



# Value of Innovation in Vietnam

Refreshing Potential of Vietnam's  
Innovative Pharmaceutical Industry



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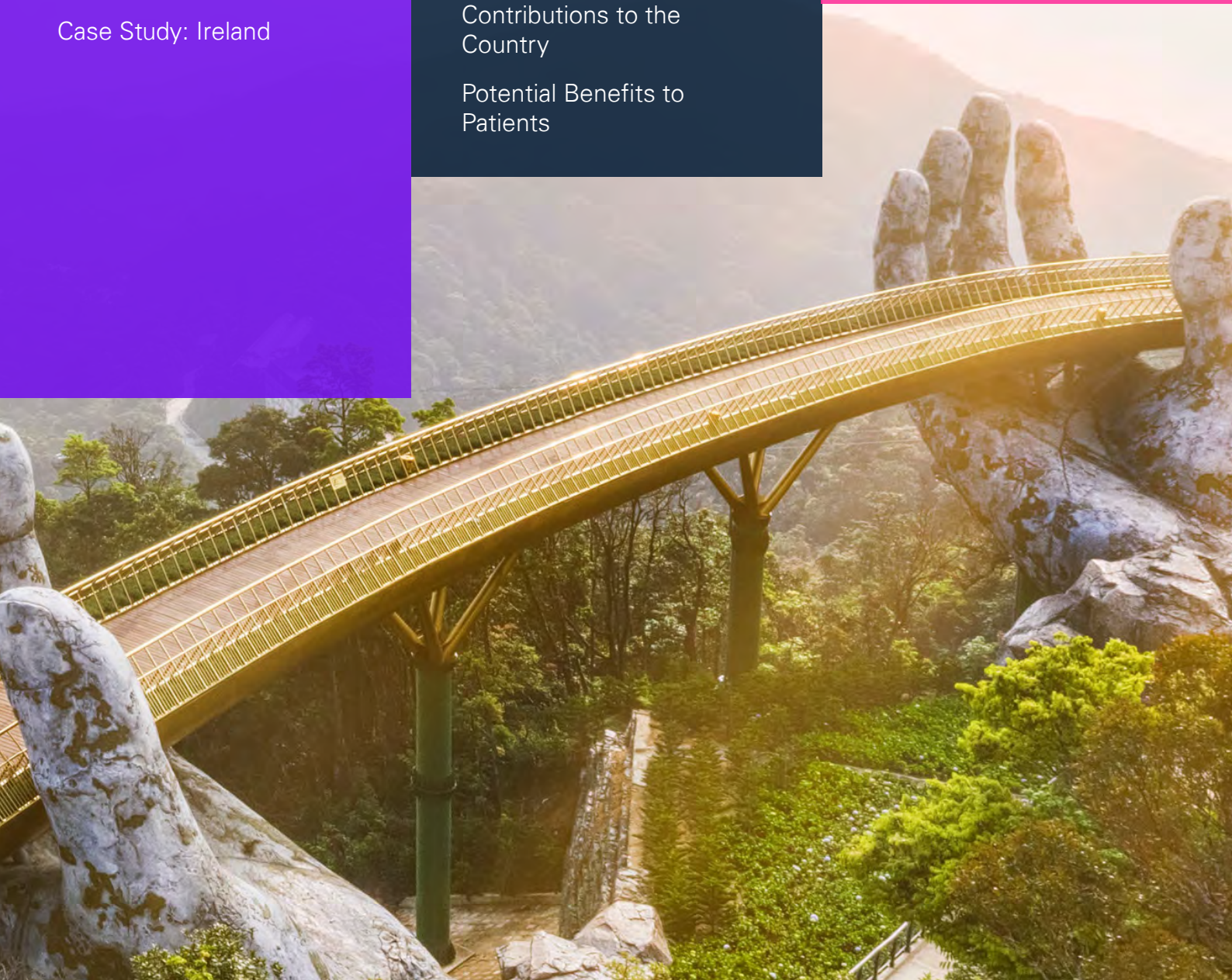
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# Executive Summary

KPMG’s “Value of Innovation” report examines Vietnam’s sector and socioeconomic ambitions, and measures growth scenarios based on key assumptions. These scenarios are informed by peer-market case studies, which create development timelines that Vietnam policymakers can study to inform policy priorities that will unlock potential value.

## The Value of an Innovative Pharmaceutical Industry



### Patient Win

**Faster access:** more innovative pharmaceutical medicines.

**Better patient support:** increased access to patient support programs.

**Better care:** latest innovative medicines for unmet medical needs.



### Government Win

**Public Private Collaboration, CSR:** Improved and more sustainable financing.

**Workforce / Human resources:** 199,500 to 609,000 jobs created from direct and indirect impact.

**Domestic R&D / clinical trials expertise development:** Attract 2-5% from global R&D investment of pharmaceutical companies.

**FDI, Tax:** Attracting more FDI and Tax from more registered Foreign Invested Enterprises.

**Clinical Trials:** Boost GDP through FDI whilst simultaneously becoming an innovation hub.



### Industry Win

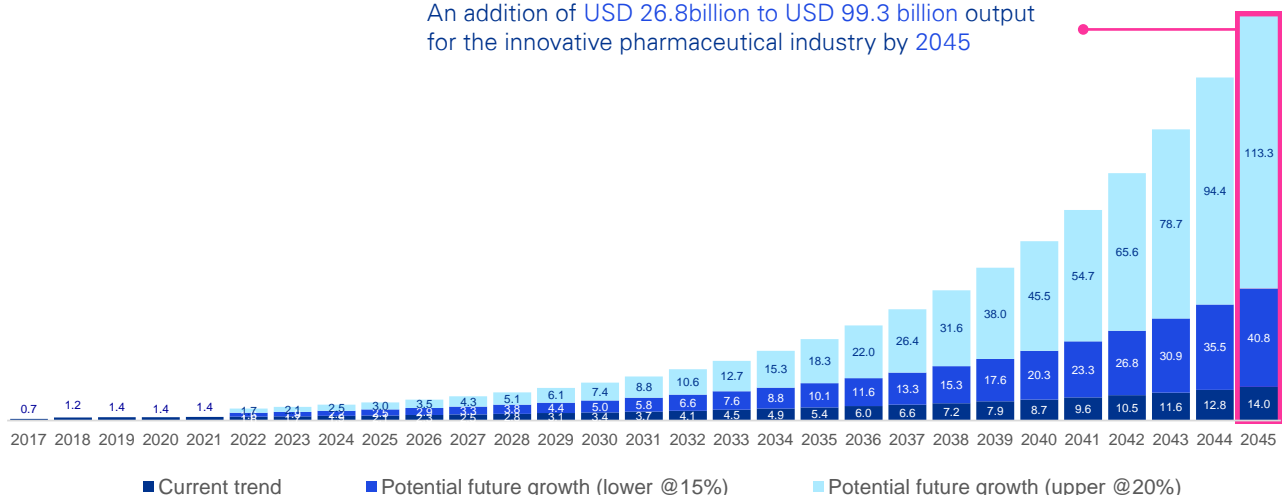
**HCP capability building:** Continuous Medical Education including novel therapeutics.

**Local pharma sector development:** contribute an additional USD 26.8 to USD 99.3 billion to GDP by 2045.

**Start-up, Entrepreneurship ecosystem:** Increasing number of start-ups.

## What does Success look like?

An addition of USD 26.8 billion to USD 99.3 billion output for the innovative pharmaceutical industry by 2045



# Unlocking Value through Policy

## Central role of dedicated innovation government department

### Collaboration amongst Government, Industry, and Academic institutions

**Vietnam:** Collaboration between government and industry to improve health financing, and with academic institutions to expand R&D capabilities.

**Example:** Translational & Clinical Research Flagship Program in Singapore.

### Workforce development lead by the institution to provide the right people

**Vietnam:** Increase emphasis on industry-focused education and training.

**Example:** National Institute for Bioprocessing Research and Training of Ireland.

### Incentives such as funds, grants, and taxation measures

**Vietnam:** Introduce incentives to drive investments into the industry.

**Example:** Korea Drug Development Fund, Health Research Board as a funding agency under Irish Ministry of Health.

### FDI Dedicated Government body to attract FDI

**Vietnam:** Empower and direct existing institutions to unlock future growth potential.

**Example:** Industrial Development Authority of Ireland.

### Innovation is the key to drive productivity

**Vietnam:** Drive health innovation through supporting expanded clinical trials industry sector.

**Example:** Science Foundation Ireland, Korea National Enterprise for Clinical Trials.

### Safety and Quality control to provide confidence in the market

**Vietnam:** Have a comprehensive legal and regulatory framework and establish dedicated institutions.

**Example:** Health Products Regulatory Authority of Ireland.

# Foreword

Over the past two decades, government health policy initiatives have accelerated Vietnam's industry development, while making laudable improvements in key healthcare indicators such as access to quality care, infant mortality, and overall clinical outcomes. Over this time, Vietnam's health industry has transitioned from an entirely public system, to one that increasingly draws on domestic and international private sector talent, technology, and knowhow to expand access to life-saving care.

Vietnam began its Universal Healthcare (UHC) journey in 1992 and has subsequently risen to the top of Asia's coverage ratios. By 2023 and 2025, the government targets coverage ratios of 93.2% and 95.15% respectively, while maintaining sustainable health financing targets.

The Vietnamese pharmaceutical market is currently expanding quickly, rising from USD5.4 billion in 2018 to an estimated USD6.5 billion in 2021, with a compound annual growth rate (CAGR) of 6.5%. This reflects growing demand for pharmaceuticals and related products. This ecosystem has now expanded to include more than 250 manufacturing plants, 200 import-export facilities, 4,300 wholesale agents, and more than 62,000 retail outlets.<sup>1</sup> Between 2018–2021, Vietnam's pharmaceutical sector added an estimated 7,000 high-skilled jobs.<sup>2</sup>

Within the total pharmaceutical industry, the innovative pharmaceutical is estimated to contribute USD1.16 billion to total GDP in 2021, and likely grow at in excess of 10% per annum going forward. This includes an estimated USD350 million in direct gross value added from the innovative pharmaceutical industry and an additional USD410 million in indirect contribution from business-to-business dealings including pharmaceutical expenditures on raw materials, shipping, sales, and marketing. Last but not least, induced spending by innovative pharmaceutical employees resulted in an additional USD400 million in economic benefits.

**These factors, combined with rising personal income, make Vietnam an attractive destination for global pharmaceutical companies looking to capitalize on emerging market growth potential.**

1. Phu Hung Securities (2020), 'Pharmaceutical Industry: Potential growth grasped by foreign firms', accessed 15 September 2022, [Link](#)
2. ODClick (2020), 'Industry Analysis: Human Resources Challenge in the Pharmaceutical Industry in a Competitive context', accessed 15 September 2022, [Link](#)





### **Attractiveness as an ASEAN regional gateway**

Vietnam's integration into new generation Trade Agreements such as Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTTP) and EU-Vietnam Free Trade Agreement (EVFTA) will strengthen its position and make it a more attractive destination.



### **Robust growth in demand for quality health products and services in Vietnam, including innovative medicines**

Vietnam has one of the fastest growing middle class in Asia. This newly-urbanized cohort is however, rapidly aging and at increased risk of developing non-communicable diseases.



### **Intergrade global development best practices from other countries**

Vietnam is in a similar position to comparable markets when they began life science industry development. Vietnam can learn from the development of its peers in their industrial planning policies. Many comparable markets began industry development in protectionist markets but adopted policies that attracted investment from leading multinational corporations (MNCs). These investments built the beginnings of a value-adding innovative health sectors.



### **Complementary benefits with national strategic development goals**

Vietnam's surrounding economic development goals are complementary and can be supported through the development of an innovative life science sector.

## **Objectives**

KPMG performed the government policies review and True Value calculation refreshment for both economic value and social value perspective with the latest data and market views. Using the assumption derived from previous report as the baseline to define market potential for Vietnam once it can accelerate the innovative pharmaceutical industry development. This report offers a view of the current and future pharmaceutical market, especially after the impact of the Covid-19 pandemic.

As other markets struggle to find a pandemic endgame, Vietnam has a unique opportunity to position itself as a hub for innovative healthcare in Southeast Asia, unlocking tremendous social and economic value for patients, the government, and the domestic healthcare industry.

All information analyzed for this project has been anonymized and company-specific data has been averaged to an industry-wide average.

## **Report Structure**

This report is structured to provide an overview of the current-state of Vietnam's innovative life sciences sector and a forward-looking view of what is possible. Vietnam's life sciences sector is analyzed, identifying factors precluding the country from achieving optimal growth. Comparative markets are then examined to identify key lessons in terms of regulation and policy which may form the framework for future Vietnam-specific policy recommendations. These sections are then combined to estimate the potential future social and economic value contributions derived from the sector. Finally, implications for policymakers and suggestions to maximize social and economic value contribution by the Innovative Pharmaceutical Industry are proposed.

Enjoy the read!



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# Current State of Pharmaceutical Industry in Vietnam

## Industry Overview

### Government Objectives & Policy Outlook

Under the “Development Program for Pharmaceuticals Industry and Domestically Produced Herbal Ingredient until 2030 and vision to 2045” (‘Development Program’), the Vietnamese Government has identified the pharmaceutical industry as a potential key sector in the future growth of the economy and wellbeing of its citizens.

Key objectives under the Development Program include:

- 1 By 2025: domestically produced drugs to account for 60% of market value, proportion of domestic herbal ingredients and herbal drugs raise by at least 10% as compared to 2020;
- 2 By 2030: domestically produced drugs to account for 70% of market value, proportion of domestic herbal ingredients and herbal drugs raise by at least 30% as compared to 2020; and
- 3 By 2045: total pharmaceuticals industry value to contribute more than USD20 billion to the national GDP.

To achieve this ambitious plan, the government has sought numerous macroeconomic and sectorial objectives under Resolution No. 2/NQ-CP; the Master Plan on pharma industry development (Decision No. 68/QD-TTg); and the Master Plan on Vietnam’s Health Program (Decision No. 1092/QD-TTg).

Under Resolution No. 2/NQ-CP<sup>4</sup>, the government aims to improve the domestic business environment and competitiveness to reach “top 4” status within ASEAN. In the short term (in 2022), this involves improving:

- 1 The quality and the ranking of the business environment indexes, the competitiveness, and the national credit ratings (Moody’s rating, S&P ranking and Fitch ranking);
- 2 Economic Competitiveness by 3 – 5 places (World Economic Forum ranking);
- 3 Global Innovation Index by 2 – 3 places (World Intellectual Property Organization ranking)
- 4 Property Rights Index by 3 – 4 places (Property Rights Alliance ranking).

In the longer term (by 2025), the government aims to rank competitiveness as below:

- 1 Competitiveness 4.0 Index (of World Economic Forum) to be named in the top 50 countries;
- 2 Sustainable Development Index (of United Nations) to be named in the top 40 countries;
- 3 Creative Innovation Index (of World Intellectual Property Organization) to be named in the top 40 countries;
- 4 E-Government Index (of United Nations) is expected to be named in the top 60 countries;
- 5 Property Rights Index (of the Property Rights Alliance) to be named in the top 60 countries;
- 6 Logistics Efficiency Index (of World Bank) is improved by at least 4 places;
- 7 Travel and Tourism Competitiveness Index (of World Economic Forum) to be named in the top 50 countries;
- 8 Cybersecurity Index (of International Telecommunication Union) is improved by at least 3 places.

3. Prime Minister (2021), ‘Decision No. 376/QD-TTg: Approving Development program for Pharmaceuticals Industry and Domestically produced herbal ingredient until 2030 and vision to 2045’, accessed 15 September 2022, [Link](#)

4. The Government (2022), ‘Resolution No. 02/NQ-CP: Main duties and measures for improving business environment and enhancing national in 2022’, accessed 15 September 2022, [Link](#)

5. Prime Minister (2014), ‘Decision: Approving the National Strategy on Development of the Vietnam Pharmaceutical Industry up to 2020, with a vision towards 2030’, accessed 15 September 2022, [Link](#)



Within the Master Plan on pharmaceutical industry development (Decision 68/QĐ-TTg<sup>6</sup>), the government aims to reduce dependence on imports and modernize the sector to be on par with regional and global peers. In the shorter term (by end of 2020), this will involve:

- 1 Ensuring a timely supply of 100% of medicine demand for prevention and cure; and
- 2 Expanding local production to account for 80% of in-country demand (in terms of value).

In the longer term, the government aims to meet basic domestic demand through localized production, while targeting the manufacturing of cure-oriented therapeutics. Vietnam also aims to build production capabilities for vaccines and biological products for epidemic prevention, and develop a system of testing, drug distribution, and drug information comparable to more advanced economies in the region.

In the Master Plan for Vietnam Health Program (Decision No. 1092/QĐ-TTg<sup>6</sup>), the government aims to address patient objectives to increase the health, physique, longevity, and living standards.

of Vietnamese citizens. In the short term, this will involve:

- 1 Ensuring a proper nutritional scheme and strengthening physical activity to improve overall civic health; and
- 2 Enhancing awareness through public education to provide behavior changes which mitigate common risk factors associated with diseases.

These programs will involve the implementation of continuous and long-term public health management programs targeted at preventable diseases and deaths.

In 2021, the drafted National Strategy on the Development of the Vietnam Pharmaceutical Industry up to 2030, with a vision towards 2045 was presented to the Prime Minister for his approval. Of which, by 2030, the government strives for 100% of medicines to be timely supplied for domestic medical treatment and prevention and by 2045, Vietnam pharmaceutical industry will be able to contribute more than USD20 billion to the national GDP.<sup>7</sup>

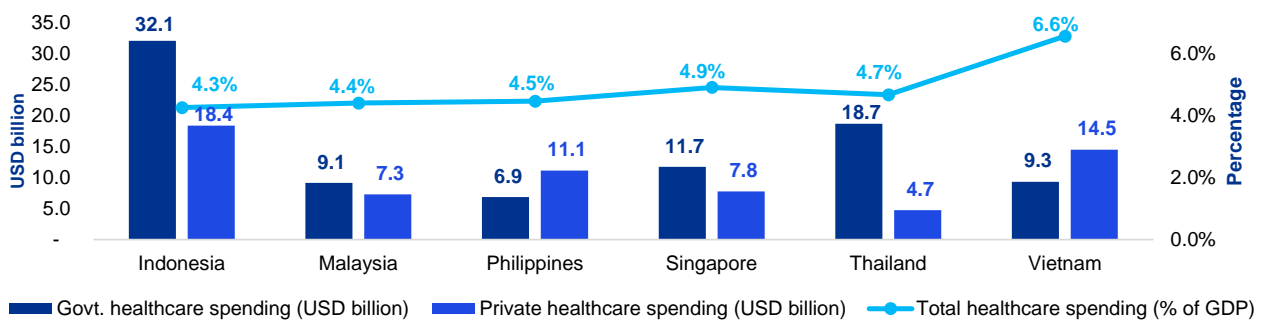
### Expanding Universal Healthcare Coverage

Vietnam has made significant progress over the past two decades on Universal Healthcare (UHC) coverage and seeks a national coverage rate of at least 93.2% by 2023 and 95.15% by 2025.

As outlined in Chart 1, total healthcare expenditure as a percentage of GDP was relatively high at ~6.6% in 2021, when compared to its peers such as Malaysia (4.4%), Thailand (4.7%) and Singapore (4.9%). However, total healthcare expenditure per capita for Vietnam (USD243) is low for its peer group, when considering ASEAN partners Malaysia (USD502), Thailand (USD335) and Singapore (USD3,309).

Healthcare spending per capita in Vietnam is forecasted to reach USD402 by 2025, leaving Vietnam considerably behind its peers and highlighting the growth potential for the market.

Chart 1: Regional comparison of healthcare expenditure 2021



	Indonesia	Malaysia	Phillippines	Singapore	Thailand	Vietnam
Healthcare expenditure pre capital (USD)	183	502	162	3,309	335	243
Total healthcare expenditure (USD billion)	50.5	16.4	18.0	19.5	23.4	23.8

Source: Business Fitch Solutions

In line with rising healthcare spending per capita, pharmaceutical expenditure per capita in Vietnam stood at USD66 in 2021 and is expected to reach USD95 by 2025. Given the opportunities outlined in this report, strong collaboration between government and industry could help bridge the per capita gap between ASEAN member states, and Vietnam's overall Universal Healthcare Coverage ambitions.

6. Prime Minister (2018), 'Decision: Approving Vietnam Health Program', accessed 15 September 2022, [Link](#)

7. Ministry of Health (2021), 'Drafted National Strategy on Development of the Vietnam Pharmaceutical Industry up to 2030, with a vision towards 2045', accessed 15 September 2022, [Link](#)

## Patient access to quality and affordable medicines

The government, in collaboration with industry, has taken several important steps to expand access to quality and affordable medicines as part of the Master Plan.

Pharmaceutical companies operating in Vietnam have made meaningful steps to help accelerate industry development and close access gaps through expanded patient support and outreach programs that provide critical pharmaceuticals to thousands of patients who otherwise would not have them. This is important momentum, but more social value can be unlocked through expanded collaborations. The following initiatives outline just a few of the programs that have expanded patient access within Vietnam:

- **Antimicrobial Resistance (AMR) (since 2018):** The Ministry of Health (MOH) and the World Health Organization (WHO) created the Antimicrobial Resistance (AMR) Program - a coordinated approach to optimizing antimicrobial use and reducing adverse consequences like antibiotic resistance.
  - **Chronic Myelogenous Leukemia (CML) and Gastrointestinal Stromal Tumor (GIST) (2005/2009—):** Novartis, MOH and VSS have assisted ~8,000 patients diagnosed with CML and GIST with access to high quality medicines (i.e. imatinib and nilotinib) at no cost to the patient through the Global Imatinib Patient Access Program (GIPAP) and Vietnam Patient Access Program (VPAP). This includes both patients with and without public health insurance.
  - **Healthy Lung Program and Non-Communicable Diseases (NCDs) (2017-2020):** the MOH and AstraZeneca Vietnam are collaborating to enhance access to effective preventative health-care and diagnosis through the provision of greater training to doctors through continuous medical education, as well as better equipment for early diagnosis.
  - **Resolve to Save Lives (since 2018):** The Ministry of Health (MOH) and the World Health Organization (WHO) are collaborating to enhance access hypertension and diabetes management and treatment services at CHS (commune health station) level through providing technical training package for 11 provinces as the first phase, and another 10 provinces at the second phase.
  - **Human Papillomavirus (HPV) and Cervical Cancer (2019-2021):** the MOH, United Nations Population Fund (UNFPA), and Merck Sharp & Dohme (MSD) are rolling-out a Human Papillomavirus Vaccination (HPV) program that will drive awareness and prevention of cervical cancer.
  - **Antimicrobial Resistance (AMR) (since 2021):** The Ministry of Health (MOH), Ministry of Agriculture and Rural Development (MARD) and the World Health Organization (WHO) created the Antimicrobial Resistance (AMR) Program, to encourage best practices of using Antimicrobials to prevent the drug resistance in treatment like antimicrobial resistance.
- Additionally, government and the private sector have come together across numerous preventative health programs to improve the efficient supply of quality and affordable medicines where most needed. These initiatives include:
- **Hypertension and diabetes:** Launching the “First Day” Program (2019-2020) between MOH and Servicer Laboratories Vietnam, aiming to inform the public about the need for early diagnosis of hypertension and diabetes, prior to irreversible complications.
  - **World Health Day:** MOH, AstraZeneca Vietnam, The Vietnam Young Physicians Association and the Youth Union are spreading awareness of preventative health measures to limit non-communicable diseases (NCDs).
  - **Young Health Program Vietnam (2019-2021):** Between 2019-2021, AstraZeneca Vietnam, Plan International Vietnam, the Hanoi Center for Disease Prevention and Control and the National Youth Centre are hosting programs focusing on preventive health activities for non-communicable diseases with a youth focus.
  - **Safe Journeys (2021):** UNICEF Viet Nam, the Ministry of Health (MOH) and World Health Organization (WHO) launched raising awareness campaign of maintaining key preventive practices (5K practices) and accelerating Covid-19 vaccination. The message was translated into ethnic languages and sign language in order to reach more mountainous and vulnerable communities.
  - **Digital channel on stroke prevention (2021-2023):** Vietnam Administration Medical Service (VAMS) and Bayer Vietnam are collaborating to develop the digital channel which will provide the information and raise the awareness of stroke disease prevention to general public.
  - **Vietnamese health system’s sustainability and resilience (2022-2025):** the partnership between the Health Strategy and Policy Institute of Vietnam (HSPI) and AstraZeneca aims to increase the sustainability and resilience of Vietnamese healthcare system, especially after the healthcare system has been severely affected by Covid-19 pandemic.

## Local industry development

As part of the third key focus area within the Master Plan, Government authorities together with international organizations, universities and multinational pharmaceutical companies have been cooperating to build up capabilities for Healthcare Practitioners in Vietnam.

Under Decision No. 2992/QĐ-BYT, the Government has outlined plans to develop a workforce for examination and disease prevention within Vietnam to create an organized system proficient in both quantity and quality. The following initiatives outline just a few of the programs that have developed such a workforce within Vietnam

Selected programs include:

- **“Cùng Sống Khỏe” Program (since 2012):** to provide training to 18,000 healthcare professionals and reaching more than 1.1m people at 1,400 Community Health Stations across 19 provinces. Awareness, prevention and screening are central in the engagement with people in these rural areas and includes areas such as fever, diabetes, hypertension and respiratory disease.  
**Stakeholders:** Provincial departments of health and Novartis.
- **Clinical Trial Program (since 2011):** across a variety of disease areas, including oncology, respiratory, dermatology and endemic diseases like malaria. With a focus on global registration trials, investments are growing every year with total millions of dollars.  
**Stakeholders:** Trial sites, Ministry of Health and Novartis.
- **i-StepD Program (Phase 2014–2016, Phase 2017–2018):** designed to improve diagnosis and management of diabetes among more than 2,000 general practitioners and internists.  
**Stakeholders:** American Diabetes Association (ADA); Vietnam Association of Diabetes & Endocrinology (VADE); University of Medicine and Pharmacy at Ho Chi Minh City; Cho Ray Hospital; Bach Mai Hospital; National Hospital of Endocrinology; and Sanofi Aventis Vietnam.
- **Immunization Management System:** enhancing national immunization coverage at the grassroots level. 63 provinces have been set up and 10 million people have been registered. The system helps healthcare professionals track infants and pregnant women due for vaccinations, reduce time required for recording and reporting immunization data and ensure quality and availability of vaccines.  
**Stakeholders:** PATH, MOH and GSK.
- **Nursing Education project (Since 2016):** providing clinical training program and materials for new graduate nurses, aims to scale up the training system national wide and strengthen healthcare system in Vietnam. Bach Mai Hospital, Saint Paul Hospital in Hanoi together with Dien

Bien, Vinh Phuc, Binh Dinh and Dong Nai province are selected for the first batch (2016-2020)

**Stakeholders:** Ministry of Health (MOH) and JICA

- **Online Medical Education project (2017–2020):** designed to enhance medical knowledge of rural physicians to improve community healthcare.  
**Stakeholders:** Ho Chi Minh City Society for Reproductive Medicine; the National Hospital of Endocrinology; and Merck Sharp & Dohme (MSD).
- **iTSEP-D Plus Online (2019-2021):** to provide online training for more than 4,000 general practitioners across country on diagnosis and management of diabetes.  
**Stakeholders:** Vietnam Association of Diabetes & Endocrinology and Sanofi Aventis Vietnam
- **IBSA e-learning platform (2020):** created for health workers in response to Covid-19 pandemic. In fact, during epidemic, e-learning allowed care workers to be similarly trained with contents of high quality and appropriate for their immediate educational needs. As a result, the attendance of more than 4,200 health care workers and more than 200 primary care workers working at the community level.  
**Stakeholders:** Ministry of Health (MOH), World Health Organization (WHO), Hai Phong Medical and Pharmaceutical University (HPMU).
- **Ventilators program (2022):** level-up clinical skill sets in use of ventilators for more than 4,000 healthcare practitioners at ICU departments who provide direct care and treatment to Covid-19 patients at healthcare centers across the nation.  
**Stakeholders:** Medical Examination and Treatment Administration Department, and Medtronic Vietnam

## Trade and Foreign Direct Investment

Vietnam has become an attractive destination for foreign investors with FDI inflows growing steadily to reach USD19.74 billion in 2021, representing a five-year CAGR of 2.4%.<sup>8</sup> As a proportion of total FDI amongst ASEAN countries, Vietnam ranks third following Singapore (USD99.1 billion) and Indonesia (USD20.1 billion); and above Philippines (USD10.5 billion), Thailand (USD11.4 billion) and Malaysia (USD11.6 billion). Between 2016 and 2020 Vietnam attracted more than USD1 billion in cumulative healthcare and life science related FDI. These investment values have steadily grown through these years at a rate of up to 60% compounded annually.

Macro-economic investment conditions for Vietnam are expected to remain positive with its expanded integration into the international system through international agreements through the EU–Vietnam Free Trade Agreement (EUFTA).

8. Ministry of Planning and Investment

# Key Challenges to Realizing Future Growth Potential

Most of the industry executives interviewed for this project indicated a positive outlook for Vietnam as an investment market. That said, several executives stated in interviews that the perceived lack of a clear sectoral vision or consistent national framework for future industry development complicates their ability to explain Vietnam's unique opportunity to global stakeholders, which has slowed further operation and investment expansion.

It should be noted that all executives interviewed for this project expressed an interest in working with the government to create the best possible market environment for Vietnam. Several specific points to note are as follow:



## Clinical trials

Research and development (R&D), particularly later-stage clinical trials, will be key to advancing Vietnam's indigenous innovative pharmaceutical industry. In addition to the direct economic benefit of the trial itself, a streamlined and efficient clinical trial process can drive the development of an innovative workforce, and broader industry capacity development, which will help accelerate Vietnam's Sustainable Development Goals.

If executed effectively, Vietnam has a clear opportunity to become the hub for innovative pharmaceutical development among ASEAN peers. To accomplish this goal, national leadership will need to make cross-ministerial coordination efforts to overcome a few industry-identified hurdles.

In interviews with industry executives, a commonly noted concern was the comparatively lengthy and complicated clinical trial application process. Simplification of this process will encourage greater trials-based investment, which will in turn drive the development of domestic scientific and workforce capabilities. Regional ASEAN neighbors, such as the Philippines, have as well identified this a key enabler, and have made a concerted effort to streamline the application.

Alongside the application process concerns, several interviewed companies have identified the following clinical-trial

**1 Review experts:** Inadequate review fee structure for studying dossiers in the initial submission, leading to restricted pool of review experts and subsequent lengthy delays;

**2 Clinical trial centers:** Lack of central research centers;

3

**Collaborative partners:** Lack of authorization and qualified organizations for standard GCP/ICH-safety training;

4

**University-level collaboration:** Lack of university-level clinical research and drug development resources; and

5

**Central clinical trials association:** No association for clinical trials in Vietnam that connects all relevant companies to work together.



## Health financing

Health financing in Vietnam has a relatively high ratio of out-of-pocket expense, which may strain long-term sustainability, given the population officially entered an 'aging phase' in 2017, becoming one of the most rapidly aging countries in the world.<sup>9</sup> Whilst these costs can be reduced, policy should balance cost and market incentives.

Out-of-pocket expenses in Vietnam accounted for ~43% in 2019, higher than regional peers such as Indonesia (35%), Malaysia (35%), and Singapore (30%). Despite this, voluntary public social insurance fees per head in Vietnam remain low at less than USD30 per head per annum on average. Moreover, external aid for Vietnam's health system is also predicted to further decrease as the economy transitions to emerging economy status.

This means the Vietnam Social Security System must address the challenge of expenditure management in the near-term. Further adoption of private supplemental health insurance, for example, could significantly ease government budget constraints, while maintaining relatively low per capita social security fee level.



## Access to innovative medicine

In Vietnam, patented drug sales only accounted 19% of total pharmaceutical sales in 2021. This value is significantly below comparable ASEAN markets such as Thailand (32.1%) and Singapore (53.3%).

In real terms, this low penetration rate means that many Vietnamese citizens do not have access to needed pharmaceuticals, generating significant economic and social impacts throughout the economy. This limits the government's ability to achieve its ambitions in the Master Plan (as outlined in page 8).

9. World Bank, (2019) 'The World Bank In Vietnam', accessed 20 September 2019, available at: [Link](#)



### Local manufacturing presence and technology transfer

Industry players noted that potentially ambiguous policies and a perceived lack of incentives could be an impediment when considering the establishment or expansion of a local manufacturing presence. Some companies noted the need for clearer incentives on procurement and quotas before they are willing to move forward. Other companies outlined the need for additional guidelines on quality tests required for locally manufactured products before they would consider establishing this function in Vietnam. At current, the ambiguous nature of policies and incentives around local manufacturing may limit the government’s ability to achieve its local industry development ambitions (as outlined in page 8)



### Public Private Collaboration

Vietnam, many industry players expressed interest in Public Private Collaborations (PPCs) but stated that the lack of a clear regulatory framework or incentive system was preventing them from exploring further or expanding beyond what is already underway. A perception among industry players persists that PPC regulations and incentives in Vietnam are more suited for infrastructure type investment projects, and may, as currently drafted, be less applicable to industries such as the pharmaceutical industry.

Despite the current identified challenges in PPC, most interviewed companies shared a desire to help improve the Vietnamese healthcare landscape through partnerships. The most common desired partnership areas included expanded patient access and education.



### Legal entity registration

Most industry players interviewed showed a strong desire to further invest in the Vietnamese market. In terms of business registration change however, many executives found the transition requirements from Representative Office to a Foreign Invested Enterprise (FIE) confusing and time consuming but indicated that the situation is improving as further guidance is now available. That said, most interviewees indicated that this issue has slowed, or stalled investment expansion plans while their organizations wait to better understand implications for domestic operations. Under Decree 54, foreign importers are required to maintain and control their own drug storage, storage equipment, and transportation. This creates higher operational and compliance costs, which may be passed to end consumers in the form of slightly higher drug prices.



### Education and workforce development

Vietnam faces several challenges in terms of ensuring continuously updated medical education for doctors

and medical staff, as well as improving the relatively low disease awareness among patients. There is a need for collaboration amongst hospitals, medical associations, and universities to provide education programs. Interviewed executives identified this as a critical bottleneck for Vietnam, but also a clear area for potential collaboration.



### Patient Support Programs

Most innovative pharmaceutical companies operating in Vietnam have some form of Patient Support Program (PSP) and many expressed an interest in expanding in the coming years. Such programs could meaningfully help Vietnam’s healthcare financing challenges, particularly for more expensive drugs. To expand, however, a few critical issues must first be addressed:

- 1 Tax treatment of discounted or free drugs:** costs due to taxation imposed on products used in the program;
- 2 Program diversity:** limited forms of PSPs (currently only free or cost shared programs are allowed, whereas in other markets there are up to five different funding models), process and timelines for new approved PSPs, expanded programs to other new hospitals;
- 3 Program incentives:** lack of clear incentives to increase program registration efficiency for example, or ability to offset the cost of donated or discounted products used in the program; and
- 4 Consistency in approach:** lack of agreement among hospitals and pharmaceutical companies in funding and running PSPs.

Addressing these key challenges could significantly assist the government in realizing its Master Plan ambitions. Challenges faced by Vietnam are not unique and have been experienced by countries around the world at similar stages of development. The following section details these challenges, and the different policy models that have allowed them to prosper.



# Lessons from Other Economies

## Overview of Innovative Pharmaceutical Sector Development in Other Economies

Globally, there are several middle-income countries that have prioritized the pharmaceutical industry as part of their national strategy. These countries can largely be categorized as either “self-funded” or FDI-driven”, depending on the source of development funds. Based on our research as part of this project, it is our opinion that Vietnam shares characteristic with so called “FDI-driven” markets. As such, we have selected markets from this category for our case study analyses.

Successful “FDI-driven” markets generally have the following characteristics in common:



**National-level vision:** Prioritizing pharmaceutical industry in national development roadmap;



**Consistent regulatory framework:** Having legal and regulatory framework with dedicated institutions for attracting foreign investment and ensuring quality control;



**Central funding mechanisms:** Injecting funds to support research and development and drive healthcare innovation;



**Clustering and collaboration:** Fostering collaboration among government agencies, private businesses, higher educations, and research institutions;

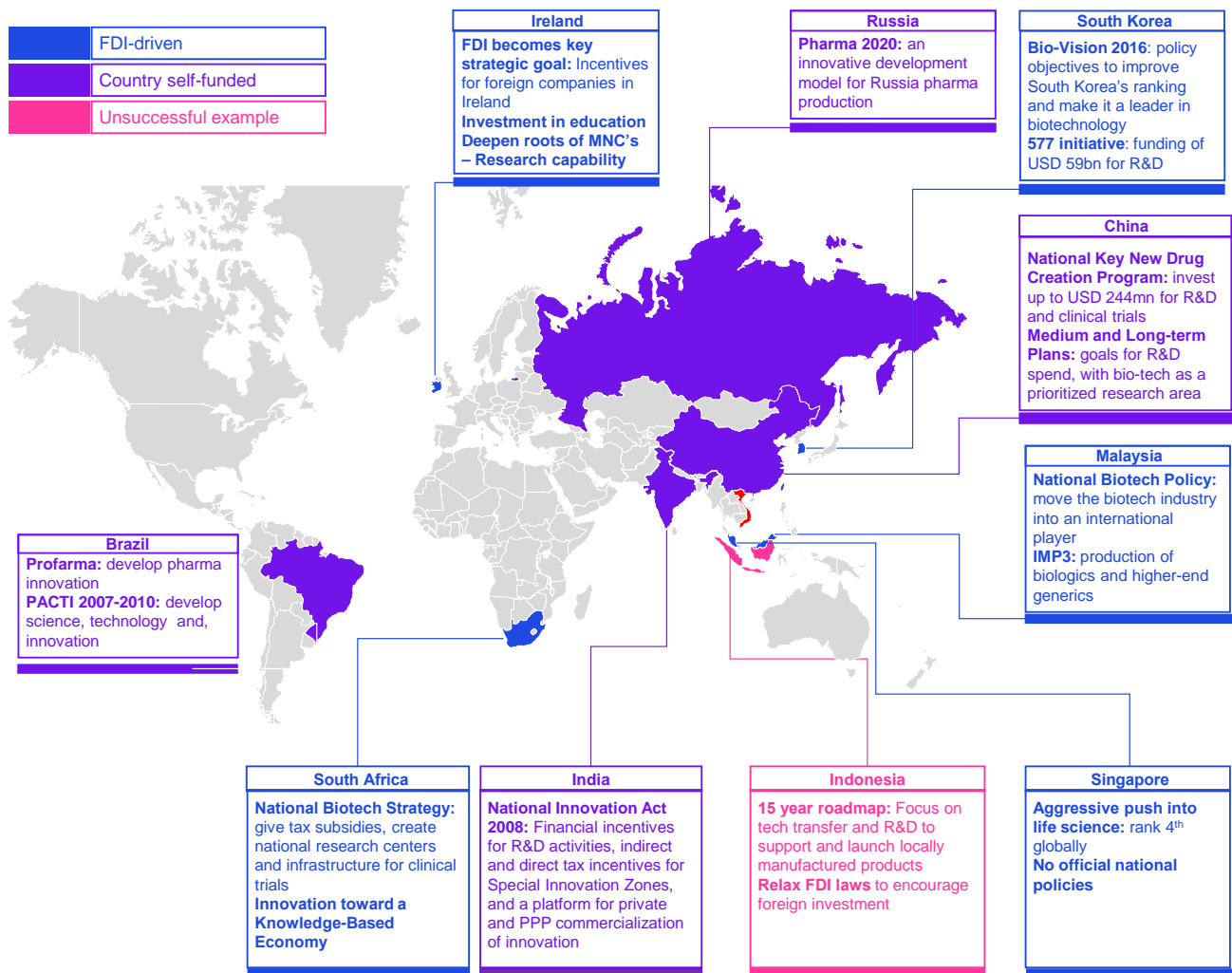


**Continuous education:** Improving education of pharmaceutical professionals and workforce to enhance domestic capabilities.

In this section, we have selected three economies with more mature pharmaceutical markets, namely Singapore, South Korea, and Ireland. It is our opinion that each of these markets have clear points of learning for Vietnam to consider if it wants to leapfrog the development of its domestic industry.



**Figure 1:** Overview of the innovative pharmaceutical sector development in other economies

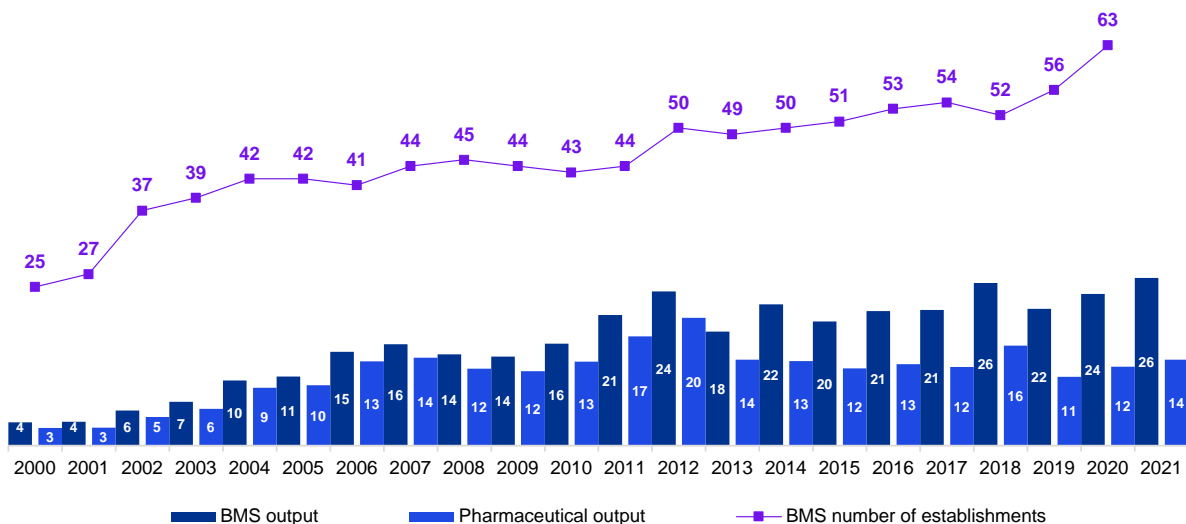


# Case Study: Singapore

## Singapore has become a pharmaceutical hub over the past two decades

Singapore’s pharmaceutical industry started to boom in 2000, when the government launched the Biomedical Sciences (BMS) initiative and prioritized pharmaceutical sector at the national policy level. The goal of BMS initiative Phase 1 was to double the BMS industry’s annual manufacturing output to SGD12 billion (USD7 billion) by 2005. In 2005, the output grew to SGD18 billion (USD11 billion), exceeding the target by 50%.<sup>10</sup> The Phase 2 continued to invest in pharmaceutical infrastructure as well as build up research and innovation capabilities.

**Chart 2:** Output (USD billion) and number of establishments of biomedical sciences



Source: Singapore Department of Statistics

Note: Biomedical sciences include pharmaceuticals and medical technology. Numbers converted from local currency to USD based on exchange rate from World Bank.

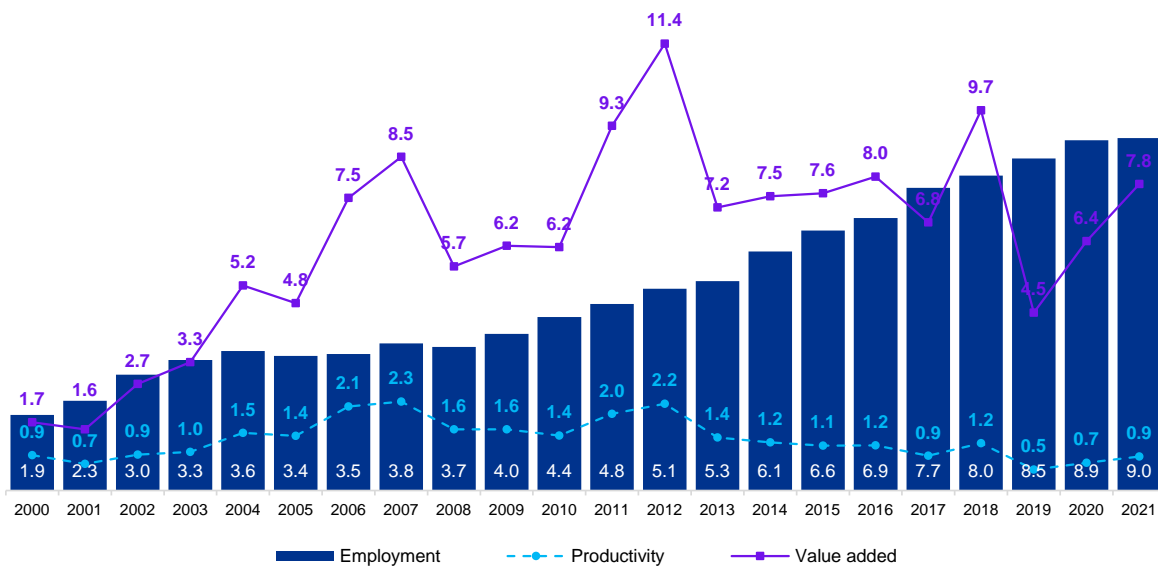
Pharmaceuticals as a sub-sector under BMS has grown rapidly over the past 21 years, and Singapore has become a regional hub for pharmaceutical manufacturing, research and innovation. The pharmaceutical output has increased from USD2.8 billion in 2000 to USD13.5 billion in 2021 at a CAGR of 7.8%. Employment has consistently grown at 7.6%, and gross value added has grown at a similar rate of 7.4% from USD1.7 billion to USD7.8 billion over the same period, increasing from 1.81% to 1.97% as a percentage of national GDP.

10. Rai, S. (2006), 'Singapore Biotechnology Boom Indicators: Overview of the BMS Industry', Asia Biotech.





**Chart 3:** Employment ('000), productivity (USD million per employee) and gross value added (USD billion) of pharmaceutical industry



Source: Singapore Department of Statistics

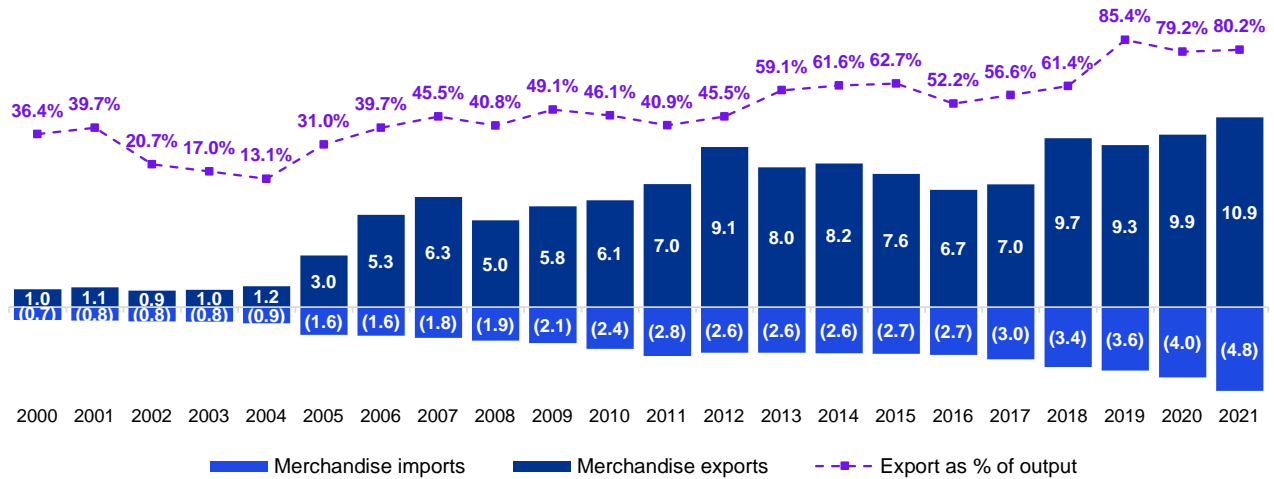
Note: Numbers converted from local currency to USD based on exchange rate from World Bank.

Industrial value-add bottomed in 2019 at the same time productivity a 20 year low of 0.5. These events coincided with the US-China trade dispute, and later the outbreak of COVID-19. Since this point, we have seen a strong recovery in both metrics, returning to near pre-trade-war values.

## Pharmaceutical exports have steadily expanded over this period

The increase in pharmaceutical output is accompanied by an increase of merchandise exports (both domestic exports and re-exports) from USD1.0 billion in 2000 to USD10.9 billion in 2021 at a CAGR of 11.9%. Accordingly, the proportion of exports in total output has grown from 36.4% to 80.2%. The growth is mainly contributed by the domestic exports, which increased from 56% to 82% of the total merchandise exports over the same period.

**Chart 4:** Merchandise exports and imports of medicinal & pharmaceutical products (USD billion)



Source: Singapore Department of Statistics

Note: Numbers converted from local currency to USD based on exchange rate from World Bank. Import values are shown in negative numbers only for presentation purpose.



## Lessons learned for policy makers

### Key government policies for the pharmaceutical industry

The Singapore government continuously supported the industry growth by having several policies and initiatives in place. The key ones include:

**Table 1:** Key policies and initiatives in Singapore

Year	Policies	Description	Impact
1999	Bio*One Capital	Bio*One Capital is the corporate investment arm of the Economic Development Board (EDB).	Dedicated to promoting and manage investments in the biomedical sciences sector.
2000	Biomedical Sciences (BMS) Initiative	Prioritize the pharmaceutical sector at national policy level and promote biomedical sciences as fourth pillar of economy. The initiative has multiple phases with each covering 5 years.	Have an overarching vision and framework for developing pharmaceutical industry; allocate fund to build up domestic capabilities; appoint agencies and institutes to take responsibilities to implement the initiatives.
2001	Tuas Biomedical Park	A world-class manufacturing hub hosting process development and manufacturing operations of major pharmaceutical companies.	Dedicated to providing infrastructure for pharmaceutical and biologics manufacturing; have a clustering impact on the industry.
2003	Biopolis hub	Established by Agency for Science, Technology and Research (A*STAR) to provide R&D space for health and biomedical sciences.	Dedicated space to promote R&D by bringing together various research and medical communities from the research institutes of molecular biology, genomics, bioinformatics, bioengineering, bioprocessing technology and chemistry.



Year	Policies	Description	Impact
2006	Translational & Clinical Research (TCR) Flagship Programme	Aim to establish Singapore as a leader in a number of strategic disease orientated areas. It achieves this by building on existing, local, highly competitive programs and providing highly productive platforms for collaboration with top overseas research institutions and industry.	Enhance collaboration with domestic and overseas research institutions and the industry; build up a critical mass of excellent researchers in the five selected therapeutic areas.
2008	Singapore Academy for Good Industry Practices Excellence	Established in National University of Singapore with joint effort between the government and pharmaceutical MNCs. Faculty members will be drawn from academia, health authorities and major industry players from across the region and the world.	Public private collaboration to enhance education and provide talent (at least 500 professionals each year) for pharmaceutical and healthcare industry; bring together international standards and local practices in the industry.
2011	Open Collaborative Fund (OCF)	A SGD590 million (USD469 million) fund to promote greater collaboration between basic science researchers and clinician scientists and to support integration of activities across the wider BMS research community.	Provide funding to integrate and collaborate the entire value chain of biomedical research; accelerate to build towards a knowledge-based economy through enhancing human capital and knowledge transfer; drive the overall competitiveness of the pharmaceutical industry.
2013	Clinical Trial Grant (CTG-Industry Collaborative Trials)	A grant supporting Industry Collaborative Trials, covering up to 30% of total projects costs inclusive of 20% indirect costs. Funding quantum for each project is open and for a duration of up to 5 years.	Support Industry Collaborative Trials that involve both clinician and company contributing intellectual inputs and funds to conduct the trial and developing novel or pre-existing therapies / drugs / medical device for new indications.
2013	Clinical Trial Grant (CTG-Investigator-Initiated Trials)	A grant supporting Investigator-Initiated Trials, capped at SGD1.5 million (USD1.2 million) for each project (inclusive of 20% indirect costs). Projects need to have a duration of up to 3 years. Those with more than 3 years will be evaluated on a case-by case basis.	Support Investigator-Initiated Trials of both early and late phase which are initiated and driven by clinicians who are interested to conduct trials on novel or pre-existing drugs / medical device / interventions for new indications.
2014	Diagnostics Development (DxD) Hub	A hub established to accelerate the transformation of IPs into clinically validated diagnostic devices that are ready for subsequent market adoption, leveraging Singapore's strengths and leading clinicians and medical consortiums.	Develop diagnostic solutions tailored to diseases predominantly found in Asia; license diagnostics technologies to MNCs, SMEs and start-ups, complete commercial contracts, attract industry co-funding, and help establish local and foreign start-ups.
2015	The Agency for Care Effectiveness (ACE)	Support the Ministry of Health Drug Advisory Committee make evidence-based recommendations for the public funding of drugs.	Standardized HTA methods and processes have been developed in line with international best practice to ensure that ACE's evaluations are conducted in a consistent and robust manner. Since ACE's establishment, subsidies are now provided earlier within a drug's life cycle, and value-based pricing has led to more cost-effective prices being negotiated with companies to improve affordability for patients and the public health care system.

Year	Policies	Description	Impact
2016	Singapore Workforce Skills Qualifications System for Process (Process WSQ)	Four-level training program by Singapore Workforce Development agency, leading to the WSQ Higher Certificate in Process Technology (Pharmaceuticals Manufacturing).	Train workers for the skills and competencies required for job roles in the Pharmaceutical Manufacturing industry.
2016	Research, Innovation and Enterprise (RIE) 2020 Plan	A national level effort to establish Singapore as a global research and development hub in various key sectors, including the pharmaceutical manufacturing industry, from 2016 to 2020.	Have an overarching road map for developing the pharmaceutical manufacturing industry; offer grants to develop technological capabilities; leverage on public sector R&D investments to grow industry R&D capabilities.
2018	Pharma Innovation Programme Singapore (PIPS)	A group of researchers from the public and private sector as well as international industry specialists, who work together to promote the transition of the pharmaceutical manufacturing industry to the pharma factory of the future.	This concerted effort spanning will resolve pertinent issues to value-add to the sector and beyond.
2019	The Experimental Drug Development Centre (EDDC)	Aims to create treatments and diagnostics that will benefit and save patients' lives in Singapore, Asia, and everywhere else.	With an emphasis on diseases that are common in Asia, EDDC works together with public sector and business partners to transform the superb knowledge resulting from Singapore's biomedical and clinical sciences R&D into cutting-edge healthcare solutions.
2020	Research, Innovation and Enterprise (RIE) 2025 Plan	A government initiative to position Singapore as a global hub for research and development in several vital industries, notably the production of pharmaceuticals, from 2020 to 2025.	Develop road map for the pharmaceutical manufacturing sector, provide grants to advance technological capabilities, and capitalize on public sector R&D spending to expand industry R&D capabilities.

### A cluster sector building approach to formulate the industry ecosystem

Tuas Biomedical Park and Biopolis Hub were built at the beginning years of the industry, acting as two pillars to establish the clustering impact and support the pharmaceutical growth in Singapore. Tuas Biomedical Park is a world-class manufacturing hub hosting process development and manufacturing operations of major pharmaceutical companies. Biopolis Hub is a dedicated R&D space to bring together various research and medical communities.

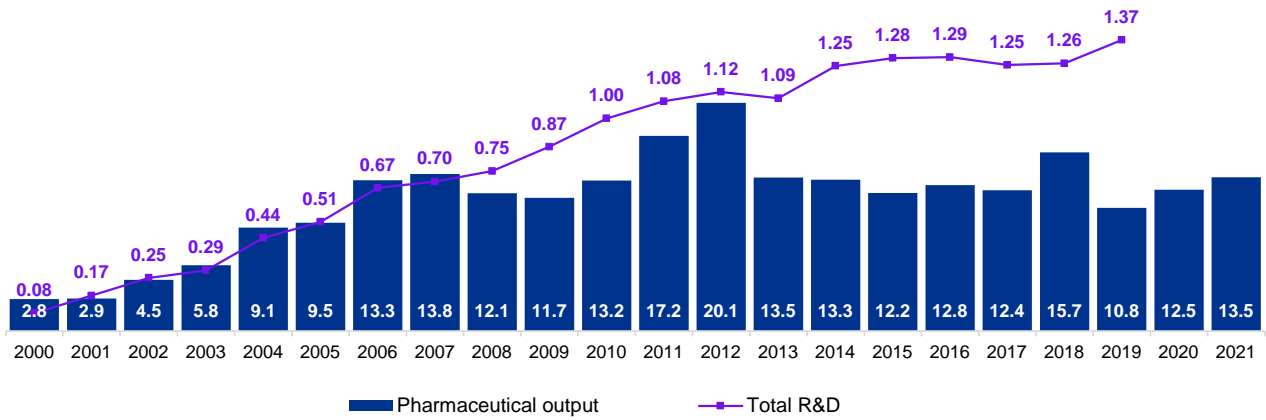
As of 2019, there are more than 350 biotechnology and medical technology companies are operating in Singapore. They carry out strategic corporate operations ranging from regional headquarters to cutting-edge research and manufacturing by utilize the country's world-class manufacturing and scientific capabilities, connectivity to other Asian markets, and business and regulatory ecosystem.<sup>11</sup>

### High value-added research activities to attract biotechnology and pharmaceutical manufacturing activities

Since the beginning of industry boom, Singapore has been aware of the importance of investment in research and development. National total expenditure on R&D has increased to USD1.37 billion in 2019 from USD80 million in 2000 with a CAGR of 15.8%, representing an increase from 0.09% to 0.36% as a percentage of national GDP.

11. Yee. G (2019), 'Overview of Singapore PharmBio Sector', Marshall Cavendish Business Information, accessed date 20 September 2022.

**Chart 5:** R&D expenditure in biomedical & related sciences versus industry output (USD billion)



Source: Singapore Department of Statistics

Note: Numbers converted from local currency to USD based on exchange rate from World Bank

Agency for Science, Technology and Research (A\*STAR) was established in 1991 under Ministry of Trade and Industry of Singapore to support R&D in health and biomedical sciences as well as other 3 areas. In 2003, A\*STAR opened Biopolis Hub to provide R&D space for biomedical sciences and promote collaboration among government, private and higher education research institutes.

Other than A\*STAR, the National Medical Research Council (NMRC) under Ministry of Health has funded various segments in medical sciences including research, human capital, enabler & infrastructure and talent development. One notable program is the Translational & Clinical Research Flagship Program, which aims to establish Singapore as a leading country in numerous strategic disease orientated areas. It provides platforms for collaboration with top overseas research institutions and industry.



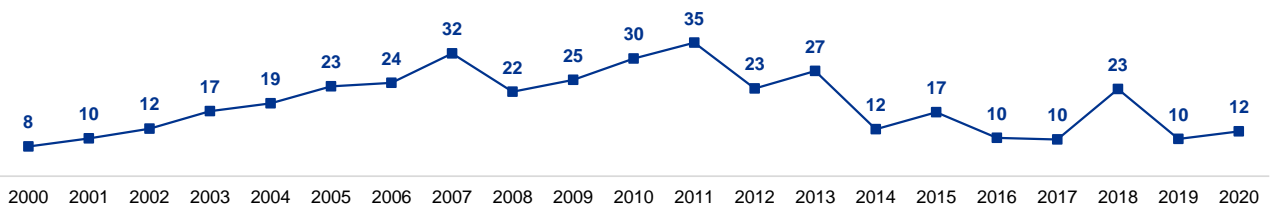
## Leveraging on private and foreign investment to build local capabilities

Apart from funding programs with government budget, Singapore has also provided several schemes to promote private investment in the industry. Bio\*One Capital, the corporate investment arm of the Economic Development Board, was set up to promote and manage investments in the biomedical sciences sector. By 2021, the firm grew considerably to manage SGD1.2 billion (USD851 million) of Singapore Biomedical Science Fund.<sup>12</sup>

Additionally, many incentives have been rolled out over the years to attract foreign investment into the industry. One example is the Productivity and Innovation Credit (PIC) where up to 400% tax deductions was available to businesses for their expenditure on acquisition and licensing of Intellectual Property Rights (IPR), registration of patents and research and development activities.<sup>13</sup>

FDI stock has largely grown before 2008 but reduced in recent years due to the global economic recession.

**Chart 6:** FDI stock for the pharmaceutical industry (USD billion)



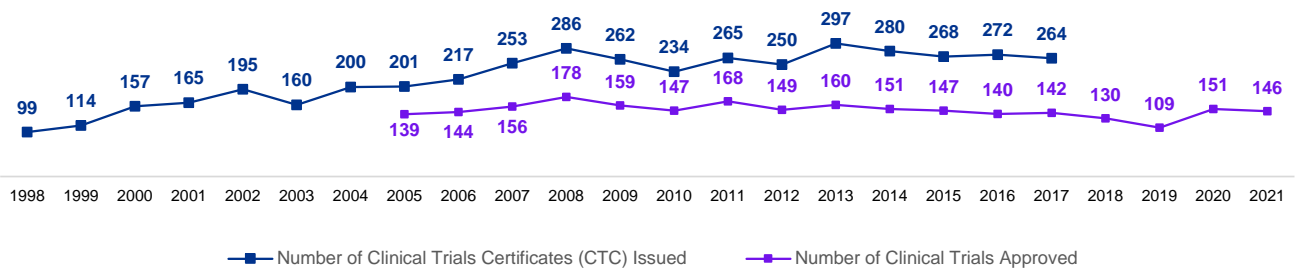
Source: Singapore Department of Statistics

Note: Numbers converted from local currency to USD based on exchange rate from World Bank.

## Increasing number of Clinical Trials Certificates and number of patients enrolled

Singapore has continued to conduct a significant number of clinical studies, with at least 130 being authorized each year excluding the drop in 2019 with only 119 approved clinical trials, the number of clinical trials approved has recovered in 2020 and 2021 by 151 and 146, respectively.<sup>14</sup> Trial composition is made up of 54% of Oncology, 10% of Infectious Diseases, 5% of Ophthalmology and 32% of others. With a CAGR of 5.3% from 1998 to 2017, the number of Clinical Trials Certificates (CTC) issued grew from 99 to 264, demonstrating a greater coverage of the trial sites in Singapore.

**Chart 7:** Number of clinical trials approved, and certificates issued



Source: Health Sciences Authority of Singapore

Note: As a Clinical Trial Certificate (CTC) is issued to each trial site of an approved clinical trial, the number of CTCs issued is greater than the number of approved clinical trials.

12. Policy Links Unit (2021), Singapore's Biomedical Cluster, Lessons from two decades of innovation and manufacturing policy accessed 20 September 2022, available at: [Link](#)

13. Inland Revenue Authority of Singapore (2019), 'Productivity and Innovation Credit Scheme', accessed 20 September 2022, available at: [Link](#)

14. Health Science Authority (HAS) (2021), 'Clinical trials statistics: accessed 20 September 2022, available at: [Link](#)

# Case Study: South Korea

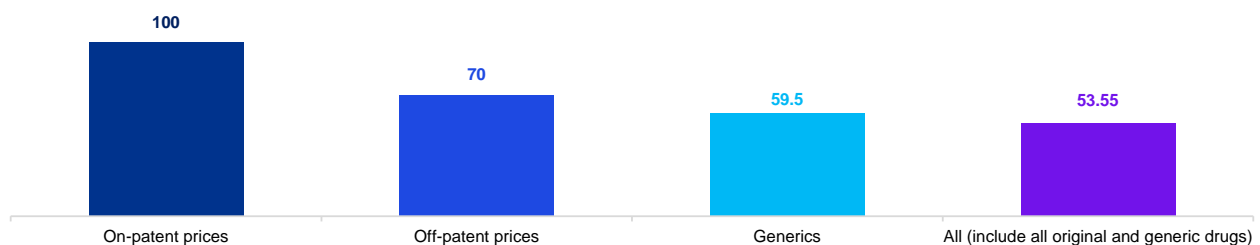
## Strong growth of Korea's pharmaceutical industry over 30 years

South Korea's pharmaceutical industry began to develop rapidly in the 1980s when the government first lifted the "ban on the imports of drugs that were made locally".<sup>15</sup> This forced local pharmaceutical firms to compete against foreign rivals.

Over the 1980s and 1990s, the government increased its support for the pharmaceutical and biotechnology industries in the country. In 1994, the Ministry of Science and Technology (MOST) formed the Biotech 2000 program, while the Ministry of Commerce, Industry and Energy (MOCIE) created the Bioindustry Vision 2000, with the aim of developing Korea's biotechnology industry to a level on par with other advanced economies.<sup>16</sup> This included enhancing the infrastructure and specialized workforces required for the progress of the industry, as well as increasing government investment in research and development.

The pharmaceutical market has grown strongly over the past decades. Employment in the industry has increased from 27,200 in 1999 to 53,600 in 2020 with a CAGR of 3.3%. Gross value added has also increased steadily from USD2.4 billion to USD12.5 billion, staying at 0.8% of national GDP.

The drop over 2007 to 2010 mainly came from the depreciation of Korean Won and an increase in the production cost of pharmaceutical products. In particular, the increasing average annual pharmaceutical expenditure per capita was 5.4% from 2009 to 2011, which was relatively higher than OECD countries. As a result, in 2011, while Korea's expenditure on pharmaceutical was estimated at 21.3% of national healthcare expenditure, in OECD countries the number was only 16.4%. Thus, on the 1<sup>st</sup> of April 2012, Korean government introduced "Single Price System (SPS)" – a new pricing mechanism, aiming to reduce the pharmaceutical expenditures and improve accessibility of medicine which in turn decreased the burden of health insurance. The new pricing after patent expiration were cut by 30% of their on-patent prices, in the parallel, the generic drugs were reduced 85% of their off-patent counterparts (or 59.5% of on-patent prices). After 12 months, the price was adjusted to be 53.55% of the on-patent prices. Approximately 6,505 products (equivalent to 40.1 of total listed drugs) were subject to price cut. A saving of nearly KRW 909 billion (USD 808.72 million) was estimated after 6 months of introduction of the SPS scheme.<sup>17</sup>



Although the productivity grew in line with gross value added in the earlier years however it became relatively stable, mainly caused by the continuous drug price control and restructuring of the industry.

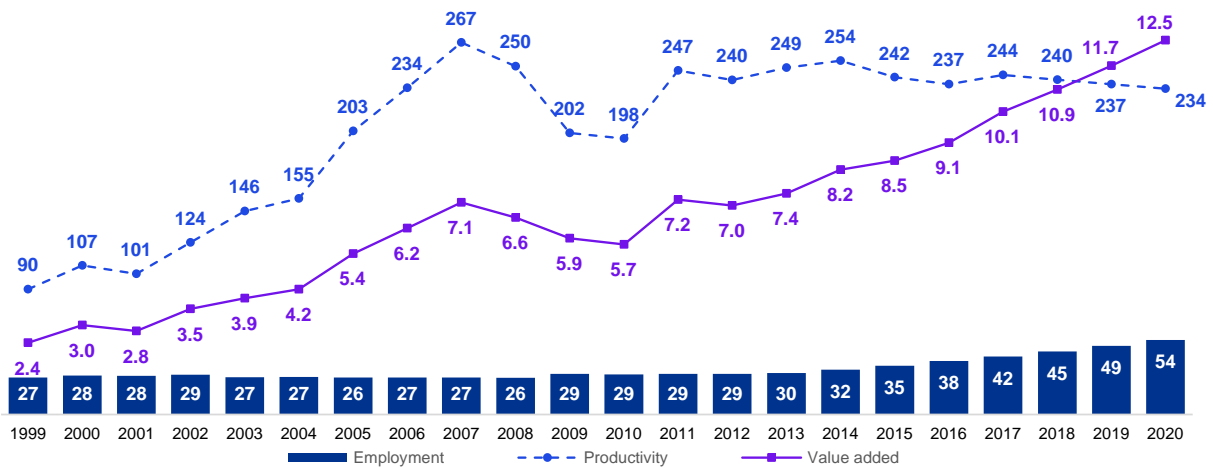
15. Kim, D., McGuire, A., Kyle, M. (2015) 'Korea pharmaceutical industry policy: lessons for Korea', 37 LSE Research Reports pp. 1-109.

16. Lim, D. (2009), 'Biotechnology Industry, Statistics and Policies in Korea', 11 Asian Biotechnology and Development Review 2, pp 1-27.

17. Hye-Young Kwon, Brian Godman (2017) 'Drug pricing in South Korea', pp.6



**Chart 8:** Employment ('000), productivity (USD thousand per employee) and gross value added (USD billion) of pharmaceutical industry



Source: Korean Statistical Information Service, KPMG's estimation

Note: Data based on establishments with employment size over 10 persons. Numbers converted from local currency to USD based on exchange rate from World Bank.

## Pharmaceutical exports have consistently expanded over the period

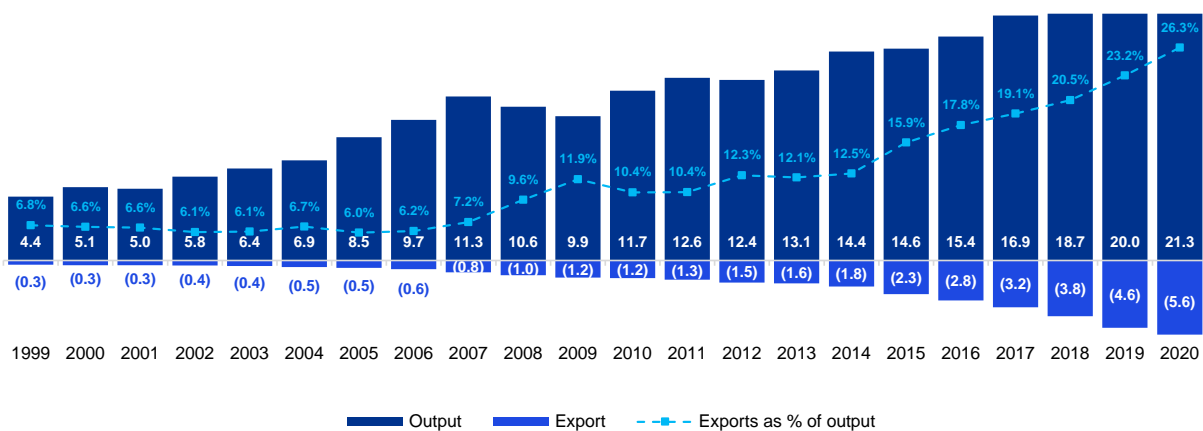
The Korean government has consistently supported the pharmaceutical and biotechnology industry, having selected healthcare as one of the 'growth engines' of the nation. In 1999 the Korean Health Industry Development Institute (KHIDI) was established as a public institution designed to improve growth and competitiveness in the industry.

Since 1999, the pharmaceutical output has increased consistently from USD4.4 billion to USD21.3 billion in 2020, with a CAGR of 7.8%. Exports have also increased significantly from USD300 million to USD5.6 billion from 1999 to 2020, at a rate of 15.0%.

The share of exports has increased from 6.8% of manufacturing output to 26.3% in 2020, pointing to the increased global competitiveness of Korean pharmaceuticals.

In more recent years, the 2011 Special Act on Supporting and Fostering the Pharmaceutical Industry helped to streamline regulator procedures in the industry, thus supporting its rapid expansion. Furthermore, the Pharma Korea 2020 Roadmap was launched in 2012, encouraging domestic pharmaceutical companies to increase innovation as well as to expand overseas.

**Chart 9:** Manufacturing output and exports of pharmaceutical products (USD billion)



Source: Korean Statistical Information Service, KPMG's estimation

Note: Gross value added, and output are based on establishments with employment size over 10 persons. Output for 2020 is estimated based on the CAGR over 2014 to 2018. Numbers converted from local currency to USD based on exchange rate from World Bank. The exports are positive values; the numbers here are shown in bracket only for presentation purpose.

## Lessons learned for policy makers

### Key government policies for the pharmaceutical industry

The government continuously supported the industry growth by having several policies and initiatives in place.

The key ones include:

**Table 2:** Key policies and initiatives in Korea

Year	Policies	Description	Impact
1980s	Lifted ban on drug imports	Lifted ban on imports of drugs that could be manufactured locally.	Local firms incentivized to increase their competitiveness to compete with foreign counterparts.
1985	Korea Research Institute of Bioscience and Biotechnology (KRIBB)	Established KRIBB to carry out research and development and other projects in bioscience and biotechnology, together with other institutes and businesses.	Dedicated to developing the field of bioscience and biotechnology; enhancing collaboration between the related organizations; disseminating results of research and discoveries to increase the benefits to all.
1987	Patent law	A comprehensive bill to amend the patent law to include patent coverage for chemical and pharmaceutical products.	Encourage research and development of pharmaceuticals within the country; attract multinational firms to invest in Korea since the patent law afford them better protection of intellectual property rights.
1994	Biotech 2000	First government-wide framework plan for biotechnology promotion in Korea.	Increase investment in the biotechnology industry.
1998	Foreign Investment Promotion Act	Eased regulations and restrictions on foreign investors, as well as increasing tax incentives.	Incentivize increased foreign investment into Korea, including attracting multinational firms to the pharmaceutical industry.
2004	Regional Clinical Trials Center (RCTC)	First RCTC established to kickstart Korea's clinical trials industry.	Increase Korea's clinical trial capabilities; adhere to global standards.



Year	Policies	Description	Impact
2006	Bio-Vision 2016	Based on global technological environment and lessons learnt from Biotech 2000, it envisions Korea being 'a health life and a prosperous bio economy' and ranking it among the world's top seven biotechnology powerhouses by 2016.	Continuously expand the industrial infrastructure and acquire competitive source technologies to actively promote the country's biotechnology to a position of global leadership; focus on driving industry R&D investment human capital.
2007	Korea National Enterprise for Clinical Trials (KoNECT)	Established as a non-profit organization by the Ministry of Health and Welfare to increase clinical trial capabilities.	Support the development of infrastructure and human resources for clinical trials; enable easy access to information through integrated information systems.
2011	Korea Drug Development Fund	Korea Drug Development Fund launched with a budget of USD1 billion, operated jointly by the Ministry of Science and ICT, Ministry of Trade, Industry and Energy and Ministry of Health and Welfare.	Sponsor projects to promote new drug development; increase investment in the sector at all stages of the drug development process.
2012	Global Center of Excellence in Clinical Trials (GCE)	Five consortia of clinical trial centers were given funding to develop clinical trial technologies and infrastructure, especially in specialized areas.	Increase the international competitiveness of Korea's clinical trials industry.
2012	Pharma Korea 2020 Roadmap	Outlined vision for Korean pharmaceutical industry and companies, such as in supporting innovative drug development and the expansion of Korean firms overseas.	Include a fund for R&D, increase investment, tax deductions for R&D and greater support for training workers.
2013	Research-driven hospitals	The Korean government designated ten research-driven hospitals.	Foster health technology research and development in university hospitals.
2018	Osong Biopolis	Korea's only biotech complex initiated by the government, to fuel the growth of the industry.	Dedicated infrastructure to develop new medicines and advanced medical devices, and it offers one-stop support for all stages of bio manufacturing, from clinical trials to approvals to manufacturing and retailing.
2019	Ambitious plan to further invest in biopharmaceutical sectors	The nation unveiled a bold USD1.7 billion five-year strategy with the goal of accelerating R&D and commercialization activities in the medical biotech industries. The ultimate goal is to assist the nation's pharmaceutical and medical device industries in capturing 6% of the worldwide market by 2030 and reaching USD50 billion in exports.	The country's pharmaceutical market is expected to increase from roughly USD19.5 billion in 2018 to more than USD23.2 billion by 2022, attracting international investment over the following five years.
2019	Center for AI-based New Drug Development Facilitation (KPBMA & KHIDI)	This facility will assist pharmaceutical firms in employing AI to produce new medications, and novel medication research, enabling pharmaceutical firms to create new drugs swiftly and safely.	Improve the efficiency in drug discovery and development, drug repurposing, improving pharmaceutical productivity in a short period.
2021	Improving Patient Access to New Drugs in South Korea	The national drug formulary system used to expand patient access to new drugs by making reimbursement decisions for new drugs as part of the South Korean national health insurance system.	To expand health insurance coverage, the South Korean government is creating rules that will increase patient access to medications with unmet needs. This is expected to have a positive effect on the drug manufacturing industry in the long run.

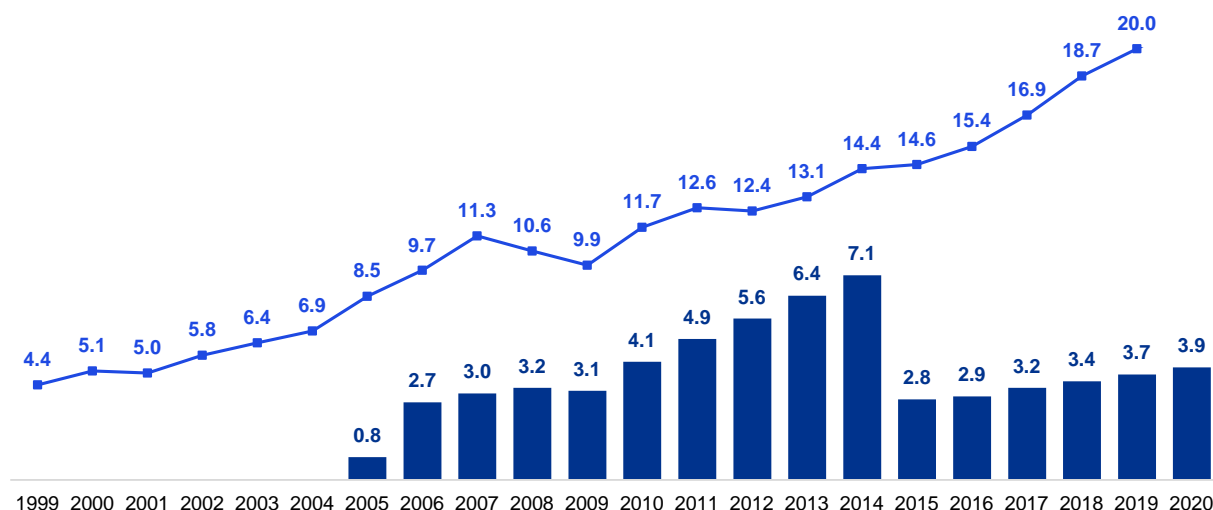
## Promoting pharmaceutical R&D by funding new drug development

The Korean government first began to promote R&D in the pharmaceutical and biotechnology in the mid-1980s. In 1985, the Korea Research Institute of Bioscience and Biotechnology (KRIBB) was established, and in 1987 the government began to recognize and grant patents.

Gross domestic expenditure on R&D in the medical and health sciences has increased consistently from 2005 onwards, from USD800 million to USD3.9 billion in 2020 with a CAGR of 11.2%. Business enterprise and higher education are the major units who perform the R&D, each accounting for around 40% of the total expenditure across the above time.

As of 2021, 48 new drugs – 35 synthetic drugs and 13 biological drugs have been developed in Korea since the first domestically developed drug in 1999, the Sunpla Injection by SK Chemical.<sup>18</sup> In 2011, the government has launched the Korea Drug Development Fund with a budget of USD1 billion for funding research into new drugs.<sup>19</sup> The Pharma Korea 2020 Roadmap also reflected the government’s emphasis on innovation, setting targets to increase the number of new drugs developed. The government’s support for R&D was further highlighted as it designated ten research-driven hospitals in 2013.<sup>20</sup> There are also around 150 universities, and 6 major public research institutes are involved in pharmaceutical research in Korea.<sup>21</sup>

**Chart 10:** Gross domestic expenditure on R&D in medical & health sciences versus industry output (USD billion)



Source: OECD; Korean Statistical Information Service, KPMG’s estimation

Note: Output is based on establishments with employment size over 10 persons. Numbers converted from local currency to USD based on exchange rate from World Bank. The drop of R&D in 2015 was due to a change in OECD’s methodology.



18. Pharma Boardroom (2018), ‘Korea: An Up and Coming Pharma Industry’, accessed 2 October 2019, available at: [Link](#).
19. Korea Drug Development Fund (2017), ‘Why “Korea” is the best place for new drug development’, accessed 2 October 2019, available at: [Link](#).
20. Ribbink, K. (2015), ‘South Korea: From Strength to Strength’, Pharma Voice, accessed 2 October 2019, available at: [Link](#).
21. Korean Pharmaceutical Innovators’ Group (2019), ‘Overview of Korean Pharmaceutical Industry’, Korea Drug Research Association, accessed 2 October 2019, available at: [Link](#).

## A series of incentives in place at an early stage to attract FDI into Korea

Furthermore, the government has put in place incentives to attract FDI into Korea. It began to recognize and grant patents starting in 1987, and the stronger intellectual property rights encouraged foreign firms to enter the Korean pharmaceutical industry. Subsequently the Foreign Investment Promotion Act was enacted in 1998 (and subsequently amended in 2012)<sup>22</sup> to ease the restrictions on foreign investment, as well as establishing tax incentives and foreign investment zones. It has also committed resources to developing a specialized workforce and infrastructure for the industry<sup>23</sup>, which act as an additional draw for multinational companies.

At present, the incentives given for FDI include tax reductions for corporate, income, and local tax as well as

customs duties. These are given especially to technologies classified as 'new growth engines' and for manufacturing in Foreign Investment Zones and Free Economic Zones. Cash grants for land purchase, lease expenses and training subsidies are available for manufacturing and R&D centers, with a minimum of 30% foreign investment. Furthermore, industrial site support is given to foreign companies to enable them to afford the locations they require for their businesses.<sup>24</sup>

FDI in the pharmaceutical industry increased from USD460 million in 1999 to USD2.6 billion in 2020. The pandemic impacted the overall Foreign direct investment, and pharmaceutical industry was not an exception, the FDI project number declined from 313 in 2019 to 281 projects in 2020.

**Chart 11:** FDI position for the pharmaceutical industry (USD billion)



Source: OECD; Korean Statistical Information Service

Note: Output is based on establishments with employment size over 10 persons. Numbers converted from local currency to USD based on exchange rate from World Bank. FDI position in 2020 is estimated based on the share of Pharmaceutical FDI in total FDI from 2013 to 2018



22. Republic of Korea Ministry of Legislation, Foreign Investment Promotion Act 2012.

23. Kim, D., McGuire, A., Kyle, M. (2015) 'Korea pharmaceutical industry policy: lessons for Korea', 37 LSE Research Reports pp. 1-109.

24. Invest Korea (2017), 'Investment Guide: FDI Incentives', accessed 2 October 2019, available at: [Link](#); see also Nicholas, F., Thomsen, S., Bang, M.H. (2013), 'Lessons from Investment Policy Reform in Korea', OECD Working Papers on International Investment 2013/02, OECD Publishing: [Link](#).

## Streamlined processes make Korea a popular location for clinical trials

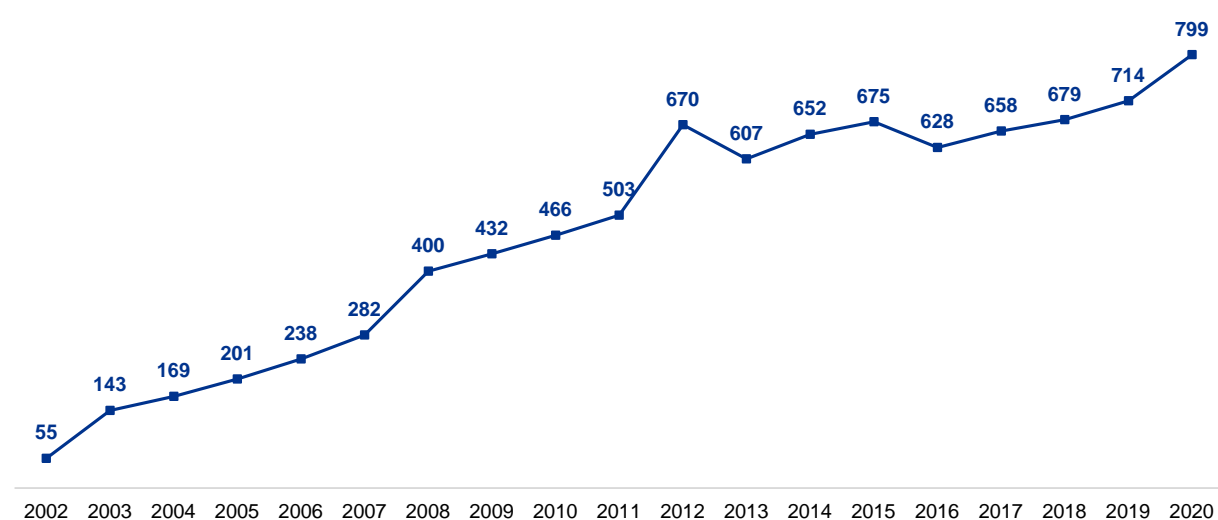
To promote clinical trials in Korea, the government initiated the programs of Regional Clinical Trials Center (RCTC), Global Center of Excellence in Clinical Trials (GCE), and the Korea National Enterprise for Clinical Trials (KoNECT).

In 2004, the first RCTC was established in Korea, a number which grew to 15 by 2016. The first GCE was built in 2012, and by 2016 there was a total of 5 GCEs.<sup>25</sup> Furthermore, the KoNECT was established in 2007 in order to foster the nation's clinical trial capabilities and to facilitate sharing of information across the sector. In 2019, there were around 184 accredited clinical trial facilities and 19 preclinical trial organizations in the country.<sup>26</sup>

Korea is now a popular location for clinical trials due to the streamlined processes. Clinical trials in Korea take only 30 days to be approved, with an average start-up time of 152 days – one of the shortest in the world.<sup>27</sup> Over 2002-2020, the number of domestic clinical trials in Korea has grown from 55 to 799 with a CAGR of 16.0%. In 2018, 57.9% of the approved clinical trials in Korea were local.<sup>28</sup>

After Korea's adoption of the International Conference on Harmonization (ICH) guidelines for clinical trials in 2007, the nation has since risen to become ranked seventh globally for clinical trial protocols<sup>29</sup>, with Seoul being one of the leading cities in the world. The global market share of Korea's clinical trial sites was 3.6% as of 2020.<sup>30</sup>

Chart 12: Number of domestic clinical trials



Source: OECD; Novotech; Business Korea

Note: Number of clinical trials in 2004-2006 and 2009-2010 are unavailable and therefore estimated based on CAGR over the period

25. Invest Korea (2016), 'Korea's Clinical Trial Industry in the Global Market', accessed 2 October 2019, available at: [Link](#).
26. Korean Pharmaceutical Innovators' Group (2019), 'Overview of Korean Pharmaceutical Industry', Korea Drug Research Association, accessed 2 October 2019, available at: [Link](#).
27. Miseta, E. 'Why South Korea is the Hottest Growth Spot for Clinical Trials', Novotech CRO, accessed 2 October 2019, available at: [Link](#).
28. Ribbink, K. (2015), 'South Korea: From Strength to Strength', Pharma Voice, accessed 2 October 2019, available at: [Link](#).
29. The Present and Future of Korea Clinical Trials (2017), 'Build world-class clinical trial capacity in Korea', accessed 15 September 2022, available at: [Link](#)
30. Clinical trials arena, accessed 15 September 2022, available at: South Korea accounts for 3.6% share of global clinical trial activity in 2020 - Clinical Trials Arena



# Case Study: Ireland

## Steady expansion of Ireland's pharmaceutical industry since 1970s

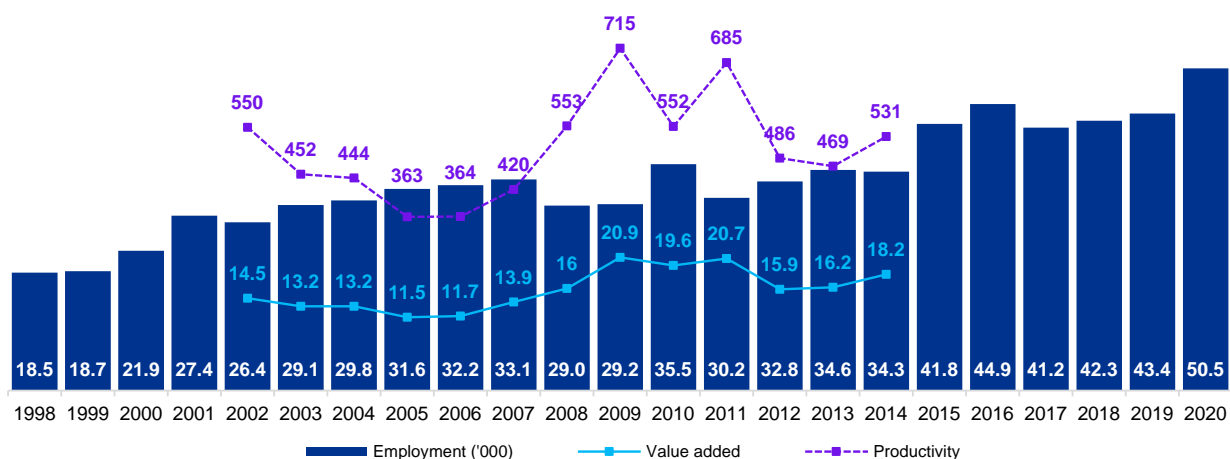
The pharmaceutical industry in Ireland started booming in the 1970s after the government's move to shift its focus on the pharmaceutical industry as one of its key sectors. Since then, the industry has been expanding steadily, with an increase in industry-level employment, value added as well as productivity levels.

Industry-level employment has increased steadily at a CAGR of 4.67%, from 18,500 people in 1998 to 50,500 people in 2020. The growth in industry employment persisted even during a period where other manufacturing industries experienced a decline. As a result, the share of the pharmaceutical industry in total manufacturing employment has increased from 6.2% to 22.1% over 1998 to 2020, which signifies the importance of the pharmaceutical industry in the Irish economy.

Over 2002 to 2014, the gross value added from pharmaceutical industry slightly declined, resulting in a relatively stable productivity of pharmaceutical industry at around USD500,000 per employee, more than doubling the productivity of general manufacturing industry.

The growth experienced by the Irish pharmaceutical industry could be attributed to the strong government support, legal and regulatory frameworks, educated labor force, easy access to the European markets, as well as strong public-private partnerships within the industry.<sup>31</sup>

**Chart 13:** Employment ('000), productivity (USD thousand per employee) and gross value added (USD billion) of pharmaceutical industry



Source: Central Statistics Office of Ireland, the value added data is no longer published after 2014

Note: Due to data limitation, gross value-added data is compiled from multiple releases of the Income and Expenditure from CSO. Numbers converted from local currency to USD based on exchange rate from World Bank.

31. Irish Pharmaceutical Healthcare Association (2019), 'Contribution to the Irish Economy', accessed 14 September 2022, available at: [Link](#).

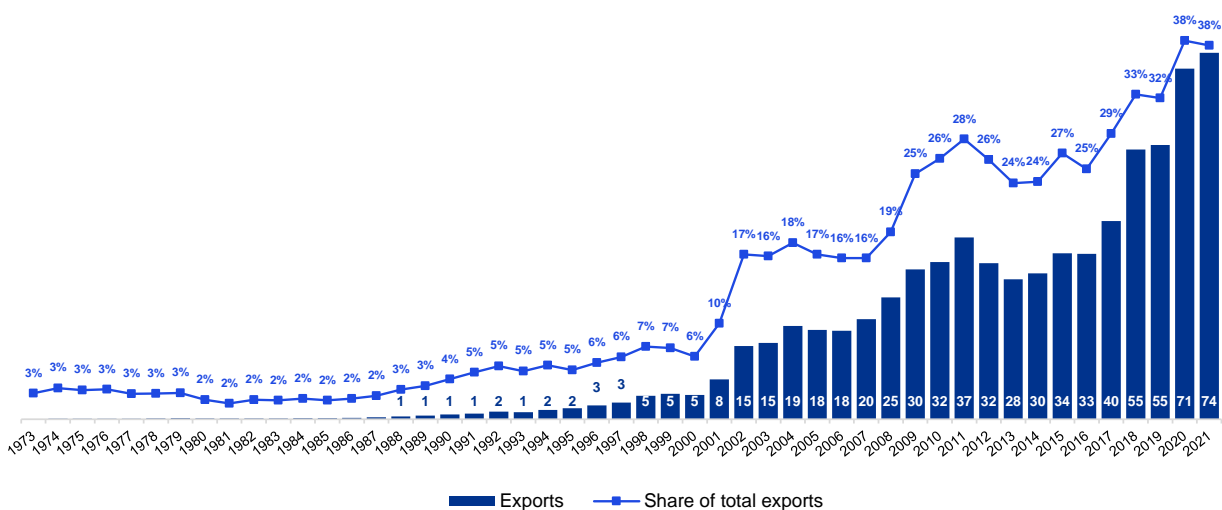


## 4.4.2 Ireland has become a key exporter of pharmaceutical products

After joining the European Economic Community (now European Union) in 1973, Ireland's trade increased by a large extent since it had previously been trading primarily with the United Kingdom. The exports of pharmaceutical and medical products increased at a CAGR of 16.2%, from USD55.7 million in 1973 to USD74.1 billion in 2021, representing an increase from 2.6% of total exports to 37.8% over the period. Faster growth has been observed since Ireland started replacing Irish Pound with Euro at the beginning of 2000s.

The country became the largest net exporter of pharmaceuticals in the EU, with pharmaceuticals accounting for over 50% of the country's net exports.<sup>32</sup> In 2020, Ireland became the largest net exporter of medicines<sup>33</sup> in the world, of which 19 of the top 20 pharmaceutical companies in the world are established in this nation.<sup>34</sup>

**Chart 14:** Exports of medical and pharmaceutical products (USD bn) and share of total exports



Source: Central Statistics Office of Ireland

Note: Numbers converted from local currency to USD based on exchange rate from World Bank.

The manufacturing base for biotechnology has grown significantly over the year. In 2022, there were 80 total manufacturing sites, of which many are owned by export-oriented foreign companies.<sup>35</sup>

The strong growth of pharmaceutical manufacturing and exports also benefited from the high labor capability in Ireland, as the country has maintained a strong focus on human capital development. The government opened the National Institute for

Bioprocessing Research and Training (NIBRT) in 2011<sup>36</sup>, primarily funded by the IDA and supported by several universities. EUR57 million (USD79 million) was committed to training workers to use the industry's specialized and state-of-the-art equipment. The pool of talent and skilled workers in Ireland contributes not only to the productivity and competitiveness of the industry, but also adds to its attractiveness as a location for both manufacturing and research.

32. Ibid.

33. OEC (2022), 'Pharmaceutical products', accessed 14 September 2022, available at: [Link](#)

34. Innopharma Education (2022), 'Why Ireland attracts top pharmaceutical companies', accessed September 2022, available at: [Link](#)

35. Get Reskilled (2022), 'Table of 205 Pharmaceuticals and Medical Devices Factories in Ireland Organized by County', accessed 14 September 2022, available at: [Link](#)

36. University College Dublin (2011), 'Minister opens €57 million facility to support biopharmaceutical industry', UCD News, accessed 15 September 2022, available at: [Link](#)

## Lessons learned for policy makers

### Key government policies for the pharmaceutical industry

The government has put in place numerous policies and initiatives to drive the industry growth. The key ones include:

**Table 3:** Key policies and initiatives in Ireland

Year	Policies	Description	Impact
1970s	Industrial Development Authority's (IDA) adoption of fine chemicals as one of its target sectors	IDA is the government agency responsible for attracting inward investment. It identified fine chemicals including pharmaceuticals as one of the key emerging sectors in 1970s.	Successfully bring in a substantial number of foreign companies to invest in manufacturing in Ireland; boost strong growth of the employment in pharmaceutical industry.
1986	Health Research Board (HRB)	Mainly funded by Ministry of Health (MOH) and serve as a leading funding agency that supports research and provides evidence to prevent illness, improve health and transform patient care.	HRB oversees a EUR45 million (USD53 million) investment in health research activity each year and manages four national health information systems; provide information and evidence in healthcare and drive healthcare innovation; promote the overall industry competitiveness.
1987	Control of Clinical Trials Act (amended in 1990)	Comprehensive legal framework on conducting clinical trials, including clinical trial application, restriction, participant, and ethics etc.	Regulate clinical trials of medicinal products at state level to ensure product quality (safety and effectiveness).
1996	Health Products Regulatory Authority (HPRA) (formerly Irish Medicines Board)	An independent regulator of health products in Ireland to protect and enhance public and animal health.	Ensure safety, quality and effectiveness of the entire healthcare products; emphasize quality control from the beginning, which improves Ireland's attractiveness to foreign investment.



Year	Policies	Description	Impact
2000	Science Foundation Ireland (SFI)	SFI provides awards to support scientists and engineers working in the fields of science and engineering that underpin biotechnology, information and communications technology and sustainable energy and energy-efficient technologies.	Provide funds in R&D and education to promote development and competitiveness of the biomedical industry, enterprise and employment.
2007	Synthesis and Solid-State Pharmaceuticals Cluster	Government invested in the research center (under SFI), to promote the development of the more specialized area in the pharmaceutical industry.	Attracts companies, researchers, conferences to Ireland; encourages more in-depth of research at all stages along the production process starting from synthesis.
2007	National Development Plan 2007-2013	Government committed to investing in the industry, including in infrastructure, R&D and human capital.	Long-term planning for investments to boost the development of the industry.
2009	Action Plan for Health Research	A task focused framework to priorities a Program of actions that are essential to creating a health research system which supports outstanding individuals, working in world-class facilities and conducting leading-edge research focused on the needs of patients and the public.	Enhance the implementation of health-related initiatives by focusing on (1) leading a national health research system; (2) developing research capacity in the health services; (3) building academic and enterprise links with the health research sector; (4) reforming the health research governance structure; (5) turning research outcomes into health benefits and economic gains.
2011	National Institute for Bioprocessing Research and Training (NIBRT)	A EUR57 million (USD79 million) facility (6,500 sqm) to support the biopharmaceutical industry by educating and training highly skilled staff and conducting ground-breaking research in collaboration with industry.	Boost the industry growth by enhancing education for pharmaceutical professionals and driving collaboration between research and industry; position Ireland as a global center of excellence in bioprocessing.



Year	Policies	Description	Impact
2015	Clinical Research Coordination Ireland (CRCI)	An independent integrated national clinical research network funded by the HRB and Enterprise Ireland to provide centralized support to the clinical research industry across the country.	Provides overarching support and expertise through infrastructure, experienced specialist and the necessary quality and oversight programs to conduct world-class patient-focused research in Ireland.
2018	Disruptive Technologies Innovation Fund (DTIF) <sup>37</sup>	Founded in 2018, the Disruptive Technologies Innovation is one of the four funds that were set up under the National Development Plan 2018 – 2027. This is a EUR500 million (USD500 million) challenge-based fund that provides financial supports disruptive innovations.	Connects international pharmaceutical companies with relevant stakeholders (other Irish enterprises, higher education institutes and research centers) to access to financial support for their R&D.
2020	National Research Ethics Committees (NRECs) <sup>38</sup>	At the request of the Ministry of Health, National Research Ethics Committees was established to support the existing local or institutional Research Ethics Committees in Ireland, with a specialization in health research. The committee acts as a Bill that works in a mixed-model system to support research ethics.	Provides a transparent and cohesive research ethics review system that strengthens the national research infrastructure in health research.
2021	National Development Plan 2021 - 2030 <sup>39</sup>	The government's human capital development plan for the biopharmaceutical industry.	Long-term planning to train new talents for the biopharmaceutical industry of the country and boost the development of Irish pharmaceutical market.
2021	National Clinical Trials Office (NCTO) <sup>40</sup>	The EUR1.7 million (USD1.7 million) National Clinical Trials Office was established in 2021 by the Health Research Board and University College Cork. The objective of National Clinical Trials Office is to connect the clinical trial sites and those involved in the design, construct and support of investigator-led and industry-sponsored trials in Ireland.	Manages relations with international sponsors of multicentre trials to help them access to financial resources for efficient trial set-up; Connects the trial community in Ireland with the European Clinical Research Infrastructure Network (ECRIN) and connects with relevant stakeholders to improve the execution of clinical trials in Ireland.
2022	The New Clinical Trials Regulation Implementation in Ireland <sup>41</sup>	Through the National Pilot Project Phase, the Health Products Regulatory Authority has been working on implementing the new EU Clinical Trial Regulation, in which clinical trials conducted in Ireland must be submitted through the Clinical Trial Information System (CTIS) – a central database for all information relating to clinical trials in the EU. The new regulation came into effect on 31 January 2022.	Unifies the policies that regulate the clinical trials in EU, ensuring a greater of harmonization in information regarding clinical trials in European Union. This will help to improve the quality of clinical trials to produce effective medicines to patients in a short period of time.

37. Department of Enterprise, Trade and Employment (2022), 'Disruptive Technologies Innovation Fund', accessed 16 September 2022, [Link](#)

38. National Office for Research Ethics Committees (2020), 'National Office for Research Ethics Committees', accessed 16 September 2022, [Link](#).

39. Government of Ireland (2021), 'National Development Plan 2021 – 2030', accessed 16 September 2022, [Link](#)

40. Health Research Board (2021), 'HRB investment boosts number, variety and quality of clinical trials in Ireland', accessed 16 September 2022, [Link](#)

41. Health Products Regulatory Authority (2022), 'New Clinical Trials Regulation', accessed 16 September, [Link](#)

## Successful partnership between the government, the pharmaceutical industry and the Industrial Development Authority (IDA)

To stimulate and develop enterprises in Ireland, the Industrial Development Authority (IDA) was set up in 1949. The pharmaceutical industry really grew after IDA adopted fine chemicals as one of its focus sectors in 1970s. From the 1970s to 1990s, a large proportion of investment in pharmaceuticals and biotechnology came from private companies, both international and local.<sup>42</sup>

FDI has played a very important role in driving the growth of pharmaceutical industry in Ireland. In the initial stage of the industry, IDA has successfully brought in a substantial number of foreign companies to invest in manufacturing to boost the domestic industry. Joint Ventures, licensing and acquisitions strengthened the local base of companies leading to the emergence of new local supply companies. It also brought scale, technology and infrastructure improvements and world class management capability to the local pharmaceutical industry. Ireland's FDI position for pharmaceutical products maintains strong growth of 24.5% annually from 2012 to 2020.<sup>43</sup>

## Establishing designated research institutes and funding pharmaceutical R&D

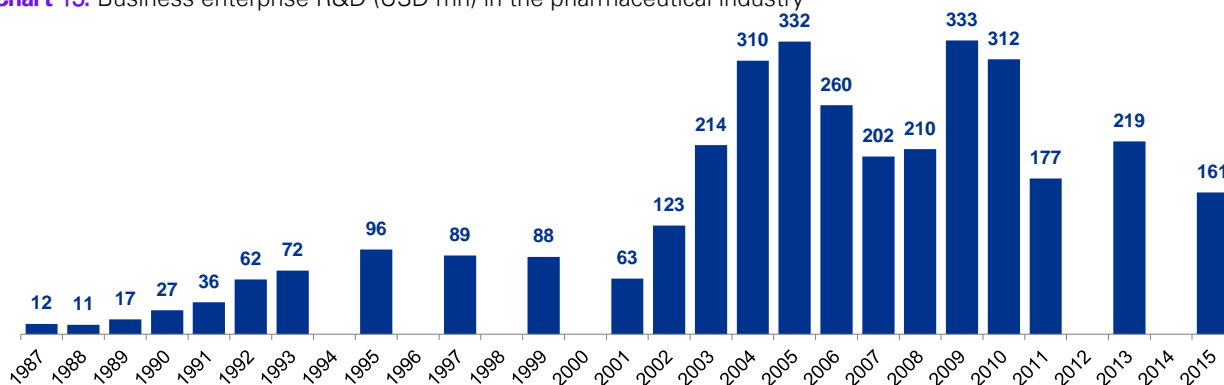
The government has played an increasing role in funding medical and health research. In the 2007-2013 National Development Plan, the planned state investment into health research was EUR301 million (USD412 million) as well as EUR5.0 billion (USD6.8 billion) into health infrastructure.<sup>44</sup>

The Health Research Board (HRB) was set up in 1986 as the leading funding agency for health research. It also manages national health information systems and resources for health practitioners, researchers and policy-makers.<sup>45</sup> It is one of the major sources of funds for health-related research, along with Science Foundation Ireland (SFI), IDA, and Enterprise Ireland.<sup>46</sup>

To develop biotechnology as an engine for Ireland's growth, SFI was established in 2000 to minister the Technology and Foresight Fund with a budget of EUR646 million (USD763 million).<sup>47</sup> It went on to establish SFI Research Centers, including the Synthesis and Solid-State Pharmaceuticals Cluster (SSPC) in 2007.<sup>48</sup> These centers attract global companies, researchers and conferences to Ireland.

At present, SFI funds research, promotes the development of the industry, and collaborates with over 300 Irish small-to-medium enterprises to enhance their research. Over 600 companies are linked to SFI research groups, of which more than 240 of them are multinational companies.<sup>49</sup>

**Chart 15:** Business enterprise R&D (USD mn) in the pharmaceutical industry



Source: OECD

Note: Numbers converted from local currency to USD based on exchange rate from World Bank. Empty columns indicate unavailable data.

42. Heavey, B. (2016), 'A Tale of Irish Biopharma', The Medicine Maker, accessed 15 September 2022, available at: [Link](#).
43. CEIC (n.d.), 'Ireland IE: Foreign Direct Investment Position: Inward: Total: Manufacture of Basic Pharmaceutical Products and Pharmaceutical Preparations', accessed 15 September 2022, available at: [Link](#)
44. Government of Ireland (2007), 'National Development Plan 2007-2013', European Social Fund Ireland.
45. Health Research Board of Ireland (2019), 'History of the HRB', accessed 15 September 2022, available at: [Link](#).
46. Government of Ireland (2009), 'Action Plan for Health Research 2009-13', Department of Health.
47. Science Foundation of Ireland (2019), 'History: Technology Foresight Ireland Report', accessed 15 September 2022, available at: [Link](#).
48. Synthesis and Solid State Pharmaceutical Centre (SSPC) (2019), 'Six Years in the Making: Looking Back & Moving Forward'.
49. Science Foundation of Ireland (2022), 'Discovery to Delivery', accessed 16 September 2022, available at: [Link](#).

## Consistent, transparent, and pro-business government fiscal and monetary policies

Ireland's pharmaceutical industry is home to nearly all the world's top 20 pharmaceutical companies. The reasons for its attractiveness to these multinational companies include its low corporate tax rate (12.5%), the availability of tax credits for research and development, an intellectual property regime that provides tax reductions, as well as international agreements on double taxation.<sup>50</sup>

The strong regulatory framework upheld by the Health Products Regulatory Authority (formerly Irish Medicines Board) also encourages investment from international companies as they are assured of world-class standards. Furthermore, Irish legislation such as for clinical trials and medicines authorization are in line with EU legislation<sup>51</sup>, thus its close connections with the rest of Europe position it well for companies seeking to reach the European market.

## Increasing number of clinical trials – generating significant benefits to the economy

Several initiatives and institutions in Ireland have also enabled the growth of its clinical research scene. The enactment of Control of Clinical Trial Act in 1987 and amendment in 1990 regulated clinical trials at state level to ensure product quality. In 2015, Clinical Research Coordination Ireland (CRCI) was established to provide centralized support to the clinical research industry across the country, funded by the HRB and Enterprise Ireland.<sup>52</sup> It was hosted by Clinical Research Development Ireland (CRDI), which is a partnership of several universities, medical schools, academic hospital and clinical research facilities.

In 2019, the number of clinical research infrastructures in Ireland was 16, of which the majority of them are based in Dublin.<sup>53</sup> The total number of clinical trials registered in Ireland totaled 4,214 from 1999 to 2021<sup>54</sup>, and the clinical trials conducted in HRB's three Clinical Research Facilities increased from 325 in 2017 to 421 in 2021.<sup>55</sup>

Conducting clinical trials has generated significant benefits to the economy. An independent analysis conducted by DKM Economic Consultants pointed out that the clinical cancer trials in 2016 had saved the Irish Health Service Executive (HSE) EUR6.5 million (USD6.5 million) in cancer drug cost, generated nearly EUR6 million (USD6 million) in tax revenues, contributed EUR16.5 million (USD16.5 million) to the country's GDP and created more than 230 new job opportunities to the labor force.<sup>56</sup>

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50. PharmaVoice (2015), 'Ireland: Set to Soar Again'.

51. Health Products Regulatory Authority (2019), 'About Us: Legislation', accessed 16 September 2022, available at: [Link](#).

52. Clinical Research Development Ireland (2018), 'Annual Report 2018', accessed 16 September 2022, available at: [Link](#).

53. Ward, O and Kennelly, H (2019), 'Review of clinical research infrastructure in Ireland', accessed 16 September 2022, available at: [Link](#)

54. World Health Organization (2022), 'Number of clinical trial registrations by location, disease, phase of development, age and sex of trial participants (1999-2021)', accessed 16 September 2022, available at: [Link](#)

55. Health Research Board (2022), 'Annual Reports 2021 Annual Reports 2007-2018', accessed 15 September 2022, available at: [Link](#).

56. Cancer Trials Ireland (n.d.), 'Economic benefits of cancer trials', accessed 16 September 2022, [Link](#)



# Opportunities for Vietnam

## Overview

Developing the innovative pharmaceutical industry will likely bring significant value to sector growth, economic contribution, and health outcomes. Vietnam has the potential to grow its domestic innovative pharmaceutical market.



### 1 PATIENT BENEFIT

- Improved treatment outcomes;
- Reduced overall cost through faster access to high quality, innovative medicines.

### 2 GOVERNMENT BENEFIT

- Social and economic growth through more high-tech investment, vocational training, and healthier workforce;
- Highlight steps to improve competitiveness, and legal and business environment.

### 3 INDUSTRY BENEFIT

- Enhancement of local manufacturing;
- Develop export capabilities;
- Increase R&D activities and become a hub for pharmaceutical sector.



# Key economic factors driving opportunity

The benefits mentioned can capitalize on several socio-economic factors key to Vietnam’s rapid economic growth.

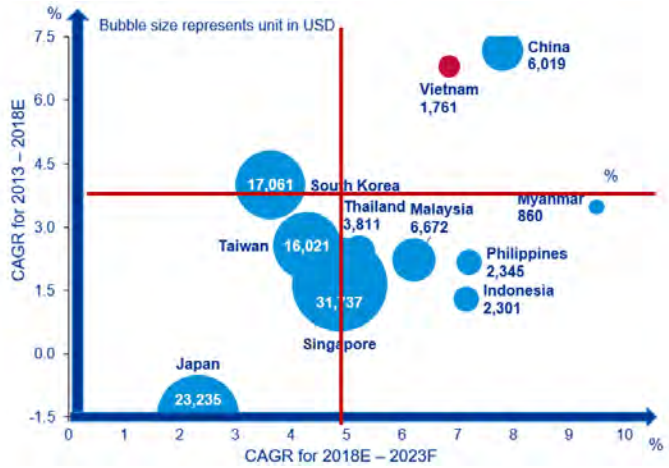


## Demographics

In terms of population, Vietnam is the 15th most populous nation in the world, with roughly 98 million residents as of 2021. The proportion of people 65 years old and older in the population, which is currently 8.2%, is predicted to rise sharply. In Vietnam, an aging populace will hasten the onset of age-related illnesses such as diabetes and cardiovascular problems.

Vietnam’s economy is now classified as low middle-income. Over the past few years, Vietnamese disposable income has increased quickly, and it is anticipated to maintain a CAGR of 6.8% until 2026. Increasing consumerism on healthcare services underpinned by growth of disposable income, is opening the door for novel healthcare solutions.

**Figure 2:** Disposable income of Vietnam versus selected countries



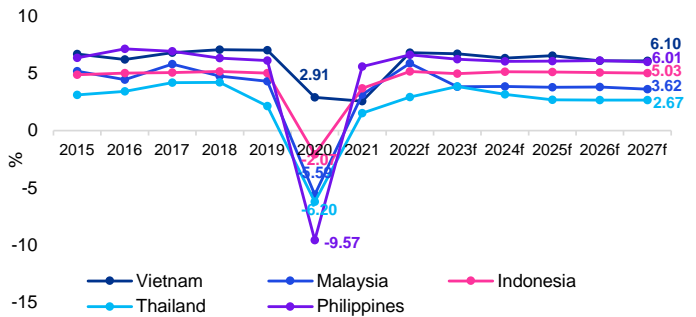
Source: Fitch Solutions



## GDP growth

Vietnam was one of the few nations to register positive GDP growth of 2.91% and 2.58% in 2020 and 2021, respectively, despite the epidemic. The country’s recovery has now accelerated to its average 6.8% growth rate in 2022 and 6.1% for the following five years, which would be comparatively stronger than other regional counterparts including Thailand (2.67%), Malaysia (3.62%), and Indonesia (5.03%). Vietnam is expected to benefit from such robust economic growth as producing an enticing growth story has been laying strong foundation to attract further FDI and facilitate the transfer of much-needed technology and knowledge.

**Figure 3:** Regional comparison of real GDP growth 2015 – 2027f



Source: Business Monitor International



## Pharmaceutical sector growth

According to latest available statistics of the Ministry of Health, as of 2021, Vietnam currently has approximately 250 pharmaceutical manufacturing sites operating in the market (both local and foreign companies) (of which, there are 222 manufacturing sites qualified GMP-WHO). Most of these companies produce generics for local consumption. 90% of the Active Pharmaceutical Ingredients (APIs) for these products come from imported sources, primarily China and India.

Going forward, macro conditions and expanded consumer spending power are expected to help maintain a similar level of Year-on-Year (YoY) growth through 2045. If the Vietnamese market can maintain this growth pattern, the total industry value could reach and exceed USD63.8 billion by 2045.

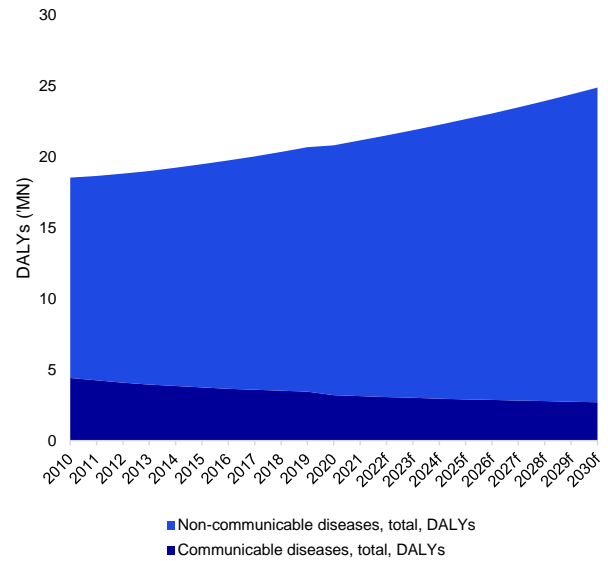


### Non-communicable diseases trend

Non-communicable diseases (NCDs) are expected to take up a larger portion of the healthcare market in Vietnam. Due to the limitations in healthcare financing, new and creative initiatives will be required to fulfill the increased demand.

In 2021, non-communicable diseases accounted for 85% of Disability-Adjusted Life Years (DALYs), the commonly used measure of disease burden. By 2030, this figure is anticipated to increase to 89%. Non-communicable diseases are primarily caused by cancer, heart disease, and musculoskeletal conditions (i.e., lifestyle diseases). 3.2 million DALYs are currently attributed to cancer, and that number is projected to rise by 900,000 by 2030. The burden of illnesses in Vietnam (8.3%) mainly results from cardiovascular diseases, particularly stroke. Vietnam exhibits one of the highest fatality rates for stroke in Southeast Asia, with 114 per 100,000 people in 2021. Therapeutics corresponding to those found in regional markets could considerably lower NCD-related mortality.

Figure 4: Vietnam burden of disease projection



Note: NCD group causes exclude consideration of 'Mental & Behavioral' group of diseases

Source: Fitch Solutions



# Potential Opportunities for the Pharmaceutical Industry

Given the above key economic factors, Vietnam needs pharmaceutical development which can meet the ambitions of government and socio-economic needs of the community.

Meeting these needs require a collaboration between policymakers and industry towards effective patient outcomes and strong sector development. With the support of government, industry has ambitions to expand their investment through clinical trials alongside industry education and broadened patient support.



## Enhance domestic capability and boost industry growth through foreign investment

Foreign investment from the innovative pharmaceutical industry will likely go into three key areas:

### 1 Leveraging clinical trials to drive industry growth

Vietnam's demographics make it uniquely suited to conduct clinical trials, which in turn will boost both domestic capabilities, and have an acceleration effect on further foreign investment. Regarding the former, expanded clinical trials would encourage the development of advanced industry knowledge within Vietnam. Such knowledge would permeate throughout the broader health-industry, developing an up-skilled, advanced workforce of healthcare and life science professionals. Encouraging and supporting the growth of clinical trials would, moreover, see heightened foreign investment in-country, supporting Vietnam's economic ambitions.

### 2 Establishing local manufacturing

Setting up or expanding local manufacturing capabilities will be one of the eventual outcomes of foreign investment. This is also aligned with the government's vision to have 60% of the market value manufactured locally by 2025.

Five of twelve companies interviewed which currently do not have local drug manufacturing in Vietnam anticipate considering such operations in the next two to four years, if certain above-described criteria is met. This could lead to an additional investment of USD5 – 20 million for each company on average. Depending on the size of manufacturing site, it would also create additional employment ranging from 10 to 100 FTEs for each company, as well as additional contribution to the pharmaceutical industry.<sup>57</sup>

Local manufacturing activities will initially be mostly contract manufacturing through qualified local partner. This would drive technology transfer, process R&D and capability enhancement of

domestic manufacturers. International standards and best practices will also come through the partnership, driving the domestic pharmaceutical industry to a faster growth trajectory.

### 3 Funding medical education and patient support programs

Innovative pharmaceutical companies have made significant investment in education (for both professionals and patient) and patient support programs in the past years and will continue expanding their investment in the future.

To enhance domestic workforce capability, these companies have provided CME programs including trainings and educational events for pharmaceutical and medical professionals. Leading companies arrange more than 600 programs a year through investing from USD2 – 15 million annually. The size of these programs ranges from 5-10 attendees to 600 – 700 attendees on average. Most companies have ambition to expand or at least maintain the current level of investment in education, which is approximately 5% to 25% of operating costs varied by company strategy.<sup>58</sup> Capability building is interlinked with foreign investment, as improving domestic capability will further attract foreign companies to establish research and manufacturing in the country.

Patient support programs mainly focus on improving patient awareness and access to innovative drugs, and usually take place through one or more hospitals. These programs are generally not commercial from the company's perspective but generate benefits to patient and the general Vietnamese population. On average, one patient support program could reach around a thousand patients depending on the number of hospitals covered in the program.<sup>59</sup>

57. Stakeholder interview.

58. Stakeholder interview.

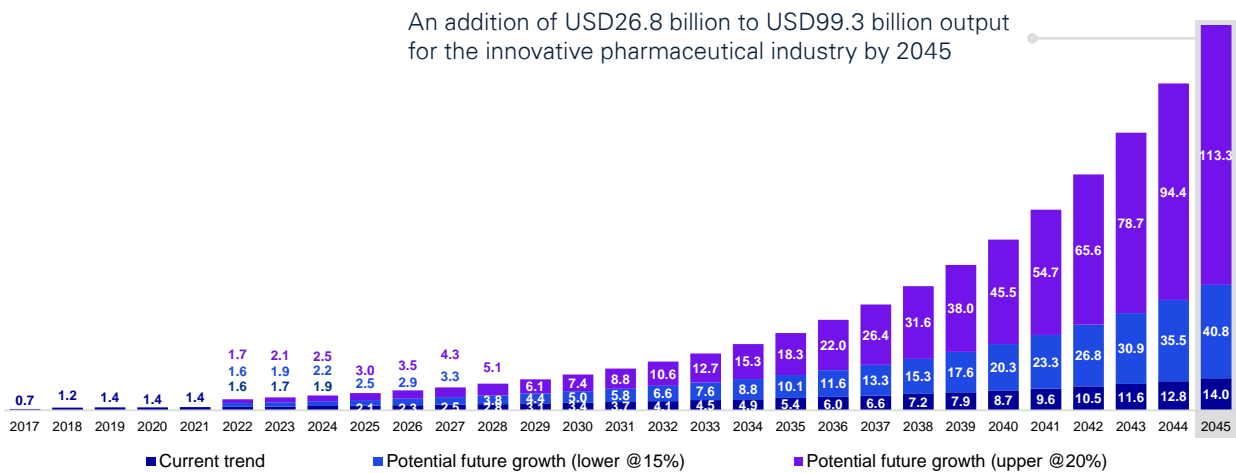
59. Stakeholder interview.



**Innovative pharmaceutical industry can potentially grow at 15% to 20% with an additional USD26.8 billion to USD99.3 billion output by 2045**

In 2020 and 2021, the market experienced a period of slowed growth, as the country implemented social isolation. However, post-pandemic, the market is expected to return to its pre-covid growth rates of 10.0% to 12% y-o-y. This base-case growth rate would translate the current market value of USD1.4 billion in 2021 to between USD14.0 billion and USD21.6 billion by 2045. With more focused initiatives to aid in the industry development, it is expected that the product of the innovative pharmaceutical industry would exhibit a higher potential of development starting in 2022 when innovative pharmaceutical companies commence their manufacturing operations domestically and contribute to the economic growth. Depending on the state of the market, the industry could experience a growth of 15% to 20% p.a. which would reach USD40.8 – 113.3 billion in 2045, growing at three times the business status quo.

**Chart 16:** Additional market value of innovative pharmaceutical industry – future potential (USD billion)



Note: 2018-2021 data is from IQVIA. The current trend is the lower bound of the business-as-usual growth which is projected at 10% based on stakeholder feedback in VOI 1. Potential future growth is projected based on the growth rate of 15% and 20% from stakeholder interviews and benchmarking for the lower and upper bound respectively. Potential growth is assumed to start in 2022.



# Potential Economic Contributions to the Country



## Improving the competitiveness of Vietnam’s pharmaceutical industry

Vietnam has the potential to become a pharmaceutical and medical hub in the region. With rapid expansion in the domestic manufacturing of pharmaceutical products, the country will subsequently have strong growth potential for pharmaceutical export as well. Export destinations would most likely be the neighboring countries including Cambodia, Laos, Myanmar and other ASEAN countries.

Innovation is the key driver for enhancing industry competitiveness. Domestic capability building will lead to spillover effect and foster entrepreneurship and start-ups in the long run. This is consistent across our case study markets. The indigenous start-up company can play a significant role to establish Vietnam’s next generation healthcare. A leading example would be the Irish life sciences and data analytics start-up Genomics Medicine Ireland, which creates scientific platform and collaborates with leading life science entrepreneurs, investors and researchers to examine human genome and explore new prevention strategies and treatments.<sup>60</sup>

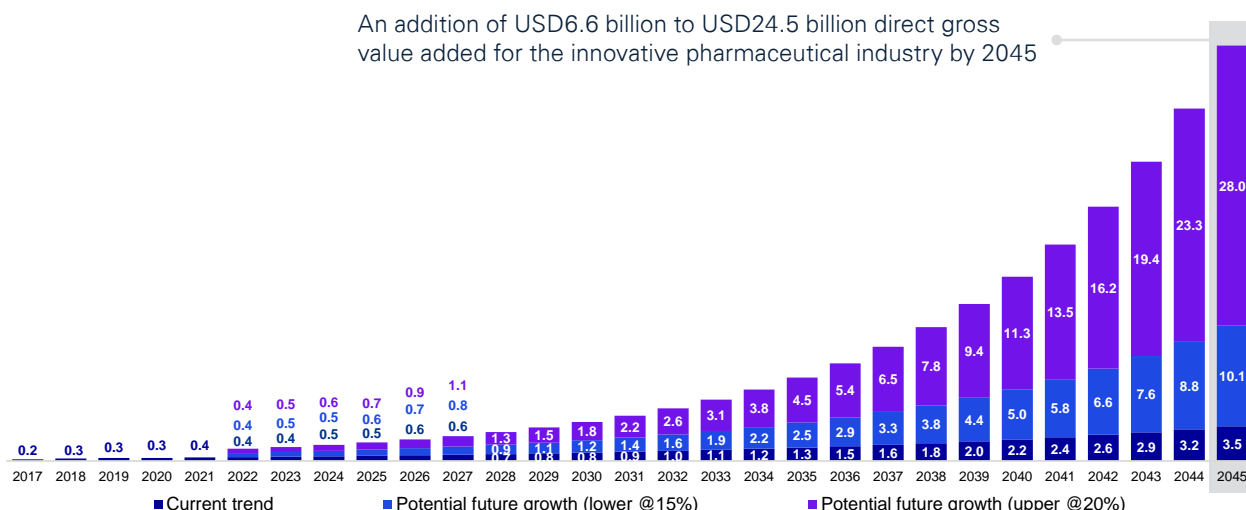


## The innovative pharmaceutical industry would contribute an of USD21.6 to USD80.5 billion by 2045 with joint effort between government and private businesses compared to business as usual

Under business as usual, the direct gross value added contribution to the national economy is projected to reach between USD3.5 billion to 5.3 billion by 2045 from USD400 million in 2021.

With proper incentives and policies in place, the strong growth of the innovative pharmaceutical industry will translate into increasing economic contribution to the GDP. We estimate that the direct gross value added from the innovative pharmaceutical industry could grow at a CAGR of 15% to 20% over 2022 to 2045 and contribute USD10.1 to USD28.0 billion by 2045.

**Chart 17:** Additional direct GDP contribution from the innovative pharmaceutical industry – future potential (USD billion)

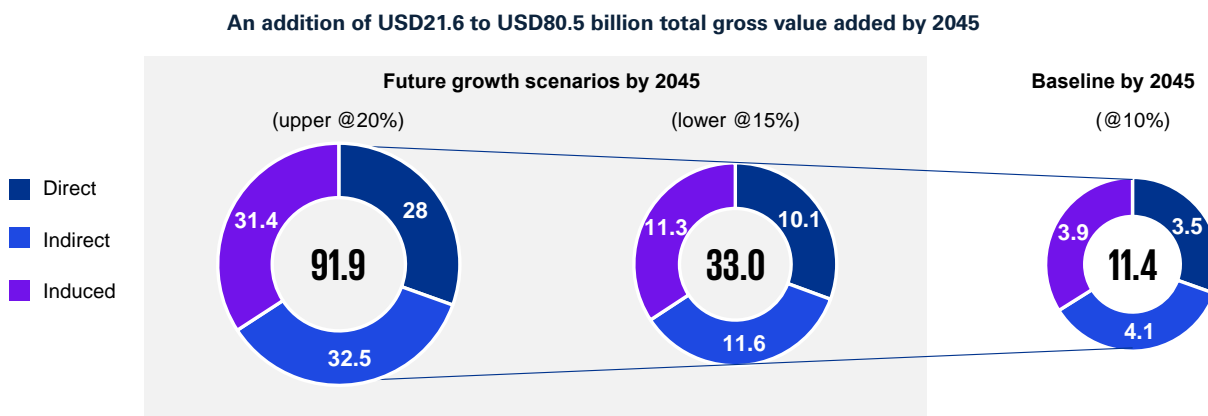


Note: GDP contribution is calculated based on the market value projection and economic multiplier derived from Input-Output table from OECD. Similar to the market value project, the current trend of GDP contribution is the lower bound of the business-as-usual growth which is projected at 10% based on stakeholder feedback. Potential future growth is projected based on the growth rate of 15% and 20% from stakeholder interviews and benchmarking for the lower and upper bound respectively. Potential growth is assumed to start in 2022.

60. Silicon Republic (2016), '150 new jobs as Genomics Medicine Ireland raises \$40m in Series A round', accessed 9 October 2019, available at: [Link](#)

Moreover, the upstream and downstream impact through business-to-business transactions caused by the operations of pharmaceutical companies will indirectly contribute to the GDP by a range of USD11.6 to USD32.5 billion by 2045. The spending from pharmaceutical companies' direct and indirect employees would contribute a range of USD11.3 to USD31.4 billion. Overall, we estimate the total GDP contribution by the innovative pharmaceutical industry would reach to USD33.0 to USD91.9 billion by 2045.

**Figure 5:** Additional total GDP contribution from the innovative pharmaceutical industry – future potential (USD billion)



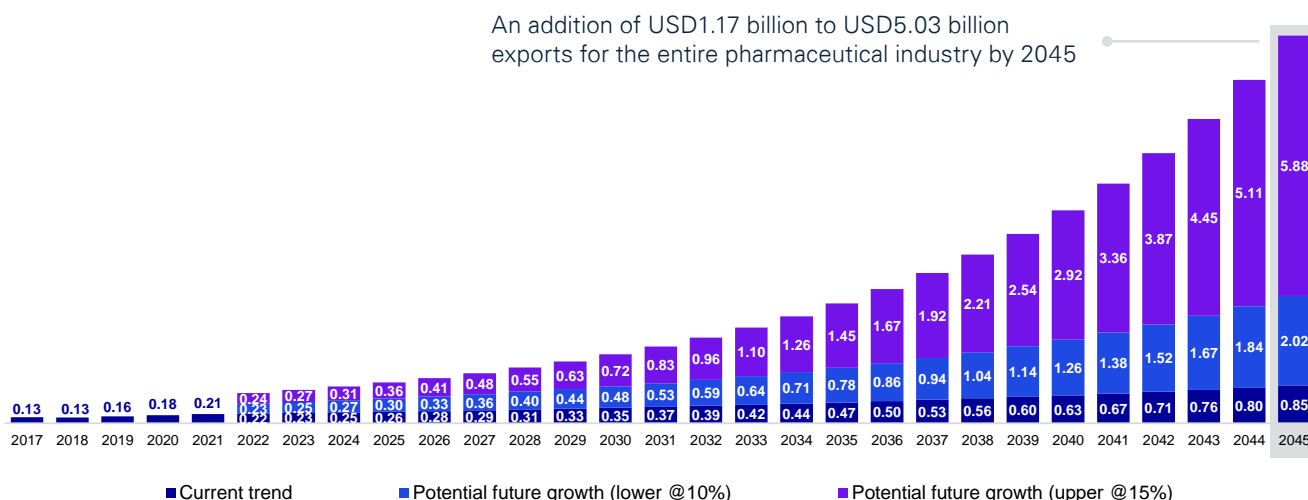
Note: GDP contribution is calculated based on the market value projection and economic multiplier derived from Input-Output table from OECD.

In summary, with joint effort between government and private businesses, the innovative pharmaceutical industry would contribute an additional USD21.6 to USD80.5 billion in total by 2045 compared to business as usual, including direct gross value added of USD6.6 to USD24.5 billion, and USD15.0 to USD56.0 billion indirectly via domestic purchases from the innovative pharmaceutical companies.

The growing market size of innovative pharmaceutical would also lead to additional tax contribution to the country, especially with more companies having ongoing plans to convert from representative offices to legal entities.

Under business as usual, pharmaceutical exports could as well grow at 6.1%, and amount to USD850 million by 2045. As there would be continuous expansion and establishment of local manufacturing of pharmaceutical products, we could observe a strong potential for Vietnam to become a key exporter in the future. We estimate the pharmaceutical exports will reach to between USD2.02 billion to USD5.88 billion by 2045, with a CAGR of 10% to 15% from 2022 onwards. This would mean an addition of USD1.17 billion to USD5.03 billion pharmaceutical exports.

**Chart 18:** Additional pharmaceutical exports – future potential (USD billion)



Note: Due to data limitation, the export values are for the entire pharmaceutical industry rather than innovative pharmaceutical only. The current trend is the business-as-usual growth which is projected based on the 6.1% growth of exports over 2013-2023 from Fitch Solutions. Potential future growth is projected based on the growth rate of 10% and 15% from benchmarking against countries include Singapore, Korea and Ireland for the lower and upper bound respectively. Potential growth is assumed to start in 2022.



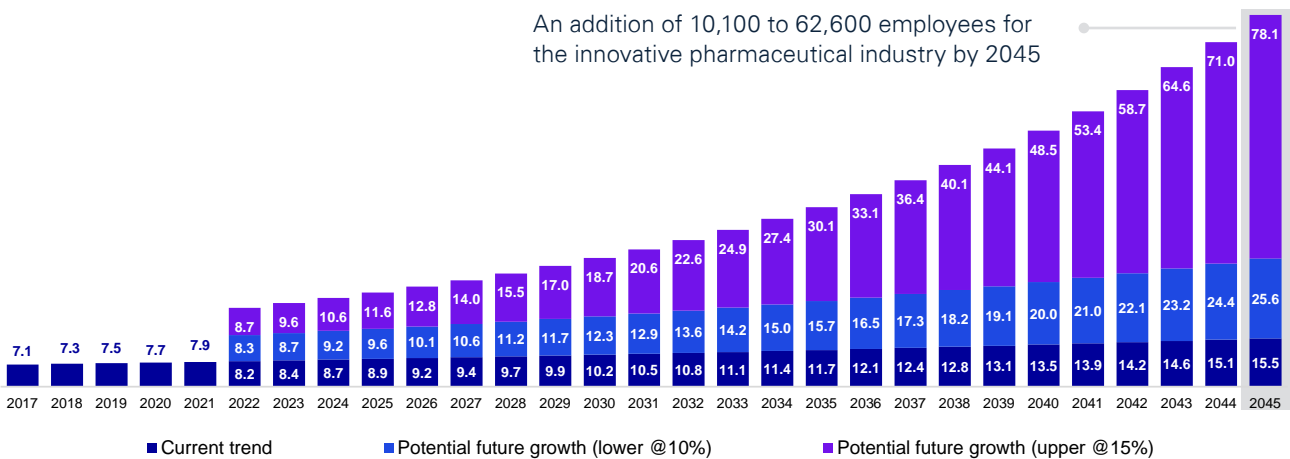
**Employment in the innovative pharmaceutical industry is likely to grow at 5%-10%, resulting in a 9% to 13% growth of labor productivity**

As the innovative pharmaceutical industry evolves and grows, the demand for the high-skilled workers is expected to increase. As the industry requires specific and specialized skill sets, labor supply will likely continue to lag industry growth demand. Base case industry employment growth will likely remain around 2.8%, which would translate to a total new created employment of 15,500 by 2045. If supply side constraints were addressed through vocational training, new created jobs in the sector could reach between 25,600 and 78,100 jobs by 2045, representing of 10,100 to 62,600 direct employments over the current baseline.

Moreover, another 173,800 to 531,000 jobs would be created through indirect and induced economic impact, reaching a total of 199,500 to 609,000 jobs by 2045.

In summary, with a joint effort between government and industry, the innovative pharmaceutical sector could create an additional 78,800 to 488,500 high-skilled and value-adding jobs by 2045, compared to compared to business as usual growth.

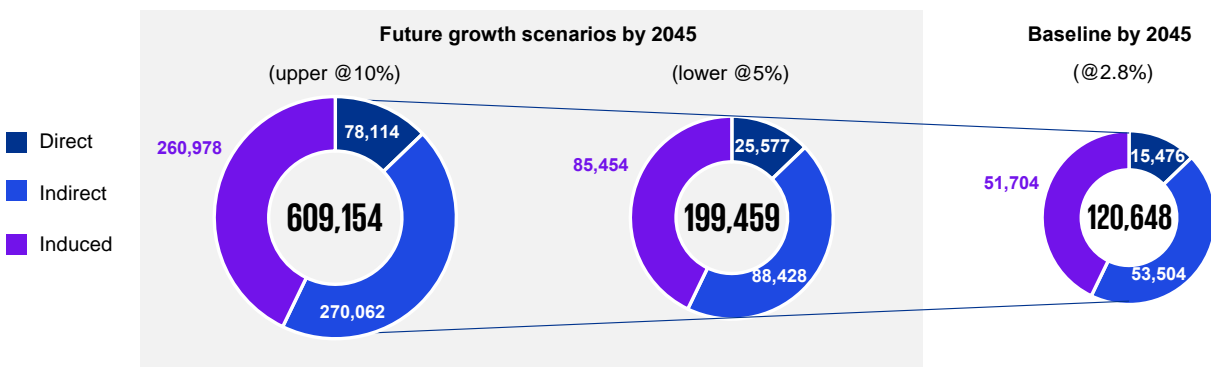
**Chart 19:** Additional jobs created directly for the innovative pharmaceutical industry – future potential (thousand)



Note: 2015-2018 employment numbers are estimates based on data from IFPMA and IQVIA. The current trend of employment is the business-as-usual growth which is projected at 2.8% based on historical growth. Potential future growth is projected based on the growth rate of 5% - 10% from stakeholder interviews and benchmarking. Potential growth is assumed to start in 2022.

**Figure 6:** Additional total jobs created by the innovative pharmaceutical industry – future potential

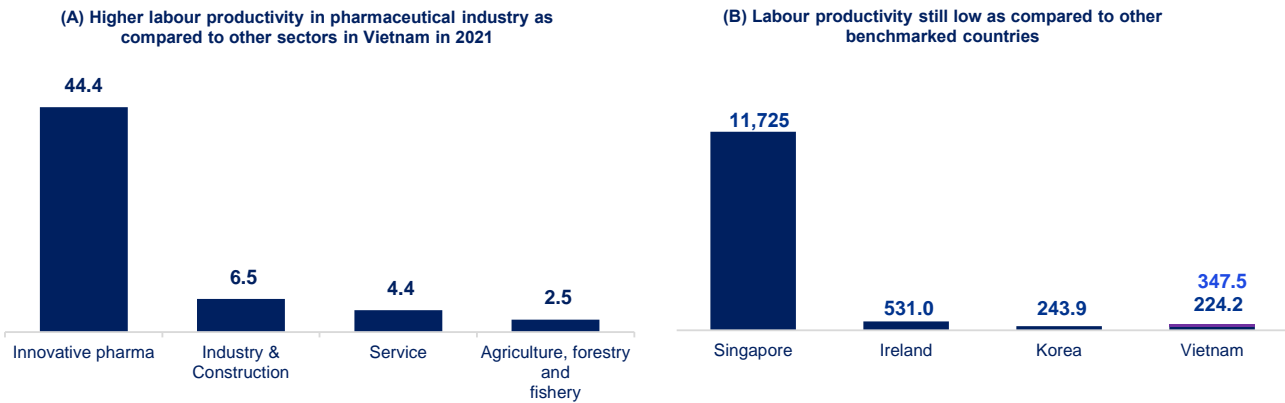
An addition of 78,800 to 488,500 total jobs created by 2045



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

Under business as usual, labor productivity is projected to reach between USD224,000 and USD347,500 with a CAGR of 7.0% to 8.9% over 2021 to 2045. Currently, the innovative pharmaceutical industry has a relatively high labor productivity as compared to other sectors in Vietnam.

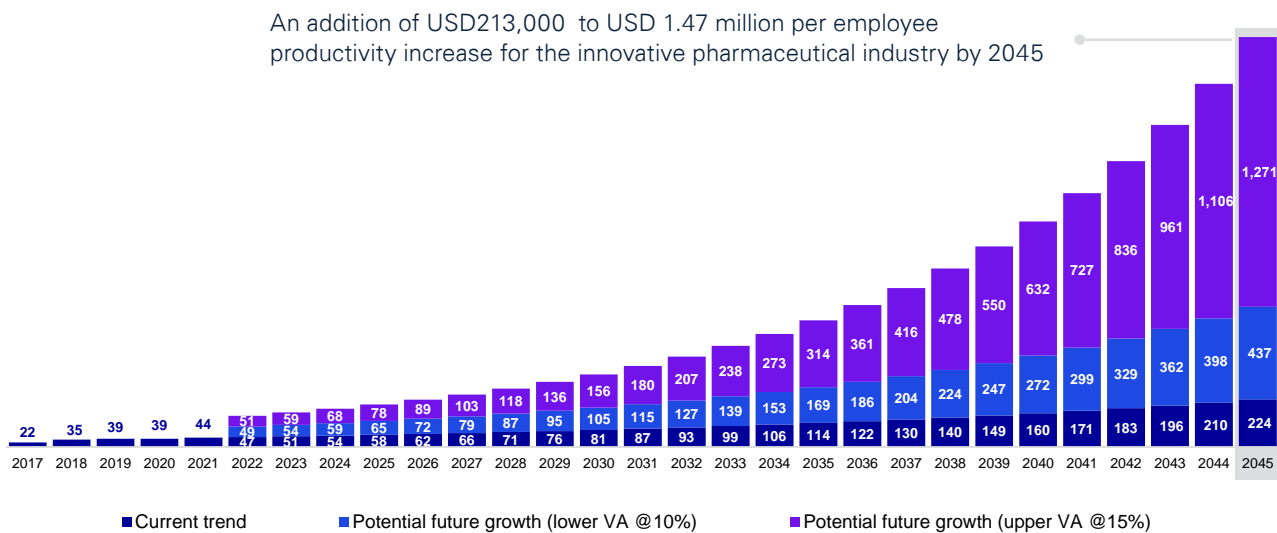
**Chart 20:** Comparison of labor productivity (USD thousand per employee) of the innovative pharmaceutical industry – business-as-usual



Note: For Figure (A), productivity for sectors is 2021 data. For Figure (B), productivity for Vietnam is 10%-12% estimation for 2045. Data for Singapore, Ireland and Korea are 2018, 2014 and 2017 respectively due to data availability.

With proper incentives and policies in place, labor productivity of the innovative pharmaceutical is estimated to reach between USD437,000 – USD1.3 million per employee by 2045. This is essentially a CAGR ranging from 10.2% to 15.0% over 2020 to 2045, as compared to 7.7% growth under the business as usual.

**Chart 21:** Additional labor productivity for the innovative pharmaceutical 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 2022.



# Potential Benefits to Patients

Vietnam's innovative pharmaceutical industry is still at its nascent stage and there is potential for further growth. With the developments in the pharmaceutical industry, the government will be closer to achieving its goal of providing a sustainable healthcare system for its citizens. By increasing investments particularly in the innovative pharmaceutical industry, quality drugs will be more accessible and disease awareness and preventive healthcare practices will be enhanced. Consequently, this will increase patients' satisfaction levels and improve their health outcomes.

The benefits forecasted in this section are based on current health conditions within Vietnam, not considering external factors, should the Vietnamese workforce become healthier. As such, results may reflect a conservative estimation.



## Improve health outcomes through better access to innovative drugs

Innovative drugs are efficient in health outcomes, thanks to rapid technological advancements and enhanced research capabilities. Consequently, patients can afford more choices with a reduced budget and thus, are more inclined to complete treatment.

### 1 Innovative drugs are more efficient in improving health outcomes

The benefits of incremental innovation on existing drugs are vital to increase the quality of healthcare. Incremental innovation refers to improvements made in safety and efficiency of the drugs, by providing new formulations to improve health outcomes of patients. Even though the development to these drugs may seem inconsequential, the cumulative effect of numerous incremental innovations can possibly have a greater economic impact than a technological breakthrough<sup>61</sup> as this will lead to increasingly useful and effective drugs available in the market.

The introduction of better innovative drugs, coupled with the advancement of medical technology and better detection techniques, has led to an improvement in health outcomes in many societies. A study conducted by Columbia Business School found that the new medication can improve health outcomes and reduce health care spending. Another investigation in 2020 on adherence levels of newer drugs showed that on average, patients who use newer drugs are more adherence to therapy. Higher adherence level is considered to associate with reduced hospital admissions and mortality.<sup>62</sup>

### 2 Patients are more inclined to complete treatment, as innovative drugs make the overall expenditure more affordable

With further developments in the pharmaceutical industry, drugs will also be made more affordable for patients. According to a study conducted, a positive relationship exists between drug age and the number of hospital stays associated with the condition. Results have shown that patients who consume newer drugs will stay in the hospital significantly less than patients who consume older drugs.<sup>63</sup> This implies that it is more cost-effective in the long run to consume newer innovative drugs than older drugs. This is because consuming newer drugs will reduce the number of stays in the hospital, and if the cost of new drugs are lower than a night's stay at the hospital, the healthcare expenditures of patients will be reduced significantly. Furthermore, by consuming newer innovative drugs, it will reduce the nondrug medical spending of patients, and this will lead to a substantial net reduction in total healthcare expenditures.<sup>64</sup>

Not only will innovative drugs result in a reduction in healthcare expenditures for patients, it will also result in significant cost savings for the entire economy. Several academic research papers have supported the claim that better quality drugs will lead to higher labor productivity. A study conducted in Ireland in 2015 has shown that 910,000 and 810,000 work days were lost due to illness and injury respectively and this is estimated to cost the economy approximately USD1.6 billion annually.<sup>65</sup> This significant cost experienced by the economy can be reduced significantly if more effective innovative drugs are made available.

61. International Policy Network (2005), 'Pharmacoevolution: the advantages of incremental innovation', World Health Organization.

62. Blankart, K.E., Lichtenberg, F.R. (2020) 'Are patients more adherent to newer drugs?'. *Health Care Manag Sci* 23, 605–618

63. Ibid.

64. International Policy Network (2005), 'Pharmacoevolution: the advantages of incremental innovation', World Health Organization.

65. Irish Business and Employers Confederation (2011), 'Employee absteneism: a guide to managing absence', IBEC Ireland.

### **3 Greater variety of innovative drugs provides alternative solutions for patients**

In addition, when more innovative drugs are being developed, regardless of whether the innovation is minor or major, there will be more drug alternatives in the market. A broad range of drugs will thus be available in the market for the same class of drugs. This ensures that in instances where initial treatments fail, there will be secondary and tertiary options available for patients. This is especially important in medical cases where the overall response rates for drugs can go as low as 50% for illnesses involving the central nervous system.<sup>66</sup> With more alternative drugs in the market, more drug options will be available to patients and it can improve their health outcomes significantly.



#### **Establish effective preventive healthcare through enhancing patient awareness and education**

There are continual developments in the medical field, with new information published regularly, and new drugs developed constantly. Having access to the latest information on healthcare options such as the cost of treatment and availability of drugs will allow patients to weigh all the options available before making an informed choice about their health. Patient awareness is essential and all key stakeholders such as the government, pharmaceutical companies and healthcare professionals have a part to play in ensuring that comprehensive scientific and clinical information is readily available. Other than making information available, the information should also be easily understood to ensure a basic understanding on the expected benefits, potential outcomes, risks and side effects of various treatment options.

Innovative pharmaceutical companies can play a part in the patient awareness and education programs as well. Due to the nature of the industry, new drugs and medical treatments are constantly developed. Innovative pharmaceutical companies, being the parties who introduce new drugs to the market, will have up to date knowledge of the latest drugs and medical developments.<sup>67</sup> Their contribution to the programs will therefore be significant in helping to reduce the information asymmetry faced by patients and healthcare professionals.

Patient education and awareness programs should not be introduced solely to patients, but also to healthcare professionals who must share this information to patients. Findings from a study conducted in 2007 indicated that doctors are ignorant about the cost of drugs.<sup>68</sup> The inability to differentiate expensive and inexpensive drugs will have an adverse effect on patients and their choice of treatment options. With proper patient support programs in place for patients and healthcare professionals, it will enhance patient awareness and allow patients to make more informed choices about their treatment. A long-term solution to a sustainable healthcare financing system is in fact the current trend to shift more focus from treatment to preventive healthcare. In return effective preventive healthcare can only be achieved through patient awareness and education which is one of the main roles of the Innovative Industry.

Apart from education for patients and healthcare professionals, public health education is also crucial. Public health education campaigns typically emphasize on disease prevention and public awareness. Through these programs, the public will be more aware of various diseases and the relevant health interventions required to prevent them. For example, the importance of public health education on transmission of COVID-19 pandemic were recognized. The study conducted in 2021 revealed that the states with good health education campaigns and high level of adherence to use of mask, social-distancing and frequent hand washing recorded lower number of infections than ones with less campaigns and low adherence to public health instructions.<sup>69</sup> Public health education will become particularly important in reducing the health risks faced by individuals and be extremely helpful in disease prevention as well as ensuring healthcare savings.

66. International Policy Network (2005), 'Pharmacoevolution: the advantages of incremental innovation', World Health Organization.

67. Bonaccorso et al (2003), 'What Information do Patients Need about Medicines?', BM Journal 327.

68. Allan, G. et al (2007), 'Physician Awareness of Drug Cost: A systematic Review', PLOS Medicine 4(9).

69. Iboi E, Richardson A, Ruffin R, Ingram D, Clark J, Hawkins J, McKinney M, Horne N, Ponder R, Denton Z, Agosto FB, Odoro B and Akinyemi L (2021) 'Impact of Public Health Education Program on the Novel Coronavirus Outbreak in the United States',



NOVOTEL

DAIKIN  
QUỐC HƯƠNG

CÁCHỆP, HÒA RỒNG  
ĐÀ NẰNG - VIỆT NAM

A person wearing a green jacket and a traditional conical hat is kneeling in a large room filled with hundreds of red, fan-shaped brooms. The brooms are arranged in neat rows, creating a strong sense of repetition and pattern. The person appears to be working on one of the brooms, possibly inspecting or finishing it. The lighting is bright, highlighting the vibrant red color of the brooms.

# Implications for Policy Makers

**A**s an emerging economic player, Vietnam has the opportunity to develop self-sustaining pharmaceutical capabilities by embracing the support of multinational pharmaceutical corporations. More specifically, by embracing such support, Vietnam will be able to provide citizens leading edge medicines at affordable prices. Moreover, fringe benefits in the form of immediate demand for labor, heightened economic productivity, increased foreign direct investment and gross domestic product will as well occur.

Vietnam is well placed with a well-educated and hard-working population of the right age. Current geopolitical tensions between the US and China, as well as the rising regional manufacturing costs, means tremendous potential for Vietnam. There is a short window of opportunity for Vietnam to make a quantum leap and the time is now with all the current geopolitical and trade tension. Case studies also show this can be achieved in a fast time frame with the right policies.

Economies that have successfully transitioned their industries from basic manufacturing to one driven by innovation have several points in common. Primary among these is the central role of the government in creating a coordinated response across the industry.

### Collaboration

Collaboration amongst Government, Industry and Academic institutions is needed to enhance PP, drive R&D, new products, and patient outcomes.

**Example:** the establishment of Translational & Clinical Research Flagship Program in Singapore

### FDI

Dedicated Governmental body focused such as working group 6116 to attract FDI to encourage intangible benefits like HCP development.

**Example:** Industrial Development Authority of Ireland

### Workforce development

This is led by the institution to provide the right types of people to support R&D, innovation activities as well as labor supply for FDI.

**Example:** National Institute for Bioprocessing Research and Training of Ireland

### Innovation

Innovation is key to drive productivity and digital solutions to unlock healthcare ambitions.

**Example:** Science Foundation Ireland, Korea National Enterprise for Clinical Trials



### Incentives

Funds, grants and various taxation measures to nurture and support FDI, innovation and R&D.

**Example:** Korea Drug Development Fund, Health Research Board as a funding agency under Irish Ministry of Health

### Safety and Quality control

Set up regulatory body for quality control and certification to provide confidence in the market.

**Example:** Health Products Regulatory Authority of Ireland

## Key Policy Implications



### Continue to prioritize the pharmaceutical industry on a national level

Though the government has detailed goals in the Master Plan, with significant socioeconomic benefits to be reaped from the developments of the pharmaceutical industry, the government should focus on creating a detailed framework of actionable steps placing obligations on different arms of government. A well-defined and actioned plan, detailing thorough obligations on different Ministry's and government institutions – at a national, regional, and local level – will create a favorable business environment for industry players and remove potential impediments to business investments and innovation. This will assist the government in achieving its pharmaceutical industry ambitions through making Vietnam a comparatively attractive investment destination for foreign investors and creating new opportunities for growth in the industry.

The Vietnamese government can learn from the other countries who developed national level policies for the pharmaceutical industry, which ultimately led to the rapid growth of the industry and the economy. Singapore launched the Biomedical Sciences Initiative in 2000 to prioritize the pharmaceutical industry as a key sector of growth in the economy, which detailed the obligations of different government institutions to support the development of the industry. Similarly, South Korea launched the Pharma Korea 2020 Roadmap in 2012 which outlined the vision for the Korean pharmaceutical industry and the role of government in facilitating this vision. Ireland also initiated an action plan for health research in 2009 to prioritize a program of government actions essential to create a sustainable health research system. These national policies provided an overarching road map to develop the pharmaceutical industry and specified the necessary actions required for government institutions to attract foreign investment and nurture the domestic industry.

The government should also open markets to competition as this encourages enterprise efficiency, benefiting consumers and businesses in the long term. With greater competition prices are driven down, which improves the accessibility of drugs to consumers. In addition, the quality of products produced will be improved and businesses will be more innovative in the face of competition. Most importantly, this ensures that the growth of the industry will be sustainable in the long term and that Vietnam will be able to hold their own against global competitors.



### Have a comprehensive legal and regulatory framework and establish dedicated support institutions

Vietnam needs a transparent, predictable, and consistent industry legal framework. This framework needs to define clear roles and responsibilities of each party in the industry including government agencies, private businesses, and research institutes. Key components are:

#### 1 Establish dedicated institution and taskforce to facilitate the industry growth Empower the existing institutional taskforce to facilitate industry growth

In recognizing this necessity, Vietnam has established a taskforce to develop the pharmaceutical industry. However, this existing body lacks the requisite power to coordinate and delegate responsibilities between government bodies to effectively facilitate industry growth. To empower the taskforce, the government could involve the Deputy Prime Minister, obliging the taskforce to report regularly to him about developments (including intergovernmental barriers to realizing growth).

#### 2 Ensure predictability and consistency of legislation

The legal and regulatory framework needs to be more predictable to facilitate corporate decision-making that will unlock Vietnam's future potential. A predictable and consistent business climate will encourage private businesses, especially foreign companies, to have longer term investments in Vietnam without concerning about the impact from change of policy.

#### 3 Focus on consistency of drug quality rather than quantity

The government has made a concerted effort to ensure the highest standards of drug quality at the national level. However, this focus on quality rather than quantity is lacking at a regional and local level, where hospitals remain unable to procure many of the innovative pharmaceutical drugs of choice for practitioners. The government should consider streamlining the drug procurement process across the national, regional and local level, to ensure innovative pharmaceutical products can adequately address unmet medical needs. A good practice of quality control would be the Health Products Regulatory Authority (HPRA) in Ireland which regulates the product safety, quality and effectiveness of the entire healthcare industry.

#### **4 Enhance efficiency of administrative procedures**

The Drugs Administration of Vietnam has increased the efficiency of procedures around application approvals by adopting a proposal to create a dedicated center for reviewing applications. However, heightened focus on implementation of efficiency measures should continue through the streamlining of broader administrative procedures surrounding the drug registration and reimbursement process, to speed up the overall time to market. This will subsequently improve patient access to new drugs and eventually benefit patient health outcome. Apart from this, the administrative framework also needs to ensure timely approval for processes including clinical trials and patient support programs.<sup>70</sup>

#### **5 Have clear and detailed regulations on public private collaboration**

Vietnam needs a clearer, more predictable regulatory framework on public private collaboration (PPC) in the pharmaceutical industry. To have a PPC framework in place would provide guidance for the industry and encourage the companies to collaborate, especially in tangible and intangible education. Vietnam needs to define the PPC schemes and detailed procurement procedures to foster such win-win opportunities.

This means the bidding and negotiation processes need to be credible and predictable for private investors especially the foreign investors.<sup>71</sup> Commonly in the most matured pharmaceutical markets, collaborations led to the establishment of specific research institutes jointly among government agencies, private businesses and academia for the research and innovation of pharmaceutical products.

Should this occur, companies will be encouraged to collaborate through the expansion of tangible and intangible education, the latter including continuous medical education and patient support programs, as outlined in page 8 of this report.

#### **6 Enhance intellectual property protection**

The protection of intellectual property (IP) is essential for attracting foreign investment and promoting pharmaceutical innovation. In developing countries such as Vietnam, empirical research has found that a 1% increase in patent rights protection correlates to a 1.65 - 2.8% increase in FDI.<sup>72</sup> Enhancing IP protection would also foster start-up and entrepreneurship ecosystem.

As outlined in page 8, Vietnam has prioritized integration

into the international system through numerous FTAs, some of which include significant IP protections. However, with the adoption of such agreements, Vietnam should now focus on ensuring greater coordination and collaboration between agencies to ensure such protection is effective. Vietnam needs to design a comprehensive IP strategy at national level and to establish designated authority to implement the strategy as well as the related policy reforms.

#### **Introduce incentives to drive investments into the industry**

To accelerate growth in the pharmaceutical industry, the government needs to increase the level of public and private investment.

As identified by this report, the full potential of the pharmaceutical industry can be unlocked by greater efficiency around the registration approval process for new innovative products that address unmet medical needs. Should the government continue its focus on streamlining the process, Vietnam will become a more attractive location for FDI and local industry development.

The government can also consider providing incentives in the form of tax deductions or reimbursements for the pharmaceutical companies. For instance, Singapore provides incentives to pharmaceutical companies when they set up operations in Singapore and invest in R&D activities<sup>73</sup>, or conduct research and clinical trials locally.<sup>74</sup> This significantly reduces companies' operation and capital expenditures and thus encourages foreign investments into the industry. Such government efforts have been effective in attracting foreign companies into the country and Vietnam could emulate this approach to boost foreign investment into the industry.

The government should also increase public funding by injecting funds to support research and development (R&D) activities and drive healthcare innovation. The pharmaceutical industry is highly dependent on R&D growth and thus R&D plays a crucial role to the success of the industry. However, obtaining sufficient funding is often a challenge, especially in the early stage of R&D. Therefore, government can achieve its ambitions through providing creative and innovative incentives to the industry on a national policy level to facilitate the drug development process and ensure that research is not impeded due to funding. An example of a national R&D project which does so is the Korea Drug Development Fund, launched in 2011. The fund has a budget of USD1 billion for 9 years to support the area of novel drug development, providing funding and business development support for R&D projects.<sup>75</sup> These initiatives will help accelerate the growth of R&D and hasten the process of drug development while encouraging further private investments into the industry.

70. Stakeholder interview

71. OCED (2018), 'OECD Investment Policy Reviews: Viet Nam 2018', OECD, pp 309-335.

72. Ezell, S., Cory, N. (2019), 'The Way Forward for Intellectual Property Internationally', Information Technology & Innovation Foundation, accessed 3 October 2019, available at: [Link](#); see also OECD (2008), 'Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries', OECD Trade Policy Working Paper No.

73. Singapore Economic Development Board.

74. Singapore National Medical Research Council.

75. Korea Drug Development Fund (2017), 'Why "Korea" is the best place for new drug development', accessed 2 October 2019, available at: [Link](#)



### Increase emphasis on industry-focused education and training

Education becomes particularly important for the pharmaceutical industry as it is a high value-added industry that requires a pool of highly skilled employees. To ensure the continued growth of the industry, there must be a continued focus on providing highly skilled workers. This means a heightened focus on a quality workforce, rather than just a larger workforce. If the government wishes to develop the pharmaceutical industry further, in this regard, continuous specialized education and training programs need to be implemented at the early stage of industry development to meet the future demands of labor in the innovative pharmaceutical industry.

Proper infrastructure should be established to ensure that the relevant specialized skills required by industry are acquired by prospective workers. Tertiary institutions such as universities and polytechnic institutes should be set up with industry-related programs offered on the undergraduate and postgraduate level to educate students in the areas ranging from research, process development quality assurance and other areas. Other than these tertiary institutions, industry-specific training institutions should also be set up to offer specialized training for prospective students. In South Korea, the Pharmaceutical Manufacturing Manager Training Institution was set up by the Korea Pharmaceutical Traders Association and it provided mandatory, specialized training on pharmaceutical manufacturing and quality control.<sup>76</sup> Likewise, the Genome Institute of Singapore was established during the early stage of development of Singapore's pharmaceutical industry in 2001, and it focused on modern genome technology through research and training.<sup>77</sup> The concerted efforts by tertiary and industry-specific institutions will play a critical role in ensuring a ready supply of highly skilled workers are available to join the workforce in the future.



### Drive health innovation

Pharmaceutical innovation is particularly important in this digital age and can go a long way to improve patients' access to drugs and improve their health outcomes. Drugs have made remarkable progress over the years and have improved the quality of life and life expectancy of many patients. New drugs developed have also changed the course of diseases such as certain cancers and hepatitis C, as well as reduced the healthcare costs of patients in the long run.<sup>78</sup>

The government has made efforts to digitize prescriptions and patient records. It is hoped that this will continue across the sector, linking data sets and

creating the foundation of a MedTech industry.

In recent years, the industry is moving towards a more patient-centric approach to engage patients. There is great potential in digital technology as it leverages on technologies such as blockchain, Internet of Medical Things, and artificial intelligence to develop better and more personalized drugs and treatment for patients while monitoring their health more consistently.

Digital innovation supports healthcare professionals in their work, accelerates the development of new drugs and significantly improves the diagnosis and treatment process. With such 'smart health' applications, it will undoubtedly increase access and affordability while improving the quality of healthcare received by patients.



### Improve health financing

The purpose of drugs and medical treatment is to save lives and improve health outcomes of patients, but they come at a cost. Therefore, healthcare resources need to be used efficiently to ensure that access to drugs and treatments is not adversely affected. In practice, and as demonstrated in section 3.0, governments around the world have developed very different models of health financing, but what is important in every case is providing sustainable financing. It is extremely important for governments to strive for financial sustainability regarding healthcare resources and implement relevant policies and measures to meet the demand for drugs while maintaining the cost and quality.

Government efforts are key as it will affect various stakeholders such as healthcare institutions, pharmaceutical companies, healthcare professionals and patients themselves. There are many benefits that come together with better health financing schemes available, such as the improvement of medical service for patients and drug quality, more drugs being developed and brought to market, expected savings of healthcare expenditures for patients and an increase in life expectancy. All these benefits can be obtained if proper measures are put in place on a national level. A possible alternative to this approach would be to set up a co-payment system with better collaboration between both public and private insurance. There could be a scheme with fixed coverage provided, and the allowance of private insurance to top up the public insurance. With an effective connection between the two types of insurance, patients will have better access to high quality medical treatments and have more choices on the type of treatment they would want to have. Furthermore, the co-payment system can be designed to encourage cost control and rational medicine use, which will lead to an improvement in the overall healthcare and pharmaceutical financing situation.<sup>79</sup>

76. Korea Pharmaceutical Traders Association.

77. Sustainable Development Impacts of Investment Incentives A Case Study of the Pharmaceutical Industry in Singapore, IISD, 2010.

78. New all oral therapy for chronic hepatitis C virus (HCV): A novel long-term cost comparison, Poonsapaya et al., 2015.

79. Pharmaceutical Financing Strategies, WHO, 2012.



## The Way Forward

Vietnam's innovative pharmaceutical industry has a high potential to create value for the nation. Despite the challenges of the regulatory environment, there are many opportunities offered by Vietnam's resources, workforce, and geopolitical position. Furthermore, leveraging on the increasingly available technologies and information of the digital era offers Vietnam's pharmaceutical industry a chance to accelerate its growth and rapidly raise its global standing. To take full advantage of these opportunities will need targeted policies and reforms in the wide variety of areas outlined above, from investment incentives and legislation to education and training. Thus, the government of Vietnam is well-positioned to promote growth in the economy through both nation-wide and industry-specific policies, and through collaboration with industry stakeholders. These partnerships will be crucial in striving towards a dynamic and vibrant future for both the industry and the nation as a whole.



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