

Healthcare, Regulatory and Reimbursement Landscape

Egypt

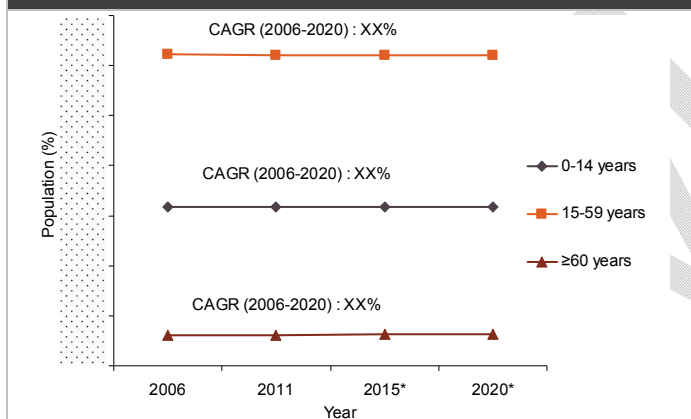
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Sociopolitical transition and instability is preventing the efficient utilization of the available human resource pool in Egypt; the negative affect on economic growth has led to a high unemployment rate

In 2011, with a population of approximately XX million, Egypt was the most populated country in the Arab region, having grown at an average rate of XX% per annum over the past few years. The urbanization rate has also increased significantly, and it is estimated that the XX% of the population will be living in urban areas by 2020. The working-age population accounted for approximately XX% of the entire population in 2011 (CAPMAS, 2012c). The improvement in the overall level of education and a large working-age population provides a suitable platform for national economic growth. However, sociopolitical transition and the resulting instability in the last couple of years have prevented the emergence of clear economic policies. The unemployment rate has increased significantly from XX% in 2008 to XX% in 2011 (The World Bank, 2012p). Poor infrastructure and a lack of new employment generation programs from the government have had a negative impact on the country's economic growth.

Age Groups, Egypt, Population Distribution (%), 2006-2020

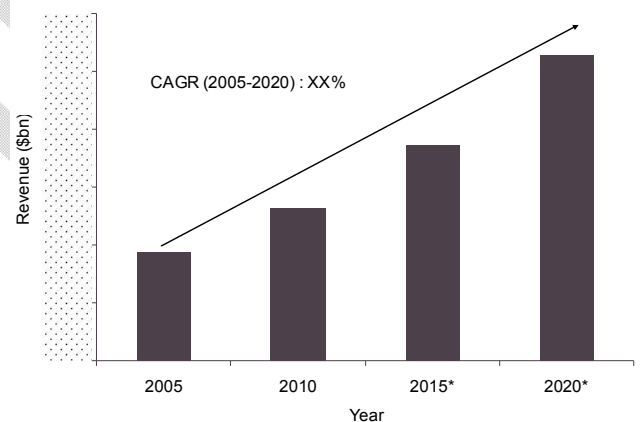


Source: GlobalData; CAPMAS, 2012c; The US Census Bureau, 2012b

Increasing demand for high-quality healthcare services, a revised pricing policy and proposed universal healthcare insurance make Egypt an attractive healthcare market

The pharmaceutical market was estimated at approximately \$XX billion in 2010. Domestic manufacturers produce mainly generic medicines and accounted for a XX% share in the country's overall pharmaceutical market in 2010. Therapeutic segments such as cardiovascular, cancer and respiratory are expected to grow in the coming years due to shifting health trends which indicate that non-communicable diseases are becoming more prevalent than communicable diseases. On October 2, 2012, the government proposed a new universal healthcare law which will provide health insurance coverage to the entire Egyptian population. Previously, in May 2011, the government introduced new pricing policies to link the price of pharmaceuticals with international prices, which will increase the value of the Egyptian pharmaceutical market. The pharmaceutical market is expected to grow at a Compound Annual Growth Rate (CAGR) of XX% from approximately \$XX billion in 2011 to \$XX billion in 2020, due to the increasing incidence of various chronic diseases and growing unmet need.

Pharmaceutical Market, Egypt, Revenue Forecast (\$bn), 2005-2020



Source: GlobalData; AlexBank, 2010

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2 Introduction

2.1 Report Guidance

- The report begins with an executive summary which gives an overview of Egypt's healthcare market and the key driving factors. It also gives a snapshot of the demographic, regulatory and reimbursement landscape as well as the country's healthcare infrastructure.
- Chapter three provides an overview of the pharmaceutical and medical device markets, including market size; market segmentation by generic, Over-The-Counter (OTC) and biologic/biosimilar products; and the key drivers and barriers. It also includes profiles of the major players, including SWOT assessments.
- Chapter four covers the reimbursement, payer and regulatory landscapes. The reimbursement and payer landscape section elaborates on the features of the healthcare reimbursement process, covering insurance providers, pricing policies and drug pricing trends. The regulatory landscape section provides an overview of the regulatory agencies and approval processes for new drugs and medical devices. The chapter also covers the licensing process for the manufacture and export/import of pharmaceuticals; the regulations for pharmaceutical advertising, labeling and packaging, and clinical trials; and an overview of the intellectual property rights landscape.
- Chapter five provides detailed analysis of Egypt's political and economic environment, focusing on economic indicators, demographics, and healthcare infrastructure and expenditure.
- Chapter six provides an overview of the opportunities for and challenges to growth in Egypt's healthcare market.

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5.3.3 Inflation

5.3.3.1 Consumer Price Index

The Consumer Price Index (CPI) measures changes in the price level of consumer goods and services purchased by households. The annual percentage change is used as a measure of inflation. In 2006, Egypt reported a CPI of approximately XX, which increased steadily to XX in 2011, indicating price acceleration in a fixed basket of goods and services. Inflation was mainly observed in oil and gas prices, manufactured goods, food products and electricity.

Figure 44: Average Consumer Price Index, Egypt, 2006-2011

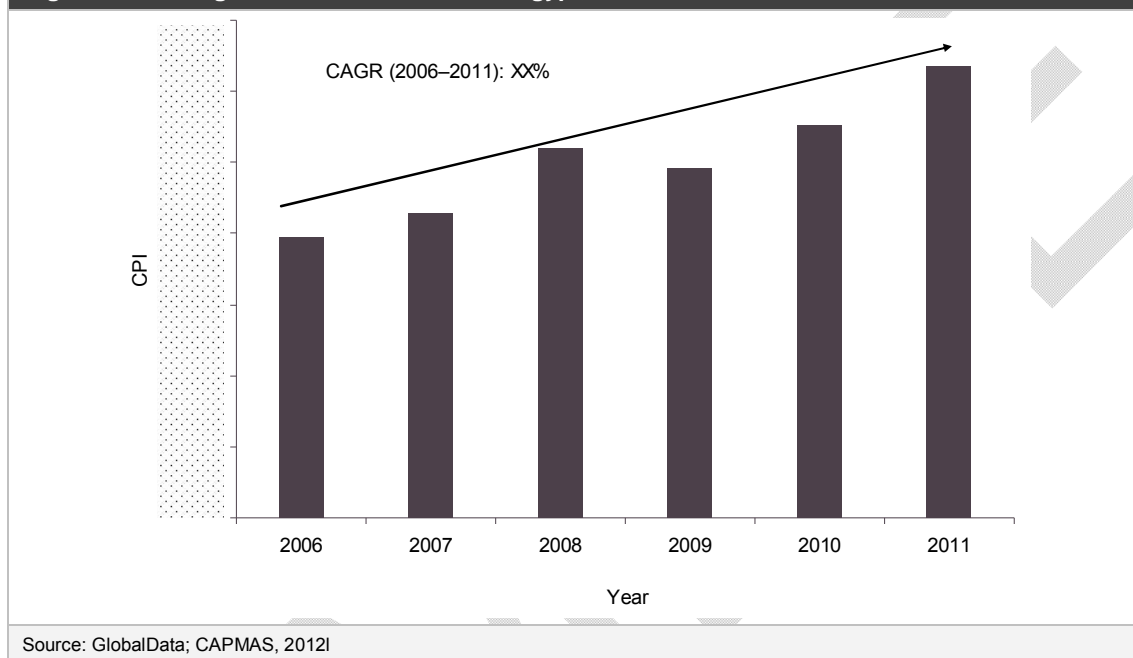


Table 49: Average Consumer Price Index, Egypt, 2006-2011

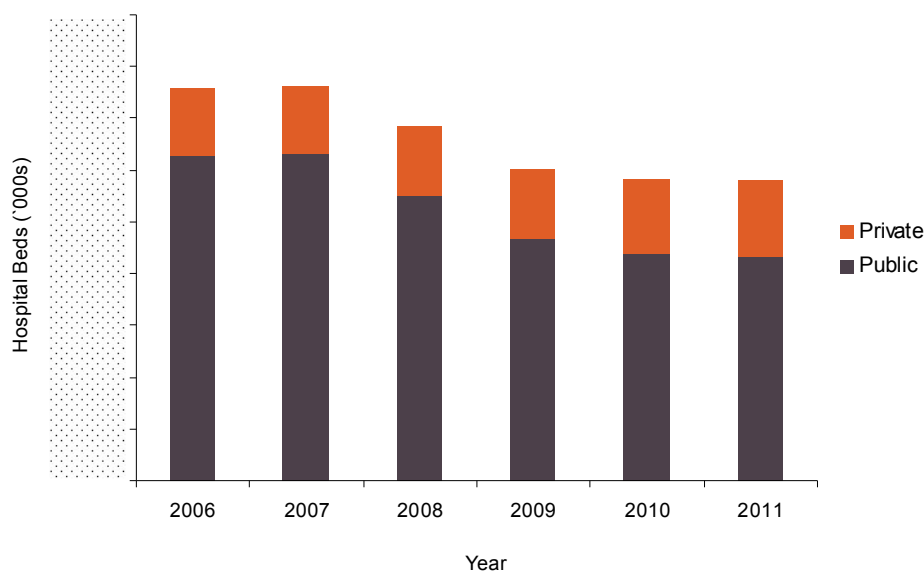
Year	2006	2007	2008	2009	2010	2011
CPI						

Source: GlobalData; CAPMAS, 2012I

5.5.1.3 Public-Private Hospital Beds

In 2006, there were approximately XX hospital beds in Egypt, which decreased steadily to XX in 2011. The number of hospital beds in the private sector increased significantly to XX in 2011 from XX in 2006. The public sector accounted for the most decrease in the number of hospital beds, mainly due to a low occupancy rate (<XX%).

Figure 80: Public-Private Hospital Beds ('000), Egypt, 2006-2011



Source: GlobalData; CAPMAS, 2012t

Table 85: Public-Private Hospital Beds ('000), Egypt, 2006-2011

Year	2006	2007	2008	2009	2010	2011
Public	XX	XX	XX	XX	XX	XX
Private	XX	XX	XX	XX	XX	XX

Source: GlobalData; CAPMAS, 2012t

5.6.2 Components of Healthcare Spending

In 2008, with a share of XX%, pharmacies accounted for most of the total healthcare expenditure, followed by private clinics and hospitals (XX%). In 2008, MoHP hospitals accounted for XX% of total healthcare spending in Egypt, which is slightly lower than XX% in 2007 and significantly lower than XX% in 2001.

Figure 93: Healthcare Expenditure, Egypt, Share of Major Components (%), 2009

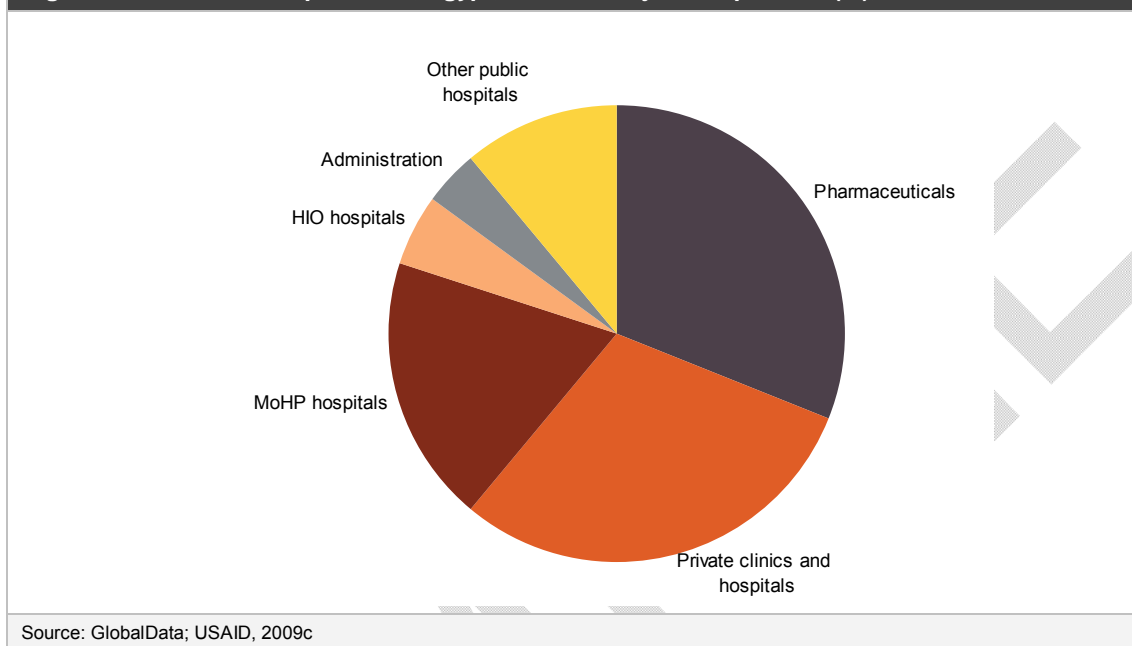


Table 98: Healthcare Expenditure, Egypt, Share of Major Components (%), 2009

Cost Components	Share
Pharmaceuticals	
Private clinics and hospitals	
MoHP hospitals	
HIO hospitals	
Administration	
Other public hospitals	

Source: GlobalData; USAID, 2009c

7 Appendix

7.1 Abbreviations

- API: Active Pharmaceutical Ingredient
- ASSD: Accelerated Stability Study Data
- BMS: Bristol-Myers Squibb
- BOD: Biochemical Oxygen Demand
- CAGR: Compound Annual Growth Rate
- CAPA: Central Administration of Pharmaceutical Affairs
- CAPMAS: Central Agency for Public Mobilization and Statistics
- CMS: Center for Medicare and Medicaid Services
- CNS: Central Nervous System
- COPD: Chronic Obstructive Pulmonary Disease
- CPI: Consumer Price Index
- CRRT: Continuous Renal Replacement Therapy
- DALY: Disability Adjusted Life Years
- DEA: Drug Enforcement Administration
- DHHS: Department of Health and Human Services
- DPT: Diphtheria, Pertussis and Tetanus
- DTR: Department of Trade Registry
- EDA: Egyptian Drug Authority
- EIPICO: Egyptian International Pharmaceutical Industries Company
- EMA: European Medicines Agency
- EPO: Egyptian Patent Office
- EPSF: Egyptian Pharmaceutical Students' Federation
- FDA: Food and Drug Administration
- FDI: Foreign Direct Investment
- Forex: Foreign exchange
- GDP: Gross Domestic Product
- GMP: Good Manufacturing Practice
- GNI: Gross National Income
- GSK: GlaxoSmithKline
- HCV: Hepatitis C Virus
- HIO: Health Insurance Organization
- HIV: Human Immunodeficiency Virus
- INN: International Nonproprietary Name
- IV: Intravenous
- MAA: Market Authorization Application
- MARS: Molecular Absorbent Recirculating System
- MDC: Medical Device Committee
- MDD: Medical Device Department
- MENA: Middle East and North Africa
- MMR: Maternal Mortality Rate

- MNC: Multinational Company
- MoF: Ministry of Finance
- MoHP: Ministry of Health and Population
- NME: New Molecular Entity
- NODCAR: National Organization for Drug Control and Research
- NORCB: National Organization for Research and Control of Biologicals
- NRC: National Research Council
- OOP: Out-Of-Pocket
- OTC: Over-the-Counter
- P/E: Price-to-Earnings
- PCR: Polymerase Chain Reaction
- PD: Procurement Department
- PTC: Procurement Technical Committee
- PTES: Program for Treatment at the Expense of the State
- SCAF: Supreme Council of the Armed Forces
- SEDICO: South Egypt Drug Industries Company
- SEZ: Special Economic Zone
- TB: Tuberculosis
- TDL: Tender Drugs List
- TFR: Total Fertility Rate
- THE: Total Healthcare Expenditure
- TPE: Therapeutic Plasma Exchange
- TRIPS: Trade-Related Aspects of Intellectual Property Rights
- USAID: United States Agency for International Development programs
- WHO: World Health Organization
- WTO: World Trade Organization

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7.3 Methodology

GlobalData's dedicated research and analysis teams consist of experienced professionals with advanced statistical expertise and marketing, market research and consulting backgrounds in the pharmaceutical industry.

GlobalData adheres to the codes of practice of the Market Research Society (www.mrs.org.uk) and the Strategic and Competitive Intelligence Professionals (www.scip.org) .

All GlobalData databases are continuously updated and revised. The following research methodology is followed for all databases and reports.

7.3.1 Coverage

The objective of updating GlobalData's coverage is to ensure that it represents the most up to date vision of the industry possible.

Changes to the industry taxonomy are built on the basis of extensive research of company, association and competitor sources.

Company coverage is based on three key factors: revenue, products and media attention/innovation/market potential.

- The estimated revenue of all major companies, including private and governmental, are gathered and used to prioritize coverage.
- Companies which are making the news or which are of particular interest due to their innovative approach are prioritized.

GlobalData aims to cover all major news events and deals in the pharmaceutical industry, updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GlobalData's expert panel (see below).

7.3.2 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and US Securities and Exchanges Commission (SEC) filings
- Industry trade journals, scientific journals and other technical literature
- Internal and external proprietary databases
- Relevant patent and regulatory databases
- National government documents, statistical databases and market reports
- Procedure registries
- News articles, press releases and web-casts specific to the companies operating in the market.

The country reports are largely based on secondary research and make use of reliable and authoritative sources such as the IMF, The World Bank, OECD, WHO, UNICEF, UN Stats, MHLW, NHS, and BEA, among others.

7.3.3 Forecasting

For the country reports, GlobalData uses the data available from reliable and authoritative secondary sources to forecast the future trends for the healthcare market for the country, as well as the parameters related to the economy and healthcare infrastructure and expenditure of the country. The trends are further validated through the secondary sources.

7.3.4 Primary Research

GlobalData conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape and future outlook of a market.
- It helps in validating and strengthening secondary research findings.
- It develops the analysis team's expertise and market understanding.

Primary research involves email correspondence and telephone interviews as well as face-to-face interviews for each market, category, segment and sub-segment across the geographies covered.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: Chief Executive Officers (CEOs), Vice Presidents (VPs), marketing/product managers, market intelligence managers and national sales managers.
- Hospital stores, pharmacies, distributors and paramedics.
- Outside experts: investment bankers, valuation experts, research analysts specializing in specific pharmaceutical markets.
- Key Opinion Leaders (KOLs): Physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of pharmaceuticals.

7.3.5 Expert Panel Validation

GlobalData uses a panel of experts to cross verify its databases and forecasts.

GlobalData's expert panel comprises marketing managers, product specialists, international sales managers from pharmaceutical companies; academics from research universities, KOLs from hospitals, consultants from venture capital funds, and distributors/suppliers of pharmaceuticals and supplies.

Historic data and forecasts are relayed to GlobalData's expert panel for feedback and adjusted in accordance with their feedback.

7.5 Disclaimer

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