due to their cost-effectiveness and accessibility. In 2018, Malaysia recorded its highest generic drug sales per capita at USD 28.9, reflecting the government's efforts in supporting generic drug policies, education, and local manufacturing incentives. Malaysia experienced a slowdown in the generic drug spending per capita in 2019 due to disruptions caused by Covid-19 shifting healthcare priorities and other factors such as market saturation and increased competition.



2.5.2 Key policies and initiatives to overcome the barriers

Table 2.6: Key policies and initiatives of Malaysia to overcome the barriers

Year	Policy	Impact
2009	Pharmaceutical Association of Malaysia	Organized workshops and CPD courses for doctors and pharmacists to improve understanding of generics' safety, efficacy, and cost-effectiveness.
2012	National Medicines Policy Update	Introduced tax reductions and subsidy programs to support the growth of local pharmaceutical manufacturing.
2022	Generic Medicines Awareness Program (GMAP)	Launched educational campaigns for physicians and patients to address misconceptions about generics and increase acceptance.
2022	Manufacturers of Pharmaceutical Products Scheme	Offered 10% tax reductions for the first decade and a 10% tax rate for the following decade to incentivize local generic drug manufacturing.
2024	Awareness Campaign on Generic Drug Safety & Efficacy	Leveraged media campaigns to reinforce the safety and regulatory compliance of generics in Malaysia.

Source: Malaysian National Medicines Policy

2.5.3 Key actions taken to develop its generic drug market

Educational programs, workshops, and CPD courses play a crucial role in building trust and promoting the adoption of generic medicines in treatment

The Pharmaceutical Association of Malaysia's[20] educational initiatives have played a key role in building healthcare professionals' confidence in generic medicines. Through workshops, CPD courses, and evidence-based research, these programs have effectively dispelled misconceptions while reinforcing the safety, efficacy, and cost-effectiveness of generics.

As a result, increased knowledge and trust have led more doctors and pharmacists to actively prescribe and recommend generics, driving greater adoption within Malaysia's healthcare system. This approach not only reduces healthcare costs but also ensures broader access to high-quality, affordable medicines for patients across the country.

Strategic Healthcare Professional Education Through GMAP

Malaysia's Generic Medicines Awareness Program (GMAP)[21] was launched to increase awareness among healthcare professionals and promote the adoption of generics. Developed in collaboration with the Pharmaceutical Services Division, MOPI (Malaysian Organization of Pharmaceutical Industries), MPS (Malaysian Pharmaceutical Society), and MAPS, the program provided scientific evidence and practical guidelines to support generic medicine use. It featured targeted educational campaigns for prescribers and standardized brand substitution guidelines for pharmacists, reinforcing confidence in bioequivalence and quality standards.

The success of GMAP highlights the impact of structured educational initiatives in bridging knowledge gaps and building trust among healthcare professionals. By addressing misconceptions and clarifying the efficacy of generics, the program played a crucial role in increasing generic drug adoption within Malaysia's healthcare system.

Effective public awareness campaigns play a crucial role in increasing trust and adoption of generic medicines

The 2024 Awareness Campaign on the Safety and Efficacy of Generic Drugs[22] has played a key role in boosting public confidence in generics across Malaysia. By utilizing media coverage in public hospitals and regional news, the campaign reassured both healthcare professionals and the public that all generics undergo rigorous testing to meet quality, safety, and therapeutic equivalence standards.

The campaign's success is evident in the growing acceptance and utilization of generic medicines. Improved public awareness and trust have contributed to a more cost-effective and sustainable healthcare system. This initiative highlights the importance of proactive government engagement in educating stakeholders, supporting wider adoption of generics, and reducing healthcare costs without compromising treatment quality.

[20] Workshop and CPD course by Pharmaceutical Association of Malaysia, Link

[21] Malaysia's Generic Medicines Awareness Program, Link

[22] Awareness Campaign on the Safety and Efficacy of Generic Drugs, Link

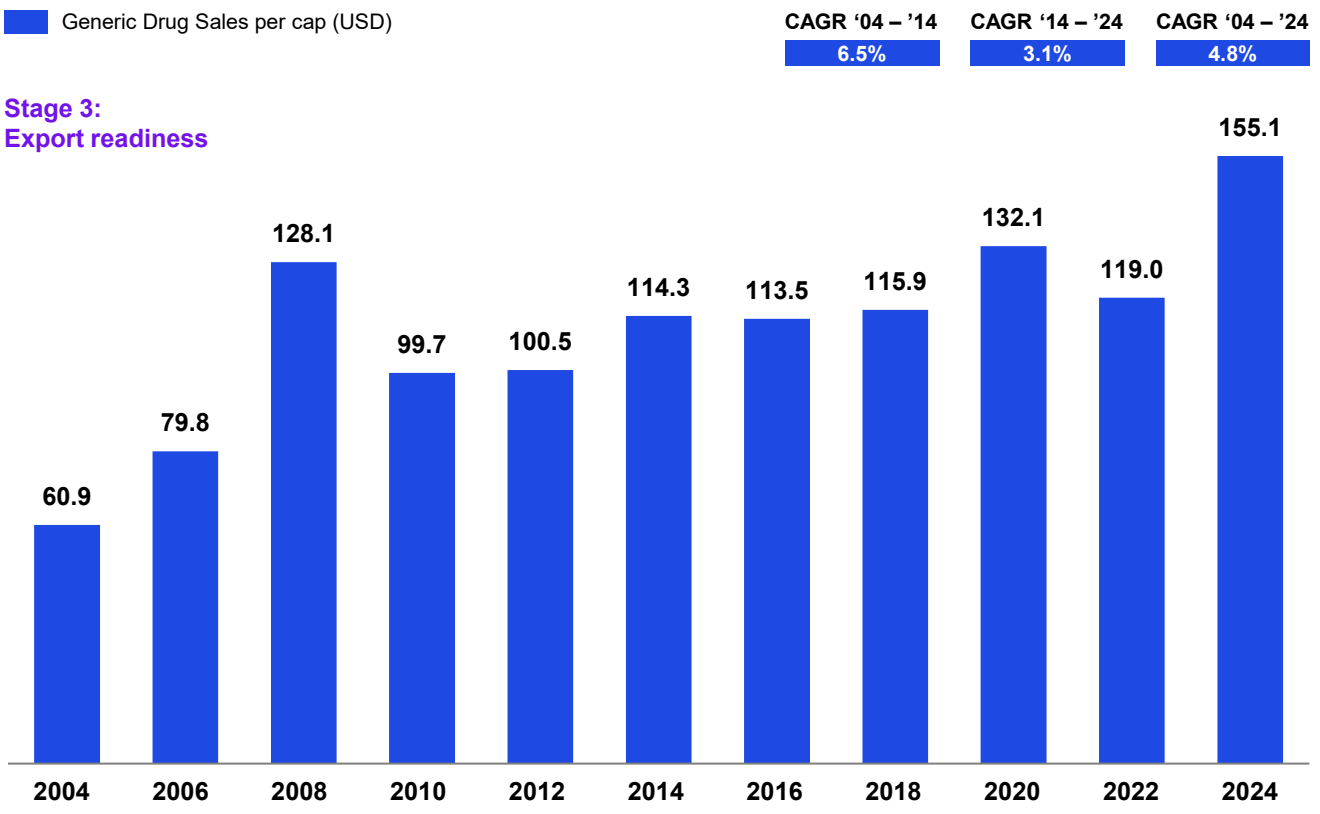
2.6 Case Study

Poland

2.6.1 Overview

Generic drugs in Poland have a long history and a strong, with steady per capita sales growth over time

Figure 2.9: Poland Generic drugs sales per capita



Source: BMI Fitch Solutions

Over the past 20 years, Poland's generic drug market has demonstrated consistent growth, with per capita sales increasing at a CAGR of 4.8% from USD 60.9 in 2004 to USD 155.1 in 2024. This steady expansion reflects the market's strong potential and the government's commitment to regulatory improvements.

Key reforms, including alignment with the EU Commission's Directive 2001/83/EC, have streamlined the approval process for generics, allowing faster and more cost-effective market entry through bioequivalence-based approvals.[23] Additionally, Poland's regular updates to reference pricing and reimbursement policies have created a competitive and cost-efficient environment for generics. In particular, the reimbursement policy from Poland, in force from November 2023, strongly supports local manufacturing of the drugs and API, further supporting the domestic generic sector. These efforts have helped Poland maintain a high market share for generics and keep drug prices lower than in many other European countries, positioning it as one of the region's leading generic drug markets.

[23] European Medicines Agency (2025), European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure'. Available at Link

2.6.2 Key policies and initiatives to overcome the barriers

Table 2.7: Key policies and initiatives of Poland to overcome the barriers

Year	Policy	Impact
1998	Introduction of Reference Pricing System (RPS)[24]	Increased generic drug adoption by linking reimbursement to the lowest-priced option, making originator drugs more expensive for patients.
2001	European Commission Directive 2001/83/EC	Allowed faster generic approvals based on EU bioequivalence standards or prior authorization, reducing regulatory burdens.
2004	Act of 27 August 2004	Established a legal framework for RPS, reinforcing priority use of generics in Poland's healthcare system.
2009-2024	Reimbursement Policy (updated on a regular basis)	Introduced a fast-track approval process and mandatory price reductions, making generics more available and affordable.
2018	Polish Drug Policy 2018-2019	Set a nationwide strategy for promoting generics, aligning with WHO recommendations for cost-effective healthcare.
2023	Amendment to the reimbursement policy regarding support for local manufacturing	Incorporated co-payment reductions of 10–15% for medicines manufactured in Poland, encouraging local generic manufacturing.

Source: KPMG Research and Analysis

2.6.3 Key actions taken to develop its generic drug market

Reference pricing and reimbursement policies boosted generic use over originators

Poland's Reference Pricing System (RPS), introduced in 1998, played a crucial role in promoting generic drug adoption. By grouping medicines with the same active ingredient and setting reimbursement limits based on the lowest-priced option, the system incentivized patients to choose generics. Patients opting for originator drugs paid higher co-pays, as reimbursement rates remained the same across the group, leading to greater generic uptake and reduced healthcare costs.

The Act of 27 August 2004 and the Pricing Law provided a clear legal framework for pricing and reimbursement. These regulations required pharmacists to inform patients about lower-cost generic alternatives, further encouraging generic substitution.

To streamline approvals and ensure affordability, Poland introduced the Reimbursement Policy (2009-2024), which has been updated on a regular basis. The reform eliminated extra evaluations from the HTA (Health Technology Assessment) Agency and mandated that generic drug prices be at least 25% lower than originator drugs. The 2023 amendment further reinforced support for local manufacturing by introducing co-payment reductions: 10% for medicines manufactured in Poland or using active substances produced locally, and 15% for medicines manufactured in Poland using locally produced active substances. These measures enhanced affordability, encourage local manufacturing, and further strengthened the role of generics in Poland's healthcare system.

Following EU Commission Directive accelerated Poland's generic approvals

Poland adopted the European Commission Directive 2001/83/EC in 2001, allowing generic drugs to be approved based on bioequivalence rather than requiring full clinical and preclinical data. This reform removed unnecessary barriers, significantly reducing approval time and costs.

Further simplifying the process, any drug approved by one of the 27 EU Member States or the European Medicines Agency (EMA) received automatic authorization in Poland, eliminating redundant evaluations. These changes accelerated the availability of generics, reduced administrative burdens, and improved patient access to affordable medicines.

By fostering a quicker and more efficient market entry for generics, Poland's regulatory framework boosted competition and helped lower healthcare costs, ensuring a sustainable and cost-effective pharmaceutical market.

[24] Health Action International Europe (2009), "Access to essential medicine in Poland", Available at Link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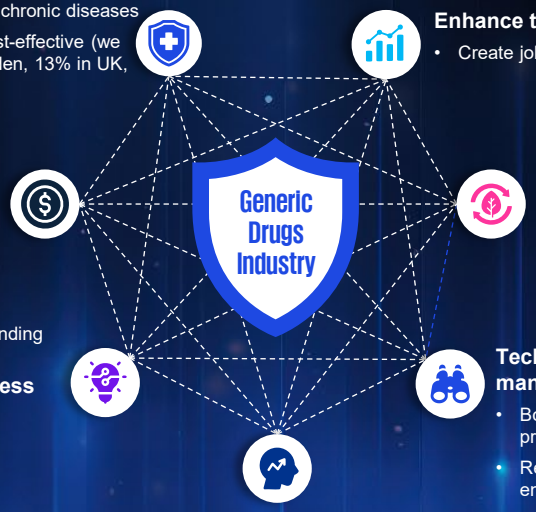
3. Value propositions for the generic pharmaceutical industry

3.1 Overview

Figure 3.1: Values of high-quality generic drugs industry



Improved health outcome

- Equivalent efficacy to branded drugs improves disease management and public health
- Expands access to life-saving treatments for chronic diseases
- Supports Vietnam's aging population with cost-effective (we saw a successful cost saved by 40% in Sweden, 13% in UK, 7% in Germany), scalable solutions.
- Reduces healthcare disparities by increasing access to medicines in underserved areas.

Boosting the economy and support sustainable healthcare growth

- Boost GDP directly and indirectly
- Saves billions annually, enabling resource reallocation to critical health needs
- Strengthens preventive care and research funding

Stimulate innovation and competitiveness

- Drives R&D through competitive market dynamics
- Ensures global compliance for safety and efficacy
- Delivers affordable, innovative drugs to consumers.

Enhance the labor market

- Create jobs and enhance productivity

Environmental sustainability

- EU generics drive sustainable, eco-friendly manufacturing
- Green chemistry cuts waste and energy use
- Lower carbon footprint for Vietnam's pharma industry

Technology transfer in generic manufacturing

- Boosts efficiency, quality, and scalability in production
- Reduces costs, improves affordability, and ensures regulatory compliance
- Bridges R&D to market, enhancing innovation and accessibility.

Become a hub of life sciences

- Strengthen Vietnam's competitive edge in pharmaceuticals
- Position Vietnam as a regional life sciences hub

1 Industry Benefit

- Technology transfer in generic manufacturing
- Stimulate innovation and competitiveness
- Environmental sustainability

2 Government Benefit

- Boosting the economy and support sustainable healthcare growth
- Enhance the labour market
- Become a hub of life sciences

3 Patient Benefit

- Improved health outcome
- Lower healthcare spendings

Source: KPMG Research and Analysis

The high-quality generic drug industry delivers value across three key areas: **industry, government**, and **patients**. **Industry**; drives technology transfer, innovation, competitiveness, and environmental sustainability. **Government**: strengthening domestic generic drug manufacturing supports sustainable healthcare, boosts employment, and stimulates economic growth. **Patients**; generic drugs offer affordable, effective treatments, improving access to essential therapies, especially in resource-limited settings. Collectively, these benefits position Vietnam as an emerging life sciences hub in Southeast Asia.

3.2 Value propositions

3.2.1 Industry Benefits

Technology Transfer in Generic Drug Manufacturing.

Technology transfer enhances production efficiency, innovation, and cost savings in the generic drug industry. By adopting advanced manufacturing techniques, producers improve operations, product quality, and waste reduction. Enhanced packaging solutions boost stability, safety, and regulatory compliance. According to Patheon, technology transfer streamlines the transition from research to market, bridging gaps between formulation, development, and production[25]. These improvements lower costs, increase scalability, and ultimately make medications more affordable and accessible.

Stimulating Innovation, Compliance, and Competitiveness

Generic medicines drive innovation, regulatory compliance, and industry competitiveness. By increasing market competition, they push brand-name manufacturers to develop new therapies to retain market share, at the same time enhance competitiveness through value-added medicines development. Strict international regulations, such as the FDA (Food and Drug Administration) Drug Competition Action Plan, ensure safety and efficacy. This process fosters continuous innovation while keeping medications affordable.

Environmental Sustainability

The EU has integrated ESG (Environmental, Social, and Governance) practices into pharmaceutical manufacturing, including generics, through EU-GMP guidelines. These standards require Environmental Risk Assessments (ERAs) and encourage green chemistry, reducing hazardous chemicals, energy use, and waste. Expanding EU generic drug supply in Vietnam can lower the industry's carbon footprint while driving innovation, competitiveness, and sustainability.

3.2.2 Government Benefits

Support sustainable healthcare spending growth

The increased use of generic medicines generates significant cost savings for healthcare systems. In 2020, the U.S. saved an estimated USD 338 billion due to generics[26]. Lower drug costs reduce government spending on medication procurement and public health programs, allowing resources to be redirected to preventive care, infrastructure, and research. In universal or subsidized healthcare systems, these savings improve accessibility, ensuring broader coverage and better health outcomes.

Become a hub for life sciences

Expanding Vietnam's generic drug market presents a major opportunity to establish the country as a leading life sciences hub in Southeast Asia. By adopting EU-GMP standards, improving incentives for global manufacturers, and streamlining regulations, Vietnam can elevate its pharmaceutical manufacturing capabilities and position itself as a key supplier of high-quality generics.

Achieving global quality benchmarks will not only increase domestic healthcare affordability but also unlock significant export potential, driving economic growth and strengthening Vietnam's competitiveness in the regional and global pharmaceutical markets. Realizing this vision requires the healthcare manufacturing sector to operate at the highest international standards, ensuring product quality, regulatory compliance, and sustained investor confidence. By embracing these improvements, Vietnam can transition from a developing pharmaceutical market to a regional leader in life sciences and pharmaceutical exports.

3.2.3 Patient Benefits

Improved Health Outcomes

High-quality generic drugs provide affordable treatment options that are 80 to 85% cheaper and[27] are comparable in efficacy to branded medications, making essential therapies more accessible to patients. This is particularly critical for managing chronic diseases, which are rising sharply in Vietnam and require long-term treatment adherence to improve patient outcomes.

Globally, the increased adoption of generics has doubled access to chronic disease treatments, leading to earlier interventions, better disease management, and improved prognosis. By lowering pharmaceutical costs, generics allow healthcare systems to invest more in patient care, medical services, and infrastructure, ultimately enhancing treatment effectiveness and overall public health. Expanding the use of generics in Vietnam can ensure more patients receive the medications they need, reducing disease complications and improving long-term health outcomes.

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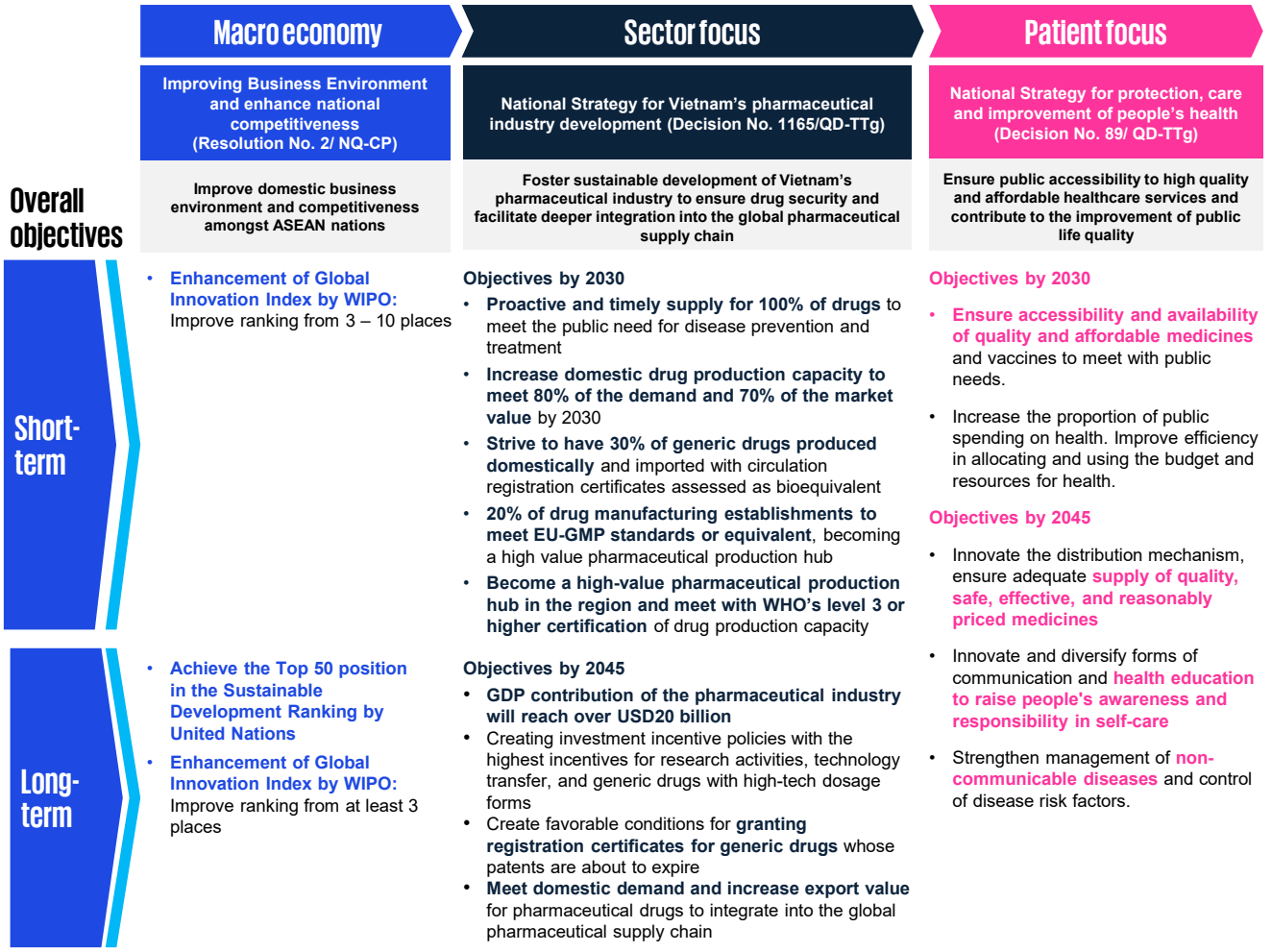
[25] Patheon (2024), Tech transfer, part 1: The critical role of tech transfer in pharma manufacturing, Available at Link

[26] Rachel Schwartz (2021), "Study Finds U.S. Generic and Biosimilar Savings Totaled A Record $338 Billion in 2020", Available at Link

[27] FDA (2021), "Generic Drugs: Questions & Answers", Available at Link

3.3 Map of Vietnam's generic drug value and sector development goals

Figure 3.2: Mapping of Vietnam's sector development goals



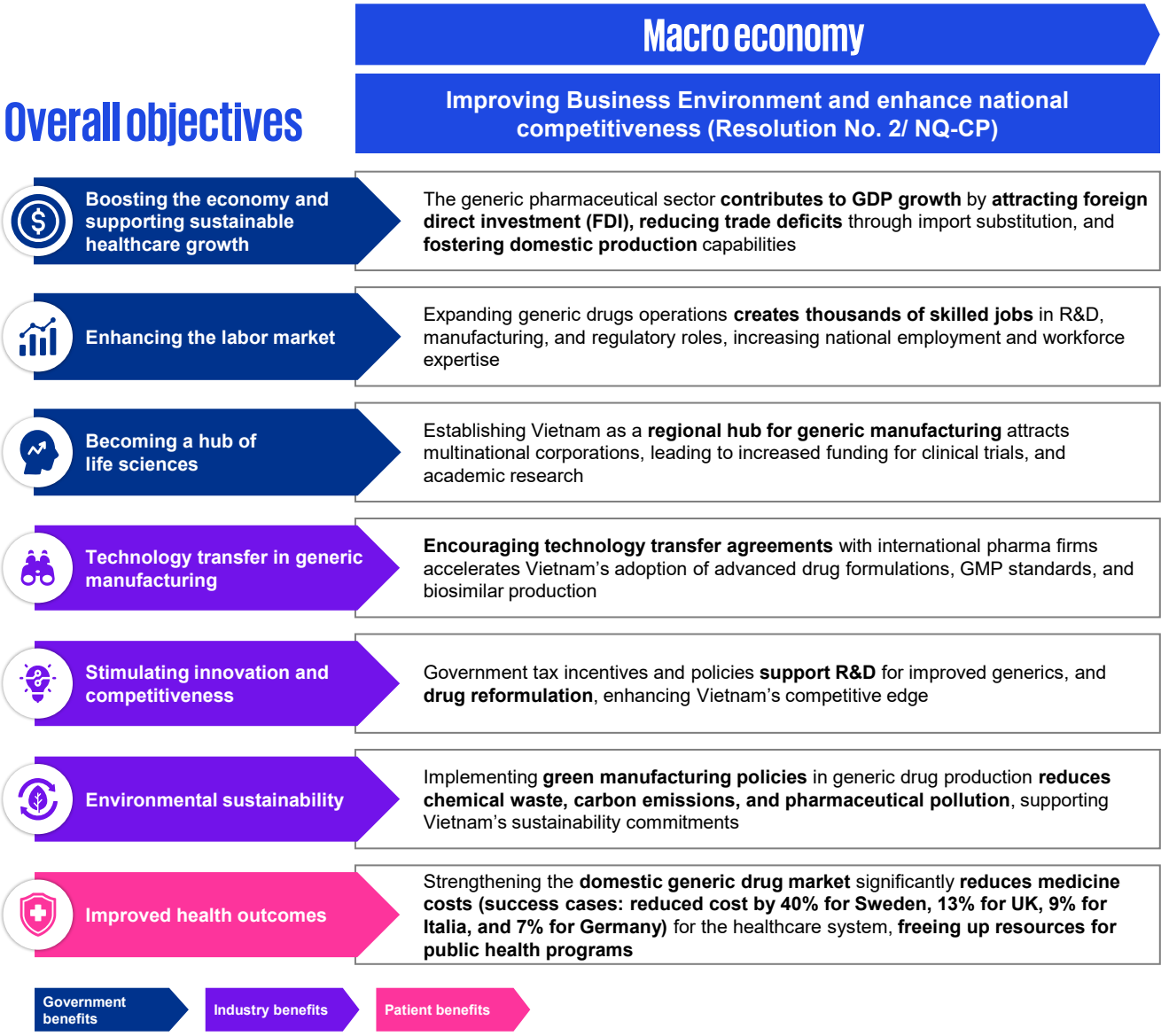
Source: KPMG Research & Analysis

Key objectives and generic drug market development alignment:

- **Ensuring the supply of drugs meets 100% of the public need for disease prevention and treatment:** EU generic drugs provide a high quality and cost-effective way to secure Vietnam's medicine supply.
- **Strive to have 30% of generic drugs produced domestically:** European generics manufacturers can form partnerships with domestic companies, boosting local production and creating avenues for technology transfer.
- **20% of drug manufacturing establishments to meet EU-GMP standards or equivalent, becoming a high value pharmaceutical production hub:** Partnerships with European pharmaceutical manufacturers can increase the adoption of EU-GMP standards, increasing Vietnam's reputation as a high-quality pharmaceutical production hub.
- **GDP contribution of the pharmaceutical industry will reach over USD 20 billion:** Generic drug manufacturing has the potential to contribute significantly to GDP growth and social development in Vietnam.
- **Increase production to meet domestic demand and increase export value:** Foreign investment in Vietnam's pharmaceutical sector can ensure the need for therapeutics is met as the chronic disease burden rises.
- **Encourage investment in developing bioequivalence testing in Vietnam. Increase the number of active ingredients requiring bioequivalence research reports:** EU-GMP manufacturing has stringent bioequivalence reporting. Most generic drugs registered in the EU must undergo bioequivalence testing. European manufacturers can help to build this capability within Vietnam.

By aligning with these national objectives, Vietnam's generic drug sector can attract international investment and position the country as a competitive force in generic drug manufacturing.

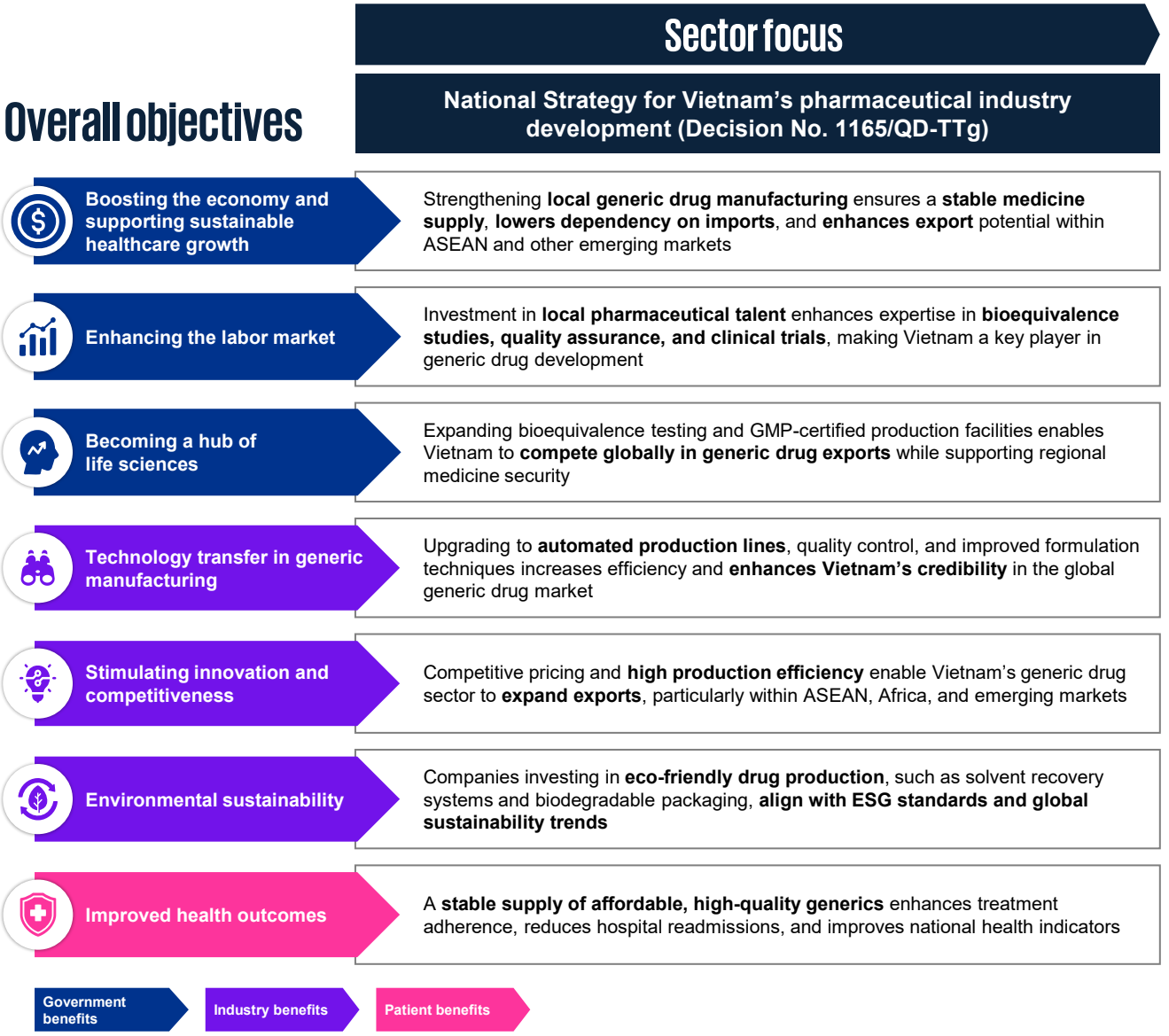
Figure 3.3: Mapping of Vietnam's sector development goals and generic drug social value creation (Macroeconomy)



Source: KPMG Research & Analysis

Vietnam's economy grew by 7.09% in 2024, creating a strong foundation for business and innovation. In January 2025, the government introduced Resolution No. 2/NQ-CP to enhance the business environment and improve global competitiveness, with a key goal of raising Vietnam's Global Innovation Index ranking by at least three places. Strengthening the investment climate will attract global collaboration in Vietnam's generic drug sector, facilitating technology transfer and boosting pharmaceutical manufacturing. A more productive industry will drive market expansion and contribute to sustained GDP growth.

Figure 3.4: Mapping of Vietnam's sector development goals and generic drug social value creation (Sector)



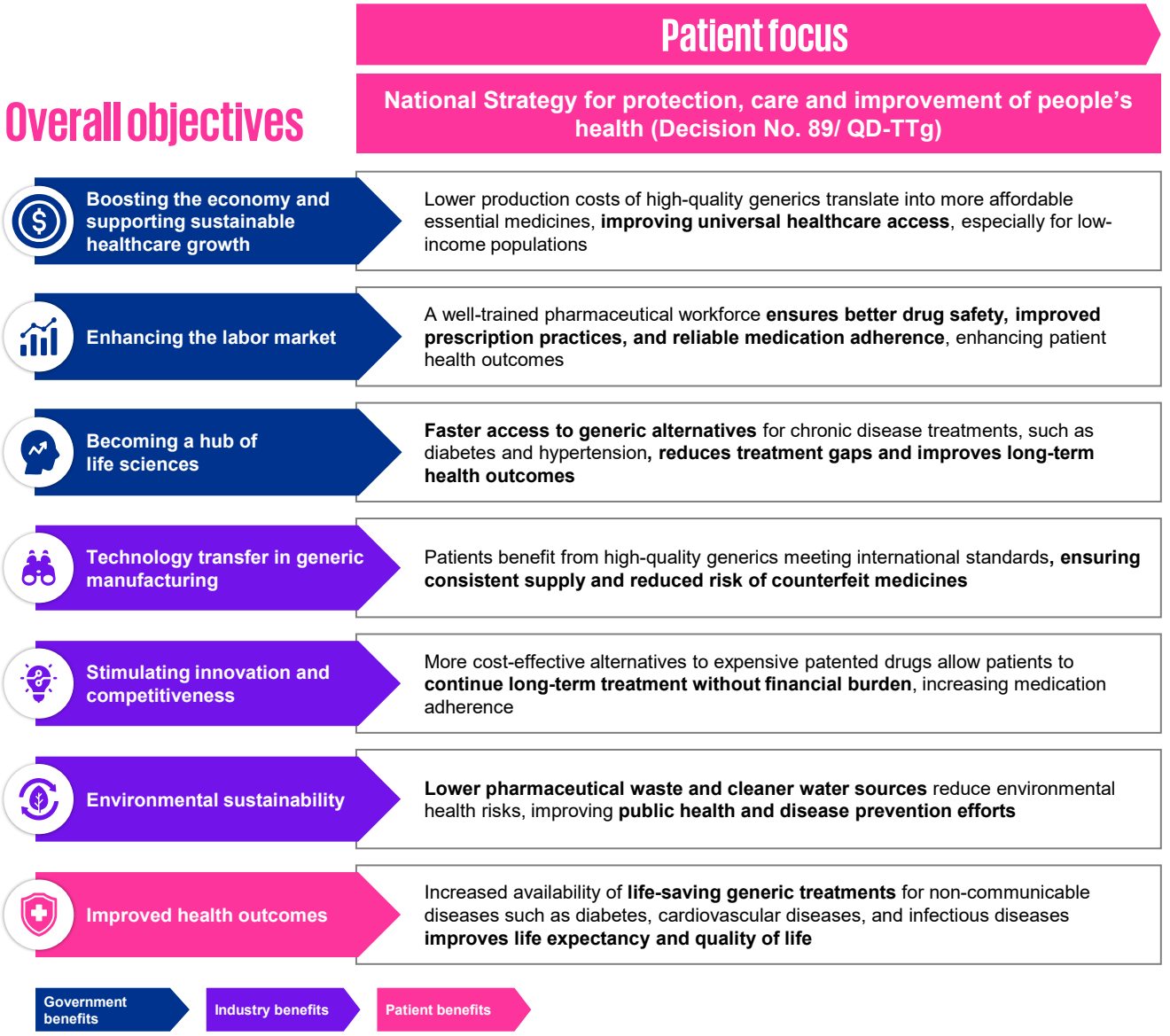
Source: KPMG Research & Analysis

Vietnam's **National Strategy for Developing the Pharmaceutical Industry through 2030**, with a vision for 2045, aims to elevate the sector to regional standards while ensuring affordable access to high-quality medicines. The strategy focuses on:

- **Establishing Vietnam as an ASEAN pharmaceutical hub** through production and technology transfer.
- **Strengthening domestic supply** to enhance self-sufficiency.
- **Increasing exports** and integrating Vietnamese pharmaceuticals into global value chains.

This initiative positions Vietnam as a key player in the regional and global pharmaceutical markets.

Figure 3.5: Mapping of Vietnam's sector development goals and generic drug social value creation (Patient)



Source: KPMG Research & Analysis

Vietnam's Strategy for the Protection, Care, and Improvement of People's Health includes a goal to enhance healthcare accessibility. This objective is closely aligned with the social benefits that come from expanding the generic drugs market in the country.

Key objectives and generic drug market development alignment:

- **Ensure accessibility of quality and affordable medicines:** Increasing the availability of quality generic medicines in Vietnam will allow the country to align with this goal, achieving better health outcomes.
- **Diversify forms of health education to raise people's awareness and responsibility in self-care:** Improved health education will empower patients to make their own healthcare decisions and enhance their understanding of the benefits generic medicines provide.
- **Strengthen management of non-communicable diseases:** Generic medicines are a critical aspect of managing Vietnam's increasing non-communicable disease burden in a cost-effective manner.

By aligning generic drug industry expansion with national health objectives, Vietnam can enhance access to quality medicines and attract global manufacturing partners. This can generate cost savings for patients and improve patient health outcomes.

3.4 Projected future economic contribution

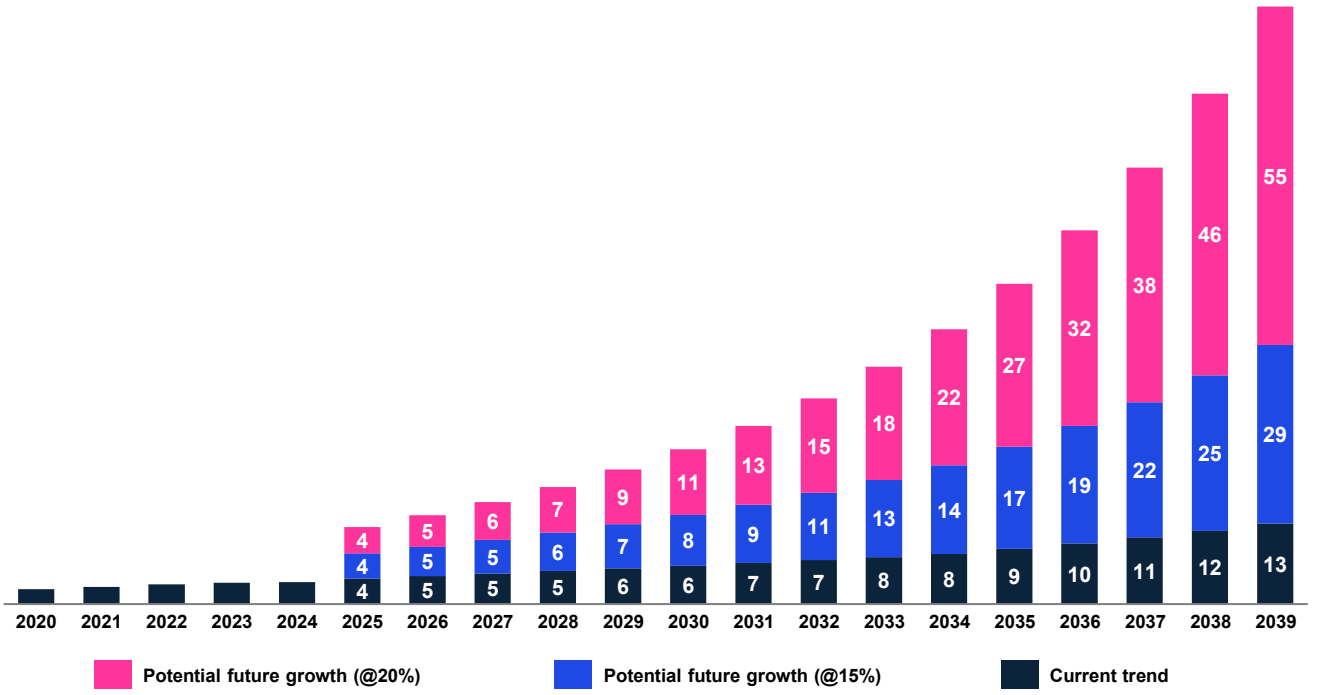
3.4.1 Macroeconomics

Economic Growth in the Pharmaceutical Sector: Vietnam's generic drug market can potentially grow to USD 55 billion by 2039

The production and distribution of generic medicines play a crucial role in driving economic growth by creating jobs across the entire supply chain, from research and manufacturing to distribution and retail. Since many generics are produced locally, they strengthen domestic industries, reduce reliance on imports, and enhance pharmaceutical self-sufficiency. Increased competition, particularly from small and mid-sized companies, fosters industry diversity, innovation, and efficiency, ensuring a more competitive and resilient pharmaceutical sector.

Beyond economic benefits, the affordability of generics improves medication accessibility, leading to better health outcomes and a more productive workforce. While the generic drug market is currently projected to reach USD 13.1 billion by 2039, streamlined regulations and investment incentives could significantly accelerate growth. With effective reforms, the industry has the potential to expand by 15%-20% annually, reaching between USD 29.0-55.0 billion by 2039, positioning Vietnam as a leading pharmaceutical hub in Southeast Asia.

Figure 3.6: Additional market value of generic drugs industry-future potential (USD billion)



Source: BMI Fitch Solutions

Note: 2020-2034 data from Fitch solution with the trend of approximately 10%.
Potential future growth is projected based on the growth rate of 15% and 20%.
Potential growth is assumed to start in 2025

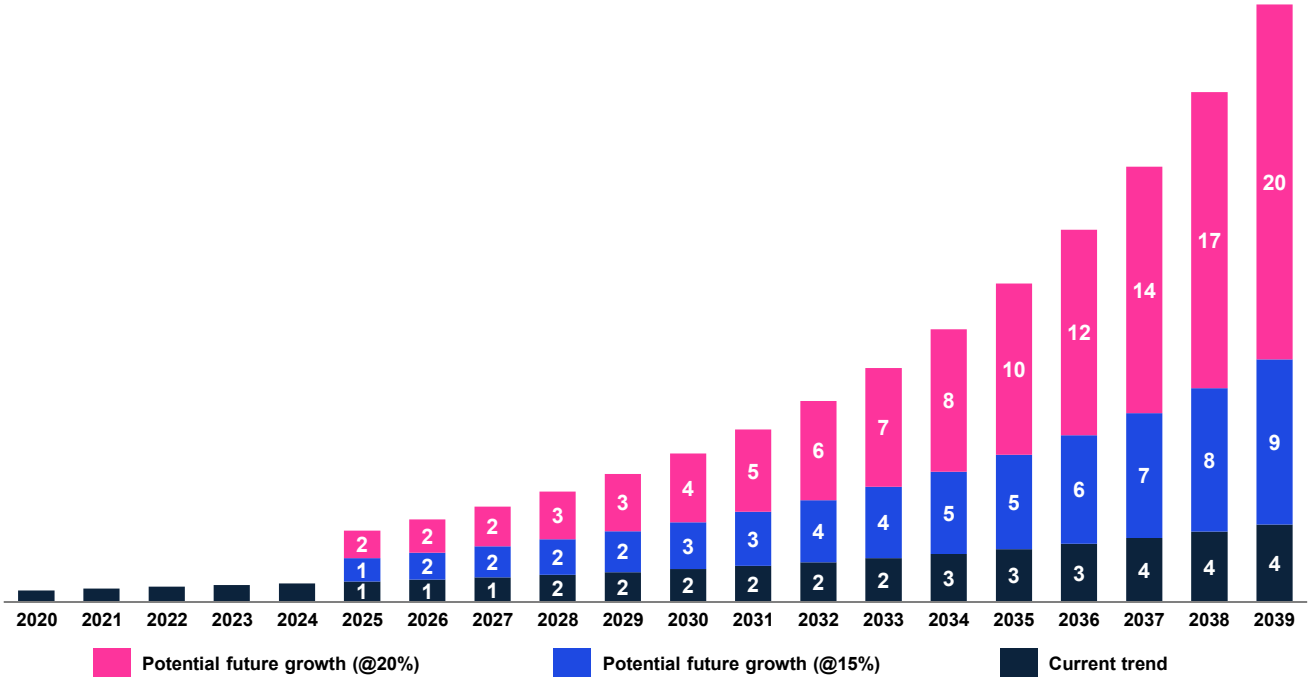
3.4.2 GDP contribution

Vietnam's generic drug industry could boost GDP to USD 20.1 billion with 20% growth

Vietnam's generic drug industry has the potential to be a major economic driver, significantly boosting GDP. Under current trends, it is expected to contribute USD 4.4 billion to GDP by 2039. With accelerated 15% annual growth, this could rise to USD 9.4 billion, and at 20% growth, the industry could reach USD 20.1 billion-a sevenfold increase over the baseline.

Beyond direct GDP contributions, higher growth would stimulate manufacturing, logistics, and healthcare services, amplifying the sector's broader economic impact. Unlocking this potential requires investment in domestic production, regulatory streamlining, and public awareness initiatives, positioning Vietnam as a key player in the global pharmaceutical market.

Figure 3.7: Additional direct GDP contribution from the generic drugs industry-future potential (USD billion)



Source: BMI Fitch Solutions, OECD

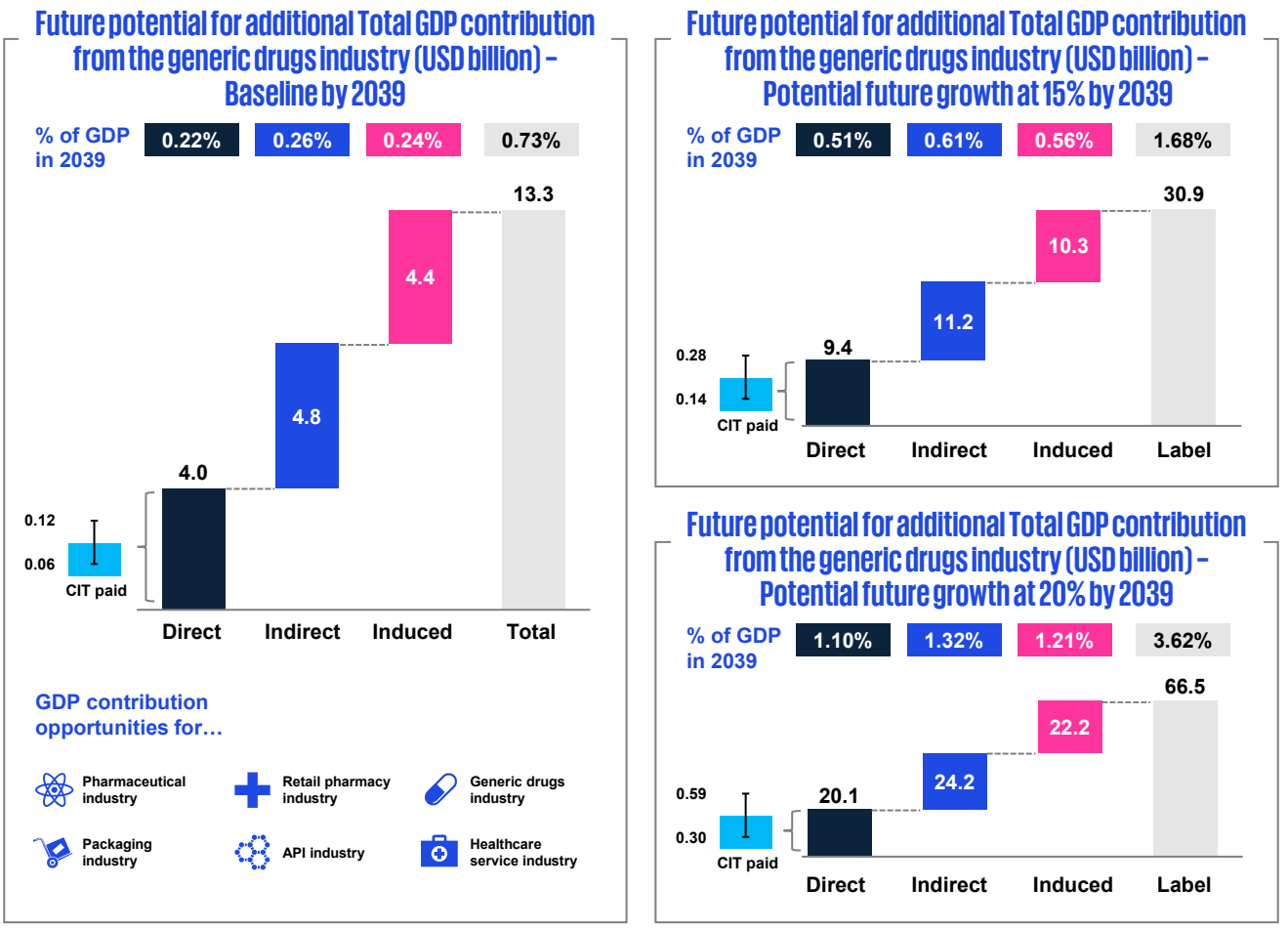
Note: GDP contribution is calculated based on the market value projection and economic multiplier derived from Input-Output table from OECD. Like the market value projection, 2020-2034 data from Fitch solution with the trend of approximately 10%. Potential future growth is projected based on the growth rate of 15% and 20%. Potential growth is assumed to start in 2025

Vietnam's generic drug industry could contribute up to USD 66.5 billion to GDP by 2039 under a 20% annual growth scenario. This includes:

- USD 20.1 billion in direct contributions from manufacturing, distribution, and sales, generating USD 0.30-0.59 billion in CIT paid.
- USD 24.2 billion in indirect contributions from supply chain activities like raw material sourcing, logistics, and support services.
- USD 22.2 billion in induced contributions, driven by increased consumer spending from sector-generated incomes.

Realizing this potential requires investment in production, regulatory improvements, and market development. These initiatives will not only drive economic growth but also position Vietnam as a global leader in high-quality pharmaceutical manufacturing.

Figure 3.8: Additional total GDP contribution from the generic drugs industry-future potential (USD billion)



Source: BMI Fitch Solutions, OECD

Note: GDP contribution is calculated based on the market value projection and economic multiplier derived from Input-Output table from OECD

The calculation of Corporate Income Tax (CIT) paid is derived from the Direct GDP contribution, with error margins reflecting variations in applicable tax rates (10%; 15%; 17% and 20%)

Even at a moderate 15% growth rate, the industry could contribute USD 30.9 billion to GDP by 2039, broken down as follows:

- USD 9.4 billion in direct contributions from manufacturing, distribution, and sales, generating USD 0.14-0.28 billion in CIT paid.
- USD 11.2 billion in indirect contributions from supply chain activities.
- USD 10.3 billion in induced benefits from increased consumer spending.

As noted by the OECD, these classifications reflect the multiplier effect, where direct activities lay the foundation, indirect contributions enhance value through interconnected industries, and induced effects drive broader economic growth. This underscores the strategic importance of Vietnam's generic drug industry in boosting economic resilience and societal well-being.

3.4.3 Employment & Productivity

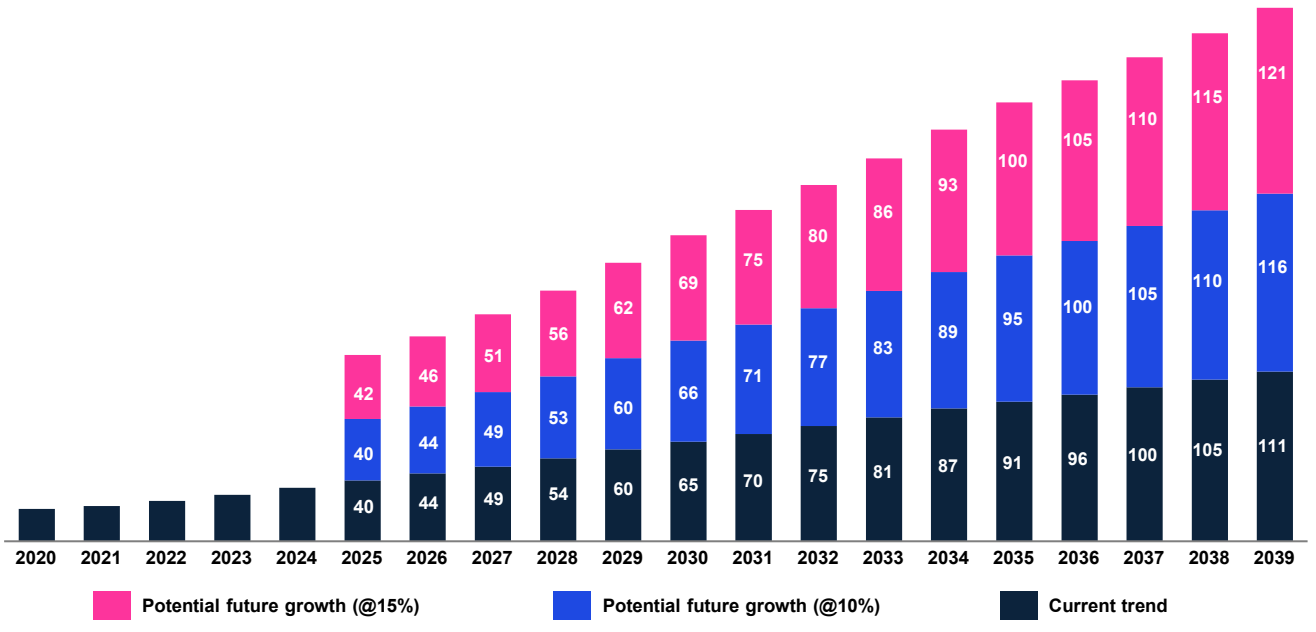
Vietnam's generic drugs industry could generate up to 0.95 million jobs annually by 2039 together with a growth in productivity

The generic drugs sector presents a major opportunity for job creation, with projections showing significant employment growth under different scenarios:

- 5% growth rate results by 2039:
  - 863,631 total jobs.
  - 110,722 direct jobs in manufacturing and sales.
  - 387,527 indirect jobs in supply chain industries.
  - 365,382 induced jobs from increased consumer spending.
- 10% growth rate:
  - 904,756 total jobs
  - 115,994 direct jobs
  - 405,980 indirect jobs in supply chain industries.
  - 382,782 induced jobs from increased consumer spending.
- 15% growth rate:
  - 945,882 total jobs created.
  - 121,267 direct jobs
  - 424,434 indirect jobs in logistics and raw materials.
  - 400,181 induced jobs from economic ripple effects.

These figures highlight the broad socioeconomic impact of the sector, reinforcing its role as a driver of employment and economic resilience. Achieving this potential requires strategic investments in infrastructure, workforce training, and supply chain efficiency. With the right policies, Vietnam's generic pharmaceutical industry could become a pillar of long-term economic growth and workforce expansion.

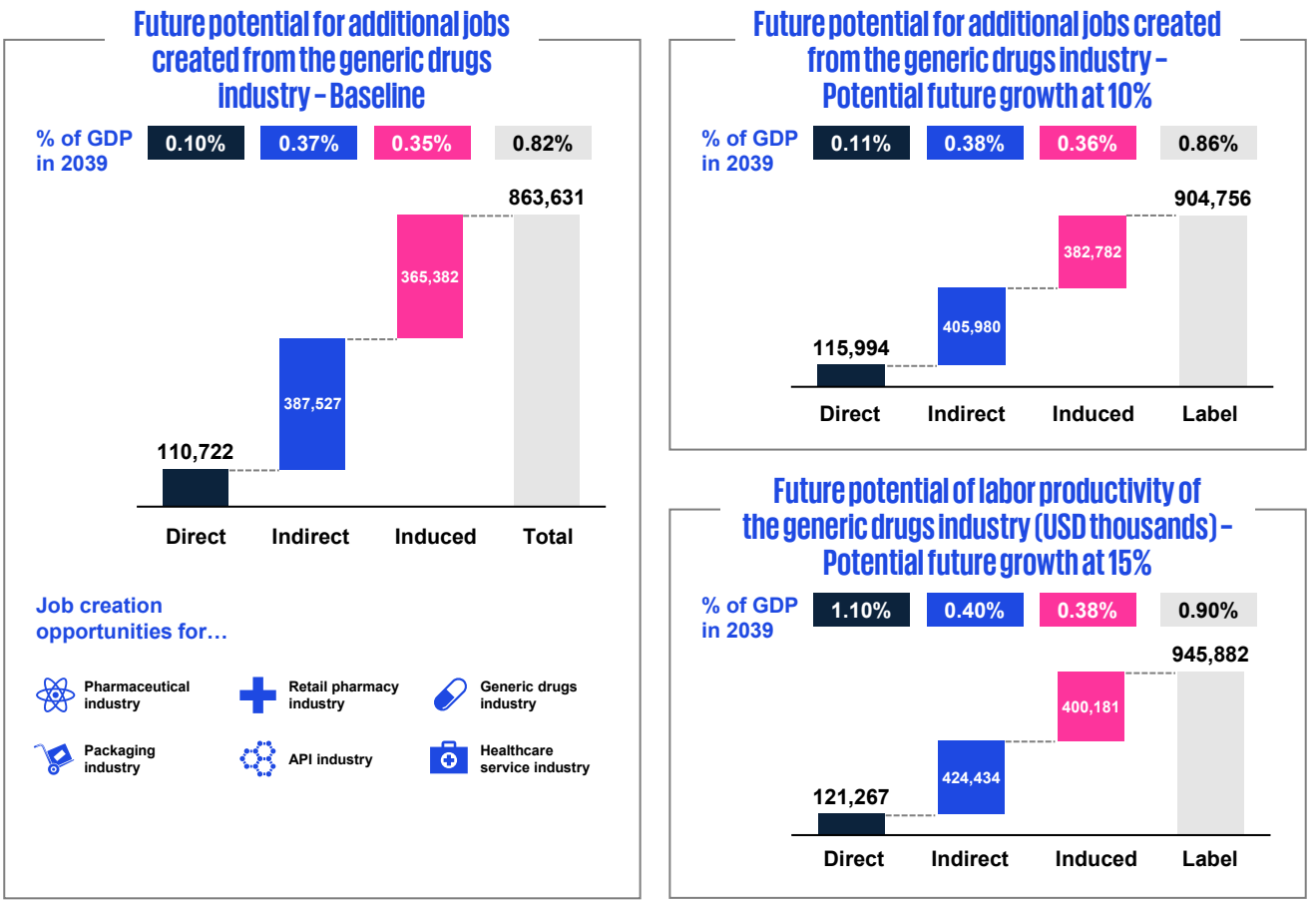
Figure 3.9: Additional jobs created directly from the generic drugs industry-future potential (thousands)



Source: BMI Fitch Solutions, OECD

Note: 2020-2034 data from Fitch solution with the trend of approximately 10%. Potential future growth is projected based on the growth rate of 5%, 10% and 15% from year 2034 to 2039. Potential growth is assumed to start in 2025

Figure 3.10: Additional total jobs created from the generic drugs industry-future potential (thousand)

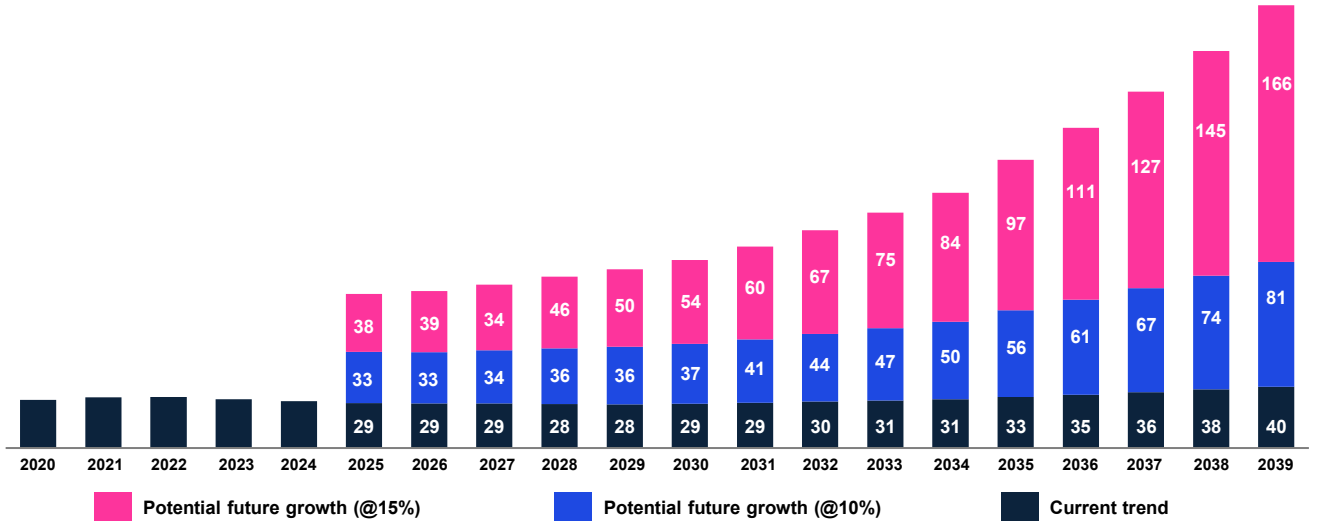


Source: BMI Fitch Solutions, OECD

Note: the total employment impact is calculated based on direct jobs created and employment multiplier

With proper incentives and policies in place, labor productivity of the generic pharmaceutical is estimated to reach between USD 80.7 thousand to USD 166.1 thousand per employee by 2039.

Figure 3.11: Additional labor productivity of the generic drugs industry-future potential (USD thousands)



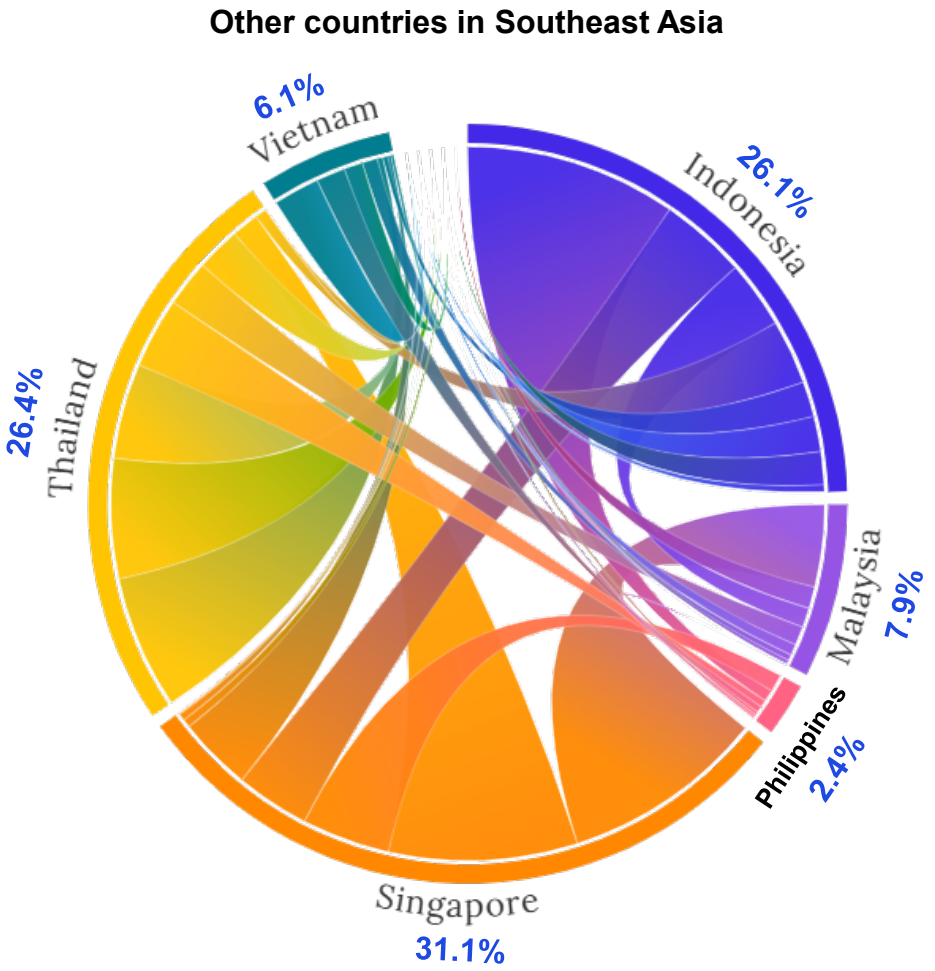
Note: Productivity is calculated as direct gross value added divided by number of employees.

Potential growth is assumed to start in 2025

3.4.4 Export potential

In addition, investments to improve the local generic drugs market will also help Vietnam to position itself as an emerging hub for generic drugs manufacturing

Figure 3.12: Share of export value for generic drugs between Southeast Asia countries in 2023



Source: TradeMap, KPMG Research and Analysis

In purple: Share of export value for generic drugs in Southeast Asia

Figure 3.13: Export value for generic drugs between Southeast Asia countries in 2023

		Export value to SEA markets in 2023 (USD mil)	CAGR '19 – '23
1	**Singapore**	206.24	3.03% ▲
2	**Thailand**	175.22	1.62% ▼
3	**Indonesia**	172.74	1.72% ▼
4	**Malaysia**	52.2	1.94% ▲
5	**Vietnam**	40.19	5.31% ▲
6	**Philippines**	16.01	8.21% ▲
Total		**662.61**	0.56% ▲

Source: TradeMap, KPMG Research and Analysis

Vietnam's export value of generic drugs to Southeast Asia reached USD 40.19 million in 2023, growing at a CAGR of 5.31% (2019-2023) and accounting for 6.1% of total exports in the region. This growth reflects Vietnam's increasing ability to meet international standards and tap into rising global demand for affordable pharmaceuticals.

Vietnam lags behind key competitors in the region:

- Singapore: 31.1% of Southeast Asia's generic drug export turnover.
- Thailand: 26.4%.
- Indonesia: 26.1%.

If all things remain equal and conditions remain unchanged, Southeast Asia's generic drug exports are expected to grow at 0.56% annually, reaching USD 685.91 million by 2029. With targeted policies to enhance manufacturing and streamline regulations, Vietnam could increase its market share to 10%, boosting export turnover to USD 68.6 million. This would reflect a strong 9.30% CAGR from 2024 to 2029, strengthening Vietnam's position in the regional pharmaceutical market.

Figure 3.14: Southeast Asian countries' generic drugs domestic performance and export performance from 2019 to 2029

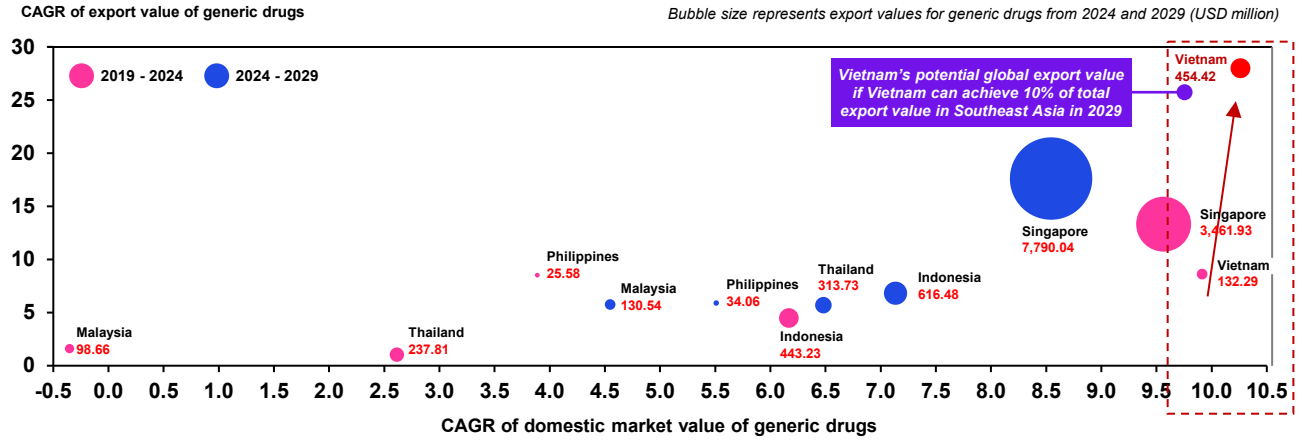


Figure 3.15: Forecasted export value of generic drugs from Vietnam to key export markets in 2029

Country	Forecasted export value in 2029	CAGR 2023-2029
Japan	$ 55,520,381	0.78%
Cyprus	$ 31,044,662	2.32%
Cambodia	$ 27,401,147	1.25%
Republic of Korea	$ 28,579,726	7.21%
Germany	$ 22,171,639	4.10%

Source: BMI Fitch Solutions, KPMG Research and Analysis

Vietnam's generic drugs market is on track to become one of the fastest-growing in the region, driven by strong domestic demand and rising exports. New policies aimed at streamlining registration and incentivizing local production are expected to push the domestic market to a 10.27% CAGR from 2024 to 2029. Additionally, the establishment of more EU-GMP-compliant manufacturing facilities will enhance Vietnam's ability to meet global demand for high-quality generics, helping Vietnam to achieve its national goal which is to become a hub for high-value pharmaceutical products in the region, as stated in Decision No. 1165/QD-TTg 2023[28]. By 2029, total export turnover is projected to reach USD 454.42 million, with a remarkable 28% CAGR. This positions Vietnam as a leading pharmaceutical manufacturing hub in Southeast Asia, improving the reciprocity in terms of trading of pharmaceutical products between Southeast Asian markets.

[28] Cited from Decision 1165/ QD-TTg 2023 on National Strategy for development of the pharmaceutical industry of Vietnam to 2030, with a vision to 2045

4. Recommendations

4.1 Overview

Figure 4.1: Strategy roadmap for Vietnam's generic drugs market

Strategy Roadmap for Vietnam's adopting high quality generic drugs will be divided into policy and non-policy recommendations

	Short-term (2025)	Medium-term (2026 - 2027)	Long-term (2028 - 2029)
Policy recommendations	• **Training program:** Partner with international experts to deliver training on compliance requirements. • **Capacity building:** Provide technical support to manufacturers to meet local standards. • **Financial support:** Provide subsidies or low-interest loans for manufacturers.	• **Digital transformation**: Implement an e-submission platform to streamline the registration process. • **Incentives for generics**: Introduce tax breaks and low-interest loans for generic drug manufacturers. • **Implement a reliance pathway**: Establish a regulatory mechanism where Vietnam can leverage approvals from stringent regulatory authority (e.g., EMA, FDA) to accelerate the approval of high-quality generic drugs. • **Capacity building:** Increase DAV staffing, enhance training programs, and allocate additional resources. • **Strengthen the regulatory framework:** Develop clear guidelines for manufacturers aligned with international standards. • **Stronger oversight:** Introduce stricter audits and inspections by regulatory bodies.	• **Inter-department coordination:** Establish centralized regulatory mechanisms to reduce duplicative documentation and bottlenecks. • **Support for raw material production:** Invest in local API (Active Pharmaceutical Ingredient) production to reduce dependency on imports. • **FDI attraction initiatives:** Organize international roadshows to attract foreign manufacturers targeting high-value market. • **Accreditation programs:** Implement a government-led certification program ensuring consistently high standards.
Non-policy recommendations	• **Released information on generic drugs:** Organizing workshops and publishing market reports on generic drugs will effectively raise awareness among stakeholders. • **Public awareness media campaigns:** These initiatives effectively enhance public understanding of the benefits of generic drugs, reaching a broader audience more quickly than solely relying on doctor-patient interactions during medical consultations.	• **Collaborate with Experts:** Partner with reputable healthcare organizations and industry professionals to promote the use of generic drugs and highlight their value to society.	• **Develop an Online Drug Evaluation Platform:** Enable users to review and share their experiences with generic medications, fostering informed decision-making and community engagement.

To fully realize its pharmaceutical sector's potential, Vietnam must adopt global best practices through a strategic mix of policy and non-policy initiatives. These recommendations, structured across short, medium, and long-term horizons, focus on enhancing regulatory efficiency, attracting investment, and ensuring quality compliance. Non-policy measures, such as trust-building, awareness campaigns, and industry collaboration, will further strengthen market confidence. By implementing these targeted strategies, Vietnam can boost its pharmaceutical capabilities, improve healthcare accessibility, and position itself as a leading player in the global generics market.

4.2 Policy recommendations

Figure 4.2: Strategy roadmap for Vietnam's generic drugs market

Areas	Solutions			Key involved stakeholders
	Short-term	Medium-term	Long-term	
Enhance the efficiency of administrative procedures		• **Digital transformation:** Implement an e-submission platform to streamline the registration process • **Implement a reliance pathway**: Establish a regulatory mechanism where Vietnam can leverage approvals from stringent regulatory authority (e.g., EMA, FDA) to accelerate the approval of high-quality generic drugs • **Capacity building:** Increase DAV staffing, enhance training programs, and allocate additional resources	• **Inter-department coordination:** Establish centralized regulatory mechanisms to reduce duplicative documentation and bottlenecks	• **Public sector:** Ministry of Health (MOH), Drug Administration of Vietnam (DAV) • **Private sector:** Technology solution providers for e-submission systems • International Regulatory Bodies (EMA, FDA, WHO)
Introduce incentives to drive the investments into the industry	• **Incentives for generics:** Introduce tax breaks and low-interest loans for generic drug manufacturers		• **Support for raw material production:** Invest in local API (Active Pharmaceutical Ingredient) production to reduce dependency on imports • **FDI attraction initiatives:** Organize international roadshows to attract foreign manufacturers targeting high-value market	• **Public sector:** Ministry of Health (MOH), Drug Administration of Vietnam (DAV) • **Private sector:** Foreign generic drug manufacturers, Local raw material suppliers and industry associations
Enhance the consistency and alleviate the cost of compliance with EU-GMP in Vietnam	• **Training program:** Partner with international experts to deliver training on compliance requirements • **Capacity building:** Provide technical support to manufacturers to meet local standards • **Financial support:** Provide subsidies or low-interest loans for manufacturers	• **Strengthen the regulatory framework:** Develop clear guidelines for manufacturers aligned with international standards • **Enhancing Compliance:** Introduce stricter audits and inspections by regulatory bodies • **Infrastructure investment:** Develop shared testing and manufacturing facilities certified to EU-GMP standards	• **Accreditation programs:** Implement a government-led certification program ensuring consistently high standards	• **Public sector:** Ministry of Health (MOH), Drug Administration of Vietnam (DAV) • **Private sector:** WHO, EU regulatory bodies, and technical consultants

4.2.1 Enhance the efficiency of administrative procedures

Vietnam's regulatory framework for generic drugs is intricate, with administrative procedures that can extend the market entry timeline. Enhancing regulatory efficiency through a more streamlined approach could help facilitate timely approvals while upholding stringent safety and quality.

Proposed solutions:

Digital transformation of regulatory processes

- Establish a centralized e-submission platform where pharmaceutical companies can submit, track, and manage their applications digitally. This will eliminate paperwork, reduce manual errors, and improve processing speed.
- Implement automated workflow tracking that provides real-time updates to applicants and regulatory authorities, ensuring greater transparency and reducing bottlenecks in approval processes.
- Integrate the platform with other national healthcare databases, such as drug safety monitoring systems and hospital procurement networks, to create a seamless regulatory ecosystem.

Reliance pathway for drug approval

- Introduce a tiered approval system where drugs already approved by stringent regulatory agencies (e.g., FDA, EMA, PMDA) can undergo an expedited review process in Vietnam.
- Create a mutual recognition agreement (MRA) with ASEAN and other international regulators, allowing Vietnam to benefit from joint regulatory assessments.
- Develop a conditional approval framework, where companies can launch their products while submitting post-market surveillance data, reducing the time to market for essential medicines.
- **Global example:**
  - Australia's Comparable Overseas Regulator (COR) pathway means that drugs registered in trusted countries including the USA, Canada, Japan, and EU members are entitled to fast-track approval in Australia.
  - Australia introduced a tiered approval system where drugs already approved by stringent regulatory agencies (e.g., FDA, EMA, Health Canada, HSA) can undergo an expedited review process across Access Consortium member countries. The consortium, comprising Australia, Canada, Singapore, Switzerland, and the United Kingdom, leverages assessments from these trusted regulators to streamline approvals, reducing duplication and accelerating access to medicines.

Capacity building and regulatory workforce expansion

- Expand the staffing capacity at the Drug Administration of Vietnam (DAV) to address delays caused by limited human resources. This includes hiring specialized reviewers with expertise in bioequivalence, pharmacovigilance, and GMP compliance.
- Launch regulatory training programs in partnership with the WHO, EMA, and other global bodies to upskill Vietnam's regulatory professionals.
- Establish a joint regulatory advisory board with experts from leading pharmaceutical markets to provide guidance on complex approvals and policy modernization.
- **Global example:** New Zealand's Medsafe invests in continuous professional development for its staff, ensuring up-to-date knowledge in regulatory affairs.

Inter-department coordination

- Establish centralized regulatory mechanisms to reduce duplicative documentation and administrative bottlenecks.
- Implement cross-agency collaboration by integrating workflows between the Ministry of Health (MOH), Drug Administration of Vietnam (DAV), and other relevant government agencies.
- Create a national regulatory committee composed of representatives from multiple departments to oversee pharmaceutical approvals, ensuring alignment and streamlining decision-making processes.
- Develop an integrated digital communication system that allows real-time data sharing and coordination between agencies to improve efficiency.
- **Global example**: The European Medicines Agency (EMA) coordinates with national agencies across the EU to streamline regulatory processes and eliminate redundancies.

Strengthen Procurement Transparency

- Establish a publicly accessible registry of pre-qualified generic drug suppliers that meet stringent quality, pricing, and ethical standards (e.g., no history of collusion). Update it quarterly and bar non-listed firms from bidding.
- Publish anonymized data on winning bids for generic drug tenders (e.g., price per unit, supplier) to prevent collusion.
- **Global example:**
  - India's Central Medical Services Society (CMSS) maintains a pre-qualified list of generic suppliers for national tenders, with disqualification for firms violating pricing norms.
  - Germany's 'GKV-Spitzenverband' public database publishes anonymized drug procurement prices for hospitals, fostering competition. A dedicated whistleblower portal also enables reporting of price manipulation.

Key stakeholders:

- Ministry of Health (MOH): Oversees regulatory reforms and ensures alignment with national health priorities.
- Drug Administration of Vietnam (DAV): Implements the new digital and reliance pathways, ensuring efficient execution.
- Technology Solution Providers: Develop and maintain digital submission platforms.
- International Regulatory Bodies (EMA, FDA, WHO): Provide technical support for reliance mechanisms and capacity-building programs.

By improving administrative efficiency through digital transformation, regulatory reliance, and enhanced coordination, Vietnam's pharmaceutical sector can achieve faster drug approvals, reduce regulatory backlog, and enhance the overall competitiveness of the industry.

4.2.2 Introducing Incentives to Drive Investments into the Industry

Vietnam's generic drug industry needs targeted incentives to attract both local and foreign investments. Strengthening domestic manufacturing capabilities will reduce dependence on imports and increase the affordability of medicines.

Proposed solutions:

Financial incentives for generic manufacturers

- A structured system should categorize manufacturers by quality levels, prioritizing higher-quality gerenic drugs manufacturers with greater support.
- Introduce corporate tax reductions and accelerated depreciation benefits for pharmaceutical companies investing in Vietnam's generic drug sector.
- Provide low-interest loans and grants to companies setting up production facilities, particularly in high-priority therapeutic areas such as cardiovascular, oncology, and antibiotics.
- Develop a public-private investment fund to co-finance infrastructure development for pharmaceutical clusters.
- **Global example:** Malaysia has implemented tax incentives to attract pharmaceutical manufacturers. Qualifying companies can benefit from tax rates between 0% to 10% for the first 10 years and 10% for the subsequent 10 years, encouraging investment in the generic drug sector.

Support for local active pharmaceutical ingredient (API) production

- Establish subsidies for API manufacturers to encourage the domestic production of essential raw materials, reducing reliance on imports.
- Create tax exemptions on API manufacturing equipment and raw material imports to lower production costs.
- Build dedicated API industrial zones with government-backed infrastructure, like India's API Parks, while strictly aligning with Vietnam's Green Growth Strategy (Decision No. 1658/QD-TTg)[29], Environmental Protection Law (Law No. 72/2020/QH14)[30], and EU sustainability policies to ensure low carbon emissions, sustainable waste management, and eco-friendly production.
- **Global example:**
  - Biocon Ltd., an Indian biopharmaceutical company, established a state-of-the-art integrated insulin manufacturing facility in Malaysia's BioXcell biotechnology park. This investment, exceeding USD 350 million, underscores Malaysia's commitment to supporting local API production and reducing dependence on imports.[31]
  - Poland amended its reimbursement policy to reduce patient co-payments by 10–15% for medicines manufactured domestically and/or using locally produced active pharmaceutical ingredients (APIs). The cost of these reductions is covered by the state budget, effectively incentivizing local production across the pharmaceutical supply chain.

Foreign direct investment (FDI) attraction initiatives

- Launch investment promotion campaigns targeting leading global generic manufacturers to set up production bases in Vietnam.
- Offer land lease incentives and infrastructure support for foreign pharmaceutical companies building manufacturing plants.
- Develop fast-track business licensing for pharmaceutical investors to reduce bureaucratic hurdles.
- **Global example:** Singapore has successfully attracted foreign pharmaceutical investments by providing robust infrastructure, research and development support, and training programs for biomedical sciences personnel. These initiatives have positioned Singapore as a competitive hub for pharmaceutical companies.[32]

Key stakeholders:

- Ministry of Health (MOH): Develops policies to attract investment in the pharmaceutical sector.
- Drug Administration of Vietnam (DAV): Facilitates regulatory approvals for new investments.
- Foreign Generic Drug Manufacturers: Invest in local production and contribute technical expertise.
- Local Raw Material Suppliers: Provide necessary inputs for pharmaceutical manufacturing.

Providing targeted incentives and fostering API production will enhance local manufacturing capabilities, reduce reliance on imports, and attract global investments, positioning Vietnam as a key player in the regional pharmaceutical market.

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[29] Government News, "National Green Growth Strategy for 2021-2030, vision towards 2050", Available in Link

[30] Thuvienphapluat, "Law on Environmental protection", Available in Link

[31] Biocon Malaysia, "BIOCON SDN BHD, MALAYSIA-MAKING A DIFFERENCE IN MALAYSIA AND BEYOND", Available at Link

[32] Hank Lim & Lim Tai Wei, "A Case Study of the Pharmaceutical Industry in Singapore", Available in Link

4.2.3 Enhancing the Consistency and Alleviating the Cost of Compliance with EU-GMP in Vietnam

Compliance with EU-GMP standards is crucial for Vietnam's pharmaceutical industry to access global markets and ensure high-quality production. The cost and complexity of achieving certification remain as barriers for many local manufacturers.

Proposed solutions:

Training programs for compliance

- Establish government-subsidized GMP training centers in collaboration with European regulatory agencies.
- Provide workshops and technical assistance for manufacturers to enhance their understanding of EU-GMP requirements, helping regulators and industry stakeholders distinguish between original drugs and generic alternatives, as well as between high-quality and low-quality generics.
- Implement a certification program for pharmaceutical professionals to create a pool of trained compliance specialists.
- **Global example:** The Centre for Biopharmaceutical Excellence (CBE) in Australia offers GMP Uplift Programs that provide participants with practical and experiential learning experiences. These programs are designed to help manufacturers understand and implement GMP requirements effectively.

Capacity building: providing technical support to manufacturers

- Offer on-site technical assistance programs to help local manufacturers meet GMP requirements.
- Develop guidance toolkits and templates to assist companies in preparing for EU-GMP certification.
- Establish mentorship programs where experienced manufacturers or regulatory experts support smaller firms in compliance efforts.
- **Global example:** In Singapore, firms like PharmOut offer consultancy services to assist manufacturers in achieving GMP compliance. These services include gap audits, remediation plans, and preparation for regulatory audits by authorities such as the HSA.

Financial support

- Introduce subsidized loans and grants to help manufacturers upgrade facilities to EU-GMP standards.
- Offer tax credits for capital expenditures related to GMP compliance.
- Establish a government reimbursement scheme for certification costs.
- **Global example:** The European Bank for Reconstruction and Development (EBRD) extended a financial package worth EUR146 million to Poland's leading pharmaceutical group, Polpharma. This loan supports the expansion of Polpharma's production facilities and underscores the role of financial assistance in achieving compliance and enhancing manufacturing capabilities.[33]

Infrastructure investment: developing shared testing and manufacturing facilities

- Establish government-backed shared facilities certified to EU-GMP standards, enabling small and medium-sized enterprises (SMEs) to access high-quality production and testing infrastructure.
- Develop public-private partnerships (PPPs) to co-finance GMP-certified contract manufacturing organizations (CMOs) that can serve multiple pharmaceutical firms.
- Create regional pharmaceutical hubs with centralized EU-GMP-compliant testing labs to ensure cost-effective quality control.
- **Global example:** Malaysia and Singapore have agreed to establish a special economic zone (SEZ) in Malaysia's Johor state, aiming to attract global investments and facilitate cross-border trade. This SEZ is set to offer tax incentives and develop key sectors, including pharmaceuticals, providing shared infrastructure and facilities to support industry growth.[34]

Strengthening the regulatory framework

- Develop clear, standardized guidelines aligned with EU-GMP to provide regulatory certainty.
- Introduce a structured roadmap for companies to transition toward EU-GMP compliance with defined milestones and government support.
- **Global example:** New Zealand has been reviewing its regulatory framework for therapeutic products, aiming to replace outdated legislation with more comprehensive regulations. The proposed Therapeutic Products Bill seeks to regulate the manufacture, testing, importation, and supply of medicines and medical devices, ensuring they meet high-quality standards.[35]

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[33] Nigina Mirbabaeva (2024), "EBRD supports development of Poland's pharmaceutical sector", Available at Link

[34] APNews (2025), "Malaysia and Singapore agree to launch a special economic zone in a rare move to attract investors", Available at Link

[35] PharmaLex (2023), "Progress on the New Zealand Therapeutic Products Bill", Available at Link

Enhancing compliance to ensure High-quality Manufacturing Standards

- Establish joint regulatory inspections with EMA and WHO representatives to align Vietnam's oversight with international best practices.
- Increase audit and inspection frequency to ensure ongoing compliance.
- Tie Incentives to Compliance: Tax breaks, subsidies and fast-track approvals incentivize drugmakers to invest in quality and innovation while keeping prices competitive.
- Compliance Rating System: Prioritizes inspections by risk, focusing on high-risk ones to optimize resources and ensure quality.
- Post-market testing: Ensures ongoing safety, efficacy, and quality of pharmaceuticals after approval-The EMA and NCAs oversee drug safety and quality in the EU under Directive 2001/83/EC and Regulation (EC) No 726/2004, ensuring strict quality control throughout a drug's lifecycle
- Require manufacturers who no longer maintain after achieving EU-GMP standards to submit and implement detailed corrective action plans within a set timeframe.
- **Global example:**
  - Australia's TGA rates drug manufacturers (A1-Good to A3-Basic) based on risk, auditing high-risk ones more and compliant ones less to ensure quality and safety[36]. By implementing this, the system improved compliance, reduced recalls by 22%, cut regulatory costs by up to 20%, and boosted consumer trust in top-rated firms.
  - China incentivizes quality drug manufacturing with fast-track approvals, tax breaks, subsidies, and large contracts via Volume-Based Procurement for meeting global standards. Manufacturers invested in WHO-GMP facilities to qualify for incentives, raising compliance rates by 35% in 3 years.

Accreditation and certification programs

- Implement a government-led certification program ensuring consistently high manufacturing standards.
- Facilitate mutual recognition of Vietnam's certifications with international regulatory agencies to ease export barriers. WHO representatives to align Vietnam's oversight with international best practices.
- Propose a project aimed at differentiating the quality of patented drugs from generic drugs while also establishing clear criteria to identify high-quality generic drugs versus lower-quality alternatives.
- **Global example:**
  - Malaysia's National Pharmaceutical Regulatory Agency (NPRA) has adopted the Pharmaceutical Inspection Co-operation Scheme (PIC/S) framework, ensuring that its Good Manufacturing Practices (GMP) align with EU standards. The NPRA enforces stringent compliance through regular audits and risk-based inspections of local and foreign pharmaceutical manufacturers. Additionally, Malaysia participates in WHO-led regulatory harmonization initiatives, fostering global alignment and ensuring that its accreditation and certification processes meet international standards.
  - The Drug Effectiveness Review Project (DERP) is a collaborative initiative among U.S. Medicaid programs, managed by the Center for Evidence-based Policy at Oregon Health & Science University. It provides objective assessments of drug efficacy and safety. DERP aids in distinguishing patented drugs from generics by comparing their effectiveness and helps classify high-quality and low-quality generics based on quality data. This initiative has supported states in improving drug management and reducing Medicaid costs.

Key stakeholders:

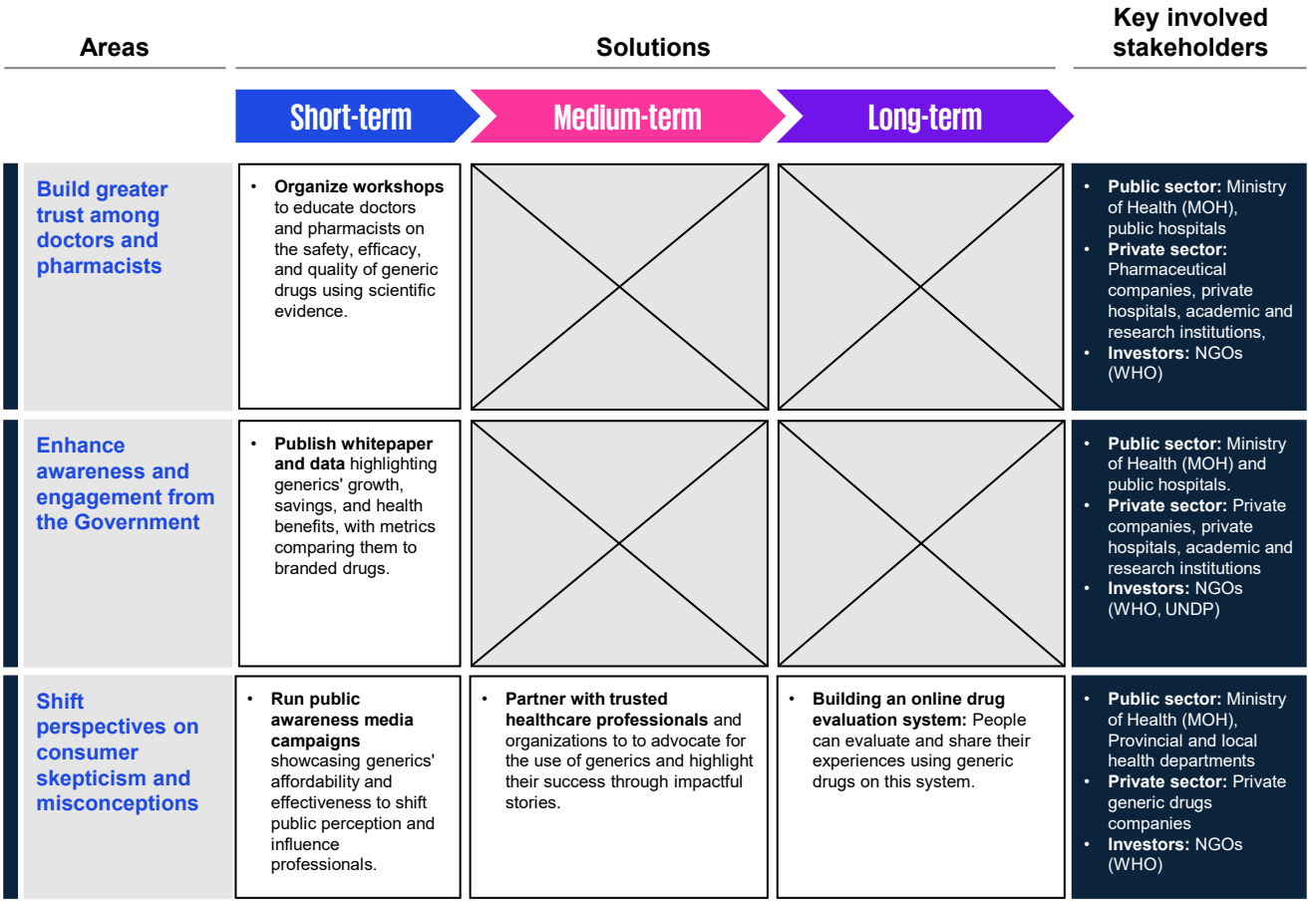
- Ministry of Health (MOH): Develops regulatory policies and oversees compliance initiatives.
- Drug Administration of Vietnam (DAV): Conducts inspections and ensures enforcement of EU-GMP standards.
- WHO and EU Regulatory Bodies: Provide technical support and certification guidelines.
- Technical Consultants: Assist manufacturers in upgrading their facilities to meet international standards.
- Public-Private Partnerships (PPPs): Fund and manage shared GMP-compliant manufacturing and testing facilities.

By strengthening regulatory frameworks, providing financial and technical support, and establishing accreditation programs, Vietnam will enhance pharmaceutical manufacturing standards, facilitating greater access to international markets and ensuring a sustainable, high-quality supply of medicines.

[36] Therapeutic Goods Administration (2022), Manufacturer GMP compliance history, Available at Link

4.3 Non-Policy recommendations

Figure 4.3: Non-policy recommendations mapped by areas and timeframe



4.3.1 Build greater trust among doctors and pharmacists

Vietnam faces a lack of awareness among doctors and pharmacists regarding the quality and effectiveness of generic drugs in treatment.

Proposed solutions:

Organizing Educational Workshops for Doctors and Pharmacists on Generic Drugs

- Acts as a platform to educate healthcare professionals on the benefits, quality, and efficacy of generic drugs.
- Provides targeted training on bioequivalence, cost-effectiveness, and regulatory standards for generics, aligned with Vietnam's pharmaceutical policies.
- Establishes clear guidelines and structured training programs to enhance knowledge transfer and technical expertise while ensuring a balanced focus on market development rather than solely on product classification.
- Offers practical sessions, including case studies and prescribing scenarios, to build confidence in generic drug use.
- Promotes strategies to integrate generics into clinical practice and public health programs, driving affordability and accessibility.
- **Global examples:**
  - Malaysia (2022) implemented the Generic Medicines Awareness Programme (GMAP) to address low awareness and enhance acceptance and confidence in generic drugs among doctors and pharmacists.

Key Stakeholders:

- Ministry of Health (MOH), public hospitals to support policy development.
- Pharmaceutical companies, private hospitals, academic and research institutions: to fund and co-offer the training.
- NGOs (WHO): to provide expertise and global best practices.

By enhancing trust through understanding stringent quality controls and fostering dialogue among stakeholders, healthcare professionals can confidently recommend generics. Involving respected industry leaders or global experts further boosts credibility.

4.3.2 Enhance awareness and engagement from the Government

Currently, Vietnam lacks an official whitepaper for this sector, making such reports crucial in demonstrating the significant cost advantages of generics over branded drugs and their role in improving healthcare accessibility. By using clear metrics to compare the effects of generics versus branded drugs on Vietnam's healthcare system, these reports can convince policymakers and investors of the long-term benefits of supporting generics.

Proposed solutions:

Conduct and publish a whitepaper on the generic drug sector to enhance awareness and engagement from the government

- Collaborate with major NGOs to produce a complete and detailed report
- The whitepeper acts as a comprehensive resource to showcase the economic, health, and policy benefits of generic drugs in Vietnam.
- Provides detailed analyses of cost savings, market potential, and public health impacts, supported by data comparing generics, high-quality generics and branded drugs.
- Offers evidence-based recommendations for policy reforms, procurement strategies, and incentives to boost generic adoption.
- Facilitates engagement by presenting actionable insights to government stakeholders, encouraging investment and regulatory support for the sector.
- Promotes collaboration with industry experts, healthcare providers, and global organizations to enhance credibility and drive national strategies.
- **Global example:**
  - Canada's CADTH Generic Drug Report (2010) provided data on savings (up to CAD 1 billion annually), influencing government policies to prioritize generics in public drug plans
  - The annual U.S. Generic & Biosimilar Medicines Savings Report enhances the government's understanding of the cost-saving value of these medications, thereby enabling the formulation of policies aligned with national strategies.

Key Stakeholders:

- The Ministry of Health (MOH) and public hospitals: Approve supportive policies, oversee the process, and invest in the development of the whitepaper.
- Private companies, private hospitals, and academic and research institutions: Contribute data and ensure the accuracy of information on Vietnam's generic drug industry.
- NGOs (WHO, UNDP): Assist in content development, ensuring quality and the most up-to-date information for the whitepaper.

This data-driven approach would foster interest and drive policy changes that make generics more accessible, affordable, and widely used in Vietnam. Partnering with global health organizations and publishing market reports will boost the credibility and accessibility of Vietnam's generic drug market, driving international interest and policy support for broader adoption.

4.3.3 Shift perspectives on consumer skepticism and misconceptions

Vietnamese consumers continue to hold reservations about generic drugs, making it essential to address and shift these perceptions to support the growth of the generic pharmaceutical industry in Vietnam.

Proposed solutions:

Run public awareness media campaigns showcasing generics' affordability and effectiveness to shift public perception and influence professionals

- Delivers engaging content, including ads, social media narratives, and personal success stories, that showcases the practical advantages and reliable quality of generic drugs.
- Supplies clear, approachable messaging via television, radio, and online platforms, crafted to transform patient attitudes and gain support from healthcare professionals for generics.
- Enhances patient involvement by clearing up misunderstandings, fostering confidence, and encouraging meaningful conversations between patients and providers about choosing generics.
- Encourages partnerships with media organizations, influencers, and medical authorities to broaden impact and trustworthiness, promoting a societal embrace of generics.
- **Global Examples:**
  - Canada's "Generics: Same Medicine, Lower Cost" Campaign (2010s), led by Health Canada, used TV and online ads to promote generics.
  - South Africa's Generic Awareness Campaign (2000s), supported by the Department of Health, leveraged radio and community media to highlight affordability, boosting generic use from 30% to over 50% within a decade.

Partnering with respected healthcare professionals and organizations is essential to advocate for generics

- Acts as a collaborative network to promote the benefits, safety, and accessibility of generic drugs to patients and the broader healthcare community.
- Provides credible advocacy through expert-led campaigns, educational materials, and testimonials highlighting the efficacy and affordability of generics.
- Offers resources, such as patient workshops, online webinars, and informational guides, delivered by trusted professionals to build patient confidence and understanding.
- Facilitates patient engagement by leveraging the authority of healthcare leaders to dispel myths, address concerns, and encourage informed adoption of generics.
- Promotes partnerships with medical associations, hospitals, and international health bodies to amplify reach and ensure consistent, evidence-based messaging.
- **Global Examples:**
  - U.S. Campaign by the American Medical Association (AMA, 2015) partnered with physicians to promote generic prescribing, contributing to a 90% generic prescription rate by educating patients on cost and quality benefits.
  - India's Jan Aushadhi Scheme (2015-present) collaborated with doctors and the Indian Medical Association to advocate for generics, increasing patient trust and expanding affordable access through dedicated pharmacies.

Building a comprehensive online drug evaluation system

- Serves as a user-friendly digital platform that informs patients about the safety, effectiveness, and cost benefits of generic drugs, enabling them to access and contribute reviews based on their experiences with generics.
- Provides interactive features, including drug search options, frequently asked questions, and online pharmacist consultations, to support patients in making informed medication choices.
- Enhances patient involvement by offering clear information on the availability and advantages of generic drugs, fostering trust and encouraging their thoughtful adoption.
- Encourages partnerships with healthcare professionals and regulatory bodies to maintain the accuracy and applicability of information, strengthening patient trust in generic options.
- **Global examples:**
  - U.S. FDA's Drugs@FDA Portal offers patients a clear database of approved generics, boosting awareness and contributing to a 90% generic prescription rate by 2018 through informed choice.
  - UK's NHS Medicines A-Z Online Tool provides easy-to-understand drug information, increasing patient trust in generics and supporting an 80%+ generic adoption rate in primary care

Key Stakeholders:

- Ministry of Health (MOH), Provincial, and Local Health Departments: Responsible for investing in the development of the portal and formulating supportive policies.
- Private Generic Drug Companies: Ensure accurate and accessible information on generic drugs for patients.
- NGOs (WHO): Support content quality, establish standards for portal activities, and provide essential guidance.

Collaborating with health organizations through publications, seminars, and policy advocacy will expand awareness and acceptance of generics in Vietnam's healthcare system. This approach reduces costs, improves access, and strengthens public health. Open discussions and knowledge-sharing will build trust, encourage wider adoption, and enhance the credibility of the generic pharmaceutical sector. Additionally, dispelling misconceptions about generics will boost patient confidence, driving sales and positioning them as a preferred, cost-effective alternative.

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