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In Saudi Arabia, A Vision Of Healthcare Spurs Growth

by David Wild

As the Kingdom of Saudi Arabia reduces its dependence on oil as an export, one sector it is building up is the life sciences industry. The government is encouraging global companies to manufacture and invest domestically and they are improving their regulatory system and working with local players to enhance access to patients.

When it comes to reaching markets in the Middle East and North Africa (MENA), global pharmaceutical companies have historically had to contend with fragmented and inefficient systems, stifling their ability to reach patients. However, the Kingdom of Saudi Arabia is hoping it can strengthen a reputation for itself as a reliable life sciences partner with a growing market. Financial inducements, regulatory improvements and infrastructure enhancements are some tools leaders are using to attract more international biopharma investment.

The Saudi Market

The Saudi pharmaceutical market is significant. It accounts for 37% of the broader MENA market, with an estimated $8.5-$10.7bn in annual sales in 2032. By 2030, it is expected to have expanded by a compound annual growth rate (CAGR) of 5.7%, according to Invest Saudi, with other forecasts placing growth as high as a CAGR of 9.6% over the next decade.

Like many countries in the MENA region, Saudi Arabia has high rates of lifestyle-related illnesses, including cancer, respiratory diseases, obesity, diabetes and cardiovascular illness. A possible differentiator from its neighbors is that the Saudi government is investing to improve the diagnosis and treatment of these illnesses.

The Saudi Ministry of Health (MoH) has created awareness-raising initiatives with the goal of preventing diseases, and one can now find mobile cancer screening units in malls and mobile mammography units in similar locations throughout the community. The government has also

made a commitment to double the number of primary healthcare center visits to screen for chronic diseases within the next several years.
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The Kingdom is also investing in widespread adoption of digital health and has allocated $1.5bn for healthcare information technology and digital transformation programs and has created an e-Health strategy to utilize telemedicine.

“The Government is investing more in the healthcare sector to ensure that more of the population is able to access medications and benefit from the healthcare system,” Rasha Ma'ayah, business development director for Saudi-based *Tabuk Pharmaceutical Manufacturing Co.*, told *In Vivo*.

The Kingdom laid out a plan for life sciences sector growth in its “Vision 2030,” an initiative launched in 2021 that is meant to shift the country away from its reliance on oil exports as a primary source of revenue. Among other commitments, the plan outlines $65bn in investments to develop the country’s healthcare infrastructure and improve the prevention and treatment of diabetes, obesity and cardiovascular diseases, which in 2020 accounted for 25-35% of the healthcare budget.

Offtake Agreements Encourage Local Production And Attract Innovation

Vision 2030 initiatives are also aimed at increasing domestic pharmaceutical production from 20% to 40% of domestic market needs. To do so, the government is rolling out several incentives to lure biopharma companies. One way the government hopes will shift pharmaceutical importing to domestic manufacturing – either through wholly owned sites or through contract manufacturing organizations (CMOs) – is by providing guaranteed offtake agreements through the Kingdom’s Saudi National Unified Procurement Company (NUPCO).

A contract with NUPCO is significant, as the agency purchases medicines and medical devices on behalf of the roughly 31 million Saudi citizens and public sector workers. In addition to the prize of a national guaranteed contract, global companies that increase local production will be able to negotiate higher drug prices with NUPCO and to distribute and sell pharmaceuticals within the country themselves, whereas imported pharmaceuticals can only be distributed through a Saudi company. The country is also using NUPCO’s purchasing heft as a quasi-stick. Specifically, by 2024, only companies with regional headquarters in Saudi Arabia will be able to submit proposals for NUPCO tenders.

As Mustafa Aljasser, chief business development officer of Riyadh-based Sudair Pharmaceutical

Company, told *In Vivo*, “We have an appetite as a company for partners that will share their technology and know-how.”

Sudair manufactures and commercializes oral and intravenous oncology products, including tablets, capsules, injectables and lyophilized products, exports these to other GCC member countries and has submitted tenders to send their products to other MENA countries outside the Gulf region. However, like many local biopharma companies, it wants to advance its manufacturing capabilities and relies on technology transfer by global companies. To date, Sudair has entered into partnerships as a CMO for India’s *Dr. Reddy's Laboratories Ltd.*, and with *Novartis AG*.Through these partnerships, it is receiving technological knowhow, as per the intention of the Saudi government, while the global partners benefit from the Vision 2030 inducements.

"The great successes through the last five years encouraged us to continue our vision and build a complex that will include, besides the anti-neoplastic and general formulation sites, four more manufacturing sites, include a dedicated site for respiratory products like inhalers, a dedicated site for vaccines, a site for Insulin products and biosimilars and last but not least a dedicated lab for cell and gene therapy," Sudair's CEO and founder, Yasser Alobaida, wrote in an email to *In Vivo*.

Major global biopharma companies have also been building local manufacturing sites in response to the Vision 2030 incentives. After the initiative was announced in 2016 (although not launched until 2021), *Pfizer Inc.* opened a $50m, 11,000-square meter manufacturing and packaging facility to produce 16 pharmaceutical products. It also committed to transferring expertise and technology to the local market. Among other terms of the investment, the company was given full ownership of its local affiliate.

GSK plc too has made additional investments in local manufacturing facilities, and has a stated goal of localizing – or “Saudizing” – 75% of their local production. And Novartis signed a deal with Saudi Arabia’s Ministry of Investment in 2022 to localize some cell and gene therapy production and clinical research and development, and to transfer these technologies locally.

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Regional pharma companies, including UAE-based Julphar Gulf Pharmaceutical Industries, have also increased their presence in Saudi Arabia since the Kingdom declared its intentions and incentives to localize manufacturing.

“We are a small population of only 33 million but we are a hub for the MENA region,” noted Sudair’s Aljasser, adding that the population swells by an additional 30 million people during the annual Hajj and Umrah and that Saudi Arabia also donates medicines to lower-income regional countries.

Shedding Light On Local Genetic Diseases

One aspect of the Saudi pharmaceutical market expected to grow in the coming years is the rare disease market. The Kingdom has a high rate of consanguineous marriages and therefore an increased rate of recessive genetic diseases. These include blood disorders such as thalassemia and sickle cell anemia (2% in Saudi Arabia vs. 0.2% globally); G6PD deficiency; chromosomal defects, most notably Down syndrome; developmental problems; and defects such as Fragile X Syndrome, as well as other autosomal-recessive disorders, such as cystic fibrosis.

Given the heightened prevalence of genetic disorders due to intermarriage, the government launched the Saudi Human Genome Program (SHGP), which is meant to reduce the time to diagnosis of genetic diseases, build databases and overall knowledge of inherited diseases in the Kingdom and identify additional genetic risk factors both for the country’s residents and for the broader region.

Researchers have developed population-specific DNA testing panels and are using next-generation sequencing tools supplied by *Thermo Fisher Scientific* and *Illumina, Inc.*. To date, SHGP researchers have sequenced over 61,000 individuals’ genomes and identified over 3,000 novel mutations causing 1,230 rare genetic disorders. With these gains, the country is on its way to replacing blood biochemical analysis with whole genome DNA analysis and rolling out a broader precision medicine approach.

Increasing Access To Rare Disease Patients

When it comes to the increasingly treatable segment of patients with rare diseases, these patients have been historically difficult to reach because of poor disease awareness and low rates of diagnosis. Misan Abu Rmaileh, executive VP, corporate and business development, of Dubai-based *NewBridge Pharmaceuticals*, which commercializes global biopharmaceutical products, told *In Vivo* the private sector is working to improve that situation. Newbridge has been collaborating with the scientific community to help them adopt advanced technologies such as genomic and

biomarker testing as well as liquid biopsy in an effort to increase diagnosis and personalize therapy.

“We work with partners and the scientific community to increase diagnosis and find new patients through optimizing the referral pathways in collaboration with the health centres and authorities, but it can be challenging and may take several months,” noted Abu Rmaileh.

However, awareness of rare and genetic diseases is rising and both the government and local manufacturers are hoping to develop gene and cell therapy manufacturing knowhow to meet the emerging market demands for these treatments. Again, they are hoping that national incentives will attract global companies to transfer their technology.

“The government is thinking about the future of treatment, about recombinant DNA and mRNA vaccines, for example,” said Sudair’s Aljasser.

A Stable Country

Improvements in healthcare infrastructure and the prospect of better access to patients are some of the reasons Saudi Arabia is attracting more biopharma investment, but, as Joe Henein, CEO of Newbridge, noted, macro-level factors are also at play.

Countries in the MENA region like Iraq, Iran, Sudan, Yemen, Syria and Lebanon were once seen as reliable markets with growth potential but financial challenges and geopolitical and domestic instability have now effectively cut them off from the global supply chain. Additionally, pricing pressures like the uncertain impacts of the Inflation Reduction Act are prompting global companies to slash their workforces in smaller markets, or to exit them altogether.

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Saudi Arabia – and to a similar extent, the wider GCC region – are politically and economically stable and are thus increasingly attractive locations for biopharmas operating in the MENA region.

“Saudi Arabia and the GCC has the fastest access to treatments in the MENA region and in some instances it is comparable to Europe and the US, and companies are looking to the region for patient access and potential growth, said Henein, who was previously managing director for the Middle East and North Africa regions for *Wyeth Pharmaceuticals*.

Regulatory and Licensing Improvements

Saudi Arabia has also made notable strides in the legal and regulatory arena of the biopharma industry. The Saudi Food and Drug Authority (SFDA) created an electronic drug registration system and in a 2018-2022 strategy, it stated an intention to introduce rapid licensing processes as well as reinforced quality assurance regulations.

Now, the SFDA offers expedited approval pathways for innovative products as well as for global companies that apply for Saudi drug approval and registration within two years of doing so with the US Food and Drug Administration or European Medicines Agency approval. (Also see "*Middle East And North Africa Dip Toes In HTA And Access Agreements*" - Pink Sheet, 2 Oct, 2020.)

Drugs approved in Saudi Arabia can expect a smooth path towards approval in other MENA countries.

Introducing a rare disease treatment into the Saudi Arabia is, “less complicated than other parts of the world because it doesn’t require generating local data, Newbridge’s Abu Rmaileh said.

"We are very fortunate that the health authorities allow us to use the dossiers submitted for regulatory approval in the US and EU for Saudi Arabia and GCC countries with minor variations,” she said.

While emerging markets often fall short on intellectual property (IP) protections, Saudi Arabia has received praise for improvements in this area. In 2017, the Kingdom established the Saudi Authority for Intellectual Property to prevent IP infringement and it consolidated its various IP departments. It also developed a national IP strategy and has made efforts to provide related services and products in a timely manner and to promote awareness across the stakeholder spectrum, according to the US Department of Commerce. In 2022, Saudi Arabia was removed from the US Trade Representative’s (USTR) Priority Watch List for IP protections, which it had been added to only a few years earlier.

To maximize the bang for its national buck, the Saudi government is – along with a handful of other MENA governments – revamping how it makes drug purchasing decisions. As part of Vision 2030, it established a health technology assessment body for centralized purchasing, pricing and reimbursement and it is using this type of evaluation to create increasingly value-based, risk-sharing agreements. Since HTAs heavily rely on real-world clinical and pharmacoeconomic studies, manufacturers with strong real-world and cost-effectiveness data have an opportunity to gain a competitive edge in the Saudi market.

The biosimilar market could also receive a boost as Saudi Arabia's national prescribing policies change. The government currently limits physician prescribing to generics when available and a similar policy for biosimilars could be implemented as more are approved.

Icelandic biosimilars maker *Alvotech* is banking on an increasingly robust biosimilars market in Saudi Arabia. It has signed commercialization deals with Dubai-based Bioventure for several of its products, including its high-concentration biosimilar to Humira, AVT02 (Simlandi in Saudi Arabia), (Also see "*Alvotech Taps Equity Financing As Venture Bears Fruit In Saudi Arabia*" - Generics Bulletin, 25 Jan, 2023.) and (Also see "*Alvotech Targets MENA In Multi-Biosimilar Commercialization Deal*" - Generics Bulletin, 12 Dec, 2022.). And *Celltrion* has penned agreements with *Hikma Pharmaceuticals plc* to commercialize biosimilars across the region. The company noted "particularly strong growth in Saudi Arabia, driven by our biosimilar products and successful new launches." (Also see "*Hikma Taps Celltrion Again To Bring In MENA Stelara Biosimilar*" - Generics Bulletin, 29 Nov, 2022.)

Infrastructure Improvements

Saudi Arabia has created a more reliable pharmaceutical infrastructure and logistical capabilities, building new storage and distribution facilities and more broadly upgrading its transportation infrastructure as well as introducing an electronic tracking system for the drug supply chain. The Kingdom received praise for its swift distribution of COVID-19 vaccines after administering 4 million doses by March 2021. That endeavor was coordinated by NUPCO, the country's national procurement agency.

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Tabuk's Ma'ayah said the private sector can now better manage products with special storage conditions and special transportation requirements.

"We've shortened the time for medications to reach the patient and end users, including in remote areas," she said, noting the company managed the distribution of Moderna COVID-19 vaccines within Saudi Arabia. Ma'ayah also noted that the country's hospitals, chain pharmacies and polyclinics are now better linked, making for a smoother medication delivery process.

Licensing Still A Strategy

Despite the slew of Saudi incentives and improvements meant to attract global biopharmas to set up shop in the country, many may still choose to sign commercialization deals for imported products.

In those cases, finding the right local partner can accelerate communication with local regulators and healthcare leaders, bringing drugs to market more quickly and also building brand loyalty, Tabuk's Ma'ayah said.

A Saudi partner can also manage marketing "ideation, campaigns, and even join forces between branded companies and generic companies so that the product is closer to the end user and closer to healthcare providers," she said.