



COUNTRY PRIVATE SECTOR DIAGNOSTIC

# EGYPT

## HEALTH SECTOR DEEP DIVE

Realizing the Full Potential of a Productive Private Sector

NOVEMBER 2023



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# ABBREVIATIONS AND ACRONYMS

<b>BCG</b>	Boston Consulting Group
<b>Bx</b>	Biologics
<b>CAGR</b>	Compound Annual Growth Rate
<b>CAPEX</b>	Capital Expenditure
<b>CAPMAS</b>	Central Agency for Public Mobilization and Statistics
<b>CMO</b>	Contractual Manufacturing Organizations
<b>CNS</b>	Central Nervous System
<b>CPSD</b>	Country Private Sector Diagnostic
<b>CT</b>	Computed Tomography
<b>DD</b>	Deep Dive
<b>EU</b>	European Union
<b>GAHAR</b>	General Authority for Healthcare Accreditation and Regulation
<b>GDP</b>	Gross Domestic Product
<b>Gx</b>	Generics
<b>HBP</b>	High Blood Pressure
<b>HCV</b>	Hepatitis C Virus
<b>IBRD</b>	International Bank for Reconstruction and Development
<b>IFC</b>	International Finance Corporation
<b>JV</b>	Joint Venture
<b>MENA</b>	Middle East and North Africa
<b>MRI</b>	Magnetic Resonance Imaging
<b>NCD</b>	Noncommunicable Disease
<b>PET</b>	Positron Emission Tomography
<b>PHC</b>	Primary Health Care
<b>PPP</b>	Public–Private Partnership
<b>TA</b>	Therapeutic Area
<b>UHI</b>	Universal Health Insurance
<b>UHIA</b>	Universal Health Insurance Authority
<b>UHS</b>	Universal Health Insurance System
<b>WHO</b>	World Health Organization

# 1. INTRODUCTION

**This Health Sector Deep Dive is a follow-up to the Country Private Sector Diagnostic (CPSD) on Egypt that the International Finance Corporation (IFC) launched in 2020.** The Egypt CPSD analyzes the challenges the private sector continues to face in Egypt and highlights opportunities for the private sector to lead economic development, investment, and job-creating growth.

**This Deep Dive assesses private sector investment in Egypt's health system.** The health system has made significant strides over the last few decades. This includes reduced maternal and child mortality, and the large-scale treatment program for Hepatitis C virus (HCV). Despite these advances, several challenges remain. Among these are high levels of out-of-pocket spending, and the need to better align the system with the country's growing and aging population. An important policy response to these challenges is the Universal Health Insurance System (UHS). This policy was formalized with the passing of the Universal Health Insurance (UHI) Law in December 2018. The law envisages mandatory coverage for all citizens including vulnerable groups, who will be subsidized by the government. This means that the UHS will be providing coverage to a population expected to grow from around 110 million in 2022 to more than 130 million by 2030.

**The private sector is expected to make an important contribution to the Universal Health Insurance System.** Providers of health services, medical devices and pharmaceuticals will all have a role to play. Across the health system, the private sector has the potential to promote the efficient, effective, and equitable provision of health services to the broader population. This paper describes leading business models that can help achieve this potential, the investment case for them, and the policy reforms that will facilitate their implementation.

**The paper focuses on three important health subsectors: (i) health facilities including hospitals, primary care, and specialty clinics, (ii) diagnostic imaging, and (iii) pharmaceuticals including generics, biosimilars, and vaccines.** Other segments such as laboratories, pharmacies, health technology, medical consumables, equipment and devices, also have a critical role to play in supporting the Egyptian health system, and IFC will continue to actively support them. IFC's support for the health sector includes investment and advisory services to private sector firms, as well as support to the government of Egypt, alongside assistance from the International Bank for Reconstruction and Development (IBRD) on regulatory and other reforms that strengthen the private sector's contribution.

## 2. HEALTH CARE SERVICES

### The UHIS is expected to transform the role of private sector health services providers.

The system, when fully established, will reimburse empaneled private providers for the provision of services to members of the universal health insurance system. This will enable private providers to reach lower-income patients otherwise unable to afford high-quality private provision from the private sector. Along with the increased demand for services will be pressure to raise clinical quality standards, improve the patient experience, and drive enhanced value. Providers will only be eligible for empanelment if they have achieved the quality standards set by the General Authority for Healthcare Accreditation & Regulation (GAHAR). Funding for the public and private facilities working under UHIS will depend on their ability to attract patients who will be free to

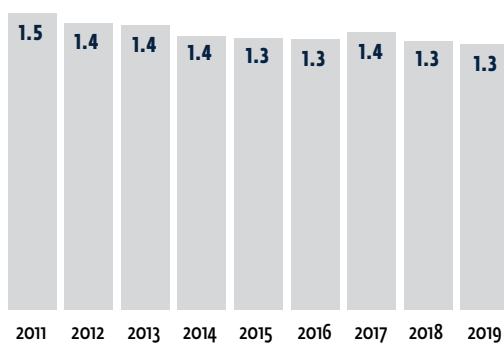
choose between secondary and tertiary facilities that are part of the system. This will provide these facilities with an incentive to actively compete for patients by providing higher quality health care services.

**There is a need for Egypt to make substantial investments over the next decade to respond to the health needs of a growing and aging population.** Figure 2.1 and 2.2 shows the result of calculations suggesting that by 2025, around 110,000 additional beds will be needed, which will involve a total estimated investment of US\$ 30–40 billion.<sup>1,2</sup> The increased investment will be needed to keep up with population growth, and growing incomes. To respond to the population's aging, Egypt is expected to need 19,000 long-term care beds by 2050 compared to the 4,000 beds currently available.

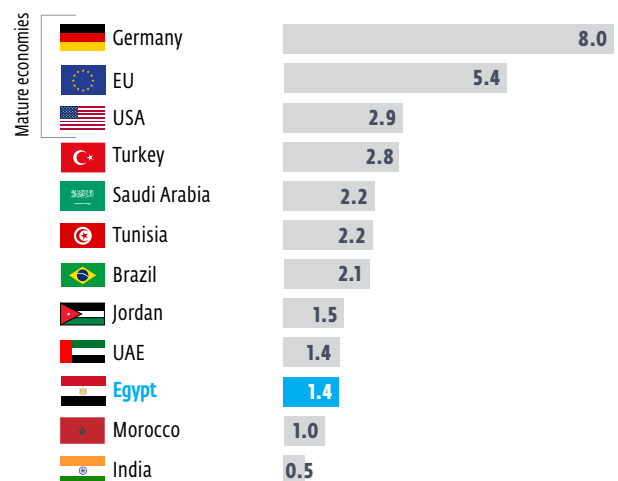
**FIGURE 2.1 NUMBER OF HOSPITAL BEDS IN EGYPT**

#### a. Number of beds has not been able to keep up with population growth in the past ten years

(Beds per 1,000 people in Egypt)



#### b. Egypt still falls below average for beds (2017)



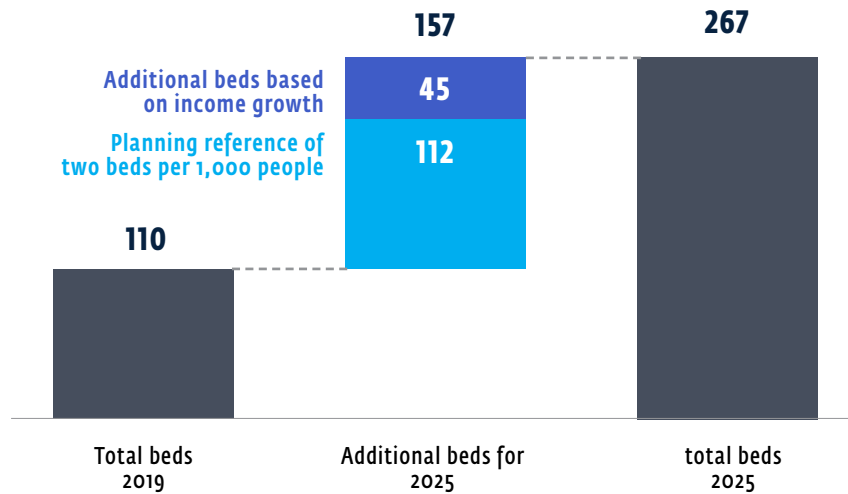
Sources: BCG analysis, CAPMAS, World Bank.

Note: EU = European Union.

1. Unless otherwise indicated, dollar amounts are in US dollars in this report.
2. At an estimated cost of roughly US\$300,000 per bed.

**FIGURE 2.2 REQUIRED INVESTMENT IN BEDS TO MEET 2025 DEMAND**

Number of beds in healthcare system (ooo's)



Sources: BCG analysis, CAPMAS, WHO, Mena Health Partners.

## | 2.1 | HEALTH FACILITIES

**To meet the needs of the UHS, private hospitals need to expand affordable, efficiently provided, and high-quality care.** Only roughly five percent of Egypt’s population falls within the “A class” income segment that is able to afford top-tier private hospitals. The affordability of private hospitals is at best partial for the “B” and “C class” income patients who make up the majority of the population. This is reflected in Figure 2.3, which shows that private health facilities working with private health insurance empaneled facilities are concentrated in the higher-income areas around Alexandria and Cairo, with relatively few outside these cities.

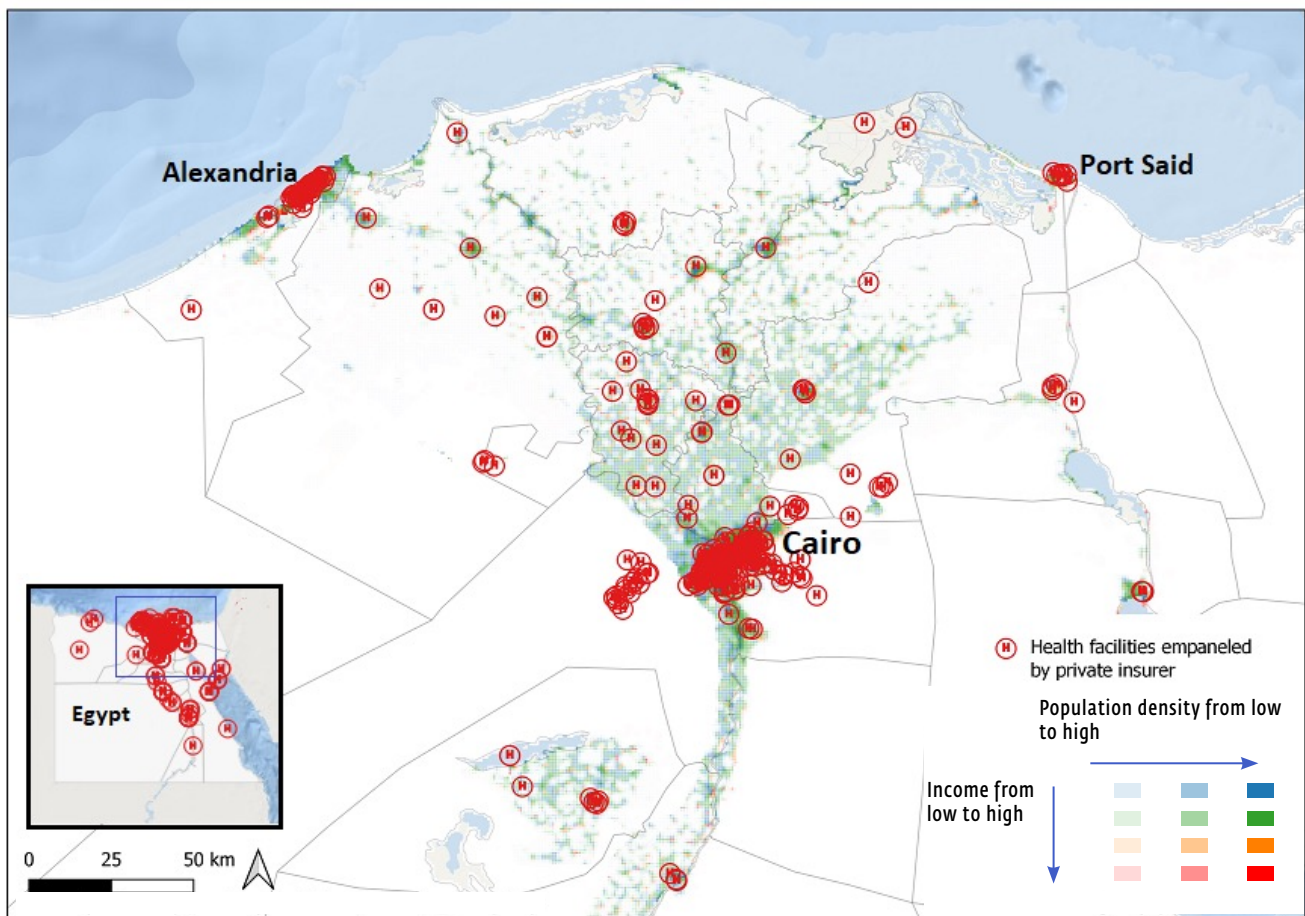
**There is potential to provide care that is more efficient, and higher quality.** A contributor to inefficiency in the system is that many hospitals are

undersized with less than 50 beds. These smaller facilities often lack crucial equipment, such as X-rays and suction equipment, and only provide basic procedures and surgeries. While these facilities work hard to meet the needs of an underserved segment of low- and middle-income patients, the quality of care is sometimes reported to be below basic standards. Few hospitals have been able to replicate innovations that have been pioneered in India and elsewhere that treat high volumes of patients in a way that reduces costs while improving health outcomes. An example of this approach is India’s Aravind Eye Hospitals. These hospitals use standardization and technology to enable their surgeons to each conduct 2,600 surgeries per year, ten times more than the average in the region.<sup>3</sup>

3. See Leahy, M "Case Study Aravind Eye Care: Contribution to global capacity building of eye care personnel" Business Call To Action [www.businesscalltoaction.org] and Wilcox, L "A market-creation story: Aravind Eye Care" The Forum at Harvard Business School [https://www.hbs.edu/forum-for-growth-and-innovation/blog/Pages/default.aspx?post=51]



**FIGURE 2.3 LOCATIONS OF EMPANELED PRIVATE HEALTH FACILITIES AND DEMOGRAPHICS (POPULATION DENSITY AND GDP PER CAPITA)**

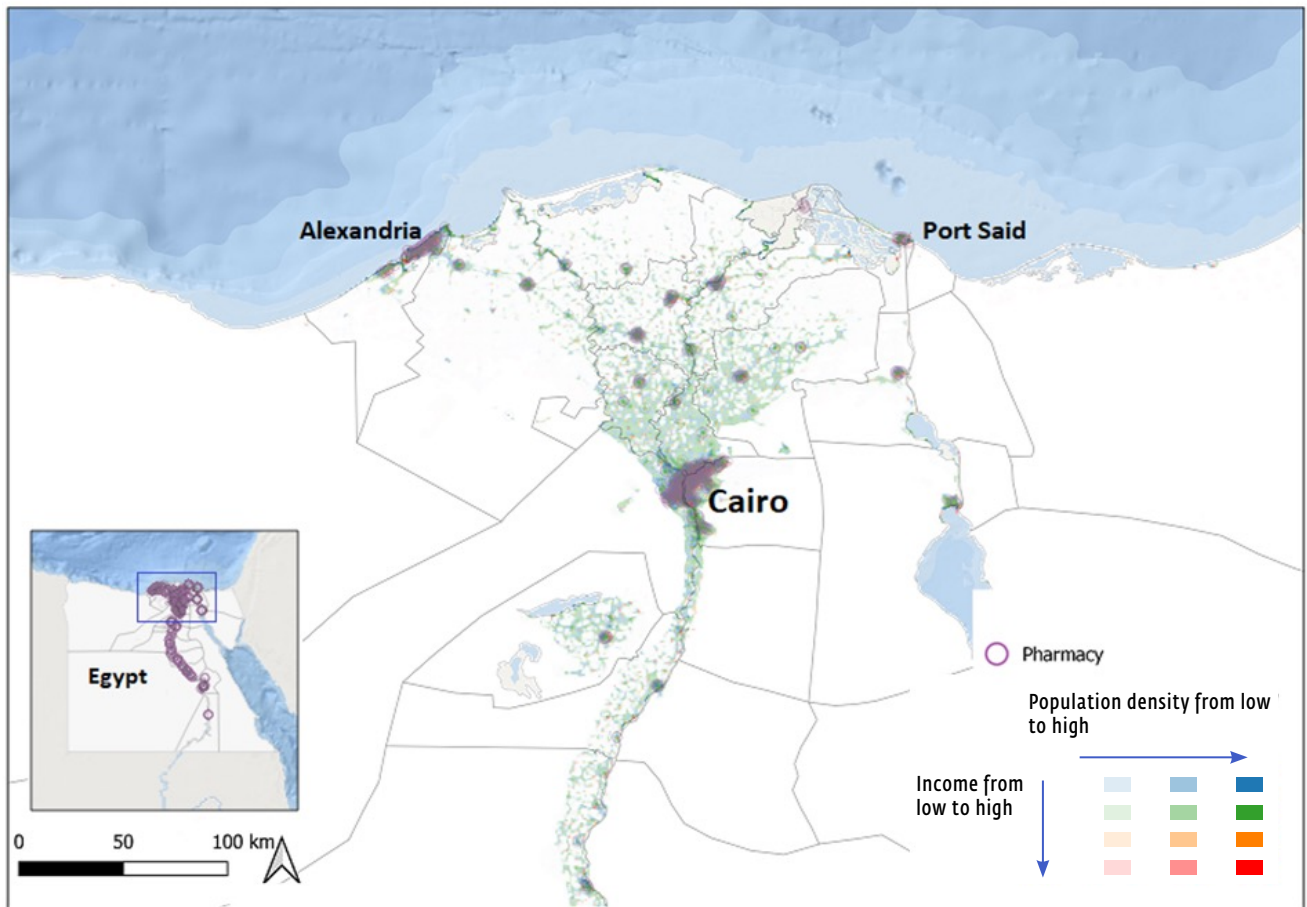


Source: OpenStreetMaps, WorldPop, Health Sites, and Kummu et al. (2018).

**The primary care sector is underdeveloped because patients often bypass it.** Patients with health problems will consult a pharmacist rather than a primary care provider such as family doctor or primary health care (PHC) facility, in part due to the wide availability of pharmacies as shown in Figure 2.4, which are convenient and affordable. If the problem persists, patients will often contact a specialist rather than a primary care provider, and typically make a self-diagnosis to determine which specialist to visit. This behavior generates a vicious cycle that reinforces the lack of primary

care. There is potential for innovative solutions to expand primary care. For example, “healthforce” in South Africa uses telemedicine to connect patients in pharmacies with doctors located centrally. This has enabled them to offer consultations with doctors at pharmacies through telemedicine. A nurse is located in the pharmacy and facilitates the consultation with the doctor. Other innovative approaches include contracting with private providers to offer services out of publicly owned facilities and supporting the expansion of primary care networks.

**FIGURE 2.4 LOCATIONS OF PHARMACIES AND DEMOGRAPHICS (POPULATION DENSITY AND INCOME)**



Source: OpenStreetMaps, WorldPop, Health Sites, and Kummu et al. (2018).

**Implementing UHS requires strengthening of the primary care system.** Primary care providers will be gatekeepers for patients entering the UHS. Patients will have to receive a referral from PHC facilities to attend secondary and tertiary care facilities. There is potential for private providers to make an important contribution to the UHS. In higher-income countries such as France and England,

PHC is provided by various types of private sector providers.<sup>4</sup> A developing country example is Indonesia, which relies on public and private primary care providers to deliver care. The need for primary care providers to organize patient inflow into the health care system will increasingly be needed in response to Egypt’s population growth, aging demographic, and higher incidence of noncommunicable diseases.

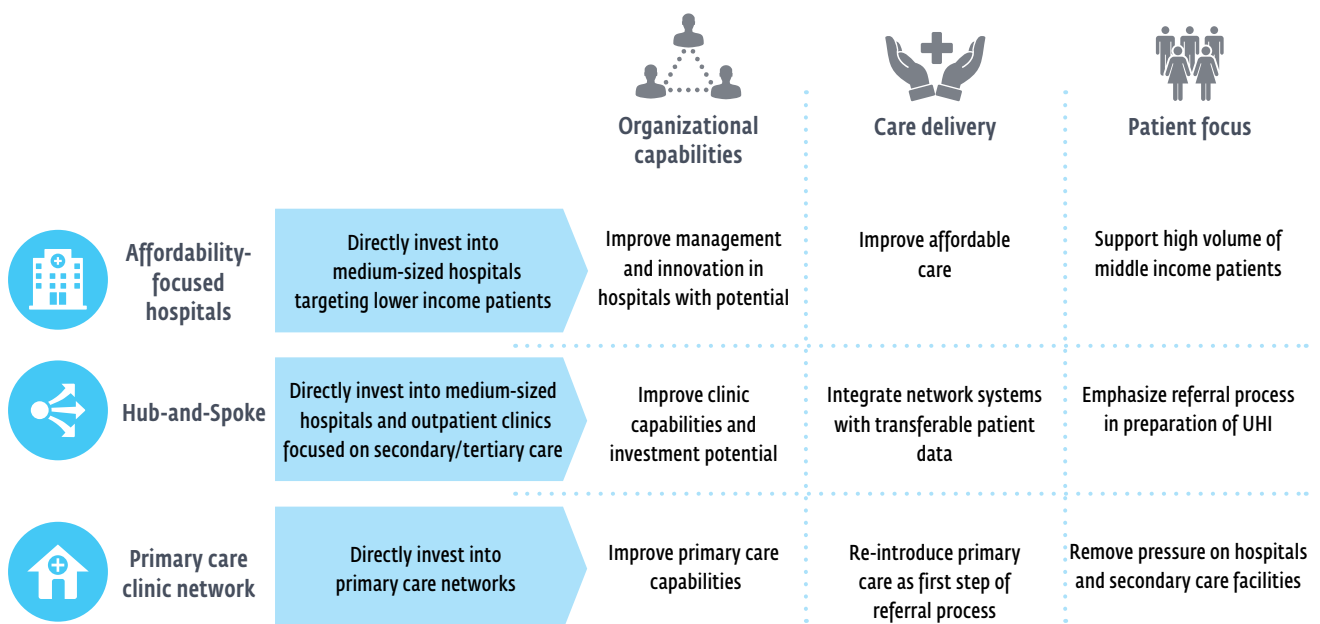
4. In England these are mainly provided through physician-owned general practices but also provided by institutions such as private companies and voluntary organizations that are contracted to provide primary care for specified populations. In France general practitioners are self-employed.

**Although specialty clinics are widely used, the sector is highly fragmented.** While a primary care clinic offers a broad range of services, a specialized clinic focuses on a specific area of medicine. Specialized clinics are often associated with a health care system or hospital group, but they can also be standalone practices. One reason for the fragmentation of the sector is the current regulatory environment. This environment is broadly permissive toward smaller less formally run clinics. These clinics operate in less costly residential buildings. This makes it more difficult for larger clinic centers to compete because they need to pay higher commercial rents and abide by stricter financial and tax reporting requirements.

**There are three promising value creation models that the private sector can use to guide investments in the health facilities sector.**

These approaches have the potential to generate appropriate financial returns while responding to key challenges facing the health system. All three approaches show promise in the current system but have greater potential under the UHIS system. As described in Figure 2.5, these models are 1) investing in affordability-focused hospitals; 2) the roll-out of a hub-and-spoke system; and 3) supporting the development of primary care networks. Primary care clinic networks can be in standalone clinics and can also be integrated with other providers such as pharmacies. These value creation models have the potential to facilitate greater access to high-quality and affordable care in areas that are currently underserved.

**FIGURE 2.5 THREE VALUE CREATION MODELS FOR INVESTMENT IN HEALTH FACILITIES**



## | 2.2 | DIAGNOSTIC IMAGING

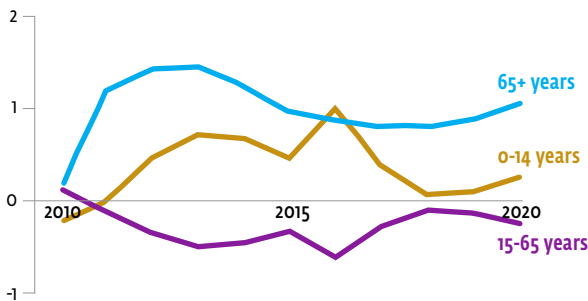
**Demand for imaging services will rise in the coming years with a compound annual growth rate (CAGR) of around 11 percent between 2020 and 2025.** Egypt's population is growing and aging with the highest growth in the over-65 age group (see Figure 2.6).<sup>5</sup> This age bracket experiences a higher incidence of noncommunicable diseases, which will result in a parallel increase in demand for diagnostics in the coming years.

**Early screening and diagnosis have great potential to improve health outcomes (Walters et al. 2013).** A study of diagnoses found that the majority of cancer patients in Egypt were diagnosed at stage 3, while the majority of patients in the United States were diagnosed at stage 1 (Aloraby and Elghazawy 2021; see Figure 2.7). Studies suggest that in well-resourced health systems, very few patients diagnosed with stage 1 or stage 2 breast cancer die. At later stages, the death rate is as much as 100 times higher. Overall, the growth in noncommunicable diseases is leading to an increasing need for laboratory services to provide testing for diseases such as diabetes and heart disease.

**FIGURE 2.6 TRENDS IN EGYPT'S POPULATION GROWTH AND HIGHER NCD INCIDENCE IN OLDER AGE GROUPS**

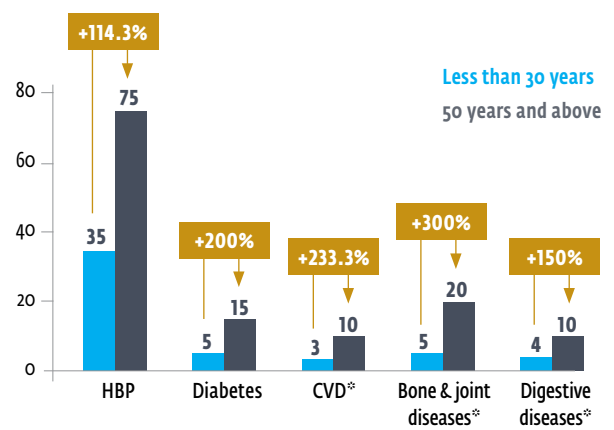
**a. Population growth is seeing a trend towards an ageing population, adverse to the trend seen in the last decade**

Growth in percentage of population within each age group



**b. NCDs are prevalent in older age groups, suggesting a rise in NCD incidence and diagnosis demand in coming years**

Rate of incidence in sample per age group



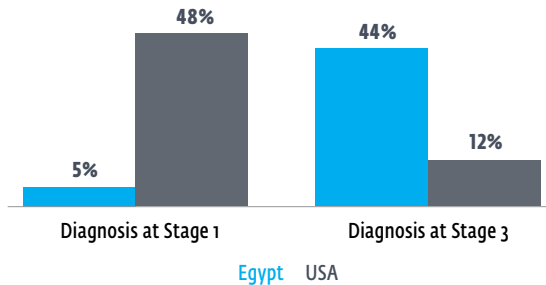
\* Diseases that require imaging for diagnosis

Note: HBP = High Blood Pressure; NCD = noncommunicable disease.

5. World Bank, "Population Ages 65 and above (% of Total Population)" (online data sheet), 2019, <https://data.worldbank.org/indicator/SP.POP.65UP.TO.ZS>.

**FIGURE 2.7 DIAGNOSES OF LATE STAGE CANCER IN EGYPT VS. THE U.S.**

% sample diagnosed at Stage 1 and Stage 3 cancer in respective countries



Sources: World Bank, Yang et al. 2015.

**The imaging market is currently underserved with widely diverging levels of service quality and accessibility within the private market.** The main private imaging chains are concentrated in Greater Cairo, Alexandria, and the main urban areas. These imaging chains offer a wide range of services, including CT, MRI, and PET scans and usually have multiple branches in their areas of operation. Most imaging chains are linked with pathology centers and can provide a full diagnostic service, leading to good patient retention. More remote areas are largely served by the public sector, with only patchy provision by the private sector, typically small players that have less advanced imaging equipment and

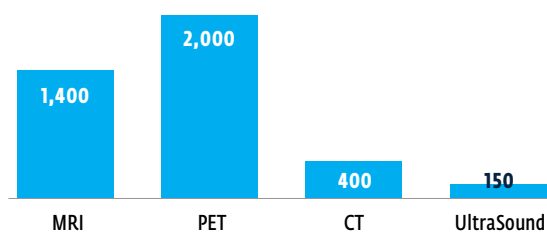
low-quality facilities. Given the high capital expense (capex) needed to open imaging centers and the lack of incentives for private investment in remote areas, expansion is limited in less-developed governorates, where economies of scale are more difficult to achieve. Patients in these areas are served at any of the several public sector facilities with integrated radiology centers.

**Effective implementation of the "hub-and-spoke" model is key to expanding the reach of diagnostics.** As shown in Figure 2.8, the high cost of imaging and diagnostics creates a strong drive to establish hubs that take advantage of economies of scale and have more advanced diagnostics. Patients in remote and underserved areas can access services at local offices which form the "spokes". The local offices provide the limited range of tests that can be offered efficiently. They are a way for patients to access the far wider range of diagnostics provided in the central hub facilities. The hub-and-spoke approach in diagnostics could lead to improved access to a wider variety of diagnostic services, standardized quality, increased scale and capacity utilization, and enables providers to train doctors across the network. An example of this approach is Alliar Centro de Imagem Diagnosticos in Brazil that uses a centralized command center to deliver services in remote areas through spoke operations. There is potential for the private sector to use the hub-and-spoke model to work with the public sector through forms of public-private collaboration such as PPPs.

**FIGURE 2.8 EXAMPLE OF A HUB-AND-SPOKE MODEL FOR IMAGING**

**The diagnostics market is characterized by very high fixed costs and capital expenditures**

Examples from imaging: Average cost of scanner (\$ 000's)



Given the high capex structure of diagnostics there is a need for a large market to support investment

**Overcoming challenges from high fixed costs by utilizing scale and teleradiology**

- Reduce capital expenditure (capex) costs through **volume discounts** with partnering suppliers
- Through **teleradiology** and the command centers system, technicians are able to operate between two and three MRI scanners simultaneously, thereby increasing productivity
- Utilizing **purchasing power** to negotiate for better price
- **Consolidating the back-office** functions in a shared services center

## | 2.3 | STRENGTHENING THE POLICY ENVIRONMENT FOR INVESTMENT IN HEALTH SERVICES

The government of Egypt can promote investment in health services to strengthen health system performance through continuing its initiatives in three major areas. These are:

1. **Implementation of the UHIS.** Investment can be encouraged if the government continues to work to provide clarity on the funding that will be available for the UHIS over the longer term from contributions, taxes, licensing and similar. This will reassure the private sector that the UHIS will have sufficient funds over the medium to long term to pay for services from the private sector and so reduce the risks associated with long-term investments. It will also be important to clarify the roles of the private and public providers. This includes providing guidance on the empanelment criteria, the role of health facility networks, including those integrating primary and other forms of care, the envisaged payment schedule, reimbursement methods, and benefits packages. It is important to provide guidance on the governance arrangements that will be used to determine these policies, and the process for making changes to them over time. Providing greater clarity on these issues will help give private providers the insight needed to make longer term investments against expected revenues from the UHIS. To inform these discussions, the Ministry of Health is developing a health map to outline the health situation geographically to assist decision-making processes including those related to investment and enhancing the participation of the private sector in providing health services.
2. **Reform of the regulatory environment to unlock existing and potential investments:**
    - **Licenses.** The current process for applying for licenses to establish facilities takes time and resources to navigate. This creates risks and uncertainty for providers investing in new facilities. The government has therefore developed an amendment to the medical licensing law to respond to many of these issues. An initiative is also under way within the government to include the health sector among the listed sectors for the Golden License, a unified approval for investors regulated by Article 20 of the Egyptian Investment Law No. 72 (2017), which aims to reduce bureaucracy through simplified processes.
    - **Mergers and Acquisitions.** This process is currently time consuming and opaque. This is off-putting for equity investors aiming to develop networks or consolidate providers, because it leads to the risk that they may be unable to sell their ownership positions or able do so only after considerable delay. This simply reduces the incentive to make equity investments in the first place. An initiative is under way within the government to address the challenge of the multiplicity of necessary approvals and the length of time required to complete mergers and acquisitions in the health sector. It will be important to continue and expand on this.
    - **Informality.** The lack of enforcement of various regulatory requirements is also an obstacle for formally run providers. This leads to informality in tax, quality, and rent compliance. This distorts competition in the health care provider market by putting larger, formally run firms, at a disadvantage.

**3. Leveraging digital technologies.** These technologies include digital devices, electronic records, health information exchanges, and telehealth. They have the potential to achieve transformative changes in the efficiency of health care service delivery, and the management of the health insurance system. Unleashing this potential requires greater clarity on the governance of the sector including regulations around the provision of telehealth. It will also require initiatives by the government to facilitate the use of digital record-keeping, and the use of this data to promote more efficient, convenient and integrated care, and interventions to promote the analysis and use of this data to support improved clinical and financial decision-making. In light of these challenges a special law is being developed to regulate the provision of telemedicine services: its purview will have to include the specific requirements for implementing telemedicine in pharmacies.<sup>6</sup>

**Ultimately the public sector, as the steward of the health system, is a key driver for private sector investment.** The approach envisaged for the private sector under UHIS, the PPPs entered into, and the regulatory environment will be the main drivers of the private sector's performance. Underpinning an effective engagement with the private sector is public– private dialogue that allows the government to better understand the challenges facing the private sector, and helps the private sector better understand the government's approach to the sector going forward. This type of dialogue has informed many of the government's reform initiatives in this sector.

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6. The effective application of telemedicine in pharmacies should consider issues such as: (i) the need to establish a set of rules or criteria that would be used to determine which locations would be appropriate for offering the service, (ii) provision of a separate consultation room or space, (iii) connecting pharmacies with primary care doctors on an effective platform, and (iv) providing the service through specialized facilitators.

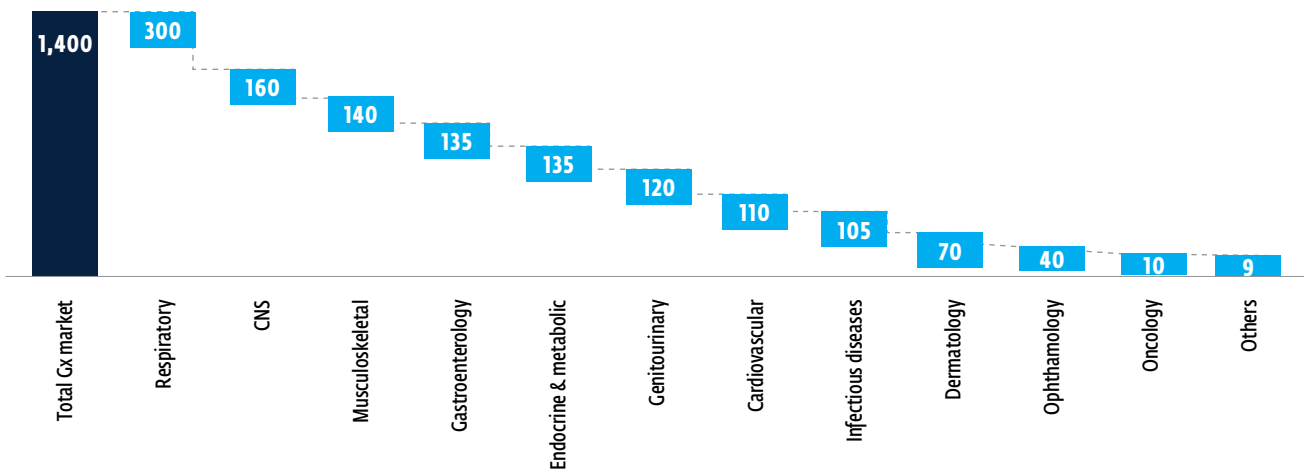
# 3. PHARMACEUTICALS

## | 3.1 | GENERIC (GX)

**Egypt has a well-established generic pharmaceutical sector that is well positioned for investment.** Generic medicines are sold in competition with those of the original patent holder “brand”, typically at lower prices than the originator. For this reason, generic medicines play a key role in lowering the cost of medicine, and thus make it more affordable to provide health care. The Egyptian generics (Gx) market was worth US\$ 1.4 billion in 2019 (30 percent of the total Egyptian pharmaceutical market). Around 90 percent of Gx volumes—accounting for 80 percent of the

value—are manufactured locally. This market is served by roughly 130 pharmaceutical sites, which suggests that many sites are not large enough to achieve the lower cost of production that come from economies of scale. Treatments for respiratory, central nervous system, and musculoskeletal conditions contribute the most to Egypt’s Gx market, accounting respectively for 20 percent, 10 percent, and 10 percent of the total Gx market (see Figure 3.1). In Egypt, small molecule pharmaceutical products dominate. There is very limited capacity in the country to produce the chemical-based compounds that are used in the manufacture of medication (called active pharmaceutical ingredients, or APIs).

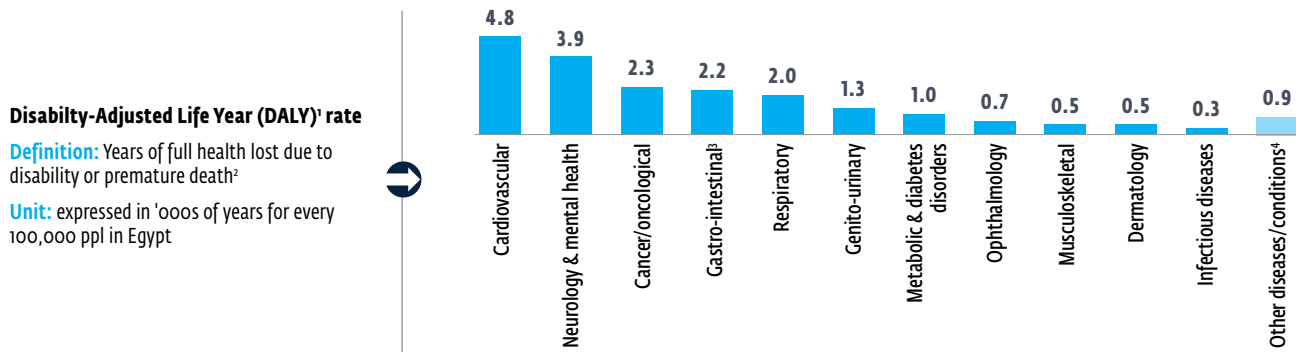
**FIGURE 3.1 GX SPENDING AND DISEASE BURDEN IN EGYPT, BY THERAPEUTIC AREA**



Sources: World Bank, expert interviews.

Note: US\$ are in 2019 values. CNS = central nervous system





1. Disability-adjusted life year: DALYs for a specific cause are calculated as the sum of the years of life lost due to premature mortality from that cause and the years of healthy life lost due to disability for people living in states of less than good health resulting from the specific cause.
2. Based on national life expectancy projected for the year 2050 by the World Population Prospects (UN Population Division)
3. Incl. hepatitis
4. Autoimmune Diseases, Blood, Otorhinolaryngology, Childhood behavioral disorders

Source: WHO 2019 data, BCG analysis

**The outlook of the Gx market is positive and the CAGR is expected to grow by 10 percent over the 2022-2027 period.** The positive market growth is being driven by sustained population growth at historical rates (two percent CAGR), an increase in GDP per capita (six percent CAGR), a growing middle class, and the increased penetration of Gx into public health spending. Potential headwinds include any delays in the roll out of UHI and increasing price pressure on Gx, especially in the public sector. Of the therapeutic areas, cardiovascular, oncology and neurological diseases have the most untapped

potential, given their contribution to the country's disease burden and underspending relative to neighboring countries.

**There are three promising approaches for the private sector to contribute to the development of the Gx industry and the Egyptian health care ecosystem.** As shown in Figure 3.2, these include: 1) horizontal expansion into new therapeutic areas (TAs); 2) consolidation to achieve scale; and 3) focusing on the expansion and development of alternative delivery systems.

**FIGURE 3.2 THREE VALUE CREATION MODELS IN GENERICS**



**Horizontal expansion**  
"Enter into new TAs"

Support investment in the **current core business** and horizontal **expansion across** key therapeutic areas in order to increase Gx availability/affordability and establish key leadership across more TAs



**Player consolidation**  
"Leverage scale"

Support consolidation in order to **leverage economies of scale** and boost **price competitiveness** in target TAs as synergies materialize



**Technological & compliance update**  
"Distinctive offering"

Support expansion and development of Gx **alternative delivery systems** (e.g., Injectors/Pens, Unit Dosing, Transmucosal, Transdermal) to capitalize on shifting preferences and technologies

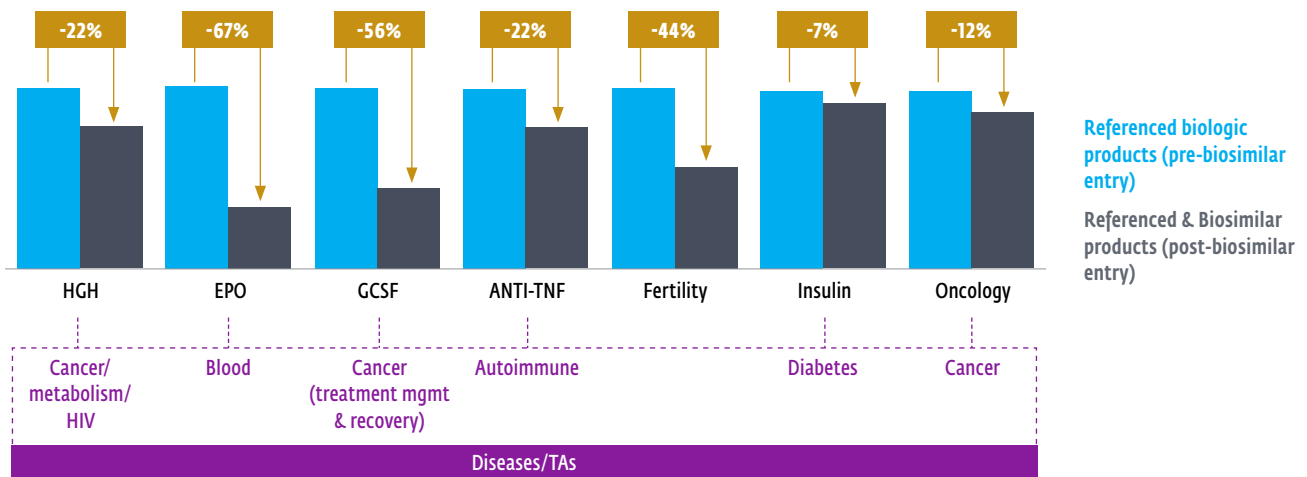
**| 3.2 |**  
**BIOLOGICS AND VACCINES**

**Biosimilars<sup>7</sup> offer an affordable treatment alternative to originators' biologic products in several important therapeutic areas for Egypt.** Biologics are very large, complex molecules or mixtures of molecules. They have been used to treat various cancers, rheumatoid arthritis and heart disease. For many diseases they are the only effective treatment but are also typically very expensive. This makes them difficult to afford for all but the wealthiest individuals, or health systems. Biosimilars are similar to generics in that they are a way to bring down prices and so extend access to these therapies. Biosimilars are gaining traction globally and have grown at a rate of 61 percent CAGR between 2014 and 2019, due to lower prices than the originator, and faster approval processes. In Middle East and North African (MENA) countries, biosimilars grew at a rate of 14 percent CAGR between 2015 and 2019, three

times faster than other segments. Furthermore, a large potential market will be created by the expiry of key biologic medicine patents by 2024. This will allow for the introduction of biosimilars that will compete with the original patent holders' brands.

**The Egyptian market for biologics is already worth US\$ 460 million<sup>8</sup> and rising at a rate of 15 percent CAGR, and it is forecast to reach more than US\$ 1 billion by 2025.** Increasing demand is seen across oncologics, insulins and analogs, immunosuppressants, antianemics, and immunostimulant and growth hormones. Any increase in the country's biosimilars market would lower treatment costs and reduce the funding required to sustain the UHIS. Historically, this is what happened in Europe with a fall in the cost per treatment per day of as much as -60 percent in classes of biologics and biosimilars within a year (Figure 3.3). In parallel, the entry of biosimilars increased patient access, as shown by significant volume growth (over 25 percent). Poor affordability and a lack of awareness have so

**FIGURE 3.3 DECREASE IN TREATMENT COSTS WITH THE INTRODUCTION OF BIOSIMILARS IN EUROPE**



Sources: IQVIA report, "The impact of Biosimilar Competition in Europe", project team research, 2021.

Notes: The price level used is the gross ex-manufacturer price (list price), which values the product at the level that the manufacturer sells without considering rebates or discounts. Price evolution is the price per treatment day in 2020 (June, moving annual total) versus year before biosimilar entry. HGH refers to Human growth hormone (HGH); Epoetin (EPO); Granulocyte-colony stimulating factor (GCSF); Anti-tumour necrosis factor (ANTI-TNF); and Fertility (FOLLITROPIN ALFA).

7. Biosimilars are the off-patent versions of biologics. Biologics are medicines that are produced using tissues from living organisms such as humans, animals, or microorganisms.

8. In Q4 2019. Source: IQVIA 2019.

far limited market development, but improvements are currently under way in Egypt. The government has provided the sector with flexibility in determining prices. This has facilitated the private sector's introduction of innovative pricing models for treating large numbers of patients while maintaining financial sustainability and establishing relationships with the government to promote awareness by publicizing their effectiveness, quality, and safety.

#### **Manufacturing biosimilars is capex intensive.**

Development costs range from US\$ 100 million to US\$ 250 million for end-to-end production (compared to US\$ 800 million for the biologic originators). This is mainly because fewer development stages are required for biosimilars as opposed to the originator of the biologic. Biosimilars only require preclinical and clinical phases I and III. Despite being a capex-intensive business, a few suppliers in Egypt are starting to emerge and develop capabilities. A leading producer in Egypt has developed an erythropoietin biosimilar for the treatment of anemia that can compete with the originator in terms of quality and cost. Despite this and other examples of Egyptian biosimilar producers, the increase in local demand combined with a shortage of manufacturers leads Egypt to still import most of its biosimilars.

**There are large barriers to entry in the biosimilars and vaccines markets including capex investments, technical capabilities, and regulatory approval pathways.** Egypt has

two different registration processes for biosimilars that depend on whether the drug is imported or manufactured locally. For imported products there are fewer stages in the approval process, since it is being applied to biosimilars that have already undergone supervisory activities by regulatory authorities in the country of manufacture. For domestic production, manufacturers must go through an exercise to confirm biosimilarity. This stepwise approach starts with a head-to-head comparison of quality, and based on these results and the totality of evidence, there may be a request for a pre-clinical and clinical comparison with a reference product.<sup>9</sup> The various barriers to entry are particularly challenging for vaccines where economies of scale are substantial, and there is a ready source of supply from large well-established producers in India and China.

#### **Four approaches show promise to unlock biosimilars and vaccine capabilities in Egypt.**

As illustrated in Figure 3.4, this includes expanding relevant organizations, establishing contract manufacturing relationships with multinationals, or entering into joint ventures. Given the unique challenges of the vaccines market in Egypt, there is clear value for vaccine producers to work closely with government agencies. Working with government agencies is particularly important when the rationale for the investment is not strictly commercial, for example ensuring security of supply for the country and thus reducing reliance on foreign suppliers.

**FIGURE 3.4 APPROACHES TO CREATING VALUE IN BIOSIMILARS AND VACCINES**



9. Pricing regulations in Egypt allow biosimilar producers to charge prices that are up to 85 percent of the originator price.

### | 3.3 | STRENGTHENING THE POLICY ENVIRONMENT FOR INVESTMENTS IN HEALTH PRODUCTS

Three major approaches can be used to promote investment in the pharmaceutical sector:

1. **Providing clarity on UHIS implementation in terms of timing and milestones, and the pharmaceutical pricing fee schedule.** The implementation of national procurement of drugs under UHIS can be expected to place downward pressure on prices. This will place pressure on higher cost manufacturers. The impact of this on investment in the sector can be mitigated through supporting consolidation in the sector; this should allow the sector to become more efficient and so produce medicine at lower cost in a financially sustainable manner. Consolidation will largely be driven by the private sector, but it will be important for the government to avoid restricting growth of firms, and mergers and acquisitions that will benefit the broader health system by allowing for more efficient production and lower prices, as well as increased investments in research and development.
2. **The enforcement of quality standards is key in the pharmaceutical products segment to meet local and international requirements and support high-quality local manufacturers.** Regulatory bodies must strive consistently and persistently to raise local quality standards to international and regional benchmarks. Continuing work to provide a clear biosimilar approval process has potential to accelerate the strategic growth and direction of this sector. The Egyptian Drug Authority has a general strategy for accelerating biologics licensure in Egypt including biosimilars. This has already led to reforms in this

area that aim to improve the approval process including the publication of various regulations, guidelines and procedures. This includes updating the Guideline for the Registration of Biosimilar Products in 2023 and the publication of procedures for Registration of Biological products through Reliance pathways in 2022. The Egyptian Drug Authority continues to work on a number of initiatives related to these areas that aim to strengthen the regulatory regime for biosimilars in Egypt.

3. **The development of a government agenda with clear priorities for supporting the sector could boost the growth of the emerging biosimilars market in Egypt.** The government could consider supporting local producers through cost and demand incentives. There is potential to appropriately support the sector's growth through the implementation of value-based pricing that has been implemented in Germany and the United Kingdom. The value-based pricing approach provides advantages over more traditional cost-plus pricing or basing prices on international benchmarking. The country can also implement regulatory and reimbursement policies that facilitate the substitution of innovative drugs with biosimilars. The government could also work to catalyze the sharing of best practices and drive innovation in the pharmaceutical space. Public-private dialogue is also critical to align private and public sector initiatives.

**Overall, there is great potential for the pharmaceutical industry in Egypt to contribute to the implementation of the UHIS and the country's industrial development.** Three pillars for the government's approach in this area are the design of the UHIS, interventions to support the industry to become more efficient and innovative, and continued strengthening of the regulatory regime for medicine approval.

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## 4. CONCLUSION

**This paper outlines how the private sector can contribute to the UHS and the country's broader economy.** It describes ways that the private sector can create value for the system in several health services sectors. This includes innovative approaches to providing hospital, clinic and diagnostic services. The key to implementing these approaches at scale will be collaboration with the public sector. This includes contracting with private providers and implementing PPPs. In medical products, there is

scope for the generics and biosimilar sectors to grow and increase their contribution toward lowering the cost of treating disease. In this area, there are a number of ways for the government to help develop the private sector, including regulatory reform and changes to reimbursement. An expanded private sector contribution to the provision of health services must be driven by government engagement, underpinned by dialogue between the public and private sectors.

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