Value of Innovation

Unlocking the Potential of the Innovative Pharmaceutical Industry in Vietnam
Opportunities for Vietnam

Overview
Key Economic Factors Driving Opportunity
Potential Opportunities for the Pharmaceutical Industry
Potential Economic Contributions
Potential Benefits to Patients

Implications for Policy Makers

Key Policy Implications
The Way Forward
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 Wins**

- **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 Wins**

- **Public Private Collaboration, CSR**: Improved and more sustainable financing
- **Workforce/Human Resources**: 156,200 to 378,000 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 Wins**

- **HCP capability building**: Continuous medical education including novel therapeutics
- **Local pharma sector development**: Contribute an additional USD 8.7 to USD 27.6 bn to GDP by 2040
- **Start-up, Entrepreneurship ecosystem**: Increasing number of start-ups
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

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

**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

What does Success look like?

An additional of USD 8.7 billion to USD 27.6 billion output for the innovative pharmaceutical industry
Foreword

Vietnam has achieved substantial improvements in key public health metrics such as average life expectancy and infant mortality. This reflects key economic reforms of the late 1980s where the healthcare system transitioned from a fully public model to one that allows greater private involvement and expanded access to quality care. In 1992, Vietnam began its efforts to provide Universal Health Coverage (UHC) and has since become a coverage ratio leader within Asia. The government has set a coverage ratio target of 90% by 2020, and 95% by 2025, while maintaining affordability and financial viability.

Today, the pharmaceutical market in Vietnam is growing at a rapid pace and has increased from USD2.7 billion in 2015 to USD3.6 billion in 2018 at a Compound Annual Growth Rate (CAGR) of 10.6% based on the growth during 2015 to 2017. This reflects the growing demand for pharmaceuticals with the industry now employing nearly 44,000 people. Of the overall industry, innovative pharmaceuticals play an important role and represent an estimated 22% of the total market value, though only about 3% of the total volume.

From 2015 to 2018, the segment grew at an estimated CAGR of 10.6% from USD594 million to USD802 million, while hiring nearly 7,300 additional people.

In 2018, the innovative pharmaceutical industry in Vietnam contributed an estimated USD571.30 million to total GDP. This comprised USD173.47 million direct gross value added from the innovative pharmaceutical industry and a further USD202.71 million indirect contribution through business-to-business transactions such as pharmaceutical companies’ expenditure on raw materials, logistics, sales, and marketing. Finally, an additional USD195.11 million economic impact was seen through induced expenditures by innovative pharmaceutical employees.

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As Vietnam transitions to the next stage of sector development, several factors will be important:

**Attractiveness as an ASEAN regional gateway**

Vietnam’s integration into new generation Trade Agreements such as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) and the EU-Vietnam Free Trade Agreement (EVFTA) will likely 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 classes in Asia. However, this newly-urbanized cohort is rapidly aging and at increased risk of developing non-communicable diseases.

**Integrate global development best practices from other countries**

Vietnam is in a similar position to comparable markets when it began life science industry development. Vietnam can learn from the industrial development policies of its peers. 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 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.

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

**Objectives**

KPMG undertook this industry investigation to examine the current and potential benefits that the innovative pharmaceutical industry could bring to Vietnam. Industry leaders were interviewed to understand the parameters that shape current and potential investment and domestic operation expansion decisions. These factors were then compared with case study markets to highlight policy areas for further consideration within Vietnam.

This analysis provides a basis for the pharmaceutical industry and government regulators to engage across a common understanding of data. This could facilitate policy formulation towards a healthier and more prosperous Vietnam. 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. The insights from 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!
Current State of the Pharmaceutical Industry in Vietnam

Industry Overview

Government objectives and policy outlook

The Vietnamese government has identified the pharmaceutical industry as a potential key driver of future economic growth and prosperity in its “National Master Plan for the Vietnamese Pharmaceutical Industry Development to 2020 with a Vision to 2030” (“Master Plan”).

Key focus areas under the Master Plan include:

1. Universal Health Coverage (UHC)
2. Patient access to quality and innovative medicine
3. Local industry development

To achieve these ambitions behind these focus areas, the government has taken policy initiatives. These include specific macro-economic and sectorial goals (Resolution No.02), the Master Plan on pharma industry development (Decision No. 68), and the Master Plan on Vietnam’s Health Program (Decision No. 1092).

Under Resolution No.02, the government aims to improve the domestic business environment and competitiveness to reach “Top 4” status within ASEAN. In the short term, this involves improving:

1. Business Environment ranking 5 — 7 places (World Bank ranking);
2. Economic Competitiveness ranking 3 — 5 places (World Economic Forum ranking)
3. Global Innovation Index ranking 2 — 3 places (World Intellectual Property Organization ranking)

In the longer term, the government aims to increase these rankings by 15 — 20 places, 5 — 10 places, and 5 — 7 places respectively.

Within the Master Plan on pharma industry development, the government aims to reduce dependence on imports and modernize the sector to be on par with regional and global peers.

In the short term (by end of 2020), this will involve:

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

In the long term, the government aims to meet basic domestic pharmaceutical 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, 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
2. Enhancing awareness through public education to provide behavior changes which mitigate common risk factors associated with diseases

In the longer term, this will involve the implementation of continuous and long-term public health management programs targeted at preventable diseases and deaths.
Expanding Universal Health Coverage

Vietnam aims to expand Universal Health Coverage (UHC) to achieve a national coverage ratio of at least 90% by 2020 and 95% by 2025.

As outlined in Chart 1, total healthcare expenditure as a percentage of GDP was relatively high at ~6% in 2018, when compared to its peers such as Malaysia (4%), Singapore (4.5%), and Thailand (3.7%). However, total healthcare expenditure per capita for Vietnam (USD149) is low relative to its ASEAN peers such as Malaysia (USD453), Thailand (USD271) and Singapore (USD3,244).

Healthcare spending per capita in Vietnam is forecasted to reach USD219 by 2025, leaving Vietnam considerably behind its peers and highlighting the growth potential for the market.

**Chart 1: Regional comparison of healthcare expenditure 2018**

<table>
<thead>
<tr>
<th>Country</th>
<th>Govt. healthcare spending (USD billion)</th>
<th>Private healthcare spending (USD billion)</th>
<th>Total healthcare spending (% of GDP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>143</td>
<td>169</td>
<td>3.7%</td>
</tr>
<tr>
<td>Malaysia</td>
<td>453</td>
<td>271</td>
<td>4.0%</td>
</tr>
<tr>
<td>Philippines</td>
<td>157</td>
<td>68</td>
<td>4.6%</td>
</tr>
<tr>
<td>Singapore</td>
<td>3,244</td>
<td>76</td>
<td>5.2%</td>
</tr>
<tr>
<td>Thailand</td>
<td>271</td>
<td>44</td>
<td>3.7%</td>
</tr>
<tr>
<td>Vietnam</td>
<td>149</td>
<td>73</td>
<td>5.0%</td>
</tr>
</tbody>
</table>

Source: Business Monitor International

In line with rising healthcare spending per capita, pharmaceutical expenditure per capita in Vietnam stood at USD56 in 2017 and is expected to reach USD85 by 2020, and USD163 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 UHC ambitions.
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. 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): Novartis, the MOH and VSS (Vietnam Social Security) 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.

— Human Papillomavirus (HPV) and Cervical Cancer (2019-2021): The MOH, United Nations Population Fund (UNFPA), and Merck Sharp & Dohme (MSD) are rolling-out an HPV program that will drive awareness and prevention of cervical cancer.

In further collaboration, the government and industry have conducted 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 the MOH and Servier Laboratories Vietnam, aiming to inform the public about the need for early diagnosis of hypertension and diabetes before 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).


Local industry development
As part of the third key focus area within the Master Plan, government authorities have collaborated with international organizations, universities, and multinational pharmaceutical companies to develop the capabilities of healthcare practitioners in Vietnam.

Under Decision No. 2992, the government has outlined plans to develop a workforce for disease prevention and treatment to create an organized system proficient in both quantity and quality. The programs outlined are just a few examples of the initiatives that have been undertaken to promote workforce skills development:

— Cùng Sống Khỏe” Program (since 2012): Providing training to 18,000 healthcare professionals and reaching more than 1.1 million 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 include areas such as fever, diabetes, hypertension, and respiratory disease.
  **Stakeholders:** Provincial health departments and Novartis

— Clinical Trial Program (since 2011): Across a variety of disease areas, including oncology, respiratory, dermatology and endemic diseases like malaria.
  **Stakeholders:** Trial sites, the 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. National rule out with 63 provinces has been set up and 10 million registration people have been registered. The system helps healthcare professionals track infants and pregnant women due to vaccinations, reduces the time required for recording and reporting immunization data, and ensures the quality and availability of vaccines.
  **Stakeholders:** PATH, the MOH, and GSK

— 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 MSD
Trade and Foreign Direct Investment

Vietnam has become an attractive destination for foreign investors with Foreign Direct Investment (FDI) inflows growing steadily to reach USD15.5 billion in 2018, representing a five-year CAGR of 10.4%. As a proportion of total FDI amongst ASEAN countries, Vietnam ranks third following Singapore (USD77.6 billion) and Indonesia (USD21.97 billion), and above Thailand (USD13.2 bn), Philippines (USD9.8 billion) and Malaysia (USD8.1 bn).

In 2018, Vietnam saw approximately 50 registered pharmaceutical industry FDI projects with a combined capital of approximately USD500 million. Of these projects, approximately 60% were designated as medicine manufacturing, 20% as medicine logistics and storage, and the remaining 20% as other types of projects.

Macro-economic investment conditions for Vietnam are expected to remain positive as the country continues to integrate internationally. For instance, more free trade agreements like the recently ratified EVFTA will likely have a positive impact on FDI.

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 noted 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 respective 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 follows:

Clinical trials

Clinical trials underpin the advancement of effective care and can deliver tangible economic and social outcomes at a local, regional, or national level. 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. Consequently, these benefits could help accelerate Vietnam’s sustainable development goals.

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

‘Circular No. 29/2018/TT-BYT Clinical Trial of Drugs’ emphasizes the government’s intention to facilitate clinical trial development. The document legalizes the undertaking of clinical trials and establishes detailed rules about clinical trial approvals and obligations of those who host them. To build on these developments, the government could consider providing further policies and incentives to streamline and expand clinical trial development.

In interviews with industry executives, a commonly noted concern was the comparatively lengthy and complicated clinical trial application process associated with legislation such as Circular No. 29.

A simplification of this process will likely 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 also identified this as a key enabler, and are making concerted efforts to streamline the application process.

Alongside the application process concerns, several interviewed industry leaders have identified the following clinical-trial related points that could be addressed in parallel:

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

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 out-of-pocket expenses ratio. This may strain its long-term sustainability, particularly since the population officially entered an ‘aging phase’ in 2017, becoming one of the most rapidly aging countries in the world. Whilst these costs can be reduced, the policy should balance cost and market incentives.

Out-of-pocket expenses in Vietnam accounted for ~45% in 2016, higher than regional peers such as Indonesia (37%), Malaysia (38%), and Singapore (31%). Despite this, public social insurance fees per head in Vietnam remain low at around USD50 per head per annum. Moreover, external aid for Vietnam’s health system is predicted to further decrease as the economy transitions to an 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 a relatively low per capita social security fee level.

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Access to innovative medicine

As a volume share of the pharmaceutical product segments, Vietnam has one of the lowest percentages of originators across Asian markets at less than 4%. In contrast, non-Rx products account for approximately 70% of the share, while branded and unbranded generics account for the remaining 26%. Comparing this to ASEAN partners like Thailand (with originators at 8%) and Singapore (14%), Vietnam has a relatively lower level of access for innovative medicines.

In real terms, this low penetration rate means that many Vietnamese citizens do not have access to necessary 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 on page 8).

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. As of now, 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 on page 10).

Public Private Collaboration

In Vietnam, many interviewed industry leaders 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 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 currently identified challenges in PPC, most 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 interviewees showed a strong desire to further invest in the Vietnamese market. However, in terms of business registration changes, many executives found the transition requirements from Representative Office to a Foreign Invested Enterprise (FIE) confusing and time-consuming. However, this 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**: Developing forms of PSPs that were only allowing free or cost-shared programs while other markets have up to five different funding models, creating timelines for new and approved PSPs, then expanding such programs to other new hospitals
3. **Program incentives**: Lack of clear incentives to increase program registration efficiency, the ability to offset the cost of donated or discounted products used in the program
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 the Innovative Pharmaceutical Sector Development in Other Economies

Globally, several middle-income countries 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 characteristics 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 the education of pharmaceutical professionals and workforce to enhance domestic capabilities

In this section, we have selected three economies with more mature pharmaceutical markets: Singapore, South Korea, and Ireland. It is our opinion that each of these markets has clear points of learning for Vietnam to consider if it wants to leapfrog its domestic industry’s development.
Figure 1: Overview of the innovative pharmaceutical sector development in other economies

- **FDI becomes key strategic goal**: Incentives for foreign companies in Ireland
  - Investment in education
  - Deepen roots of MNC’s – Research capability

- **Russia**
  - Pharma 2020: An innovative development model for Russia’s pharma production

- **South Korea**
  - Bio-Vision 2016: Policy objectives to improve South Korea’s ranking and make it a leader in biotechnology
  - 577 Initiative: Funding of USD 59bn for R&D

- **China**
  - National Key New Drug Creation Program: Invest up to USD 244mn for R&D and clinical trials
  - Medium and Long-term Plans: Goals for R&D spend, with bio-tech as a prioritized research area

- **Brazil**
  - Profarma: Develop pharma-innovation PACTI 2007-2010: Develop science, technology, and innovation

- **India**
  - National Biotech Strategy: Give tax subsidies, create national research centers and infrastructure for clinical trials
  - Innovation toward a Knowledge-Based Economy

- **Indonesia**
  - National Innovation Act 2008: Financial incentives for R&D activities, indirect and direct tax incentives for Special Innovation Zones, and a platform for private and PPP commercialization of innovation

- **Singapore**
  - National Biotech Policy: Move the biotech industry into an international player
  - IMP3: Production of biologics and higher-end generics

- **South Africa**
  - National Biotech Strategy: Give tax subsidies, create national research centers and infrastructure for clinical trials

- **South Korea**
  - Bio-Vision 2016: Policy objectives to improve South Korea’s ranking and make it a leader in biotechnology

Relative level of implementation success

- **Example of success**
  - High potential with good implementation
  - High potential
  - Less successful
  - Unsuccessful

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Singapore has become a pharmaceutical hub over the past two decades

Singapore’s pharmaceutical industry started to boom since the beginning of 2000 when the government launched the Biomedical Sciences (BMS) initiative, prioritizing the 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 USD7 billion by 2005. In 2005, the output grew to SGD18 billion (USD11 billion), exceeding the target by 50%. Phase 2 continued to invest in pharmaceutical infrastructure as well as build up research and innovation capabilities.

Pharmaceuticals as a sub-sector under BMS has grown rapidly over the past 18 years. Also, Singapore has become a regional hub for pharmaceutical manufacturing, research, and innovation. The pharmaceutical output has increased from USD2.8 billion in 2000 to USD15.7 billion in 2018 at a CAGR of 10.0%. Employment has consistently grown at 8.2%, and gross value added has grown at a similar rate of 9.7% from USD1.7 billion to USD9.3 billion over the same period, increasing from 1.81% to 2.55% as a percentage of national GDP.

The growth of both employment and value-added resulted in relatively unchanged productivity over the period. The industry experienced rapid growth from 2000 to 2007 as gross value added increased fivefold to USD8.5 billion, corresponding with a more than doubling growth in labor productivity from USD900 thousand per employee to USD2.3 million per employee.

The industry experienced a drop in 2008 due to the global economic slowdown. It rebounded over 2010 to 2012 before another decrease in 2013 due to a demand drop for Singapore’s manufacturing exports. The productivity decline since 2013 was mainly due to economic stagnation in recent years.
**Pharmaceutical exports have steadily expanded**

The increase in pharmaceutical output is accompanied by an increase in merchandise exports (both domestic exports and re-exports) from USD1 billion in 2000 to USD9.7 billion in 2018 at a CAGR of 13.3%. Accordingly, the proportion of exports in total output has grown from 36.4% to 61.6%. The growth is mainly attributed to domestic exports, which increased from 56% to 79% of total merchandise exports over the same period.

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

![Merchandise exports and imports chart](chart)

- Merchandise exports
- Merchandise imports
- Exports as % of output

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.

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Policies</th>
<th>Description</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>Bio*One Capital</td>
<td>Bio*One Capital is the corporate investment arm of the Economic Development Board (EDB)</td>
<td>Dedicated to promoting and managing investments in the biomedical sciences sector</td>
</tr>
<tr>
<td>2000</td>
<td>Biomedical Sciences (BMS) Initiative</td>
<td>Prioritize the pharmaceutical sector at the national policy level and promote biomedical sciences as the fourth pillar of the economy. The initiative has multiple phases with each covering 5 years</td>
<td>Have an overarching vision and framework for developing pharmaceutical industry; allocated funds to build up domestic capabilities; appointed agencies and institutes to take responsibilities to implement the initiatives</td>
</tr>
<tr>
<td>2001</td>
<td>Tuas Biomedical Park</td>
<td>A world-class manufacturing hub hosting process development and manufacturing operations of major pharmaceutical companies</td>
<td>Dedicated to providing infrastructure for pharmaceutical and biologics manufacturing, having a significant impact on the industry</td>
</tr>
<tr>
<td>2003</td>
<td>Biopolis Hub</td>
<td>Established by Agency for Science, Technology and Research (A*STAR) to provide R&amp;D space for health and biomedical sciences</td>
<td>Dedicated space to promote R&amp;D by bringing together various research and medical communities from the research institutes of molecular biology, genomics, bioinformatics, bioengineering, bioprocessing technology, and chemistry</td>
</tr>
<tr>
<td>Year</td>
<td>Policies</td>
<td>Description</td>
<td>Impact</td>
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</tr>
<tr>
<td>2006</td>
<td>Translational &amp; Clinical Research (TCR) Flagship Programme</td>
<td>Aims to establish Singapore as a leader in several 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.</td>
<td>Enhanced collaboration with domestic and overseas research institutions and industry; built up a critical mass of excellent researchers in the five selected therapeutic areas</td>
</tr>
<tr>
<td>2008</td>
<td>Singapore Academy for Good Industry Practices Excellence</td>
<td>Established in the National University of Singapore with a 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</td>
<td>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</td>
</tr>
<tr>
<td>2011</td>
<td>Open Collaborative Fund (OCF)</td>
<td>An SGD590 million (USD469 million) fund to promote greater collaboration between basic science researchers and clinician-scientists, and to support the integration of activities across the wider BMS research community</td>
<td>Provided funding to integrate and collaborate the entire value chain of biomedical research; accelerated to build towards a knowledge-based economy through enhancing human capital and knowledge transfer; drove the overall competitiveness of the pharmaceutical industry</td>
</tr>
<tr>
<td>2013</td>
<td>Clinical Trial Grant (CTG-Industry Collaborative Trials)</td>
<td>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</td>
<td>Supported Industry Collaborative Trials that involved both clinician and company contributing intellectual inputs and funds to conduct the trial and developing novel or pre-existing therapies/drugs/medical devices for new indications</td>
</tr>
<tr>
<td>2013</td>
<td>Clinical Trial Grant (CTG-Investigator-Initiated Trials)</td>
<td>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</td>
<td>Supported Investigator-Initiated Trials of both early and late phase which were initiated and driven by clinicians who are interested to conduct trials on novel or pre-existing drugs/medical device/interventions for new indications</td>
</tr>
<tr>
<td>2014</td>
<td>Diagnostics Development (DxD) Hub</td>
<td>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</td>
<td>Developed diagnostic solutions tailored to diseases predominantly found in Asia; licensed diagnostics technologies to MNCs, SMEs and start-ups, completed commercial contracts, attracted industry co-funding, and helped establish local and foreign start-ups</td>
</tr>
<tr>
<td>2016</td>
<td>Singapore Workforce Skills Qualifications System for Process (Process WSQ)</td>
<td>Four-level training program by Singapore Workforce Development agency, leading to the WSQ Higher Certificate in Process Technology (Pharmaceuticals Manufacturing)</td>
<td>Trained workers for the skills and competencies required for job roles in the pharmaceutical manufacturing industry</td>
</tr>
<tr>
<td>2016</td>
<td>Research, Innovation and Enterprise (RIE) 2020 Plan</td>
<td>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</td>
<td>Have an overarching road map for developing the pharmaceutical manufacturing industry; offered grants to develop technological capabilities; leverage public sector R&amp;D investments to grow industry R&amp;D capabilities</td>
</tr>
</tbody>
</table>
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.

Today, over 100 global biomedical sciences companies have leveraged Singapore’s world-class manufacturing and scientific capabilities, connectivity to other Asian markets, and business and regulatory ecosystem, to carry out strategic business operations ranging from regional headquarters to cutting-edge research and manufacturing.5

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

Since the beginning of industry growth, Singapore has been aware of the importance of investment in research and development. National total expenditure on R&D has increased to USD1.31 billion in 2016 from USD80 million in 2000 with a CAGR of 18.7%, representing an increase from 0.09% to 0.41% as a percentage of national GDP.

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

Source: Singapore Department of Statistics
Note: Numbers converted from local currency to USD based on exchange rate from World Bank.

The Agency for Science, Technology, and Research (A*STAR) was established in 1991 under the Ministry of Trade and Industry of Singapore to support R&D in health and biomedical sciences. 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 the Ministry of Health has funded various segments in medical sciences including research, human capital, 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 the 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 2012, the firm grew considerably to manage an investment portfolio estimated at more than SGD790 million (USD632 million). 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 tax deductions up to 400% were available to businesses for their expenditure on the acquisition and licensing of Intellectual Property Rights, registration of patents, and R&D activities.

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

Source: Singapore Department of Statistics
Note: Numbers converted from local currency to USD based on exchange rate from World Bank.

Leveraging on private and foreign investment to build local capabilities

Over the years, Singapore has approved at least 130 clinical trials each year. The Clinical Trials Certificates (CTC) issued has increased from 99 to 264 from 1998 to 2017 with a CAGR of 5.3%, indicating a larger coverage of the trial sites in Singapore. In 2015, the proportions of Phase I, II, III, and IV trials are respectively 25%, 29%, 33%, and 14%. Based on data from the Singapore Clinical Research Institute (SCRI), the number of patients enrolled in clinical trials has grown from 5,442 to 13,638 over 2014 to 2017 with a CAGR of 35.8%.

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.

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Case Study: South Korea

Strong growth of South 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 import ban on drugs that were manufactured locally. 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 Biotech2000 program, while the Ministry of Commerce, Industry, and Energy (MOCIE) created the Bioindustry Vision 2000, with the aims of developing Korea’s biotechnology industry to a level on par with other advanced economies. 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 41,600 in 2017 with a CAGR of 2.4%. Gross value added has also increased steadily from USD2.4 billion to USD10.1 billion, staying at 0.6% of the national GDP. The drop from 2007 to 2010 mainly came from the depreciation of Korean Won and an increase in the production cost of pharmaceutical products. Productivity grew in line with gross value added in the earlier years. The recent stagnation of the pharmaceutical industry was mainly as a result of continued drug price control and restructuring of the industry.

Pharmaceutical exports have consistently expanded over the period

The South 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 USD16.9 billion in 2017, with a CAGR of 7.8%. Exports have also increased significantly from USD300 million to USD3.8 billion from 1999 to 2018, at a rate of 14.3%. The share of exports has increased from 6.8% of manufacturing output to 19.1% in 2017, 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 regulatory procedures in the industry, thus supporting its rapid expansion. Furthermore, the Pharma Korea 2020 Roadmap was launched in 2012, encouraging domestic companies to increase innovation as well as to expand overseas.

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

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

Source: Korean Statistical Information Service

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.
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 are outlined in Table 2.

Table 2: Key policies and initiatives in Korea

<table>
<thead>
<tr>
<th>Year</th>
<th>Policies</th>
<th>Description</th>
<th>Impact</th>
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</thead>
<tbody>
<tr>
<td>1980s</td>
<td>Lifted ban on drug imports</td>
<td>Lifted ban on imports of drugs that could be manufactured locally</td>
<td>Local firms incentivized to increase their competitiveness to compete with foreign counterparts</td>
</tr>
<tr>
<td>1985</td>
<td>Korea Research Institute of Bioscience and Biotechnology (KRIBB)</td>
<td>Established KRIBB to carry out research and development and other projects in bioscience and biotechnology, together with other institutes and businesses</td>
<td>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</td>
</tr>
<tr>
<td>1987</td>
<td>Patent law</td>
<td>A comprehensive bill to amend the patent law to include patent coverage for chemical and pharmaceutical products</td>
<td>Encouraged research and development of pharmaceuticals within the country; attracted multinational firms would invest in Korea since the patent law afford them better protection of intellectual property rights</td>
</tr>
<tr>
<td>1994</td>
<td>Biotech 2000</td>
<td>First government-wide framework plan for biotechnology promotion in Korea</td>
<td>Increased investment in the biotechnology industry</td>
</tr>
<tr>
<td>1998</td>
<td>Foreign Investment Promotion Act</td>
<td>Eased regulations and restrictions on foreign investors, as well as increasing tax incentives</td>
<td>Incentivized an increase in foreign investment into Korea, including attracting multinational firms to the pharmaceutical industry</td>
</tr>
<tr>
<td>2004</td>
<td>Regional Clinical Trials Center (RCTC)</td>
<td>First RCTC established to kickstart Korea's clinical trials industry</td>
<td>Increased Korea’s clinical trial capabilities, adhering to global standards</td>
</tr>
<tr>
<td>2006</td>
<td>Bio-Vision 2016</td>
<td>Based on global technological environment and lessons learned from Biotech 2000, it envisioned Korea being ‘a health life and a prosperous bio-economy’ and ranking it among the world’s top seven biotechnology powerhouses by 2016</td>
<td>Continuously expanded the industrial infrastructure and acquire competitive source technologies to actively promote the country’s biotechnology to a position of global leadership; focused on driving industry R&amp;D and investment in human capital</td>
</tr>
<tr>
<td>2007</td>
<td>Korea National Enterprise for Clinical Trials (KoNECT)</td>
<td>Established as a non-profit organization by the Ministry of Health and Welfare to increase clinical trial capabilities</td>
<td>Supported the development of infrastructure and human resources for clinical trials; enabled easy access to information through integrated information systems</td>
</tr>
<tr>
<td>2011</td>
<td>Korea Drug Development Fund</td>
<td>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</td>
<td>Sponsored projects to promote new drug development; increased investment in the sector at all stages of the drug development process</td>
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<table>
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<tr>
<th>Year</th>
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<tbody>
<tr>
<td>2012</td>
<td>Global Center of Excellence in Clinical Trials (GCE)</td>
<td>Five consortia of clinical trial centers were given funding to develop clinical trial technologies and infrastructure, especially in specialized areas</td>
<td>Increased the international competitiveness of Korea’s clinical trials industry</td>
</tr>
<tr>
<td>2012</td>
<td>Pharma Korea 2020 Roadmap</td>
<td>Outlined vision for Korean pharmaceutical industry and companies, such as supporting innovative drug development and the expansion of Korean firms overseas</td>
<td>Included a fund for R&amp;D, increased investment, tax deductions for R&amp;D and greater support for training workers</td>
</tr>
<tr>
<td>2013</td>
<td>Research-driven hospitals</td>
<td>The Korean government designated ten research-driven hospitals</td>
<td>Fostered health technology research and development in university hospitals</td>
</tr>
<tr>
<td>2018</td>
<td>Osong Biopolis</td>
<td>Korea’s only biotech complex initiated by the government, to fuel the growth of the industry</td>
<td>Dedicated infrastructure to develop new medicines and advanced medical devices, and it offers one-stop support for all stages of biomanufacturing, from clinical trials to approvals to manufacturing and retailing</td>
</tr>
</tbody>
</table>

Promoting pharmaceutical R&D by funding new drug development

The South 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. By 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 USD7.1 billion in 2014. Business enterprise and higher education are the major units that perform the R&D, each accounting for around 40% of the total expenditure.

As of 2017, 29 new drugs have been developed in Korea since the first domestically developed drug in 1999, the Sunpla Injection by SK Chemical. In 2011, the government launched the Korea Drug Development Fund with a budget of USD1 billion for funding research into new drugs. 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. There are also around 150 universities and 6 major public institutes are involved in pharmaceutical research in Korea.

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

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. The drop of R&D in 2015 was due to a change in OECD’s methodology.
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)\(^\text{15}\) to ease the restrictions on foreign investment, as well as establishing tax incentives and foreign investment zones. It has also committed resources to develop a specialized workforce and infrastructure for the industry\(^\text{16}\), which acts as an additional draw for multinational companies.

As of now, 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.\(^\text{17}\)

In the pharmaceutical industry, the FDI position increased from USD460 million in 1999 to USD6.07 billion in 2017, with a large amount of this having been made in more recent years.

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

![Chart showing FDI position from 1999 to 2017](chart.png)

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.

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\(^\text{15}\) Republic of Korea Ministry of Legislation, Foreign Investment Promotion Act 2012.


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 that grew to 15 by 2016. The first GCE was built in 2012, and by 2016 there was a total of 5 GCEs. Furthermore, the KoNECT was established in 2007 to foster the nation’s clinical trial capabilities and facilitate the sharing of information across the sector. Currently, there are around 163 accredited clinical trial facilities and 19 pre-clinical trial organizations in the country.

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. Over 2002-2017, the number of domestic clinical trials in Korea has grown from 55 to 658. In 2013, 58.6% of the approved clinical trials in Korea were local.

After Korea adopted 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, with Seoul being one of the leading cities in the world. The CAGR for the global market share of Korea’s clinical trial sites was 9.34% as of 2016.

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

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 4.2%, from 18,500 people in 1998 to 42,300 people in 2018. 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 18.3% over the same period, which signifies the importance of the pharmaceutical industry in the Irish economy.

From 2002 to 2014, the gross value added from the pharmaceutical industry slightly declined, resulting in stable productivity at around USD500,000 per employee. This represents more than double the productivity of the general manufacturing industry.

The growth experienced by the Irish pharmaceutical industry could be attributed to 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.  

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 to a large extent since it had previously been trading primarily with the United Kingdom. The exports of pharmaceutical and medical products increased from USD60 million in 1973 to USD54.5 billion in 2018, representing an increase from 2.6% of total exports to 32.8% over the period. Faster growth was observed when Ireland replaced the Irish Pound with the Euro at the beginning of 2000.

The country became the largest net exporter of pharmaceuticals in the EU, with pharmaceuticals accounting for over 50% of the country’s net exports.26 In recent years, Ireland became the largest net exporter of medicines in the world and the eighth-largest producer.26

**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 years, from two manufacturing sites in 2003 to 18 in 2017. There were 62 total manufacturing sites in 2018, of which many are owned by export-oriented foreign companies.

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, 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 industry’s productivity and competitiveness but also adds to its attractiveness as a location for both manufacturing and research.

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 are outlined in Table 3.

<table>
<thead>
<tr>
<th>Year</th>
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<th>Policies Description</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970s</td>
<td>Industrial Development Authority’s (IDA) adoption of fine chemicals as one of its target sectors</td>
<td>IDA is the government agency responsible for attracting inward investment. It identified fine chemicals including pharmaceuticals as one of the key emerging sectors in the 1970s</td>
<td>Successfully brought in a substantial number of foreign companies to invest in manufacturing in Ireland; boosted strong growth of the employment in pharmaceutical industry</td>
</tr>
<tr>
<td>1986</td>
<td>Health Research Board (HRB)</td>
<td>Mainly funded by the Department of Health and serve as a leading funding agency that supports research and provides evidence to prevent illness, improve health and transform patient care</td>
<td>HRB oversaw a EUR45 million (USD53 million) investment in health research activity each year and manages four national health information systems; provided information and evidence in healthcare and drove healthcare innovation; promoted the overall industry</td>
</tr>
<tr>
<td>1987</td>
<td>Control of Clinical Trials Act (amended in 1990)</td>
<td>Comprehensive legal framework on conducting clinical trials, including clinical trial application, restriction, participant, ethics, etc.</td>
<td>Regulated clinical trials of medicinal products at state level to ensure product quality (safety and effectiveness)</td>
</tr>
<tr>
<td>1996</td>
<td>Health Products Regulatory Authority (HPRA) (formerly Irish Medicines Board)</td>
<td>An independent regulator of health products in Ireland to protect and enhance public and animal health</td>
<td>Ensured safety, quality and effectiveness of the entire healthcare products; emphasized quality control from the beginning, which improved Ireland’s attractiveness to foreign investment</td>
</tr>
<tr>
<td>2000</td>
<td>Science Foundation Ireland (SFI)</td>
<td>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</td>
<td>Provided funds in R&amp;D and education to promote development and competitiveness of the biomedical industry, enterprise and employment</td>
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<th>Year</th>
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</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>Synthesis and Solid-State Pharmaceutical Cluster</td>
<td>Government invested in the research center (under SFI), to promote the development of the more specialized area in the pharmaceutical industry</td>
<td>Attracted companies, researchers, conferences to Ireland; encouraged more in-depth of research at all stages along the production process starting from synthesis</td>
</tr>
<tr>
<td>2007</td>
<td>National Development Plan 2007-2013</td>
<td>Government committed to investing in the industry, including in infrastructure, R&amp;D and human capital</td>
<td>Long-term planning for investments to boost the development of the industry.</td>
</tr>
<tr>
<td>2009</td>
<td>Action Plan for Health Research</td>
<td>A task focused framework to prioritize 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</td>
<td>Enhanced 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</td>
</tr>
<tr>
<td>2011</td>
<td>National Institute for Bioprocessing Research and Training (NIBRT)</td>
<td>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</td>
<td>Boosted 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</td>
</tr>
<tr>
<td>2015</td>
<td>Clinical Research Coordination Ireland (CRCI)</td>
<td>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</td>
<td>Provided overarching support and expertise through infrastructure, experienced specialist and the necessary quality and oversight programs to conduct world-class patient-focused research in Ireland</td>
</tr>
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</table>
Successful partnership between the government, the pharmaceutical industry and the Industrial Development Authority (IDA)

To stimulate and develop enterprises in Ireland, the IDA was set up in 1949. The pharmaceutical industry grew after IDA adopted fine chemicals as one of its focus sectors in the 1970s. From the 1970s to the 1990s, a large proportion of investment in pharmaceuticals and biotechnology came from private companies, both international and local.30

FDI has played a very important role in driving the growth of the pharmaceutical industry in Ireland. In the initial stage of the industry, IDA 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 has maintained strong growth of 11.7% annually on average.

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.31

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 policymakers.32 It is one of the major sources of funds for health-related research, along with Science Foundation Ireland (SFI), IDA, and Enterprise Ireland.33

To develop biotechnology as an engine for Ireland’s growth, SFI was established in 2000 to minster the Technology and Foresight Fund with a budget of EUR646 million (USD763 million).34 It went on to establish SFI Research Centers, including the Synthesis and Solid-State Pharmaceutics Cluster (SSPC) in 2007.35 These centers attract global companies, researchers, and conferences to Ireland.

Currently, SFI funds research, promotes the development of the industry, and collaborates with close to 500 multinational companies and 400 small and medium-sized enterprises. 36

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.

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

Ireland 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, and an intellectual property regime that provides tax reductions, as well as international agreements on double taxation.\(^\text{37}\)

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\(^\text{38}\), thus its close connections with the rest of Europe position it well for companies seeking to reach European markets.

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 Acts in 1987 and amendment in 1990 regulated clinical trials at the 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.\(^\text{39}\) It was hosted by Clinical Research Development Ireland (CRDI), which is a partnership of several universities, medical schools, academic hospitals, and clinical research facilities.

The number of clinical trial sites has increased from 134 in 2014 to 291, as of May 2019.\(^\text{40}\) The clinical trials under Cancer Trials Ireland increased from 969 in 2008 to 3,569 in 2017, and the clinical trials conducted in HRB’s three Clinical Research Facilities increased from 126 in 2012 to 325 in 2017.\(^\text{41}\)

Conducting clinical trials has generated significant benefits to the economy. A study pointed out that each patient recruited in a clinical trial will generate an average benefit of EUR13,500 (USD15,900) to the economy. The savings of health service would amount to an average of EUR 5,900 (USD7,000) per participant.\(^\text{42}\)
Overview

Developing the innovative pharmaceutical industry in Vietnam will drive sector and economic growth, and improved health outcomes. Vietnam has the potential to grow its domestic innovative pharmaceutical market.

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

2. Government Benefits
   - 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 Benefits
   - Enhancement of local manufacturing
   - Develop export capabilities
   - Increase R&D activities and become a hub for pharmaceutical sector
Key economic factors driving opportunity

There is a significant opportunity in Vietnam to attain the benefits associated with the innovative pharmaceutical industry. This is driven by several economic factors.

Demographics

Vietnam is ranked as the 13th most populous country in the World, with a population of approximately 96 million people as of 2018. The percentage of the population aged 65 and above currently accounts for 11.9% and is expected to increase significantly from this level. A rapidly aging population will likely accelerate the onset of age-related diseases such as diabetes and cardiovascular issues in Vietnam.

Meanwhile, Vietnam has reached low middle-income economy status. The disposable income of citizens has rapidly increased over the past several years and is expected to continue at 6.8% through 2023. Growing disposable income will likely boost consumer spending in overall healthcare services and pave the way for innovative healthcare solutions.

GDP growth

Vietnam is one of the fastest-growing economies in ASEAN. The country is expected to maintain an average GDP growth of 6.5% per year for the next 5 years, which will be one of, if not the, highest for the region when compared to its peers such as Malaysia (4.3%), Thailand (3.5%) and Indonesia (5.5%). This strong economic expansion will likely benefit Vietnam by creating an attractive growth story that could drive further FDI, bringing much-needed technology and knowledge transfer.

Figure 2: Disposable income of Vietnam versus selected countries

Figure 3: Regional comparison of real GDP growth 2013 – 2023

Pharmaceutical sector growth

According to the latest available statistics of the Drug Administration of Vietnam (DAV), as of August 2019, Vietnam has approximately 184 pharmaceutical manufacturers operating in the market (both local and foreign companies) (of which, there are 225 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 2040. If the Vietnamese market can maintain this growth pattern, the total industry value could reach and exceed USD34.1 billion by 2040. This value, if measured today, would rank Vietnam as a top-25 global market.

Non-communicable diseases trend

Non-communicable diseases (NCDs) are set to assume a greater share of Vietnam’s healthcare sector. This will likely translate into the need for new innovative approaches to address the expanded demand while facing constraints in healthcare financing.

In 2017, NCDs made up 80% of disability-adjusted life years (DALYs), which is the standard expression of disease burden. This value is forecasted to reach 87% by 2025. Cancer, cardiovascular diseases, and musculoskeletal disorders are primary drivers of non-communicable diseases (i.e., lifestyle diseases). Cancer currently accounts for 2.8 million DALYs and is expected to increase by 400,000 in 2025. Cardiovascular diseases, especially stroke, contribute significantly to Vietnam’s overall burden (8%). In Southeast Asia, Vietnam has one of the highest mortality rates for stroke with 158.9 per 100,000 people. The availability of therapeutics consistent with peer markets could significantly reduce NCD-related mortality.

Figure 4: Vietnam’s burden of disease projection

Note: NCD group causes exclude consideration of ‘Mental & Behavioral’ group of diseases
Potential Opportunities for the Pharmaceutical Industry

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

Meeting these needs requires collaboration between policy-makers and industry towards effective patient outcomes and strong sector development. With the support of the government, the industry has ambitions to expand its 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 likely both boost domestic capabilities and accelerated 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 likely be one of the eventual outcomes of foreign investment. This is also aligned with the government’s vision to have 80% of the market value manufactured locally by 2020.

   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 key challenges described earlier in this document are met. This could lead to an additional investment of USD5-20 million for each company on average. Depending on the size of the manufacturing site, it would also create additional employment ranging from 10 to 100 Full-time Equivalent (FTE) employees for each company, as well as an additional contribution to the pharmaceutical industry.

   Local manufacturing activities will initially be mostly contract manufacturing through a qualified local partner. This would drive technology transfer, process R&D, and capability enhancement of domestic manufacturers. International standards and best practices will come through partnerships, which will drive growth in the domestic pharmaceutical industry.

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 Continuous Medical Education (CME) programs including training 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. Most companies have the ambition to expand or at least maintain the current level of investment in education, which ranges from approximately 5% to 25% of operating costs. Capability building is interlinked with foreign investment, as improving domestic capability further attracts 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 perceptive but generate benefits to patients and the general Vietnamese population. On average, one patient support program is able of reaching around a thousand patients depending on the number of hospitals covered in the program.
Innovative pharmaceutical industry can potentially grow at 15% to 20% with an additional USD8.7 billion to USD27.6 billion output by 2040

Based on our stakeholder interviews with 13 innovative pharmaceutical companies, the innovative pharmaceutical industry is expected to grow at a CAGR of 10.0% to 12.0% under current trends. Accordingly, the market value is estimated to reach between USD6.5 billion to USD9.7 billion by 2040, from USD800 million in 2018.

Legal and regulatory frameworks can be implemented to encourage investments and develop the innovative pharmaceutical industry. With more concerted efforts to facilitate the industry growth, we estimate that the output of the innovative pharmaceutical industry would display a higher growth potential from 2022 onwards when innovative pharmaceutical companies start manufacturing locally and generating additional benefits to the economy. Depending on the market condition, the industry would potentially grow at 15% to 20% annually and reach to USD15.2-34.1 billion in 2040, representing a threefold growth over the current baseline.

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

Note: 2015-2017 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. 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 the rapid expansion in the domestic manufacturing of pharmaceutical products, the country could 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 likely 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 a scientific platform and collaborates with leading life science entrepreneurs, investors and researchers to examine the human genome and explore new prevention strategies and treatments.47

The innovative pharmaceutical industry would contribute an additional USD6.1 to USD19.6 billion to GDP by 2040 with joint effort between government and private businesses compared to business as usual

Under current trends, the direct gross value-added contribution to the national economy is projected to reach between USD1.4 to USD2.1 billion by 2040 from the current value of USD200 million.

With proper incentives and policies in place, the strong growth of the innovative pharmaceutical industry will likely translate into an increasing economic contribution to the GDP. We estimate that the direct gross value added could grow at a CAGR of 15% to 20% over 2022 to 2040, contributing USD3.3 to USD7.4 billion by 2040.

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

An addition of USD 1.9 billion to USD 6.0 billion direct gross value added for the innovative pharmaceutical industry by 2040

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 projection, 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.

Moreover, the upstream and downstream impact through business-to-business transactions caused by the operations of pharmaceutical companies will likely contribute indirectly to GDP by a range of USD3.8 to USD8.6 billion by 2040. The spending from pharmaceutical companies’ direct and indirect employees would contribute a range of USD3.7 to USD8.3 billion. Overall, we estimate the total GDP contribution by the innovative pharmaceutical industry would reach to USD10.8 to USD24.3 billion by 2040.

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

An addition of USD 6.1 to USD 19.6 billion total gross value added by 2040

<table>
<thead>
<tr>
<th>Future growth scenarios by 2040</th>
<th>Baseline by 2040</th>
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<tr>
<td>Direct (upper @20%) 24%</td>
<td>Baseline (lower @15%) 10%</td>
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<td>Direct (upper @20%) 36%</td>
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<td>Induced (upper @20%) 0%</td>
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Note: GDP contribution is calculated based on the market value projection and economic multiplier derived from Input-Output table from OECD.

In summary, with a joint effort between government and private businesses, the innovative pharmaceutical industry could contribute an additional USD6.1 to USD19.6 billion in total by 2040 compared to business as usual, including direct gross value added of USD1.9 to USD6.0 billion, and USD4.3 to USD13.6 billion indirectly via domestic purchases from the innovative pharmaceutical companies.

The growing market size of the innovative pharmaceutical industry will contribute to additional tax revenue for the country. This will be true after companies convert from representative offices to locally registered legal entities.

Under current trends, pharmaceutical exports could grow at 6.1% and amount to USD460 million by 2040. As there would be continuous expansion and establishment of local manufacturing of pharmaceutical products, there is a strong potential for Vietnam to become a key exporter in the future. We estimate the pharmaceutical exports will reach between USD920 million to USD2.2 billion by 2040, with a CAGR of 10% to 15% from 2022 onwards. This would mean an addition of USD640 million to USD1.7 billion pharmaceutical exports.

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

An addition of USD640 million to USD1.69 billion exports for the entire pharmaceutical industry by 2040

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 BMI data. 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

Employment in the innovative pharmaceutical industry is likely to grow at 2.8% under current conditions, reaching around 13,500 by 2040. With more concerted efforts to facilitate industry growth, employment is likely to grow at 5% to 10% from 2022 onwards, reaching between 20,000 and 48,500 by 2040. This represents an additional 6,500 to 35,000 direct new jobs.

Moreover, another 136,200 to 329,500 additional jobs would be created through indirect and induced economic impact, reaching a total of 156,200 to 378,000 jobs by 2040.

In summary, with a joint effort between government and industry, the innovative pharmaceutical industry would create an additional 50,800 to 272,600 highly educated and highly value-added jobs in total by 2040 compared to business as usual, including 6,500 to 35,000 direct jobs, and 44,300 to 266,100 indirectly for peripheral industries by 2040.

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

Frieda growth scenarios by 2040

An addition of 6,500 to 35,000 employees for the innovative pharmaceutical industry by 2040

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 50,800 to 272,600 total jobs created by 2040

Note: GDP contribution is calculated based on the market value projection and economic multiplier derived from Input-Output table from OECD.
Under current trends, labor productivity is projected to reach between USD104,500 and USD155,300 with a CAGR of 7.0% to 8.9% by 2040. Currently, the innovative pharmaceutical industry has relatively high labor productivity compared to other sectors in Vietnam. However, Vietnam is still likely to fall behind other benchmarked countries in 2040 under current trends due to the shorter period for sector growth and lower value-added activities that the local pharmaceutical firms are involved in.

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

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

*Note: Productivity is calculated as direct gross value added divided by number of employees. Potential growth is assumed to start in 2022.*

With proper incentives and policies in place, labor productivity of the innovative pharmaceutical is estimated to reach between USD152,000-368,000 per employee by 2040. This is essentially a CAGR ranging from 8.8% to 13.3% over 2018 to 2040, as compared to 7.0% growth under current trends.

**Chart 21:** Additional labor productivity for the innovative pharmaceutical industry – future potential (USD thousands)

![Chart 21: Additional labor productivity for the innovative pharmaceutical industry – future potential (USD thousands)](image)

*An addition of USD 48,000 to USD 264,000 per employee productivity increase for the innovative pharmaceutical industry by 2040*

*Note: Productivity is calculated as direct gross value added divided by number of employees. Potential growth is assumed to start in 2022.*
Innovative pharmaceutical industry to help unlock Vietnam’s full potential

The innovative pharmaceutical industry in Vietnam has a lot of possibilities in the future by bringing together the right policy framework and incentive from the government as well as the industry capability and investment from private businesses.

Our study shows that the direct GDP contribution from the innovative pharmaceutical industry has the potential to reach USD7.4 billion by 2040.

Figure 7: Vietnam’s potential growth in the innovative pharmaceutical industry

Note: The innovative pharmaceutical industry started to boom in 1970s, 1980s and 2000 respectively for Ireland, Korea and Singapore. Size of innovative pharmaceuticals for Singapore and Korea is estimated respectively based on 59% and 41% market share in total pharmaceutical industry from IQVIA; market share of innovative pharmaceutical for Ireland is estimated based on an average of 72% for developed pharmaceutical markets from WIFOR’s report on ‘The Economic Footprint of the Pharmaceutical Industry’. Vietnam’s potential market size is based on the upper bound growth estimation of direct gross value added and employment at 20% and 10% respectively.
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 likely 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 forecast in this section is based on current health conditions within Vietnam and does not consider external factors. As such, results may reflect a conservative estimate.

Improve health outcomes through better access to innovative drugs

Innovative drugs play an important role in improving health outcomes, especially in an age of rapid technological advancements and enhanced research capabilities. This is because innovative drugs are more efficient in improving health outcomes, patients are more inclined to complete treatment due to reduced expenditure, and ultimately providing more choices.

Innovative drugs are more efficient in improving health outcomes

The benefits of incremental innovation on existing drugs are vital to increasing the quality of healthcare. Incremental innovation refers to improvements made in the safety and efficiency of the drugs, by providing new formulations to improve the health outcomes of patients. Even though the development of these drugs may seem inconsequential, the cumulative effect of numerous incremental innovations can possibly have a greater economic impact than a technological breakthrough48 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 in 2001 revealed that newer drugs are more effective than older drugs in improving patients’ health outcomes.49 Results from the study indicated that patients who consume newer drugs were less likely to die by the end of the study, which shows how the development of new drugs can potentially improve health outcomes considerably.

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. Patients consuming new drugs will require shorter hospital stays than patients that take older drugs, implying that in the long run, it is more cost-effective to consume newer, innovative drugs than older ones.50 This is because consuming newer drugs will reduce the number of stays in the hospital, and if the cost of new drugs is 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 non-drug medical spending of patients, and this will lead to a substantial net reduction in total healthcare expenditures.51

Not only will innovative drugs result in a reduction in healthcare expenditures for patients, but it will also result in significant cost savings for the entire economy. Several academic research papers have

50. Ibid.
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 workdays were lost due to illness and injury respectively and this is estimated to cost the economy approximately $1.6 billion annually.\textsuperscript{52} This significant cost experienced by the economy can be reduced significantly if more effective innovative drugs are made available.

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

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.\textsuperscript{53} With more alternative drugs in the market, more drug options will be available to patients which could improve their health outcomes significantly.


**Establish effective preventive healthcare by increasing 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 of the expected benefits, potential outcomes, risks, and side effects of various treatment options.

Innovative pharmaceutical companies can play a part in 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.\textsuperscript{54} 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 with patients. Findings from a study conducted in 2007 indicated that doctors are oftentimes not aware of the cost of drugs.\textsuperscript{55} The inability to differentiate expensive and inexpensive drugs will harm patients and their choice of treatment options. Implementing appropriate patient support programs could help enhance the healthcare professional’s knowledge of treatment costs and thus provide patients with more informed treatment options. A long-term solution to a sustainable healthcare financing system is 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 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. In some cases, early detection and treatment can significantly improve health outcomes. For example, a mammography is a screening tool commonly used to detect tiny lumps of early breast cancer. If detection and subsequent treatment are given to the patient at an early stage, the patient can remain well and disease-free after five years or more with a 90% probability.\textsuperscript{56} 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.

Implications for Policy Makers

As 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 likely 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 likely occur.

Vietnam is well placed with an educated and hard-working population of the right age. Current geopolitical tensions between the United States and China, as well as rising regional manufacturing costs, means tremendous potential for Vietnam. There is a short window of opportunity for Vietnam to take a quantum leap and the time is now. Case studies have shown that the time necessary to achieve results depends on the policies implemented.

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

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

Innovation

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

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

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 objectives in the Master Plan, with significant socio-economic 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 ministries and government institutions – at a national, regional, and local level – will likely create a favorable business environment for industry players and remove potential impediments to business investments and innovation. This will likely assist the government in achieving its pharmaceutical industry ambitions by 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 likely be more innovative in the face of competition. Most importantly, this ensures the sustainable long-term growth and competitiveness of the industry.

**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. The key components are:

1. **Establish dedicated 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 a Deputy Prime Minister level leadership, 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 likely encourage private businesses, especially foreign companies, to have long-term investments in Vietnam.

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 levels, 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 the 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 outcomes. Apart from this, the administrative framework also needs to ensure timely approval for processes including clinical trials and patient support programs.57

**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 guide 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 for private investors, especially foreign investors.58 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 likely be encouraged to collaborate through the expansion of tangible and intangible education, the latter including continuous medical education and patient support programs, as outlined on 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.59 Enhancing IP protection would also foster a start-up and entrepreneurship ecosystem.

As outlined on page 6, 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 the 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 pharmaceutical companies. For instance, Singapore provides incentives to pharmaceutical companies when they set up operations in Singapore and invest in R&D activities60, or conduct research and clinical trials locally.61 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, thus R&D plays a crucial role in the success of the industry. However, obtaining sufficient funding is often a challenge, especially in the early stage of R&D. Therefore, the government can achieve its ambitions by 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 nine years to support the area of novel drug development, provide funding, and support business development for R&D projects.62 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.

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57. Singapore Economic Development Board.
58. Singapore National Medical Research Council.
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 levels 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. 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. 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.

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 engaging patients. There is great potential in digital technology as it leverages technologies such as block-chain, the 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 the 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 on page 8, 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. Many benefits 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’s design can be made to encourage cost control and rational medicine use, which will lead to an improvement in the overall healthcare and pharmaceutical financing situation.

The Way Forward

Vietnam’s innovative pharmaceutical industry has potential to create value for the nation. Despite the challenges of the regulatory environment, there are many opportunities offered by Vietnam’s resources and workforce. To take full advantage of these opportunities, the government should consider implementing 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 targeted and informed policies, and collaboration with industry stakeholders. These factors will be crucial in developing a dynamic and vibrant future for both the industry and the nation as a whole.
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