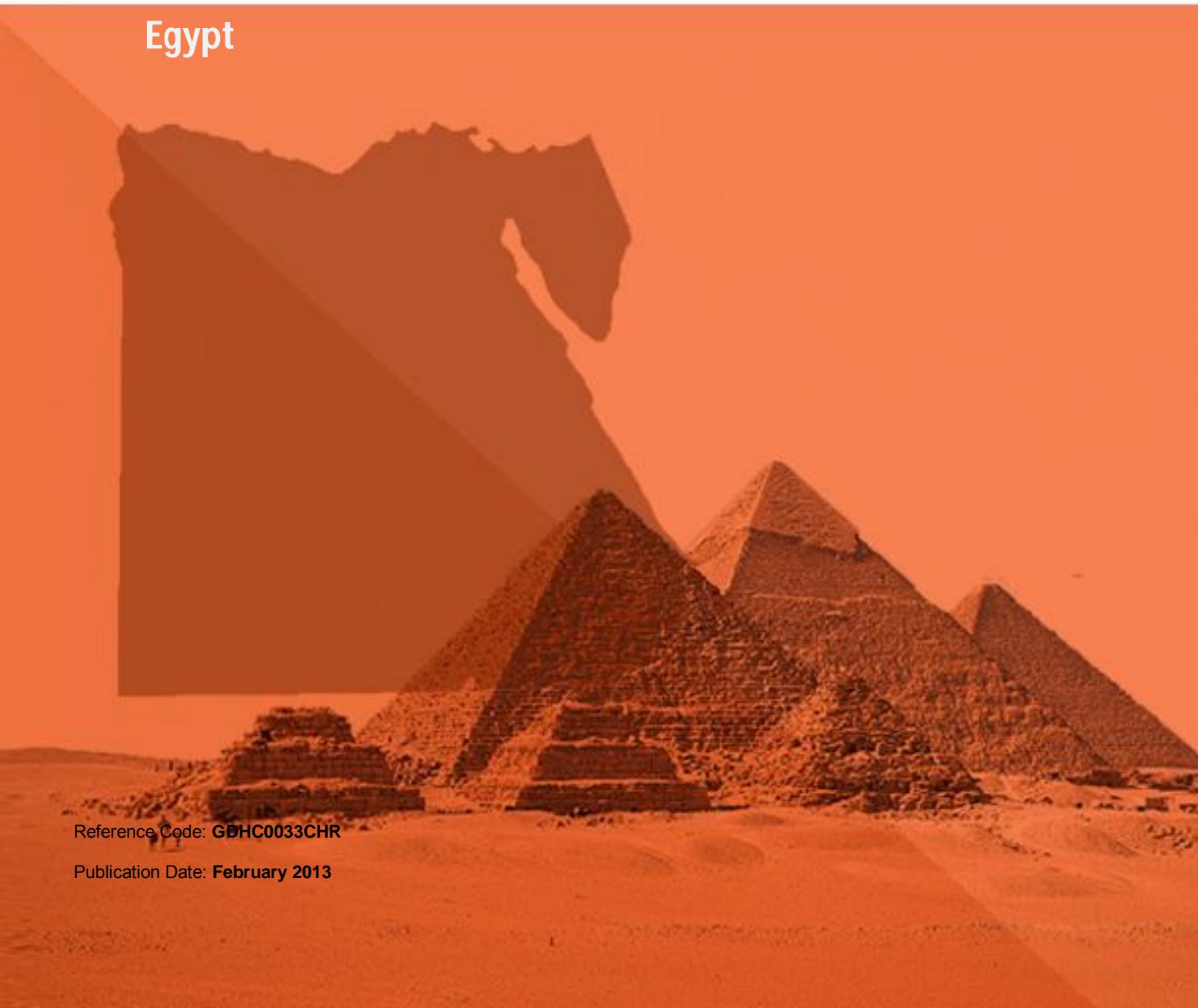




# Healthcare, Regulatory and Reimbursement Landscape

## Egypt

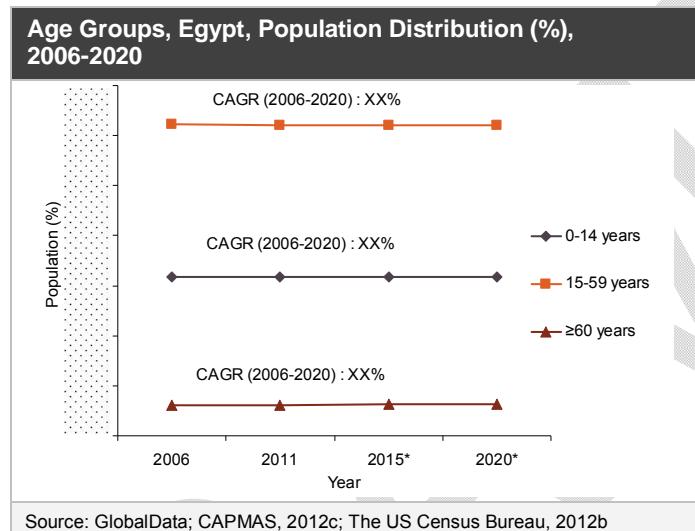


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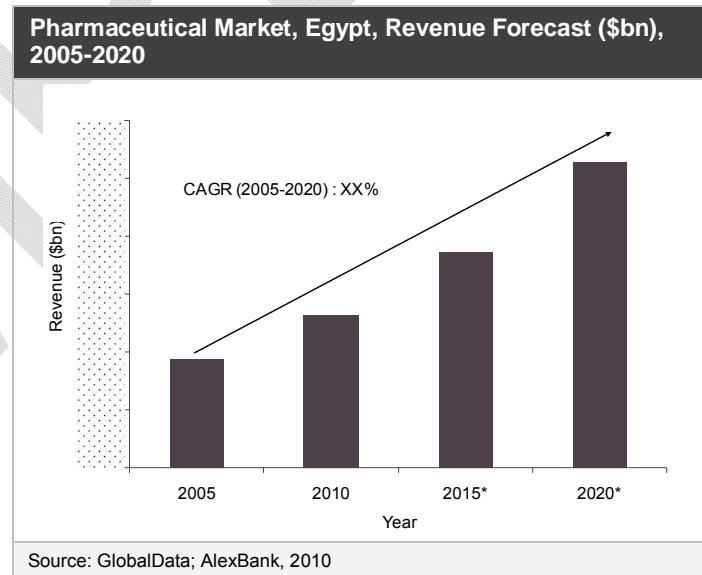
**Sociopolitical transition and instability is preventing the efficient utilization of the available human resource pool in Egypt; the negative affect on economic growth has led to a high unemployment rate**

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.



**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.



## 1 Table of Contents

1	Table of Contents .....	5
1.1	List of Tables.....	7
1.2	List of Figures.....	9
2	Introduction .....	11
2.1	Report Guidance .....	11
3	Overview of the Pharmaceutical and Medical Device Market.....	12
3.1	Pharmaceutical Market .....	12
3.1.1	Market Overview.....	12
3.1.2	Supply Channels .....	15
3.1.3	Market Segments .....	16
3.1.4	Major Therapeutic Areas .....	20
3.1.5	Major Players .....	22
3.2	Medical Device Market .....	43
3.2.1	Market Overview.....	43
3.2.2	Overview of Top Five Segments.....	45
3.2.3	Major Players .....	56
3.3	Market Drivers and Barriers .....	74
3.3.1	Drivers .....	74
3.3.2	Barriers .....	74
4	Market Access.....	76
4.1	Reimbursement and Payer Landscape.....	76
4.1.1	Overview of Healthcare System .....	76
4.1.2	Reimbursement Process.....	77
4.1.3	Overview of Insurance Providers.....	78
4.1.4	Patient Share of Healthcare Spending .....	82
4.1.5	Drug Price Trends.....	83
4.1.6	Pricing Policies .....	84
4.2	Regulatory Landscape.....	85
4.2.1	Overview of Regulatory Agencies.....	85
4.2.2	Drug Approval Procedure for Pharmaceutical Products .....	86
4.2.3	New Medical Device Approval Process.....	89
4.2.4	Licensing Process for Pharmaceutical Manufacturing.....	91
4.2.5	Licensing Process for Pharmaceutical Exports and Imports .....	92
4.2.6	Intellectual Property Rights .....	92
4.2.7	Clinical Trial Regulations.....	95
4.2.8	Pharmaceutical Advertising Regulations.....	95
4.2.9	Pharmacy Regulations.....	97
4.2.10	Labeling and Packaging Regulations .....	98
5	Country Analysis.....	99
5.1	Political Environment .....	99
5.1.1	Political Structure.....	99
5.1.2	Analysis of the Current Political Environment .....	99
5.1.3	Healthcare Policy Initiatives .....	100
5.2	Economic Landscape .....	101
5.3	Economic Indicators .....	103
5.3.1	Gross Domestic Product .....	103
5.3.2	Gross National Income.....	106
5.3.3	Inflation .....	107
5.3.4	Currency Exchange Rate .....	110
5.3.5	Foreign Direct Investment .....	111
5.3.6	Foreign Exchange Reserves .....	112
5.3.7	Trade Balance .....	113
5.3.8	Gross Fiscal Deficit.....	115
5.3.9	Gross Domestic Debt.....	116
5.3.10	Government Structural Balance.....	117
5.3.11	Major Industries .....	118
5.4	Demographics.....	119
5.4.1	Population .....	119
5.4.2	Education and Literacy.....	135

5.4.3	Employment .....	137
5.4.4	Disease Burden .....	138
5.5	Healthcare Infrastructure .....	140
5.5.1	Healthcare Facilities .....	140
5.5.2	Healthcare Parameters .....	144
5.5.3	Environmental Health.....	146
5.5.4	Healthcare Personnel .....	151
5.6	Healthcare Expenditure .....	153
5.6.1	Pharmaceutical Expenditure.....	154
5.6.2	Components of Healthcare Spending .....	155
5.6.3	Share of Public and Private Sectors .....	156
5.6.4	Spending in Pharmaceutical R&D.....	157
5.7	Trade Associations.....	158
5.7.1	Arab Union of Manufacturers of Pharmaceuticals and Medical Appliances.....	158
5.7.2	Federation of Egyptian Industries .....	158
5.7.3	Egyptian Pharmaceutical Students Federation .....	158
5.7.4	Insurance Federation of Egypt.....	158
5.8	Trade Fairs .....	159
6	Opportunities and Challenges .....	160
6.1	Opportunities.....	160
6.2	Challenges.....	160
7	Appendix .....	162
7.1	Abbreviations .....	162
7.2	Bibliography .....	163
7.3	Methodology .....	169
7.3.1	Coverage .....	170
7.3.2	Secondary Research .....	170
7.3.3	Forecasting .....	170
7.3.4	Primary Research.....	170
7.3.5	Expert Panel Validation.....	171
7.4	Contact Us .....	171
7.5	Disclaimer.....	171

## 1.1 List of Tables

Table 1: Pharmaceutical Market, Egypt, Revenue (\$bn), 2005-2010 .....	13
Table 2: Pharmaceutical Market, Egypt, Revenue Forecast (\$bn), 2011-2020 .....	14
Table 3: Distribution Channel, Egypt, Price Margins (%), 2012 .....	15
Table 4: Drugs Going Off-Patent, Global, Revenue (\$m), 2011-2015 .....	16
Table 5: Over-the-Counter Drugs Market, Egypt, Revenue (\$m), 2006-2011 .....	17
Table 6: Over-the-Counter Drug Use, Egypt, Segment Share (%), 2009 .....	18
Table 7: Major Therapeutic Areas, Egypt, Hospital Admissions ('000), 2011 .....	20
Table 8: Major Products, GlaxoSmithKline, Global, Revenue (\$m), 2011 .....	22
Table 9: Late-Stage Pipeline, GlaxoSmithKline, 2012 .....	23
Table 10: Major Products, Sanofi, Global, Revenue (\$m), 2011 .....	27
Table 11: Late-Stage Pipeline, Sanofi, 2012 .....	28
Table 12: Major Products, Novartis, Global, Revenue (\$m), 2011 .....	31
Table 13: Planned Filings, Novartis, 2012 to ≥ 2016 .....	32
Table 14: Major Products, EIPICO, 2012 .....	37
Table 15: Major Products, SEDICO, 2012 .....	40
Table 16: Medical Device Market, Egypt, Revenue (\$bn), 2006-2011 .....	43
Table 17: Medical Device Market, Egypt, Revenue Forecast (\$bn), 2012-2020 .....	44
Table 18: Medical Device Market, Egypt, Revenue by Segment, (\$m), 2011 .....	45
Table 19: Nephrology and Urology Devices Market, Egypt, Revenue (\$m), 2006-2011 .....	46
Table 20: Nephrology and Urology Devices Market, Egypt, Sales Trend for Major Players*, 2011 .....	47
Table 21: In Vitro Diagnostics Market, Egypt, Revenue (\$m), 2006-2011 .....	48
Table 22: In Vitro Diagnostic Devices, Egypt, Sales Trend for Major Players*, 2010 .....	49
Table 23: Diabetes Care Devices Market, Egypt, Revenue (\$m), 2006-2011 .....	50
Table 24: Diabetes Care Devices Market, Egypt, Sales Trend for Major Players*, 2011 .....	51
Table 25: Drug Delivery Devices Market, Egypt, Revenue (\$m), 2006-2011 .....	52
Table 26: Drug Delivery Devices Market, Egypt, Sales Trend for Major Players*, 2010 .....	53
Table 27: Cardiovascular Devices Market, Egypt, Revenue (\$m), 2006-2011 .....	54
Table 28: Cardiovascular Devices Sales Trend for Major Players*, Egypt, 2011 .....	55
Table 29: Major Medical Device Companies, Egypt, Revenue (\$m), 2010 .....	56
Table 30: Major Products, Roche, Global, Revenue (\$m), 2010 .....	57
Table 31: Late-Stage Pipeline, Roche, 2012 .....	58
Table 32: Major Product Segments, Fresenius Medical, Global, Revenue (\$m), 2011 .....	61
Table 33: Major Products, Gambro, 2012 .....	65
Table 34: Major Product Division, B. Braun, Global, Revenue (\$m), 2011 .....	69
Table 35: Major Products, GlaxoSmithKline, Global, Revenue (\$m), 2010 .....	72
Table 36: HIO Beneficiaries, Egypt, Premium Rates (%) 2012 .....	78
Table 37: HIO Beneficiaries, Egypt, Share (%), 2010 .....	79
Table 38: Sources of HIO Healthcare Spending, Egypt, Share (%), 2009 .....	80
Table 39: HIO Expenditure by Provider, Egypt, Share (%), 2009 .....	81
Table 40: Healthcare Spending, Egypt, Patient Share (%), 2005-2010 .....	82
Table 41: Inflation, Healthcare, Egypt, Annual Growth (%), 2006-2011 .....	83
Table 42: Medical Device Registration Fee (\$), Egypt, 2012 .....	89
Table 43: Patent Examination Fee by Type of Applicant (EPG, \$), Egypt, 2012 .....	93
Table 44: Patent and Utility Models Fees (EPG, \$), Egypt, 2012 .....	93
Table 45: GDP Per Capita (\$), Egypt, 2006-2011 .....	103
Table 46: GDP Per Capita (\$), Egypt, Forecast, 2012-2020 .....	104
Table 47: GDP, Egypt, Annual Growth (%), 2006-2011 .....	105
Table 48: GNI Per Capita (\$), Egypt, 2006-2011 .....	106
Table 49: Average Consumer Price Index, Egypt, 2006-2011 .....	107
Table 50: Average Consumer Price, Egypt, Annual Change (%), 2006-2011 .....	108
Table 51: Average Consumer Price, Egypt, Annual Change (%), Forecast, 2012-2020 .....	109
Table 52: Currency Exchange Rate (EGP/\$), Egypt, 2006-2011 .....	110
Table 53: Foreign Direct Investment (\$bn), Egypt, 2006-2011 .....	111
Table 54: Foreign Exchange Reserves (\$bn), Egypt, 2006-2011 .....	112
Table 55: Imports (\$bn), Egypt, 2006-2011 .....	113
Table 56: Exports (\$bn), Egypt, 2006-2011 .....	114
Table 57: Gross Fiscal Deficits (% of GDP), Egypt, 2006-2011 .....	115
Table 58: Gross Domestic Debt (\$bn), Egypt, 2006-2011 .....	116
Table 59: General Government Structural Balance (\$bn), Egypt, 2006-2011 .....	117
Table 60: Major Industries, Egypt, GDP (\$bn), 2011 .....	118
Table 61: Population (m), Egypt, 2006-2011 .....	119
Table 62: Population (m), Egypt, Forecast, 2012-2020 .....	120

Table 63: Urban and Rural Population, Egypt, Share (%), 2006-2011 .....	121
Table 64: Urban and Rural Population, Egypt, Share (%), Forecast, 2012-2020.....	122
Table 65: Age Groups, Egypt, Population Distribution (%), 2006-2011 .....	123
Table 66: Age Groups, Egypt, Population Distribution (%), Forecast, 2012-2020.....	124
Table 67: Births (Per 1,000 Population), Egypt, 2006-2011.....	125
Table 68: Mortality (Per 1,000 Population), Egypt, 2006-2011.....	126
Table 69: Major Causes of Mortality (%), Egypt, 2010 .....	127
Table 70: Children <5 Years, Egypt, Mortality Rate (Per 1,000 Live Births), 2006-2011 .....	128
Table 71: Immunization Rate (%), Egypt, 2005-2010.....	129
Table 72: Major Causes of Male Mortality (%), Egypt, 2010 .....	130
Table 73: Major Causes of Female Mortality (%), Egypt, 2010 .....	131
Table 74: Gender Ratio (Females Per 1,000 Males), Egypt, 2006-2011 .....	132
Table 75: Life Expectancy at Birth (Years), Egypt, 2006-2011.....	133
Table 76: Life Expectancy at Birth (Years), Egypt, Forecast, 2012-2020 .....	134
Table 77: Levels of Education, Egypt, Students Enrollment ('000), 2011 .....	135
Table 78: Higher Education, Egypt, Students Enrollment (%), 2011 .....	136
Table 79: Unemployment Rate (%), Egypt, 2006-2011 .....	137
Table 80: Hospital Admissions by Specialty ('000), Egypt, 2011.....	138
Table 81: Major Diseases, Egypt, DALYs (Per 100,000 Population), 2004 .....	139
Table 82: Public Hospitals, Egypt, 2006-2011 .....	140
Table 83: Hospitals by Specialty, Egypt, 2011.....	141
Table 84: Health Centers, Egypt, 2006-2011.....	142
Table 85: Public-Private Hospital Beds ('000), Egypt, 2006-2011.....	143
Table 86: Hospital Beds (Per 1,000 Population), Egypt, 2005-2010 .....	144
Table 87: Physicians (Per 10,000 Population), Egypt, 2006-2011 .....	145
Table 88: CO <sub>2</sub> Emissions (Million Tons), Egypt, 2005-2010 .....	146
Table 89: PM-10 Emissions (µgm/cubic meter), Egypt, 2005-2010 .....	147
Table 90: Biochemical Oxygen Demand (mg/l), Egypt, 2005-2010 .....	148
Table 91: Sources of Solid Waste, Share (%), Egypt, 2009.....	149
Table 92: Waste Handling, Egypt, Share (%), 2010.....	150
Table 93: Nurses (Per 10,000 Population), Egypt, 2006-2011.....	151
Table 94: Pharmacists (Per 10,000 Population), Egypt, 2006-2011.....	152
Table 95: Dentists (Per 10,000 Population), Egypt, 2006-2011 .....	152
Table 96: Healthcare Expenditure (% of GDP), Egypt, 2005-2010 .....	153
Table 97: Pharmaceutical Expenditure (% of Total Healthcare Expenditure), Egypt, 2005-2010.....	154
Table 98: Healthcare Expenditure, Egypt, Share of Major Components (%), 2009.....	155
Table 99: Healthcare Expenditure, Egypt, Share (%), 2005-2010.....	156
Table 100: Source of Healthcare Expenditure, Egypt, Share (%), 2009.....	157
Table 101: Major Healthcare Trade Fairs, Egypt, 2012.....	159

## 1.2 List of Figures

Figure 1: Pharmaceutical Market, Egypt, Revenue (\$bn), 2005-2010 .....	13
Figure 2: Pharmaceutical Market, Egypt, Revenue Forecast (\$bn), 2011-2020 .....	14
Figure 3: Distribution Channels, Egypt, 2012 .....	15
Figure 4: Over-the-Counter Drugs Market, Egypt, Revenue (\$m), 2006-2011 .....	17
Figure 5: Over-the-Counter Drug Use, Egypt, Segment Share (%), 2009 .....	18
Figure 6: Major Therapeutic Areas, Egypt, Hospital Admissions ('000), 2011 .....	20
Figure 7: Medical Device Market, Egypt, Revenue (\$bn), 2006-2011 .....	43
Figure 8: Medical Device Market, Egypt, Revenue Forecast (\$bn), 2012-2020 .....	44
Figure 9: Medical Device Market, Egypt, Revenue by Segment (\$m), 2011 .....	45
Figure 10: Nephrology and Urology Devices Market, Egypt, Revenue (\$m), 2006-2011 .....	46
Figure 11: Nephrology and Urology Devices Market, Egypt, Sales Trend for Major Players*, 2006-2011 .....	47
Figure 12: In Vitro Diagnostics Market, Egypt, Revenue (\$m), 2006-2011 .....	48
Figure 13: In Vitro Diagnostic Devices Market, Egypt, Sales Trend for Major Players*, 2006-2010 .....	49
Figure 14: Diabetes Care Devices Market, Egypt, Revenue (\$m), 2006-2011 .....	50
Figure 15: Diabetes Care Devices Market, Egypt, Sales Trend for Major Players*, 2006-2011 .....	51
Figure 16: Drug Delivery Devices Market, Egypt, Revenue (\$m), 2006-2011 .....	52
Figure 17: Drug Delivery Devices Market, Egypt, Sales Trend for Major Players*, 2006-2010 .....	53
Figure 18: Cardiovascular Devices Market, Egypt, Revenue (\$m), 2006-2011 .....	54
Figure 19: Cardiovascular Devices Market, Egypt, Sales Trend for Major Players*, 2006-2011 .....	55
Figure 20: Major Medical Device Companies, Egypt, Revenue (\$m), 2010 .....	56
Figure 21: Healthcare Market, Egypt, Drivers and Barriers, 2012 .....	75
Figure 22: Key Influencers in Decision-Making Process in Healthcare System, Egypt, 2012 .....	76
Figure 23: Public Insurance Reform Milestones, Egypt, 1964-2012 .....	78
Figure 24: HIO Beneficiaries, Egypt, Share (%), 2010 .....	79
Figure 25: Source of HIO Healthcare Spending, Egypt, Share (%), 2009 .....	80
Figure 26: HIO Expenditure by Provider, Egypt, Share (%), 2009 .....	81
Figure 27: Healthcare Spending, Egypt, Patient Share (%), 2005-2010 .....	82
Figure 28: Inflation, Healthcare, Egypt, Annual Growth (%), 2006-2011 .....	83
Figure 29: Structure of the Drug Regulatory Authority, Egypt, 2012 .....	85
Figure 30: Overview of General Drug Application Process, Egypt, 2012 .....	87
Figure 31: Application Process for Local New Drug, Egypt, 2012 .....	87
Figure 32: Application Process for Imported Generic and New Drugs, Egypt, 2012 .....	88
Figure 33: Application Process for Local Generic Drugs, Egypt, 2012 .....	88
Figure 34: Medical Device Registration Process, Egypt, 2012 .....	90
Figure 35: Licensing Process for Manufacturing Site, Egypt, 2012 .....	91
Figure 36: Licensing Process for New Production Line, Egypt, 2012 .....	91
Figure 37: Patent Registration Process, Egypt, 2012 .....	94
Figure 38: Advertisement Registration Process, Egypt, 2012 .....	96
Figure 39: Pharmacy Establishment Process, Egypt, 2012 .....	97
Figure 40: GDP Per Capita (\$), Egypt, 2006-2011 .....	103
Figure 41: GDP Per Capita (\$), Egypt, Forecast, 2012-2020 .....	104
Figure 42: GDP, Egypt, Annual Growth (%), 2006-2011 .....	105
Figure 43: GNI Per Capita (\$), Egypt, 2006-2011 .....	106
Figure 44: Average Consumer Price Index, Egypt, 2006-2011 .....	107
Figure 45: Average Consumer Price, Egypt, Annual Change (%), 2006-2011 .....	108
Figure 46: Average Consumer Price, Egypt, Annual Change (%), Forecast, 2012-2020 .....	109
Figure 47: Currency Exchange Rate (EGP/\$), Egypt, 2006-2011 .....	110
Figure 48: Foreign Direct Investment (\$bn), Egypt, 2006-2011 .....	111
Figure 49: Foreign Exchange Reserves (\$bn), Egypt, 2006-2011 .....	112
Figure 50: Imports (\$bn), Egypt, 2006-2011 .....	113
Figure 51: Exports (\$bn), Egypt, 2006-2011 .....	114
Figure 52: Gross Fiscal Deficits (% of GDP), Egypt, 2006-2011 .....	115
Figure 53: Gross Domestic Debt (\$bn), Egypt, 2006-2011 .....	116
Figure 54: General Government Structural Balance (\$bn), Egypt, 2006-2011 .....	117
Figure 55: Major Industries, Egypt, GDP (\$bn), 2011 .....	118
Figure 56: Population (m), Egypt, 2006-2011 .....	119
Figure 57: Population (m), Egypt, Forecast, 2012-2020 .....	120
Figure 58: Urban and Rural Population, Egypt, Share (%), 2006-2011 .....	121
Figure 59: Urban and Rural Population, Egypt, Share (%), Forecast, 2012-2020 .....	122
Figure 60: Age Groups, Egypt, Population Distribution (%), 2006-2011 .....	123
Figure 61: Age Groups, Egypt, Population Distribution (%), Forecast, 2012-2020 .....	124

Figure 62: Births (Per 1,000 Population), Egypt, 2006-2011.....	125
Figure 63: Mortality (Per 1,000 Population), Egypt, 2006-2011.....	126
Figure 64: Major Causes of Mortality (%), Egypt, 2010 .....	127
Figure 65: Children <5 Years, Egypt, Mortality Rate (Per 1,000 Live Births), 2006-2011 .....	128
Figure 66: Immunization Rate (%), Egypt, 2005-2010.....	129
Figure 67: Major Causes of Male Mortality (%), Egypt, 2010 .....	130
Figure 68: Major Causes of Female Mortality (%), Egypt, 2010 .....	131
Figure 69: Gender Ratio (Females Per 1,000 Males), Egypt, 2006-2011 .....	132
Figure 70: Life Expectancy at Birth (Years), Egypt, 2006-2011.....	133
Figure 71: Life Expectancy at Birth (Years), Egypt, Forecast, 2012-2020 .....	134
Figure 72: Levels of Education, Egypt, Student Enrollment ('000), 2011.....	135
Figure 73: Higher Education, Egypt, Student Enrollment (%), 2011 .....	136
Figure 74: Unemployment Rate (%), Egypt, 2006-2011 .....	137
Figure 75: Hospital Admissions by Specialty ('000), Egypt, 2011.....	138
Figure 76: Major Diseases, Egypt, DALYs (Per 100,000 Population), 2004 .....	139
Figure 77: Public Hospitals, Egypt, 2006-2011 .....	140
Figure 78: Hospitals by Specialty, Egypt, 2011.....	141
Figure 79: Health Centers, Egypt, 2006-2011.....	142
Figure 80: Public-Private Hospital Beds ('000), Egypt, 2006-2011.....	143
Figure 81: Hospital Beds (Per 1,000 Population), Egypt, 2005-2010 .....	144
Figure 82: Physicians (Per 10,000 Population), Egypt, 2006-2011 .....	145
Figure 83: CO <sub>2</sub> Emissions (Million Tons), Egypt, 2005-2010 .....	146
Figure 84: PM-10 Emissions (µgm/cubic meter), Egypt, 2005-2010 .....	147
Figure 85: Biochemical Oxygen Demand (mg/l), Egypt, 2005-2010 .....	148
Figure 86: Sources of Solid Waste, Share (%), Egypt, 2009.....	149
Figure 87: Waste Handling, Egypt, Share (%), 2010 .....	150
Figure 88: Nurses (Per 10,000 Population), Egypt, 2006-2011.....	151
Figure 89: Pharmacists (Per 10,000 Population), Egypt, 2006-2011.....	152
Figure 90: Dentists (Per 10,000 Population), Egypt, 2006-2011 .....	152
Figure 91: Healthcare Expenditure (% of GDP), Egypt, 2005-2010 .....	153
Figure 92: Pharmaceutical Expenditure (% of Total Healthcare Expenditure), Egypt, 2005-2010.....	154
Figure 93: Healthcare Expenditure, Egypt, Share of Major Components (%), 2009 .....	155
Figure 94: Healthcare Expenditure, Egypt, Share (%), 2005-2010.....	156
Figure 95: Source of Healthcare Expenditure, Egypt, Share (%), 2009.....	157
Figure 96: Opportunities and Challenges, Healthcare Market, Egypt, 2012.....	161

## 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

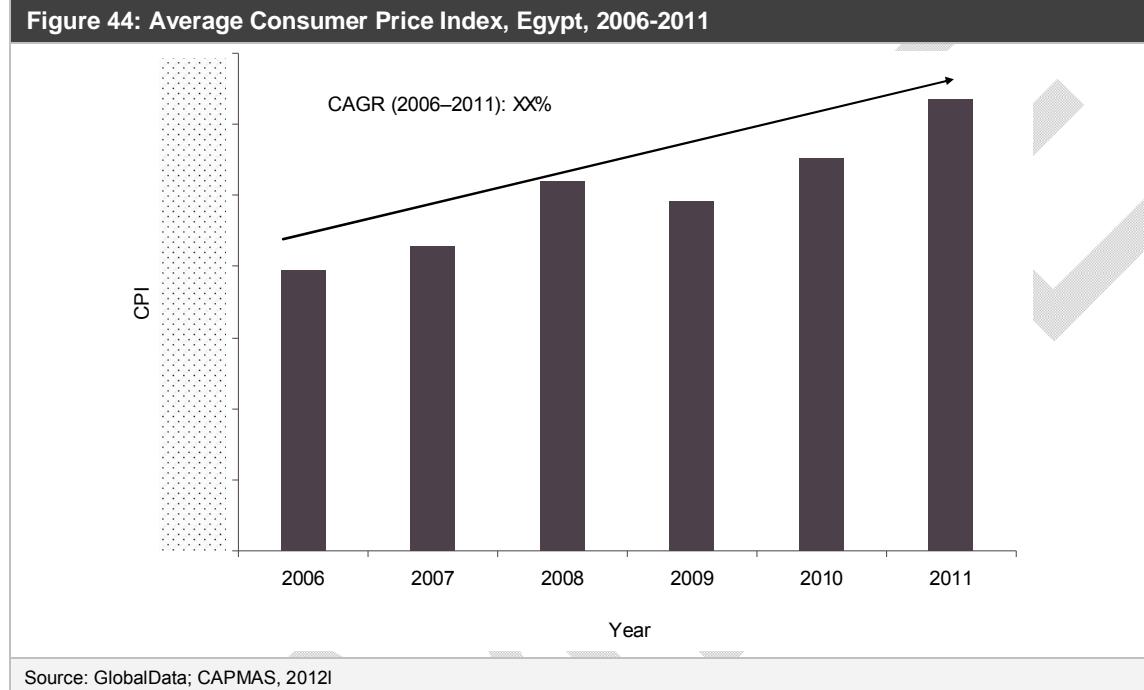


Table 49: Average Consumer Price Index, Egypt, 2006-2011

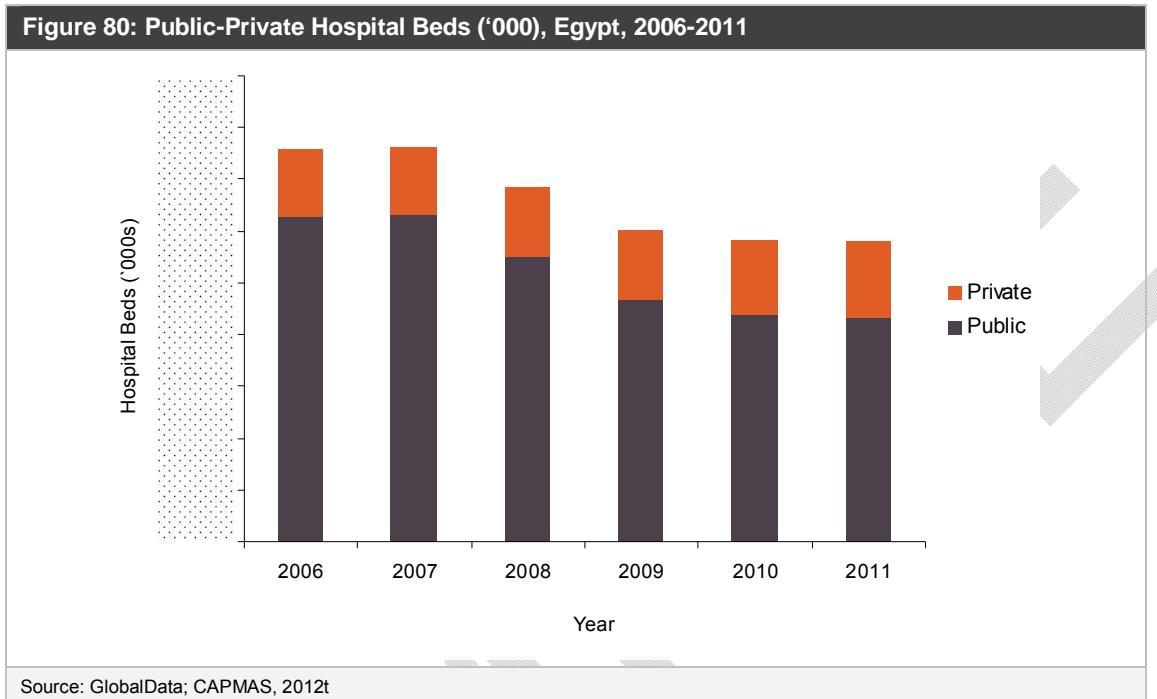
Year	2006	2007	2008	2009	2010	2011
CPI	XX	XX	XX	XX	XX	XX

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**



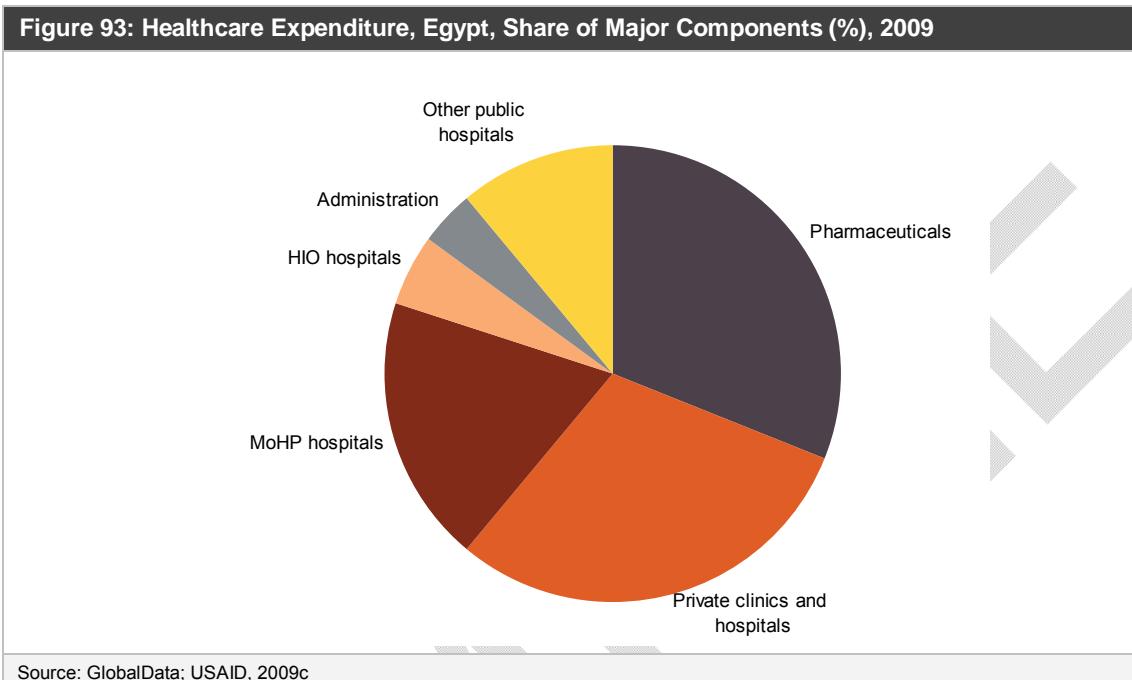
**Table 85: Public-Private Hospital Beds ('000), Egypt, 2006-2011**

Year	2006	2007	2008	2009	2010	2011
<b>Public</b>	XX	XX	XX	XX	XX	XX
<b>Private</b>	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.



**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](http://www.mrs.org.uk)) and the Strategic and Competitive Intelligence Professionals ([www.scip.org](http://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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