From Pharmaceutical Innovation to Revenue Generation: The Asian Experience

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Abstract: Asia's pharmaceutical sector has experienced remarkable growth over the last two decades, with companies in the region producing bulk of the world's specialty generics, biologicals, and active pharmaceutical ingredients (APIs). The Asian pharma growth story has had several pillars for a strong and sustainable foundation that provided non-linear growth. This report introduces three models showing how Asian countries at different development stages — India, South Korea, and Singapore — have nurtured their own, self-sustaining pharmaceutical sectors.

1. Introduction

Asia's pharmaceutical sector has experienced remarkable growth over the last two decades, with companies in the region now producing close to half of the world's specialty generics, biologicals, and active pharmaceutical ingredients (APIs).

This development did not happen spontaneously, nor did countries in the region replicate the path taken by advanced economies. They developed their unique roadmaps with support from governments that adopted specific policies that supported the growth and development of the pharmaceutical sector. Across the region, a distinctive feature was to support revenue-generating industries. The region did not simply mimic the technological advancement by development methodology adopted in developed economies. Modalities were diverse, but the common goal was to tap into strong distribution networks, cost-efficient production, and a critical mass of local talent to focus on high-volume branded generics, high-value contract manufacturing, and participation in global supply chains. Hikino et al., Kim, and Kim[1] have shared their research on Asia's general focus on industrialization without the competitive advantage of pioneering technology. Our hypothesis elaborates on this in the context of the pharma sector in the region.

The Asian pharma growth story has had several pillars for a strong and sustainable foundation that provided non-linear growth. India focused on protective intellectual property rights (IPR), Korea acquired strategic assets internationally, and Singapore tapped into the global value chains and adopted developed market regulatory approval standards. These strategies were especially well adapted to their development levels. These countries were largely supported by 1) their respective government's sectoral policies and actions, 2) the country's inherent scientific talent and government action to nurture talent and upskilling such a biotechnology support programs, 3) actions aimed at generating talent and skilled labor, 4) support to specific firms to develop their technological capabilities, 5) the country's stance on IPR, and 6) the development of clusters and industry parks. The countries took concrete action in these areas of intervention in their unique ways.

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In this exploratory paper, we discuss the key action points on the topics mentioned above in more detail. For India, the government had the advantage of a huge domestic market and internal demand, and drove IPR policies that led to development that had been built on a state-led import-substitution strategy. In 1991, India embraced market liberalization, in a way that allowed it to link its pharmaceutical industry with the world economy. For Korea, the key to success was to buy biotech assets and technology platforms from advanced economies and use their capacity and networks to "learn from doing" and to build home-grown products that could serve both domestic needs and foreign markets. Korea had adopted a similar policy approach to other sectors, starting from appliances, continuing with cars and then with electronics. Pharmaceuticals was one more step up the value-added ladder. For Singapore, rather than a strategy targeted just towards the pharmaceutical sector, it attracted diverse companies because of its pro-business environment, low corporate tax, negligible corruption, and high legal and compliance standards. Considering its small size and population, the government chose to target a growth strategy for high-skilled labor. Singapore's Economic Development Board has focused on developing higher-value-added sectors that can provide quality jobs and careers for the Singapore workforce.

The Asian experience offers valuable lessons to countries in Latin America and the Caribbean. Some countries in Latin America and the Caribbean have significant innovation capacity, but few have managed to develop a self-sustaining pharmaceutical industry. There may be lessons to draw from the Asian experience, and the implications of understanding and applying few of these concepts could be profound for countries in Latin American and the Caribbean to realize its full potential. With public health expenditures falling short of the funding needed to provide universal health coverage, and with changing demographics leading to a growing demand for drugs and health services, out-of-pocket expenditures in the region are rising rapidly.[2] Countries in Latin America and the Caribbean would therefore benefit from developing a broad portfolio of branded and complex generic products that can be taken from the lab for commercialization and would allow for local production that is compliant with global quality standards and regulations.

This paper is exploratory and takes a methodological approach that describes three unique case studies and roadmaps adopted by three Asian countries to establish their own self-sustaining pharmaceutical and biopharmaceutical industries. These are India, Korea, and Singapore—three success stories that took place despite very different income levels that have wider spans than the entire development range observed among countries in Latin America and the Caribbean.

However, these successes also involved different strategies. Korea focused on local companies acquiring strategic assets internationally, with strong government support. India promoted its own version of IPR while tapping into its abundant talent pool of life sciences. It worked with the private sector to develop products of international quality standards that could not only support the large domestic market but also export into both emerging and developed markets. Singapore promoted a conducive business environment and nurtured top human capital to attract

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investment and became a global supply chain hub for pharmaceuticals and biotech. These strategies were especially well adapted to the initial income and capacity levels of each country.

2. India

India has emerged as the pharmacy of the world, supplying affordable generics, vaccines, and other drugs to its 1.4 billion population and exporting them to more than 100 countries. This success owes to the availability of a large domestic market and to the opening of U.S. and other advanced economies to generics drugs. However, two other factors played a crucial role in India's story: an idiosyncratic version of IPR that was essential for nurturing homegrown innovation and attracting foreign investment, and the ability to tap into an abundant talent pool in life sciences.

Since its independence, India has sought to take a development path aimed at promoting self-reliance, spurring rapid industrialization, and lifting its large, agrarian population out of poverty. As with other industries, the government was keen to develop its own pharmaceutical sector and it initially ended protections for patented goods to encourage domestic manufacturers to reverse engineer foreign drugs and produce cheaper, home-grown versions.

This first development attempt, centered on creating large industrial state-owned enterprises, foundered.[3] However, in 1991, India embraced market liberalization, slashing tax rates and import duties, removing price controls and restrictions on the establishment of new firms, and welcoming foreign investment. These reforms set the stage for the development of a homegrown pharmaceutical industry linked to the world economy. It was only then that Indian companies began to export generics to the U.S. and Western Europe, and to enter joint ventures and mergers with international pharmaceutical firms.[4]

Policy Milestones

1970: The Patent Act ended recognition of Western-style patents on food, chemicals, and drugs, enabling Indian manufacturers to reverse engineer proprietary products on the market and develop their own cheaper versions. This was done mainly to guarantee that the Indian public would have access to low-cost drugs.

1974: The Ministry of Education opened the Biochemical Engineering Research Centre at Indian Institute of Technology (IIT) Delhi with substantial assistance from the Swiss Federal Institute of Technology to make available state-of-the-art infrastructure for education, training, and research in biochemical engineering and biotechnology.

1978: India's Drug Policy was introduced with the goal of increasing local production of bulk drugs, encouraging growth of the local industry, and reducing prices of important drugs along with formulations. The policy permits foreign companies producing in excess of their licensed capacity to part with 50 percent of this production to non-associated Indian formulator firms.[5]

1979: India introduced the Drug Price Control Order, which exempts drugs developed through research in India from certain government approvals, including pricing.[6] The order was aimed at encouraging local pharmaceutical's research and development. Because of it, by 2005, the government had capped prices on only 74 bulk drugs and 260 formulations, accounting for a mere 25 percent of India's retail pharmaceutical market.

1986: The Ministry of Science and Technology formed the Department of Biotechnology (DBT), which sponsors research at universities working in the basic areas of life sciences. In the government's annual budget for FY22–23, DBT has been allotted a budget of US $343 million for the development of basic infrastructure, genetic engineering, technologies and bioinformatics, agriculture biotechnology, and training programs for skilled professionals.[7]

1995: India joined the World Trade Organization (WTO), and as a result, it was required to comply with the WTO's trade-related intellectual property agreement obligations, including those related to pharmaceutical production.

2005: India passed the Patents (Amendments) Act 2005, which reintroduced Western patent protections and ended protection for Indian companies engaged in reverse engineering of foreign pharmaceuticals.[8] However, the evergreening of patents — extensions of their coverage for improvements that do not concern their core therapeutical properties — was substantially restricted, in contrast to the policies of Western countries.

India's Department of Biotechnology under the Ministry of Science & Technology launched the Small Business Innovation Research Initiative (SBIRI) scheme to boost public-private partnerships in the country. This funding mechanism allows research and investment into disease areas and medical treatment curative options that are unique to the Indian popu-

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lation and are considered "high-risk" elsewhere and thus would not otherwise get funded.

2012: The Department of Biotechnology set up the Biotechnology Industry Research Assistance Council (BIRAC). This nonprofit, public sector enterprise aims to stimulate, foster, and enhance the strategic research and innovation capabilities of the Indian biotech industry, particularly start-ups and small and medium-sized enterprises. As an industry-academia interface, BIRAC provides grants to academic researchers as well as industrial partners.

2015: The Department of Biotechnology launched the National Biotechnology Development Strategy 2015–2020 program. The government was aware of how challenging the biotechnology field was and how important it was to create an ecosystem to support this field. The goal was to intensify research in the fields of vaccines, human genome, and infectious and chronic diseases. Some 316 start-up companies received support to generate US$125 million in revenues from 2012-2016. The international adoption of human health biotechnology was researched in several emerging countries including India.[9] The private sector in these countries developed a two-pronged approach of developing "imitation" products such as biosimilars and novel biotech products such as bio-betters.[10]

2021: The "Make in India" program aimed at reducing its dependence on China for active pharmaceutical ingredients (APIs), especially for essential medicines. It included three production-linked incentive (PLI) schemes that in the first two years of implementation disbursed nearly US$2 billion to 55 firms, especially to finance the production of 35 of 53 APIs upon which India had substantial import dependence.[11]

The National Research Foundation (NRF) received US$1.4 billion annually for five years to fund interdisciplinary research in science and technology, social sciences, and arts and humanities at colleges and universities. In parallel, the Department of Biotechnology saw a 25 percent increase in its budget.

Key Players

Public organizations: The National Regulatory Authority (NRA) of India includes the State Drug Regulatory Authorities, Pharmaco-vigilance Program of India (PvPI) and Adverse Events Following Immunization (AEFI) structures at the central and state levels. It also encompasses the Central Drugs Standard Control Organization (CDSCO), India's national regulatory body for cosmetics, pharmaceuticals, and medical devices, which serves a similar function to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

India's Department of Biotechnology supports the industry and cuts through red tape. Other public institutions include 37 Council of Scientific and Industrial Research (CSIR) labs, 39 outreach centers, three innovation complexes, and nine biotechnology parks — several of them established in partnership with the private sector.

The country's robust public education infrastructure generates a vast pool of qualified engineers and technologists. Currently, India is home to 3,500 engineering colleges, 3,400 polytechnics, and 200 design and architecture schools. The government has also supported the creation of seven NIPERS (National institutes of pharmaceutical education & research) to address most-in-demand occupations in pharmaceuticals and biotech.

International partnerships: Many of the largest global pharmaceutical companies have set up joint ventures with India's biggest players. These multinationals include Pfizer, Bayer, Merck, AstraZeneca, and GSK.[12]

Five major local companies—Cipla Limited, Dr. Reddy's Laboratories Ltd, Emcure Pharmaceuticals Limited, Sun Pharmaceutical Industries Limited, and Torrent Pharmaceuticals Limited—collaborated on the domestic clinical development of the investigational oral antiviral drug molnupiravir for the treatment of mild Covid-19 in an outpatient setting in India in 2021. These local companies had individually entered into a nonexclusive voluntary licensing agreement with Merck Sharpe Dohme (MSD) to manufacture and supply molnupiravir to India and abroad. Similar agreements in biotechnology have been between Dr Reddys and Merck KGaA, Biocon and Mylan, and Intas and Apotex.

Domestic companies: Today, India has more than 3,000 pharmaceutical companies and approximately 10,500 manufacturing plants. The country's top companies include Divis Labs, Dr. Reddy's Laboratories, Lupin, and Sun Pharma (table 3).

Main Outcomes

India has developed its own, innovative pharmaceutical products. For example, Sun Pharma Advanced Research Company Ltd. (SPARC), a clinical stage biopharmaceutical company that earns its revenues from license fees and royalties on technology and R&D services, has developed two drugs approved by the U.S. FDA: Xelpros and Elepsia, which are used to treat

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Table 1
Growth Focus for India's Top Pharmaceutical Players

Company	Founded	Size (2021 Revenue Estimates)	Market Segments	Key Focus
Divis Labs	1990	US$1.2 billion, 85% Exports	Contract Manufacturing for MNCs	Active pharma ingredients (APIs)
Dr Reddys	1984	US$2.8 billion, 80% Global Generics	Top 5 manufacturers, early direct entry into EM	Branded products across multiple therapies
Lupin	1968	US$1.8 billion	Top 5 generics in US and India	Cardio, anti-infectives, cephalosporin
Sun Pharma	1983	US$4 billion	Largest generics manufacturer, CNS, Cardio	US$2 billion R&D spend in last decade

Source: Moneycontrol, Screener.in website, company sources

glaucoma (eye) and epilepsy, respectively. The drugs have been licensed to six manufacturing partners.

However, India's main strength is in the manufacturing of a wide range of drugs, including vitamins, antibiotics, steroids, hormones, biologicals, plasma derivatives, and vaccines, as well as specialty medicines for chronic diseases such as diabetes, cancer, and cardiovascular disease.

India is today the largest supplier of generic drugs globally. It exports its products to more than 100 countries, meeting more than half of global demand for vaccines, and supplies 40 percent of the generic products sold in the US. Globally, India ranks third in pharmaceutical production by volume. Its domestic pharmaceutical market clocked revenues of US $42 billion in 2021 and is forecast to reach US $120 to 130 billion by 2030.[13]

India is a major supplier of affordable medicines to Latin America and the Caribbean with US$ 1.3 billion in exports. It is the largest supplier of oncology products, HIV drugs, and vaccines to the region. During the Covid pandemic, Serum Institute of India shipped two million doses of the Covidshield vaccine to Brazil.[14] Twenty-five Indian companies are playing an active role in the region, and several have invested in a total of 14 manufacturing plants, some via acquisitions to fuel growth. Sun Pharma and Lupin have manufacturing facilities in Brazil and Mexico, while Dr Reddys has an API manufacturing plant in Mexico.[15]

There is also potential for increased official collaboration, including with supranational entities such as the Pan American Health Organization, and public-private-partnerships, such as those that cater to Brazil's health system. For example, Brazil partnered with India's Aurobindo Pharma Limited to produce a generic version of an HIV/AIDS drug that saved the country US$237 million.[16] And the governments of India and Colombia intend to collaborate in vaccines, biosimilars, and medical devices.[17]

2. Korea

Korea not only transformed its biotech sector into an engine of domestic growth, but it has also emerged as a global leader in the industry, with the world's tenth-largest pharmaceutical market.[18] Key to the country's success was an early focus on biotechnology backed by strong, systematic support from the government.

Korea's economy began to take off in the 1960s, initially driven by the manufacturing of cheap products for export. Dubbed one of the four "Asian tigers," in just a few decades it transitioned from being a poor country to becoming a global leader in innovation and technology. Its manufacturers started by producing television sets and washing machines, before turning to automobiles and high-tech electronics.

The country did not stumble accidentally into the pharmaceutical sector. Rather, the government made a strategic decision in the early 1980s to promote biotechnology as a key industry and then adopted a systematic approach toward achieving this goal. It invested in infrastructure and workforce development and created a beneficial regulatory framework. It also offered financial incentives to support the industry, from tax benefits to a postponement of drug price reductions to preferential research funding. Between 1994 and 2008, government investment in the biotech sector grew at an average rate of more than 24 percent per year.[19]

However, an important way to step up the value-added ladder was to acquire biotech assets and technology platforms from advanced economies and to tap their capacity and networks to build home-grown products. Joint ventures with leading global pharmaceutical companies spurred technology and knowl-

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edge transfers, helping Korean companies leapfrog. This asset acquisition strategy is a distinctive feature of Korea's pharmaceutical development.

Policy Milestones

1982: The Korean development strategy focused on shifting the country from traditional to higher-value manufacturing. Across sectors, policies were adopted to support local companies to invest in foreign assets and produce for world markets. In line with this broader strategy, the Ministry of Science and Technology selected biotechnology as a priority sector and initiated the Biotechnology Promotion Policy.

1985: The Korea Research Institute of Bioscience and Biotechnology was established to facilitate collaboration between academia and industry.

1987: Korea introduced its product patent system. Under this system, the government granted patent term extensions (PTE) to certain types of chemical compound patents or related patents (for example, patents claiming a composition or process of manufacturing) if they pertained to an approved medicinal product.

1994: The country unveiled the Basic Plan for the Promotion of Biotechnology, with the goal for the sector to catch up with advanced economies by 2007.[20] The government pledged to invest US$18 billion in the sector over 14 years.

1998: In the context of the Asian Financial Crisis, the government remained committed to its biotechnology focus, with the associated investments undertaken despite a struggling economy.[21]

2006: The government's Bio-Vision 2016 laid out an ambitious plan to invest US$ 16.6 billion in biotechnology over ten years and transform Korea into a global leader by 2016.[22] Strategies included acquiring internationally competitive source technologies, increasing coordination among ministries, and developing advanced industrial infrastructure. During the phase since 1982, the attempts by the Government were yielding gradual changes. This Biovision plan was a key milestone to effectively coordinate various governmental policies and actions into an effective strategy and propel the private sector to grow the biotechnology industry.[23]

The vision aimed to strengthen the core infrastructure necessary to develop and commercialize world-class original technologies toward an integrated biotechnology sector cycle, from R&D to licensing, manufacturing, and marketing. Its main axes were enhancing coordination between government institutes, training people to acquire with advanced skills, upgrading infrastructure, accelerating R&D investment, activating technology transfer, and improving laws and regulations on bioethics and biosafety.

2007: The government was aware of how demanding the investment thresholds for pharma and biotechnology were to produce innovative products and services. It created state-owned organizations such as Korea Biotechnology Commercialization center (KBCC), which was a contract manufacturing organization. It also established the Korea National Enterprise for Clinical Trials (KoNECT) with the idea to make the country a global clinical trial center by providing it with adequate infrastructure and staff training.[24] It was supportive for the private sector to have such organizations and create public-private governance structures. However, it seems the private sector companies such as Samsung and Celltrion were more efficient and effective in being focused to create products and services with sustainable growth.

2011: The government enacted the Special Act on the National Strategic Technology. Its goal was to build an institutional foundation and provide a legal base for the designation and management of strategic technologies and strengthen priority R&D investment, foster outstanding talent, and facilitate industry-academia cooperation, as well as international cooperation.[25] This special act helped establish the Korea Drug Development fund (KDDF) in 2011 to invest in local research and develop new drugs.

2012: The Korea-US Free Trade Agreement[26] took effect, laying the ground for tariff cuts and greater market opening on both sides. The agreement included provisions to facilitate high-quality healthcare knowledge exchange and to improve access to safe and effective innovative pharmaceutical products. The agreement also required Korea to strengthen data protection and enforce intellectual property protections.

2023: The Korea Drug Development Fund (KDDF) had by then made a cumulative investment of US$ 2 billion to fund more than 1,000 projects to develop new drugs in various disease areas including oncology, cardiovascular, diabetes and providing grant support or matching private funds for achievement of milestone-based research objectives.[27]

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Table 2
Home-Grown Korean Pharmaceutical Companies

Company	Founded	Size (2021 Revenue Estimates)	Market Segments	Key Focus
Celltrion	2002	US$1.5 billion	Monoclonals for oncology	Herzuma, Truxima
SK Bio	1993	N/A; Subsidiary of SK Group, US$133 billion	Central nervous system	XCOPRI®
Samsung Biologics	2011	US$1.2 billion, Subsidiary of Samsung Group	Biosimilars – autoimmune and oncology	Infliximab, Adalimumab, and Trastuzumab
Green Cross	1967	US$1.2 billion	Plasma proteins, recombinant proteins	IV Immunoglobulin, Albumin

Reference: WSJ, Company websites.

Key Players

Public organizations: They include six major public research institutes (e.g., Korean Institute of Science & Technology), various investment funds (Korea Drug Development Fund, Korea Investment Corporation, National OncoVenture, and Hitech Medical Clusters in Osong and Daegu-Gyeongbuk), and several public universities (among them Seoul National University, Korea Advanced Institute of Science & Technology, Pusan National University).

International partnerships: Several Korean private sector companies have formed partnerships with established global companies:

- In 2002, a group of Korean investors joined with San Francisco-based Vaxgen to found Celltrion, with the goal of producing vaccines and recombinant therapeutic proteins. VaxGen had earlier built a smaller biopharmaceutical plant in the US Bay Area biotech hub, for clinical and commercial-scale manufacture. This plant trained many of the Korean staff employed by Celltrion and served as a pilot. The new plant, in Songdo New City, was built by Fluor's world class engineering and construction team, with bioreactors designed by Swiss BioEngineering, and was backed by a supply agreement with Bristol Myers Squibb. With a 150,000-liter biotech lab, it became one of the world's largest biotechnology facilities.
- In 2010, Korea's Samsung announced that the biopharmaceutical sector was one of five new strategic businesses that would lead the group's future growth.[28] It forged a strategic joint venture with Biogen Idec, called Samsung Bioepsis, to work on biosimilars across immunology, oncology, ophthalmology, and endocrinology. Samsung contributed $255 million for an 85 percent stake while Biogen Idec contributed US $45 million and its expertise in protein engineering and biologics manufacturing. This collaboration was the catalyst for the creation of a contract manufacturing development organization (CDMO).
- Samsung Bioepis in turn entered into a strategic collaboration agreement with Japanese pharma giant, Takeda Pharmaceutical, to jointly fund and co-develop multiple novel biologic therapies in unmet disease areas. It also established a manufacturing partnership with Astra Zeneca for Covid-19 and cancer therapies.
- In 2020, Hanmi Pharmaceutical entered an exclusive licensing agreement with Merck Sharpe & Dolme for the development, manufacture, and commercialization of efinopegdutide.[29] Hanmi Pharmaceutical had developed this novel diabetes drug and owns the intellectual property. Under the terms of the agreement, it received an upfront payment of $10 million and is eligible to receiving payments of up to US $860 nillion for the development, regulatory approval, and commercialization of the drug, as well as royalties on its sale.
- In 2021, Daewoong Pharmaceutical and Hanall Biopharma, two Korea-based companies, invested in U.S. biotech firm Alloplex Biotherapeutics for joint drug development as part of global open innovation efforts.
- In 2022, Korea's GC Pharma (formerly Green Cross Corporation) acquired 100 percent of the shares of BioCentriq, Inc., a pioneering U.S.-based CDMO that designs and develops scalable cell and gene technologies. GC Pharma

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established Curevo Inc., a Seattle-based start-up by partnering with global health organizations IDRI (Infectious Disease Research Institute) and MIBR (Mogam Institute for Biomedical Research), to tap into the US R&D ecosystem and augment its vaccine-development activities.

Domestic companies: By 2004, more than 500 Korean companies included biotechnology as part of their businesses. Key companies include Celltrion Healthcare, SK Biopharma, Samsung Biologics, and GC Pharma (table 2). Twelve of them were part of the US $1 billion sales club in 2020, with Celltrion and Samsung ranking first and eight, respectively, among global biosimilar companies.[30] There are also 19 preclinical trial organizations (IQVIA, PRA, C&R) and 163 clinical trial facilities supporting companies in the end-to-end process to discover, develop, and commercialize novel therapeutic products.[31] Several private universities emerged to cater to the STEM fields in the education sector (Korea University, Yonsei University, Sungkyunkwan University).

Main Outcomes

By the mid-2010s, Korea ranked as the world's second-most R&D-intensive country after Israel, investing more than 4 percent of its GDP in it and displaying many characteristics of a highly developed innovation system.[32] A highly developed education system has become one of the country's greatest assets in this respect, with about 30 percent of students enrolling in science and technology fields.[33]

Korea also ranked fourth globally in terms of patents, behind the US, China, and Japan.[34] Even more significant than the increase in the number of patents is the trend in their composition, with the growing share related to platform technologies indicating expertise at the forefront of new technology paradigms.

The introduction of the substance patent system stipulated by the Korea-US trade agreement initially had made local companies apprehensive that it would reinforce the technology domination of advanced economies.[35] But they soon realized that patent protections also allowed them to develop new substances and invest in R&D without worrying about domestic piracy. The US-Korea trade agreement did not create significant barriers to the timely approval of generic drugs either.[36]

Korean companies have shifted from producing generic branded drugs to new drug discovery, with a focus on biosimilars—biologic drugs that are equivalent to the original products manufactured by other companies. Korean regulators have approved 33 new drugs developed by domestic companies, with 16 of them approved by the US FDA and the EU EMEA.[37]

One of the FDA-approved drugs is cenobamate, developed by SK Biopharma to treat partial-onset seizures in adults.[38] The company's pipeline also includes eight compounds in development for the treatment of central nervous system disorders, including epilepsy. The prospects are promising enough to envision increasing corporate assets to more than US$ 50 billion and the number of employees to 20,000 by the end of 2025.[39]

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Another star company is Celltrion, which secured US FDA Current Good Manufacturing Practice approval for its plant and began making biosimilar monoclonal antibodies to supply developed and emerging markets. Celltrion makes remsima (a biosimilar for infliximab, which is used to treat rheumatoid arthritis), truxima (a biosimilar for rituximab, for autoimmune diseases and cancer), and herzuma (biosimilar of trastuzumab, for breast cancer). It holds 54, 24, and 13 percent of the corresponding markets in Europe, and 32, 28 and N/A percent in the US.[40]

Korean pharmaceutical companies have launched about 300 finished drugs and APIs into overseas markets, including the US and EU. They have also licensed about 200 new drug candidates and technologies to 30 countries.[41] As a result of this flurry of activity,

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Korea's exports of medicines and medical equipment have surged from US$7.2 billion in 2017 to more than US$12 billion in 2022.

The expansion of Korean pharmaceutical companies into Latin America and the Caribbean has been slower, taking place mainly through strategic alliances. Thus, in 2022 SK Biopharma entered into a licensing agreement with Brazil's Europharma to locally develop and commercialize cenobamate, whereas Celltrion has partnered with Costa Rica-based Stein to market and distribute its products in the region.

3. Singapore

Singapore has established itself as a global hub for biotechnology manufacturing, with hundreds of local biotech and medical technology companies and investments by many of the world's leading pharmaceutical firms. It achieved this success by promoting a conducive business environment, featuring low corporate taxes, high legal and compliance standards, and negligible corruption. However, the government also focused specifically on the pharmaceutical sector, providing support for its infrastructure and human capital development.

The island had flourished as an entrepot in colonial times before emerging as one of four "Asian tigers," with export manufacturing fueling rapid economic growth through the 1990s. However, after China began to dominate global manufacturing, the Singaporean government shifted to a growth strategy based on higher-end production serviced by a highly educated and skilled workforce. To this end, it embraced a favorable business environment, strong quality and compliance standards, long-term public investments in R&D, and international connectivity.

Singapore began to focus on biotechnology starting in the 2000s. It did so by working with the private sector to establish education and training programs that nurtured local talent, providing upskilling and reskilling opportunities for workers interested in shifting into the pharmaceutical industry. The government also invested heavily in infrastructure, such as industrial and laboratory space, to support pharmaceutical companies interested in setting up manufacturing operations in the country.

Policy Milestones

1997: The Singapore government partnered with multinational pharmaceutical manufacturers, contract manufacturing organizations, and contract development and manufacturing organizations to expand the country's capacity for commercial and clinical-scale production. In the context of these partnerships, Merck set up its first ever manufacturing plant in Singapore and over the next 25 years invested a total of US $2 billion.[42]

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Subsequently, the Economic Development Board entered a joint venture with defense contractor Singapore Technologies Engineering (STE) and U.S. pharmaceutical company Chiron Corporation US, establishing S*BIO, Singapore's first biotech company.[43] S*BIO used small-molecule and genomic technology to conduct research on cancer and infectious diseases.

2000: The government identified pharmaceuticals, biotechnology, diagnostics, and biological sciences as priority sectors within the science, technology, engineering, and mathematics (STEM) fields. In line with these priorities, it launched the Biomedical Sciences Strategy (BMS), aimed at making Singapore a global hub for biomedical sciences with world-class capabilities ranging from basic and clinical research to manufacturing and healthcare delivery.[44] To make biomedical sciences the fourth pillar of its economy, it invested US $570 million to establish three biotechnology institutes.[45]

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2005: The JTC Corporation set up Tuas Biomedical Park (TBP) to provide industrial and laboratory space for pharmaceutical companies to set up manufacturing platforms, including process development and operations. In close proximity to the Jurong Port and checkpoint to Malaysia, TBP's 280-hectare campus had all essential infrastructure. Third parties provide utilities such as steam, natural gas, chilled water, and waste treatment services.

TBP started housing companies to set up production lines at a smaller upfront capital cost in 2018. Currently, the park hosts more than 30 manufacturing plants. Tenants include major pharmaceutical, biotechnology, and medical technology companies such as Abbott, Abbvie, Alcon, Amgen, CIBA, GSK (GlaxoSmithKline), Lonza Biologics, Novartis, Pfizer, Roche, and Wyeth.

2006: The National Research Foundation (NRF)[46] was created as a department within the Prime Minister's office. The Foundation's mandate was to set the national direction for research and development. NRF funds strategic initiatives and builds R&D capabilities by nurturing research talent. It supports the Research, Innovation, and Enterprise Council (RIEC), which is comprised of cabinet ministers and chaired by the Prime Minister.

2007: Through industry organizations such as Washington, DC-based Biotechnology Innovation Organization (BIO), Singapore offered college students and graduates opportunities for paid internships at top biotechnology companies in the US and other advanced economies — including Merck, Amgen, GSK, Thermofisher, Roche, and IQVIA.

2017: Singapore introduced the Attach and Train (AnT) program, a talent development program aimed at building up a pipeline of skilled manpower for the manufacturing sector.[47] Participants undergo on-the-job training for up to 21 months with leading pharmaceutical companies, such as Lonza, Amgen and GSK, to deepen their technical competencies. This program facilitates mid-career professionals who want to upskill and work for more forward-looking sectors, particularly in the manufacturing of biologicals and vaccines.

2018: An intellectual property commercialization vehicle was established within NRF, with Singapore's Temasek Holdings and the Singaporean government each committing US$ 50 million to back it. This vehicle seeks to invest in start-ups whose business models are underpinned by intellectual property generated from publicly funded research. In parallel, Singapore's Health Sciences Authority (HSA) set up an innovation office to provide scientific and regulatory advice related to early-stage clinical product development of innovative therapies.

2019: Project Zodiac was launched with the goal of building a strong pipeline of leaders for the biopharmaceutical sector. The Biopharmaceutical Manufacturers' Advisory Council (BMAC), which comprises of a group of government agencies and 16 companies, started the program as a pilot with the leadership training company Forest Wolf. Leadership training workshops help middle and senior managers to develop self-awareness and adaptive skills such as effective communication, problem solving, and resilience. Close to 200 middle-management professionals from over 14 companies have benefited from the program.

The government announced a plan to invest S$80 million to establish three manufacturing technology research programs on cell and gene therapies. These programs aim to deepen the understanding of cell attributes relating to safety and efficacy, and to develop technology to assess product quality during manufacturing.

2020: Singapore sets up the Professional Conversion Program (PCP) for professionals, managers, executives, and technicians. This new scheme replaces the AnT program for biologics manufacturing, extending it to include specializations in pharmaceuticals manufacturing, and cell and gene therapy.[48] The 18-month PCP program for advanced biopharmaceuticals manufacturing professionals and executives was set to benefit 300 participants in 2020–21.

Key Players

Public organizations: Major players in this space include the Economic Development Board, Singapore's Health Sciences Authority, Workforce Singapore, SkillsFuture Singapore, universities, funds and incubators (such NRF), industrial parks (especially Tuas Biomedical Park), and training and upskilling initiatives (Professional Conversion Program).

International companies: Singapore has attracted eight of the world's top ten pharmaceutical companies to have a manufacturing presence in the island (table 1). These include GSK, Merck Sharp & Dohme, Pfizer, Novartis, Roche, Sanofi, AbbVie, and Amgen. Several of these production sites have received approvals by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA). Contract

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Table 3
Multinational Investment in Singapore in Recent Years

Company	Date	Investment Size (Singapore $)	Key Focus Areas	Key Products
Abbvie	2017	US$320 million manufacturing facility	Small molecule API and Biologics manufacturing facility	Rheumatoid Arthritis, Oncology
Amgen	2017	US$150 million manufacturing facility	120,000 sq ft next-gen biomanufacturing	Contract manufacturing
Merck KGaA	2017	S$20 million Biosafety testing facility	Biological samples testing, biosafety services	Contract Testing
GSK	2019	S$130 million manufacturing facility	Continuous Mfg for CKD drug and APIs	Daprodustat
Merck Sharpe and Dolme	2020	US$500 million manufacturing facility	72 acre Tuas site, 2nd packaging, Inhaler production	Keytruda, Gardasil 9
Wuxi	2022	US$1400 million manufacturing facility	120KL drug substance/drug product biomanufacturing	Contract manufacturing
Sanofi	2022	US$434 million Manufacturing	Fully digitalized and Modular Vaccine Production	Vaccines
GSK	2022	US$33 million Manufacturing	Cytotoxic manufacturing for Antibody Drug Conjugate	Oncology

Source: EDB, Fierce Pharma, Fierce Biotech, and company press release

development organizations and manufacturing organizations, such as Lonza, Cellvec, and ESCO Aster, have also expanded their capacity in Singapore.

Domestic companies: As of 2019, Singapore had more than 350 biotechnology and medical technology companies operating in areas ranging from oncology to infectious diseases, and 50 manufacturing plants. Homegrown companies are expanding through international partnerships; for example, MediSix Therapeutics, a Singapore-based immune engineering biotechnology firm, successfully raised US $20 million in Series A funding as led by Lightstone Ventures, Temasek Holdings, and Osage University Partners.

Main Outcomes

Singapore's strategies and actions have helped to transform the country into an innovation hub, with the pharmaceutical sector generating 5 percent of the country's GDP and poised for continued, sustainable growth over the next 10 to 20 years. Since 2000, the growth in biomedical manufacturing jobs has outstripped overall job growth in the economy, and the sector employed more than 24,000 people in 2019. The sector has also seen clear increases in value-added growth—approximately 9 percent over this period, almost twice that in the wider manufacturing sector and the rest of the economy.[49]

Singapore is now home to the manufacturing facilities of the world's top-selling pharmaceuticals and APIs.[50] The number of pharmaceutical and biological product manufacturers grew from 25 in 2000 to 52 in 2018, representing an average annual growth rate of 4 percent. Pharmaceutical products manufactured in Singapore include small molecules, biologics, cell therapy, and medical nutrition, but the sector also has a strong focus on advanced pipeline assets such as manufacturing technology, and research on cell and gene therapies.

Economic cooperation and trade with Latin America and the Caribbean have increased steadily in recent years.[51] Singapore currently has free trade agreements with Costa Rica, Panama, and Peru and is working on establishing similar pacts with Mercosur — which comprises Argentina, Brazil, Paraguay, and Uruguay — and with the Pacific Alliance — which includes Chile, Colombia, Peru, and Mexico. However, the two sides appear to have little direct engagement in the pharmaceutical sector so far.

4. Conclusion

Latin America and the Caribbean face huge health and pharmaceutical needs as imperfect health care coverage and population aging aggravate disease burdens. Affordable, quality generics produced locally could help to alleviate the strain on healthcare sys-

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tems caused by insufficient public health expenditures and rising out-of-pocket expenses. Brazil, Mexico, Argentina, and Colombia already have pharmaceutical companies that produce strong branded generics for domestic markets, and a handful have developed a pan-regional presence, including Roemmers, Technopharma, and Europharma. These four countries have a unique opportunity to further grow their pharmaceutical industries with the support of the private sector and government, while other countries in Central America could follow their lead.

This report introduces three models showing how Asian countries at different development stages — India, Korea, and Singapore — have nurtured their own, self-sustaining pharmaceutical sectors. These countries not only offer valuable lessons to Latin America but also could present opportunities for cooperation in pharmaceutical research, development, and manufacturing.

Given their income levels and scientific capacity, the insights from the Korea and India approaches could be considered. The private sector from both countries is already working with partners in the region and these collaborations should be deepened with talent exchange programs. Both countries have pharma and biotech companies that are trying different approaches for value creation via lower-cost innovation or fast imitation and are trying to catch-up with the developed economies in terms of patents, innovative products and services and capture a higher global market share. This has not been easy and despite heavy investments, it has been a constant challenge to keep pace with the innovation frontiers. For example, the number of their own proprietary innovative products that have been globally approved and accepted are far and few. The Singaporean approach to pharmaceutical development may be currently out of reach for countries in Latin America and the Caribbean and they themselves are still evolving with not much to show as their own proprietary innovative global products. However, Singapore has a rich talent pool, deep expertise and track-record, and want to forge alliances in Latin America and the Caribbean, all of which could be explored.

For example, India is currently trying to understand how to discover and develop novel and proprietary medicines for diabetes and other noncommunicable diseases — an effort that could be advanced through South-South collaboration with the private sector in Latin America and the Caribbean. Such collaboration could include sharing of expertise in preclinical and clinical development, process R&D and manufacturing, and development of global products.

Similarly, Korea is already licensing U.S.-approved products to the region and funding the global clinical development and the product development and various other marketing activities. The private sector in Latin America and the Caribbean could share the costs for developing such products, taking advantage of its better access to the medical community and its knowledge of local disease trends.

And all three Asian countries reviewed — Singapore, Korea and India — could be attractive destinations for research exchanges with students and young professionals from Latin America and the Caribbean. Academic institutes in the three countries could help establish R&D ties with local research institutes to train scientists and engineers and grow the local talent pool. The private sector in the region could also set up advisory boards comprising top scientists from three Asian countries, to identify key focus areas where the government and the private sector should join forces to fund and prioritize research.

For many countries in Latin American and the Caribbean, India's conditions and development model may be most relevant. Shared characteristics include large populations, similar local disease patterns, an ambition to address the local health needs of the population, and societies that value the "prestige" associated with degrees in chemistry, biological sciences, and engineering. They could be collaborations to conduct clinical trials in the region and be part of the global clinical trial data and repository to explore new approaches to treat and if possible slow down disease progression or prevent them with proactive lifestyle and clinical options. A special roundtable could be held to bring together CEOs from both regions to explore collaboration opportunities and kick-start a more sustainable strategic platform that allows both regions to reach higher competitive levels and a bigger share of the global pie.

Besides strengthening collaboration with Asia, countries in Latin America and the Caribbean should tap into the global talent base to attract scientific and leadership talent back to their home. They should strengthen academic partnerships and research into disease patterns and therapies that are customized for their local populations and develop creative hypothesis and models that can develop innovative drug therapies that can be studied both internally as well as partnered for global collaborations. And companies and governments should increase funding to nurture talent and engage in research and development. Strong mid-tier and top-tier companies could forge global expansion into new geographies such as Africa, which have a high-growth potential and limited

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pharma infrastructure and know-how. For example, Portuguese is the official language in six Africa countries — Angola, Mozambique, Guinea-Bissau, Cape Verde, Sao Tome and Principe, and Equatorial Guinea and this could offer strategic partnership opportunities for Brazilian companies into the region.

The creation of a strategic roadmap with key R&D and clinical development objectives could help countries to identify opportunities for growth and provide a path toward developing a strong, sustainable pharmaceutical industry in Latin America over the next two decades.

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