



## Economic Brief

# Pharmaceutical Sector Update

### Overview

Saudi Arabia has the largest pharmaceutical market in the Middle East due to its large population and high levels of both government spending and per-capita income. The Kingdom's economic development and rising incidences of non-communicable lifestyle diseases has also driven greater demand for pharmaceutical products. The comparatively high level of healthcare services in Saudi Arabia also makes it a regional destination for medical tourism. The Saudi pharmaceutical market is driven by imported products, though local firms are playing a growing role in supply and distribution, domestic research, and manufacturing.

Local firms enjoy competitive advantages stemming from favorable government policies such as pricing offsets and expedited licensing. This regulatory approach reflects an effort to elevate the viability of local commercial activity in an industry dominated by large multinational companies (MNCs) with vast global operations. Recent reforms have seen relaxed foreign ownership and local employment requirements as Saudi Arabia balances the fostering of domestic economic activity with attracting international investments. As the Kingdom transitions into a knowledge and innovation-based economy, local pharmaceuticals and biotechnology represent an attractive opportunity to produce high-skilled local jobs, enable knowledge and technology transfers with international industry leaders, enhance existing industrial supply chains, and support local companies to meet growing demand.

### Market Determinants

#### Population & Health

Saudi Arabia's economic development has led to cultural shifts such as changes in dietary habits and less physical activity which have contributed to a rise in non-communicable diseases (NCDs). According to a World Bank report, NCDs are the leading cause of death in Saudi Arabia, accounting for 73 percent of mortalities with the lead cause being cardiovascular disease. The treatment coverage rates for hypertension, diabetes, and dyslipidemia were 83 percent, 42 percent, and 60 percent, respectively, according to Ministry of Health data. Among Saudi residents aged 65 or older, self-reported hypertension was a remarkably high 49 percent. The rate for diabetes in the same age group was 47 percent. The number of residents considered overweight or obese was estimated at 68 percent and 35 percent, respectively. Despite rising life expectancy, obesity remains a top health concern, driving higher rates of diabetes and other chronic conditions which are frequently managed with pharmaceutical protocols.

The Institute for Health Metrics and Evaluation (IHME) estimated there were 2.1 million new cases of cancer, 185K new cases of cardiovascular disease, 303.5K new cases of chronic respiratory diseases, and 176K new cases of diabetes in Saudi Arabia during 2019. Comparing the rate of new cases to 10 years earlier, IHME found increases in the incidence of diabetes (+94 percent), cardiovascular disease (+50 percent), and all cancer types (+50 percent). While the government has recently sought to mitigate these trends by promoting more healthy lifestyles and physical fitness through civic and educational programs, the impact of lifestyle diseases on the healthcare system is set to accelerate given the high number of Saudis entering the 50+ age bracket over the next 5-10 years. As this portion of the population grows, rates of chronic disease will likely increase and drive hospital visitation and therefore greater demand for health services. Although more than two-thirds of Saudi Arabia's population is under 35, there will be a growing need for more medications and treatments of chronic diseases in the future as life expectancy increases and this population segment moves into middle age. Consequently, many of the leading pharmaceutical products in Saudi Arabia address NCDs such as statins like Lipitor and insulin products such as Lantus.

#### Top Pharmaceutical Products in Saudi Arabia

Rank	Product	Type	Distributor	Sales (USD Million)
1	Prevnar	Pneumococcal vaccine	Pfizer	190
2	Humira	Biologic immunosuppressive	AbbVie	140
3	Lipitor	Statin	Pfizer	103
4	Lantus	Insulin	Sanofi	91
5	Menactra	Meningococcal vaccine	Sanofi	82
6	Nexium	Proton pump inhibitor	AstraZeneca	68
7	Norditropin	Growth hormone	Novo Nordisk	62
8	Aranesp	Erythropoiesis stimulant	Amgen	61
9	Novomix	Insulin	Novo Nordisk	55
10	Rekson	Antibiotic	Tabuk Pharma	54

## Business Environment

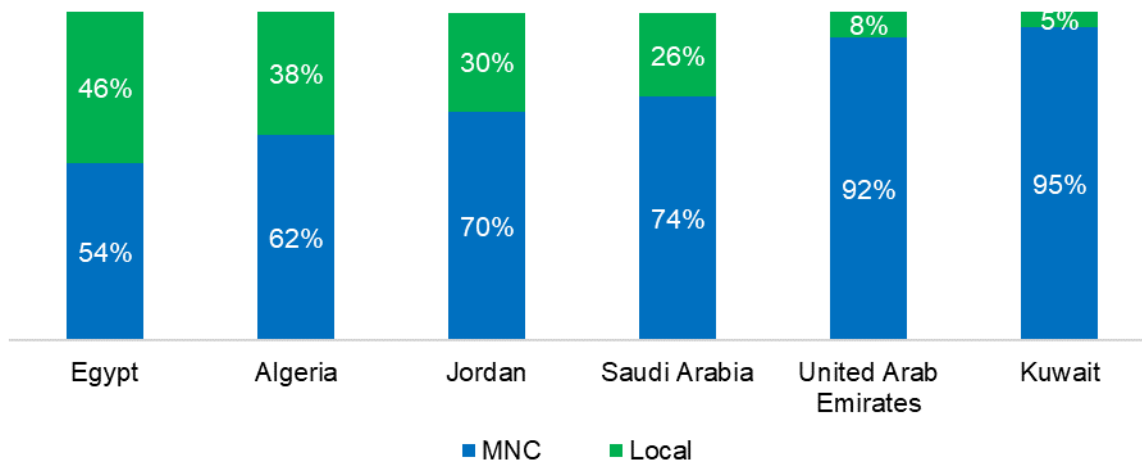
The Ministry of Health (MoH) is the chief regulatory authority of Saudi Arabia's healthcare sector. MoH is involved in the selection and procurement of medicines as well as the regulation of hospitals, clinics, and retail pharmacies. Another key government entity is the Saudi Food & Drug Authority (SFDA) which grants licenses for pharmaceuticals and pharmaceutical manufacturing. SFDA is responsible for ensuring efficacy, quality, and safety of registered medicinal products. The National Unified Procurement Company (NUPCO), which is wholly owned by the Public Investment Fund (PIF), is a third government body tasked with optimizing supply chains and partnerships related to medicines, medical devices, and medical supplies. NUPCO has increasingly played a leading role in the procurement of pharmaceuticals by providing a centralized procurement mechanism to healthcare providers in the Kingdom. The Local Content and Government Procurement Authority (LCGPA) has also exercised a greater role in setting localization policies affecting pharmaceutical activity in Saudi Arabia. LCGPA sets policies aimed towards increasing the market share of locally manufactured pharmaceuticals.



Saudi Arabia's pharmaceutical sector is primarily import-driven with an estimated 74 percent of sales originating from foreign companies, according to IQVIA data. U.S. pharmaceutical giant Pfizer is the leading foreign pharmaceutical company in Saudi Arabia under its local name Pfizer Saudi. Pfizer received the Ministry of Investment's first pharmaceutical trading license, which granted 100 percent foreign ownership of its legal entity in Saudi Arabia in 2016. The license granted Pfizer Saudi the ability to import, export, and trade in wholesale and retail products, equipment, and instruments in the pharmaceutical sector. Pfizer Saudi subsequently opened a manufacturing and packaging facility in 2017 at the Industrial Valley in King Abdullah Economic City (KAEC). The SAR188 million (\$50 million) manufacturing facility produces medicine and packaging that includes 16 of Pfizer's pharmaceutical products serving cardiovascular, neurology, urology, pain, and anti-infection patients. In addition to Pfizer, U.S. firms Johnson & Johnson, MSD (Merck), Lilly, Amgen, and AbbVie also have significant commercial operations in Saudi Arabia. Other non-U.S. foreign companies leading the Saudi pharmaceutical market include Sanofi, Novartis, GSK, Hikma Pharmaceuticals, Novo Nordisk, and AstraZeneca.

There are approximately 27 domestic pharmaceutical manufacturers in Saudi Arabia, which account for 26 percent of the national market. Saudi Pharmaceutical Industries & Medical Appliances Corporation (SPIMACO) is the largest domestic pharmaceutical company in Saudi Arabia. SPIMACO and its subsidiaries can be categorized into the manufacturing and sale of pharmaceutical products, medical services, and distribution services. Manufacturing activity by SPIMACO includes local and regional production of capsules, tablets, injections, creams, and numerous other products. SPIMACO signed its first manufacturing agreement with Pfizer in 1990 and subsequently became the Kingdom's first major pharmaceutical exporter. Saudi Arabia's local pharmaceutical market share is higher than other GCC countries such as the U.A.E. or Kuwait in which local companies comprise only 8 percent and 5 percent of the national market, respectively. Saudi Arabia is comparable to Jordan in its relative level of local market share while other North African countries such as Egypt and Algeria have higher levels of localization.

### Pharmaceutical Market Share by Company Type



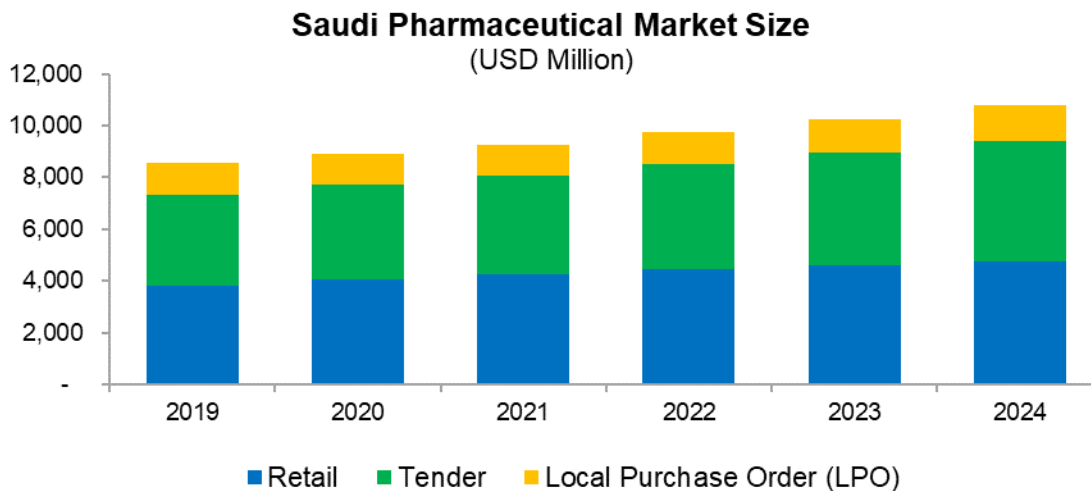
Source: IQVIA



Other major Saudi pharmaceutical firms include Tabuk Pharmaceuticals, Jamjoom Pharma, Riyadh Pharma, and AJA Pharma. Domestic players in the Saudi pharmaceutical market tend to focus on branded generics manufacturing. This off-patent manufacturing activity is often initiated through manufacturing contracts with international leaders such as Pfizer, GSK, and Johnson & Johnson. Leading domestic pharmaceutical firms have historically been involved in the importation, packaging, marketing, and delivery of medicines. However, the role of local firms has grown in recent years as domestic research activity, favorable regulatory incentives, foreign direct investment, and government spending has expanded in-Kingdom capacity.

## Market Size

The total pharmaceutical market of the Middle East & North Africa (MENA) stood around SAR90 billion (\$24 billion) of which Saudi Arabia has historically contributed an approximated 35 percent market share, according to SPIMACO. Saudi Arabia’s pharmaceutical market size was estimated at SAR32 billion (\$8.6 billion) in 2019 (pre-pandemic) and is expected to reach SAR36.5 billion (\$9.7 billion) by the end of 2022, according to SPIMACO. The market is forecasted to grow at a compound annual growth rate (CAGR) of 4.7 percent through 2024. Retail pharmaceutical activity accounted for approximately 46 percent of the total market in 2021. The retail market is considered private economic activity as this segment primarily represents medicines dispensed through private chain pharmacy accounts. The tender market is dominated by government procurement activity while local purchase orders (LPO) refer to individual hospital and clinic requests. Tender activity accounted for 41 percent of the market while LPOs accounted for 13 percent.



Source: SPIMACO Annual Report 2021

Pharmaceutical sales as a percentage of government health spending was approximately 17 percent. Government health spending stood at SAR170 billion (\$45.2 billion) in 2020 but has since declined to SAR138 billion (\$36.8 billion) in 2022, representing 14.4 percent of the Kingdom’s total budget. The segment still represents one of the government’s leading expenditures, but the decline in health spending reflects broader fiscal consolidation measures and greater private sector and PIF-led economic investments.



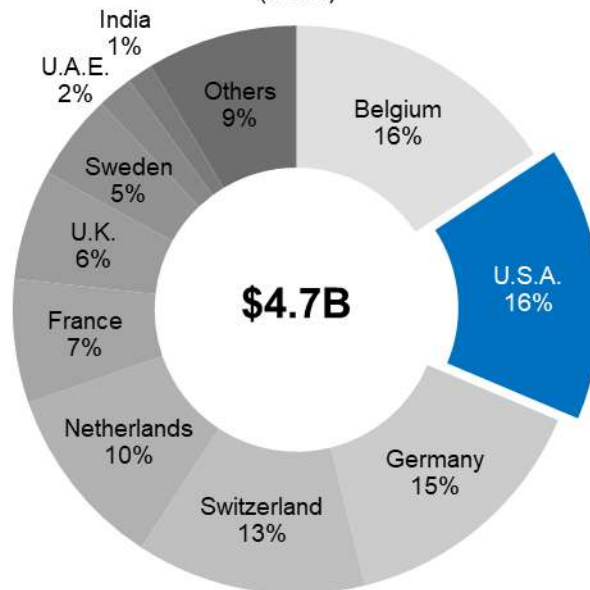
The Saudi market is estimated to have a roughly 90-10 split between prescription drug sales and over the counter (OTC) drug sales. Among prescription sales in Saudi Arabia, consumers tend to prefer patented, or branded, drugs which account for 60 percent of prescription sales in the Kingdom. Generic drug sales accounted for 40 percent of the prescription market in Saudi Arabia.

### U.S.-Saudi Trade

The U.S. is a leading exporter of pharmaceuticals to Saudi Arabia, accounting for SAR2.8 billion (\$741 million) in pharmaceutical goods in 2021. Pfizer is also the leading MNC in the Kingdom’s pharmaceutical sector and Pfizer Saudi has served as a leader in offset, localization, and domestic manufacturing. Given its advanced pharmaceuticals and biotechnology sectors, the U.S. has also served as a key partner in establishing joint ventures, partial offtake agreements, research partnerships, and other means of private investment. In 2021, the U.S. accounted for 16 percent of Saudi Arabia’s total pharmaceutical imports and was tied with Belgium as the leading sovereign source of pharmaceutical goods. In addition to the pneumococcal and meningococcal vaccine, which were in high demand pre-COVID, the COVID-19 vaccines were a significant source of exports to the Kingdom last year. Of the SAR2.8 billion (\$741 million) in total U.S. pharmaceutical exports to Saudi Arabia in 2021, vaccines accounted for SAR1.3 billion (\$343 million) followed by medicaments, hormones, and immunological products. As of June 2022, year to date U.S. pharmaceutical exports to Saudi Arabia was only 4 percent behind the same period through June 2021 levels despite significantly lower volumes of exported COVID-19 vaccines. Non-vaccine export segments such as miscellaneous medicaments, hormones, and immunological products have continued to grow over that period.

### Saudi Arabia Pharmaceutical Imports

(2021)



Source: U.N. Comtrade



## Regulatory

A new Pharmaceutical Law approved in April 2020 has substantially changed the business landscape for international companies looking to enter or expand into the Saudi market. The new law replaced the old Pharmaceutical Law enacted in 2004, which maintained restrictions on foreign ownership in several key areas. Most notably, the new law permits 100 percent foreign ownership for pharmaceutical wholesale warehouses and medicinal consultation centers. The law also entitles SFDA to waive the clause limiting the promotion and introduction of pharmaceutical and herbal substances in the Kingdom to Saudi nationals. The localization policies remaining in effect have been carried over from the old Pharmaceutical Law. These regulations include ownership of manufacturing plants and scientific offices as well as promotional activity within the pharmaceutical sector. Saudi Arabia also utilizes legally fixed profit margins for wholesalers and retailers in-Kingdom, typically enticing international suppliers to cut prices to access the Saudi market. Price control mechanisms have helped domestic firms to compete with MNCs.

While some pharmaceutical ownership regulations have been liberalized, local content requirements have continued to expand since the launch of Vision 2030. LCGPA announced in September 2020 that 208 locally produced products in the medicine, pharmaceutical, and medical supply sector would receive a 10 percent price preference over market competitors. Further regulations approved in June 2022 expanded LCGPA's local content requirements and price preference mechanism beyond government procurement to any company in which the government holds a 50 percent stake or more. These changes are aimed at making both SMEs and large national firms more competitive within the Saudi market in addition to incentivizing commercial relationships between international companies and local producers.

### Highlighted Pharmaceutical Ownership Regulations

Activity	Old Pharmaceutical Law	New Pharmaceutical Law
Wholesale warehouses	Must be owned and managed by Saudi national	May be 100% foreign-owned and managed
Manufacturing plants	Technical manager must be a Saudi pharmacist	Technical manager must be a Saudi pharmacist
Medicinal consultation and analytical centers	Must be owned and managed by a Saudi pharmacist	May be 100% foreign owned and managed
Promotion and introduction of pharma and herbal products	Limited to Saudi pharmacist	Limited to Saudi Pharmacist
Scientific offices	Must be managed by a Saudi national	Must be managed by a Saudi national

Source: Saudi Press Agency, King & Spalding



The recent government announcement of a new policy effective January 2024 that will prevent foreign companies without a regional headquarters in Saudi Arabia from contracting with the Saudi government has attracted foreign entities to localize. Following the announcement of this new policy, U.S. companies Eli Lilly, Boston Scientific, and Medtronic announced plans to open regional headquarters in Saudi Arabia.

## Financing

Companies seeking to invest in a local pharmaceutical project in Saudi Arabia can benefit from up to 75 percent project financing provided by the Saudi Industrial Development Fund (SIDF). SIDF was established to support medium and long-term lending facilities for private sector industrial projects in Saudi Arabia. Lending rates under the SIDF typically fall into three categories depending on location, project size, and commercial viability: 1) a 15-year loan up to 50 percent financing, 2) a 20-year loan up to 60 percent financing, and 3) a 20-year loan up to 75 percent financing. SIDF offers Land & Loan facilities in partnership with the Saudi Authority for Industrial Cities and Technology Zones (MODON) with incentives that include lease discounts up to 15 percent and reduced or delayed fee scheduling. Land & Loan facilities are aimed at promoting investment in Saudi Arabia's industrial areas and economic cities such as KAEC or Yanbu Industrial City among others. The Fund has also offered loans to finance the purchase of raw pharmaceutical materials up to six months in the past to support pharmaceutical SMEs.

Pharmaceutical projects may also benefit from special export facilities from the Saudi EXIM bank, faster licensing, and access to more favorable regional export terms due to the Kingdom's free trade agreements with GCC and OIC countries. Saudi companies have used a combination of SIDF facilities, conventional commercial facilities, and Islamic banking facilities (Murabaha) with local and regional banks for pharmaceutical project financing. International companies engaged in joint ventures with local firms are permitted to apply and obtain SIDF facilities, providing a strong incentive for MNCs to find a local Saudi partner.

## Sector Strategy

Saudi Arabia aims to localize 40 percent of the pharmaceuticals market and 15 percent of the medical devices market by 2030. Pharmaceuticals and biotechnology are identified together under Vision 2030 as a priority industry cluster for investment and growth. New regulatory practices affecting procurement, pricing, and ownership are intended to stimulate domestic capacity-building in research and manufacturing. The development of industrial clusters through a combination of local and foreign investment is supported by favorable regulatory incentives. The Kingdom also aims to leverage Saudi Arabia's geographical position for supply chain optimization, and consequently boost exports and re-exports of pharmaceutical and biotechnology products. In addition to the Kingdom's Red Sea supply chain routes crucial to global trade and logistics, Saudi Arabia's highly developed oil & gas industries provide strategic advantages for production of downstream chemical products used in active pharmaceutical ingredients (API) and other products. Petroleum is a crucial feedstock for healthcare products including pharmaceuticals, plastics, and medical supplies. However, partnerships with industry leaders in pharmaceuticals will be critical in tapping the potential for API and other pharmaceutical product manufacturing.



Localization through knowledge and technology transfer agreements with foreign entities continue to serve as a leading model for the industry's development. Recent agreements with Johnson & Johnson and GSK have been specifically aimed towards the local manufacture of generic drugs. Many MNCs have engaged in contract manufacturing with Saudi firms to save costs and benefit from regulatory incentives. One example is a December 2016 agreement between Saudi Pharma Pharmaceutical Industries (PPI) and U.S. firm Merck (operating as MSD) in which PPI, the local firm, gained exclusive rights to manufacture a slate of Merck products.

Partnerships between U.S. and Saudi companies have led to notable successes for the sector. AbbVie, an Abbott Labs spin-off company, announced in July 2020 that it reached the milestone of one million packages of biologic medicines produced in-Kingdom following a 2014 agreement with Arab Company for Pharmaceutical Products (ARABIO). AbbVie launched a partnership with ARABIO to manufacture Humira and other drugs in Saudi Arabia. Saudi Chemical Company Holding recently signed an agreement with U.S. firm Eli Lilly to manufacture insulin locally in Saudi Arabia. SPIMACO and U.S.-based Amgen signed an agreement to localize the rights to market and partially offtake manufacturing steps for a drug used in the treatment of autoimmune disorders at SPIMACO's plant in Qassim Province. Pfizer, Sanofi, Merck KGaA's Serono division, Novo Nordisk, Eli Lilly and Bayer have either established or are working on production and distribution operations in the country.

## Challenges

The global pharmaceutical industry is dominated by a handful of advanced global pharmaceutical companies. It is also an industry that requires high levels of R&D and human capital investments to remain globally competitive. The concentration of large MNCs in the sector have made it challenging for local firms in Saudi Arabia to compete. The government has taken steps such as price controls and expedited licensing to shield local firms from the full degree of international competition.

The Kingdom has taken strides in enforcing intellectual property (IP) laws to meet international standards while promoting local industry competitiveness. Specifically, Saudi Arabia remains committed to local production of generics and international knowledge and technology transfer agreements with the aim of enforcing transparent IP rights. Consequently, Saudi Arabia was removed from the Office of the U.S. Trade Representative's (USTR) Priority Watch List in its 2022 Special 301 Report on Intellectual Property due to steps the Kingdom took to publish its IP enforcement procedures, increase enforcement against counterfeit and pirated goods, and create specialized IP enforcement bodies.

Other challenges include the nascency of research and development activities in Saudi Arabia. The most active organizations in pharmaceutical research based on publications were King Saud University, King Faisal Specialist Hospital & Research Center, and King Abdulaziz University. There are several specialist research centers such as King Abdullah International Medical Research Center (KAIMRC) at major Saudi hospitals. However, widespread drug discovery and clinical trial activity has yet to be established in the Kingdom. Research and manufacturing in Saudi Arabia are currently in an early development phase where international partnerships will remain a key source of capacity-building.



## Market Outlook

Foreign direct investment is set to increase following liberalized business regulations, while offset and technology transfer agreements are increasingly being adopted for business partnerships in the Saudi pharmaceutical sector. Since 2021, the Ministry of Investment has signed agreements with Pfizer, Janssen Pharmaceuticals, AstraZeneca, GSK, and Roche all of which invoke similar strategic frameworks. Recent agreements signed between Saudi entities and these leading pharmaceutical companies have emphasized knowledge transfer, clinical R&D capacity advancement, and local talent development. More specifically, research and product areas of high interest include generics manufacturing, cell and gene therapy, biologics and biosimilars, vaccine formulation fill and finish, sterile injectables, solid oral dosages, active pharmaceutical ingredients (APIs), plasma production, and bioequivalence testing. These areas are considered high-priority investment targets in the sector.

Localization policies represent the potential for cheaper medical products, supply chain security, economic development, high-skill jobs, and ultimately a transition towards an innovation economy. The SFDA recently granted SPIMACO a license for the first Saudi-made medicine for the treatment of hepatitis C. In January 2022, SPIMACO signed a deal with Swiss firm Vifor Pharma to localize production of an iron replacement injection medication. However, the predominance of imported products from industry-leading MNCs will remain in place for the foreseeable future as the sector's development is conditioned on MNC access to the Saudi market for knowledge transfer. Joint ventures with local firms could allow U.S. companies to benefit from preferential regulatory treatment granted to local majority-owned firms while benefitting from market access.

The growth of the Kingdom's physical infrastructure in the form of reliable electricity, clean water supply, and access to transportation and logistics infrastructure bodes well for local manufacturing. Saudi Arabia's economic stability and potential for high level of healthcare capacity has increased regional medical tourism that will support the development of local industrial clusters over the medium-term. The Kingdom's development zones such as KAEC's Industrial Valley are a way to leverage government resources and centralize production in areas with low energy and transportation costs, as well as convenient access to warehousing, feedstock supply, academic research facilities, and other supporting resources. However, the sector also requires a large reservoir of skilled workers necessary to staff manufacturing, research, and testing facilities. Furthering national education and training in health and pharmaceutical sciences will be central to the Kingdom's innovation strategies over the long-term. In the near-term, knowledge transfers from foreign companies doing business in the Kingdom as well as skilled workers will be paramount in meeting the government's Vision 2030 goals.



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