Fitch Solutions

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Egypt

Pharmaceuticals & Healthcare Report

Includes 10-year forecasts to 2027

Contents

Key View

Key View: *The proposal for a new drug authority in Egypt will improve the medicine regulatory environment. Risks in the form of delays to implementation and macroeconomic challenges will persist. Pharmaceutical market growth remains on a robust trajectory, outperforming the MENA average.*

Headline Expenditure Projections

- **Pharmaceuticals:** EGP38.3bn (USD2.1bn) in 2017 to EGP41.3bn (USD2.3bn) in 2018; +7.9% in local currency terms and +9.1% in US dollar terms. *Forecast unchanged this quarter.*
- **Healthcare:** EGP134.5bn (USD7.5bn) in 2017 to EGP147.1n (USD8.3bn) in 2018; +9.4% in local currency terms and +10.7% in US dollar terms. *Forecast unchanged this quarter.*

HEADLINE PHARMACEUTICALS & HEALTHCARE FORECASTS (EGYPT 2016-2022)

Indicator	2016	2017	2018f	2019f	2020f	2021f	2022f
Pharmaceutical sales, USDbn	3.538	2.148	2.344	2.523	2.653	2.787	2.939
Pharmaceutical sales, % of GDP	1.31	1.13	0.98	0.89	0.83	0.78	0.75
Pharmaceutical sales, % of health expenditure	28.9	28.5	28.1	27.7	27.3	27.0	26.6
Health spending, USDbn	12.245	7.537	8.343	9.105	9.709	10.339	11.052

f = Fitch Solutions forecast. Source: WHO, National Sources, Fitch Solutions

Latest Updates

- In October 2018, proposals to build a Kazakhstan-Egypt Pharmaceutical Park in Almaty were put forward at the Kazakh Ministry of Foreign Affairs.
- In August 2018, the Egyptian Parliament prioritised a draft law published by the Ministry of Health on a new Egyptian Drug Authority.
- In July 2018, the World Bank announced plans to invest EGP9.5bn (USD530mn) towards Egypt's healthcare system as part of the country's health reform package, which aims to upgrade 600 primary health facilities and 27 hospitals.

Risk/Reward Index

Egypt will remain a highly challenging pharmaceutical market for innovative drugmakers, with low per capita medicine expenditure and persistent market access barriers resulting in a score of 38.6 out of 100 in Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index. Increasing political will to develop the healthcare sector poses some upside risk for market entry opportunities, with restrictive market access barriers presenting a major impediment to innovative drugmakers.

Key Economic View

Real GDP growth is set to accelerate in Egypt as exports and investment pick up - boosted by the country's fast-expanding gas sector. Non-hydrocarbon investment and consumption will recover more gradually, as inflation and interest rates remain relatively elevated, keeping Egyptian households and businesses under pressure.

Key Political View

Egyptian President Abdel Fattah el-Sisi may move to extend or abolish presidential term limits in the next few years. Our core view

would be for this process to pass with limited public opposition - although if matched against a backdrop of still-dire economic conditions, widespread protests could not be ruled out.

SWOT

SWOT Analysis	
Strengths	• Well-established manufacturing industry comprised of both state-owned and privately-owned local companies. • Low labour costs and a large pool of highly trained doctors, pharmacists, engineers and skilled technicians.
Weaknesses	• Strict pricing controls and reference pricing system reduces innovative drugmaker potential earnings. • Challenging regulatory regime for foreign firms. Patent laws remain notably below international standards, with data protection and enforcement being major concerns.
Opportunities	• A new proposal for advancing public health in Egypt, with a focus on healthcare insurance. • A growing number of free trade agreements and increasing political will to develop the healthcare sector. • Proposals for a new Egyptian Drug Authority.
Threats	• Elevated political and security risks will continue to discourage investment in the short-term at least. • Rapid and unchecked population growth could derail government's plans to improve healthcare insurance and provision.

Industry Forecast

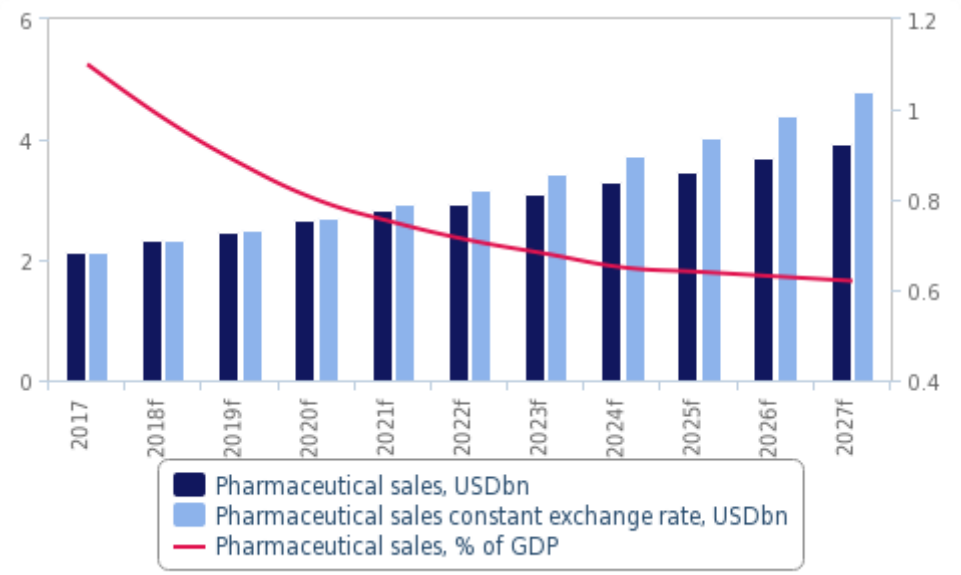
Pharmaceutical Market Forecast

Key View: *Egypt's medicine supply remains precarious, with conflicting interests between local stakeholders firmly in place. The proposal for a new drug authority in Egypt will improve the medicine regulatory environment. Egypt's long-term story is more positive, and the country will benefit from a number of key pharmaceutical market drivers, supporting a greater multinational presence.*

Latest Updates

- In October 2018, proposals to build a Kazakhstan-Egypt Pharmaceutical Park in Almaty were put forward at the Kazakh Ministry of Foreign Affairs.
- In August 2018, the Egyptian Parliament prioritised a draft law published by the MoH on a new Egyptian Drug Authority (EDA).

Pharmaceutical Market Forecast
(2017-2027)



f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, local news sources, domestic companies, Fitch Solutions

Structural Trends

Egypt's pharmaceutical sales are forecast to grow from EGP38.3bn (USD2.1bn) in 2017 to EGP56.6bn (USD2.9bn) by 2022 with a CAGR of 8.1% in local currency terms and 6.5% in US dollar terms. Annual rates of growth are expected to remain similar over the second half of the 10-year forecast period with sales amounting to EGP85.5bn (USD3.9bn) by 2027.

The introduction of a new drug authority bodes well for pharmaceutical market growth. In August 2018, the Egyptian Parliament prioritised a draft law published by the MoH on a new EDA. Speaking at the CPhI Middle Exhibition Centre (ADNEC) in Abu Dhabi in September 2018, Sedico Pharmaceuticals' Chairman & Managing Director Dr Awad Gabr announced that 'the reformed EDA will be inaugurated in the coming weeks; making up part of a strategic decision by the MoH to further expedite the growth of Egypt's pharmaceutical market. The jurisdiction of the new body will increase the number of product registrations and further enhance pharmaceutical exports'. Moreover, Member of Parliament Abdel Aziz Hamouda highlighted the importance of reforming the EDA to

achieve medicine sustainability.

Egypt's evolving disease profile mirrors Western trends. One of the key drivers behind Egypt's pharmaceutical market growth is the rapidly growing chronic disease burden that has accompanied the ageing and fast-growing population. The emergence of respiratory illness, heart disease and cardiovascular diseases in particular are driving the growth of higher value prescription medicines in Egypt. Epidemiological studies by the WHO suggest that non-communicable diseases are the main causes of morbidity and mortality in Egypt. The health issues associated with young people are increasingly mirroring those in more developed countries, such as the prevalence of mental health disorders. According to our Disease Database, there will be a notable increase in the number of disability-adjusted life years (DALYs) for chronic diseases in Egypt from 2017 to 2030, such as for chronic respiratory diseases (+58%), cancers (+47), ischemic heart disease (+23%), musculoskeletal disorders (+46%), mental and behavioural disorders (+47%) and cardiovascular diseases (+20%). The aforementioned diseases pose the heaviest burden on Egypt's population as measured by DALYs lost. There are signs that the situation for domestic drugmakers in Egypt is improving. In July 2017, Egypt's Export Council of Medical Industries (ECMI) announced the establishment of EGYCOPP Company, which will serve as a launching base for Egyptian pharmaceutical products into Africa. The company will work alongside Egyptian pharmaceutical firms and local African drugmakers to form contract manufacturing agreements as to save on transportation costs and opaque registration laws. The ECMI is targeting a 3% annual increase of Egyptian pharmaceutical goods by 2030.

PHARMACEUTICAL SALES, HISTORICAL DATA AND FORECASTS (EGYPT 2017-2022)

Indicator	2017	2018f	2019f	2020f	2021f	2022f
Pharmaceutical sales, USDbn	2.148	2.344	2.479	2.675	2.820	2.939
Pharmaceutical sales, USDbn, % y-o-y	-39.28	9.14	5.74	7.92	5.42	4.22
Pharmaceutical sales, EGPbn	38.335	41.348	44.658	48.289	52.247	56.582
Pharmaceutical sales, EGPbn, % y-o-y	7.73	7.86	8.00	8.13	8.20	8.30
Pharmaceutical sales constant exchange rate, USDbn	2.148	2.317	2.502	2.706	2.928	3.170
Pharmaceutical sales, USD per capita	22.0	23.6	24.5	26.0	26.9	27.6
Pharmaceutical sales, % of GDP	1.10	0.98	0.88	0.80	0.75	0.71
Pharmaceutical sales, % of health expenditure	28.5	28.1	27.7	27.3	27.0	26.6

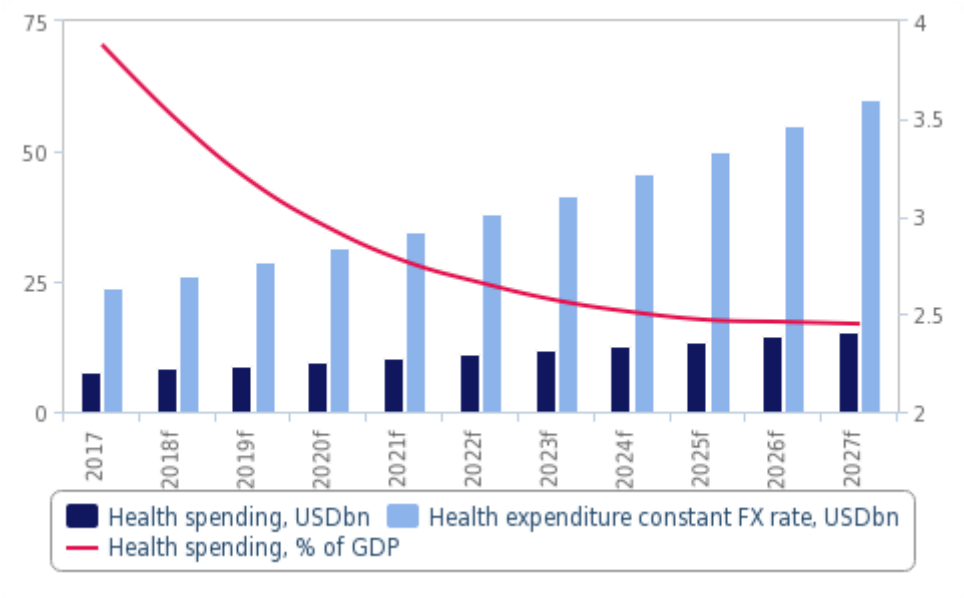
f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, local news sources, domestic companies, Fitch Solutions

Healthcare Market Forecast

Key View: *The governments efforts to further develop Egypt's healthcare sector is increasing. Legislative changes and financial backing from the World Bank will boost the success of the country's healthcare reform project. However, healthcare reforms pose upside risks for drugmaker opportunities.*

- In July 2018, the World Bank announced plans to invest EGP9.5bn (USD530mn) towards Egypt's healthcare system as part of the country's health reform package, which aims to upgrade 600 primary health facilities and 27 hospitals.
- On July 8 2018, Egypt implemented the first phase of its new health insurance law, which was rolled out in one of the Canal Zone governorates of Egypt, Port Said Governorate.

Healthcare Expenditure Forecast
(2017-2027)



f = Fitch Solutions forecast. Source: World Health Organization (WHO), Fitch Solutions

Structural Trends

Healthcare spending accounted for 4.0% of GDP in 2017, reaching a value of EGP134.5bn (USD7.5bn), which was 9.2% higher than in 2016 in local currency terms, partly due to the continuation of elevated inflation levels. In US dollar terms, this value was -38.4% lower than in the previous year owing to the significant weakening of the Egyptian pound. We forecast the country's total healthcare spending to post a local currency CAGR of 9.6% through to 2022 (8.0% in US dollar terms) to reach EGP212.8bn (USD11.1bn). We forecast a similar growth rate over the next 10 years, at a local currency CAGR of 9.7% (7.5% in US dollar terms), with the market forecast to be valued at EGP337.6bn (USD15.5bn) in 2027.

Health spending per capita is forecast to reach USD104 by 2022 and USD135 by 2027, rising from USD77 in 2017, which is low compared with other countries in the Middle East. While this emphasises that public sector healthcare spending needs to increase beyond this point and at a faster rate than simple growth drivers such as population, we also note that it still indicates a high proportion of private healthcare spending. The recent decision to raise medicine prices including a small portion for chronic disease treatments, will benefit the population's access to much-needed medicines in short supply.

In July 2018, the World Bank announced plans to invest EGP9.5bn (USD530mn) towards Egypt's healthcare system as part of the country's health reform package. The investment will be staggered over the coming five years to 2022 and will be implemented via

the Egyptian Ministry of Health and Population (MoHP) (*See 'Healthcare Reforms Pose Upside Risks For Drugmaker Opportunities', 9 April 2018*). Key aims of the five-year project 'Transforming Egypt's Healthcare System' include:

- Scaling up Egypt's Hepatitis C programme to treat 1.5mn patients per annum.
- Screening 20mn adults against non-communicable diseases and risk factors.
- Introducing a new universal health insurance system.
- Improving the quality of care across 600 primary healthcare facilities and 27 hospitals, with new digital tools being introduced.

Egypt's new health insurance scheme is likely to face questions regarding feasibility and long-term financial sustainability, yet it highlights increasing political will in Egypt to develop the healthcare sector. Moreover, legislative changes aimed at expanding access to medical services for the population will bode well for Egypt's attractiveness to international pharmaceutical companies.

HEALTHCARE EXPENDITURE TRENDS, HISTORICAL DATA AND FORECASTS (EGYPT 2017-2022)

Indicator	2017	2018f	2019f	2020f	2021f	2022f
Health spending, USDbn	7.537	8.343	8.946	9.789	10.465	11.052
Health spending, USDbn, % y-o-y	-38.44	10.69	7.23	9.42	6.90	5.62
Health spending, EGPbn	134.515	147.144	161.167	176.699	193.858	212.759
Health spending, EGPbn, % y-o-y	9.22	9.39	9.53	9.64	9.71	9.75
Health expenditure constant FX rate, USDbn	23.956	26.206	28.703	31.469	34.525	37.891
Health spending, USD per capita	77.3	84.0	88.4	95.1	100.0	103.9
Health spending, % of GDP	3.88	3.49	3.17	2.94	2.77	2.66

f = Fitch Solutions forecast. Source: World Health Organization (WHO), Fitch Solutions

GOVERNMENT HEALTHCARE EXPENDITURE TRENDS, HISTORICAL DATA AND FORECASTS (EGYPT 2017-2022)

Indicator	2017	2018f	2019f	2020f	2021f	2022f
Govt. health spend, USDbn	2.281	2.528	2.714	2.976	3.191	3.382
Govt. health spend, USDbn, % y-o-y	-38.41	10.79	7.39	9.65	7.20	6.00
Govt. health spend, EGPbn	40.715	44.580	48.899	53.722	59.104	65.105
Govt. health spend, EGPbn, % y-o-y	9.28	9.49	9.69	9.86	10.02	10.15
Govt. health spend, % total health spend	30.27	30.30	30.34	30.40	30.49	30.60

f = Fitch Solutions forecast. Source: World Health Organization (WHO), Fitch Solutions

PRIVATE HEALTHCARE EXPENDITURE TRENDS, HISTORICAL DATA AND FORECASTS (EGYPT 2017-2022)

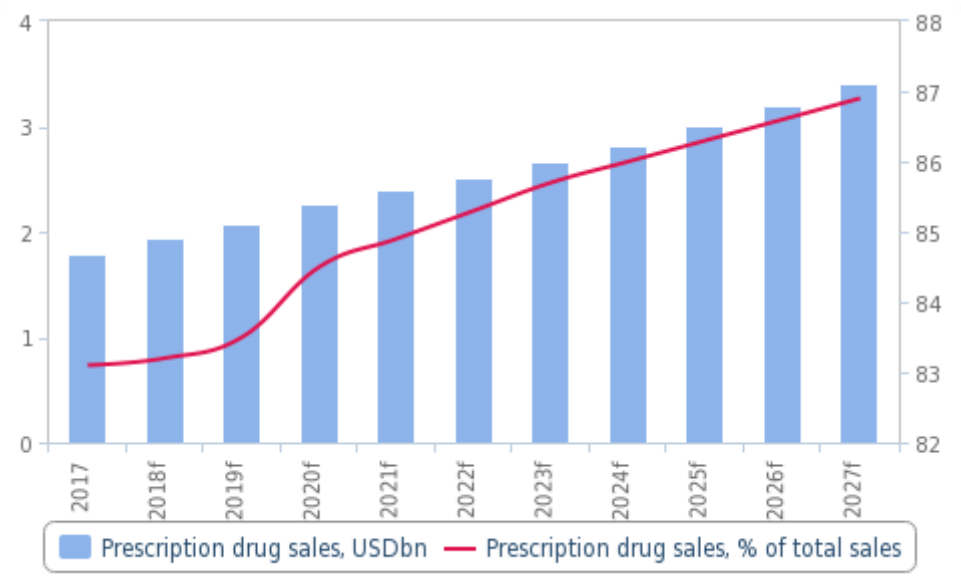
Indicator	2017	2018f	2019f	2020f	2021f	2022f
Private health spend, USDbn	5.256	5.815	6.232	6.813	7.274	7.670
Private health spend, USDbn, % y-o-y	-38.46	10.64	7.17	9.33	6.77	5.45
Private health spend, EGPbn	93.799	102.564	112.268	122.977	134.754	147.654
Private health spend, EGPbn, % y-o-y	9.19	9.34	9.46	9.54	9.58	9.57
Private health spend, % total health expenditure	69.73	69.70	69.66	69.60	69.51	69.40

f = Fitch Solutions forecast. Source: World Health Organization (WHO), Fitch Solutions

Prescription Drug Market Forecast

Key View: *Egypt's epidemiological profile, characterised by a high chronic disease burden, will drive prescription medicine expenditure over the coming years. Rapid population growth and a gradually ageing population represents potential for pharmaceutical firms to expand, with the emergence of diabetes, hypertension and cardiovascular diseases driving the growth of higher value prescription medicines.*

Prescription Drug Market Forecast
(2017-2027)



f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, local news sources, domestic companies, Fitch Solutions

Structural Trends

We forecast prescription drug spending in Egypt to increase from EGP31.8bn (USD1.8bn) in 2017 to EGP48.2bn (USD2.5bn) by 2022, at a CAGR of 8.7% in local currency terms (7.0% in US dollar terms). By this point, the prescription drug segment will account for 85% of all spending on pharmaceuticals in the country, rising slightly from 83% at the end of 2017. By the end of our current forecast period in 2027, we forecast that prescription medicine sales will account for 87% of pharmaceutical sales at EGP74.3bn (USD3.4bn), corresponding to a local currency CAGR of 8.8% (6.7% in US dollar terms).

Prescription drug sales in Egypt will benefit from a robust set of growth drivers over the coming years. Despite the government's focus on reducing healthcare costs, a rapidly growing population and rising chronic disease burden will ensure that prescription drugs remain the dominant market segment. With cost-containment initiatives on the rise, generic drugmakers could be the greatest beneficiaries from Egypt's pharmaceutical trends over the long term given their more competitive prices.

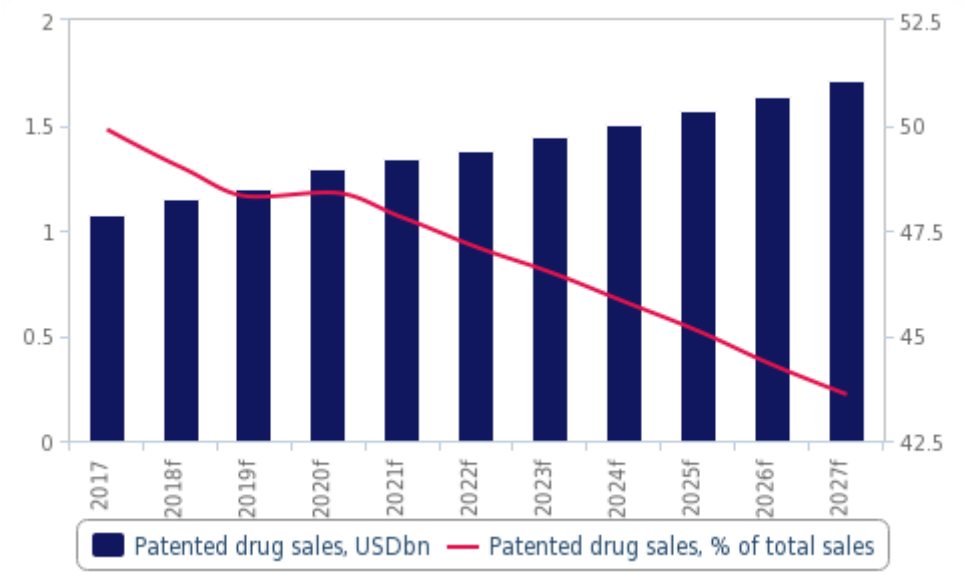
PRESCRIPTION DRUG MARKET INDICATORS, HISTORICAL DATA AND FORECASTS (EGYPT 2017-2022)						
Indicator	**2017**	**2018f**	**2019f**	**2020f**	**2021f**	**2022f**
Prescription drug sales, USDbn	1.784	1.950	2.069	2.262	2.394	2.506
Prescription drug sales, USDbn, % y-o-y	-38.85	9.27	6.12	9.32	5.87	4.65
Prescription drug sales, EGPbn	31.843	34.388	37.273	40.825	44.357	48.238
Prescription drug sales, EGPbn, % y-o-y	8.50	7.99	8.39	9.53	8.65	8.75
Prescription drug sales, % of total sales	83.1	83.2	83.5	84.5	84.9	85.3

f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, local news sources, domestic companies, Fitch Solutions

Patented Drug Market Forecast

Key View: *The Egyptian government's pursuit of cost-containment in the pharmaceutical sector will place downward pressure on Egypt's patented medicine sales over the coming years. Moreover, a reduction in the strength of the Egyptian pound will increase the costs of medicines imported to Egypt, albeit stabilising in recent quarters. Despite these factors, the subsector will maintain a steady growth forecast as supporting factors in the form of a rising chronic disease burden and gradual expansion of private healthcare lie ahead.*

Patented Drug Market Forecast
(2017-2027)



f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, local news sources, domestic companies, Fitch Solutions

Structural Trends

We calculate that the value of Egypt's patented drug market will rise from EGP19.1bn (USD1.1bn) in 2017 to EGP26.6bn (USD1.4bn) by 2022, at a CAGR of 6.9% in local currency terms and 5.2% in US dollar terms. From 2017 to 2027, we forecast Egypt's patented drug market to be worth EGP37.3bn (USD1.7bn), corresponding to a CAGR of 6.9% and 4.8% in local currency and US dollar terms respectively. We believe that patented drug spending will decrease as a proportion of total pharmaceutical spending from 50% in 2017 to 44% in 2027, as expansion of healthcare and pharmaceutical access requires more cost-effective strategies.

The rising popularity of generic drugs will place downward pressure on Egypt's patented medicines sales over the coming years. Egyptian drugmakers are unlikely to make forays into the patented sector unless restricted to the OTC segment, largely because pricing policies and the regulatory environment carry unresolved issues and, therefore, increased risk. Indeed, we believe the outlook for patented drugs is therefore not as positive as the outlook for the generic sector.

Domestic drugmakers in Egypt are focused mainly on generic and OTC medicines and therefore contribute a limited amount to the patented product list. As a result, patented products from abroad are more expensive owing to import costs - especially given the local currency weakness - and their patented protection status. Innovation and R&D are currently limited in Egypt and the increasing preference for generic drugs will promote logical drug prescription. Even so, drug purchasing power in the country was low at around USD30 per capita in 2017, further limiting the drive for innovation and lowering Egypt's attractiveness as an export destination for patented drugs.

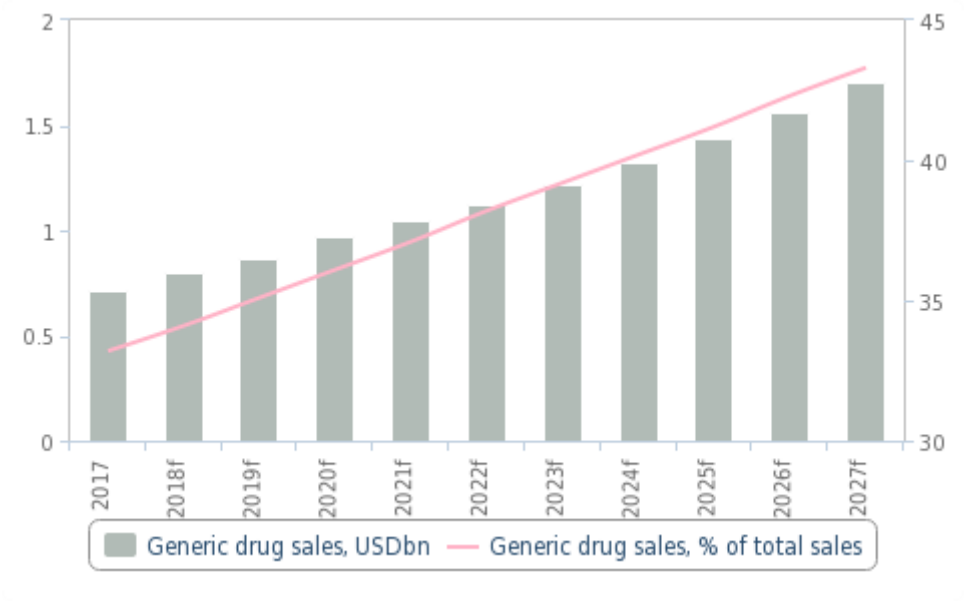
PATENTED DRUG MARKET INDICATORS, HISTORICAL DATA AND FORECASTS (EGYPT 2017-2022)						
Indicator	**2017**	**2018f**	**2019f**	**2020f**	**2021f**	**2022f**
Patented drug sales, USDbn	1.072	1.149	1.198	1.295	1.347	1.384
Patented drug sales, USDbn, % y-o-y	-39.74	7.23	4.25	8.10	3.99	2.76
Patented drug sales, EGPbn	19.129	20.271	21.585	23.378	24.951	26.644
Patented drug sales, EGPbn, % y-o-y	6.93	5.97	6.48	8.31	6.73	6.78
Patented drug sales, % of prescription sales	60.1	58.9	57.9	57.3	56.3	55.2
Patented drug sales, % of total sales	49.9	49.0	48.3	48.4	47.8	47.1

f = Fitch Solutions forecast. Source: Ministry of Health, local news sources, domestic companies, Fitch Solutions

Generic Drug Market Forecast

Key View: *Egypt's generic drug market will experience robust growth in the long term, driven by the government's focus on cost-containment, the impending patent cliff and greater awareness of generic medicines as a substitute for expensive patented medicines.*

Generic Drug Market Forecast
(2017-2027)



f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, local news sources, domestic companies, Fitch Solutions

Structural Trends

The generic drug market will increase in value from EGP12.7bn (USD712mn) in 2017 to EGP21.6bn (USD1.1bn) by 2022, at a local CAGR of 11.2% (9.5% in US dollar terms). By 2022, the generic drug market will account for a notably higher 38% of the total drug spending and 45% of all prescription spending, with the subsequent five years to continue witnessing similarly strong segment growth. Actual volumes could rise even more dynamically as generic drugmakers increase production to meet rising demand and cost-containment measures encouraged by the Egyptian government, especially as major products come off patent. By 2027, we forecast spending on generic medicines to reach EGP37.0bn (USD1.7bn), representing 43% of drug sales and 50% of prescriptions in value terms. This corresponds to a local currency CAGR of 11.3% (9.1% in US dollar terms).

The local production of generic products still overwhelmingly accounts for most local demand. However, in value terms patented drugs have a larger market share. Domestic firms import the majority of their raw materials, which means they are particularly susceptible to the fluctuations of the Egyptian currency, having to shoulder devaluation costs themselves in the absence of price increases.

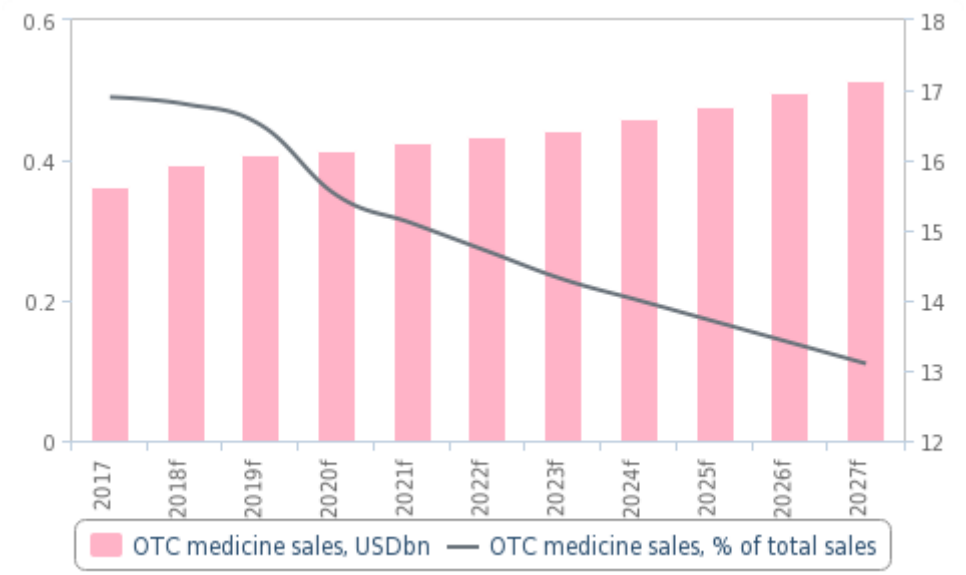
GENERIC DRUG MARKET INDICATORS, HISTORICAL DATA AND FORECASTS (EGYPT 2017-2022)						
Indicator	**2017**	**2018f**	**2019f**	**2020f**	**2021f**	**2022f**
Generic drug sales, USDbn	0.712	0.800	0.871	0.967	1.048	1.122
Generic drug sales, USDbn, % y-o-y	-37.47	12.35	8.80	10.99	8.38	7.09
Generic drug sales, EGPbn	12.715	14.117	15.688	17.447	19.406	21.595
Generic drug sales, EGPbn, % y-o-y	10.94	11.03	11.13	11.21	11.23	11.28
Generic drug sales, % of prescription sales	39.9	41.1	42.1	42.7	43.7	44.8
Generic drug sales, % of total sales	33.2	34.1	35.1	36.1	37.1	38.2

f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, local news sources, domestic companies, Fitch Solutions

OTC Medicine Market Forecast

Key View: *Egypt's OTC drug sector will continue to grow as rising health awareness and self-medication practices become more popular. Key growth factors include greater health awareness and willingness to self-medicate. Increasing urbanisation will also help drive the OTC sector in Egypt, as more of the population is affected by issues such as pollution. However, a lack of distinction between prescription and OTC medicines makes the size of the sub-sector difficult to estimate, posing a downside risk to our forecast as many prescribed medicines can be bought OTC.*

OTC Medicine Market Forecast
(2017-2027)



f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, local news sources, domestic companies, Fitch Solutions

OTC medicine spending in Egypt will rise from EGP6.5bn (USD364mn) in 2017 to EGP8.3bn (USD433mn) by 2022 at a CAGR of 5.1% in local currency terms (3.6% in US dollar terms). Hospitals remain the primary point of access for healthcare services, and the distribution of consumer health products is only permitted through pharmacies. By 2027, OTC spending is forecast to reach EGP11.2bn (USD515mn), by which point it will account for a further reduced 13% of total pharmaceutical expenditure, compared to 17% in 2017. This corresponds to a 10-year CAGR of 5.6% in local currency terms and 3.5% in US dollar terms.

Low-income households and those without health insurance tend to favour OTC medicines. However, the market's development has been hampered by factors such as the lack of healthcare awareness among patients and the low prices of OTC medicines, which are rigidly controlled by the Ministry of Health. To add to this, the OTC healthcare market, despite its relatively large size, suffers from an absence of advertising and consumer-orientated marketing. Although we expect some form of subsidised healthcare to be introduced in the long run, we also believe interest in OTCs is changing, with customers moving away from essential medicines like analgesics and into more evolved therapeutic categories like dermatologicals, digestives and vitamins. Due to this development, the OTC market will be well-placed to take advantage of Egypt's growing middle class and increasingly affluent population over the medium to long term in particular, despite the dominance of prescription medicines.

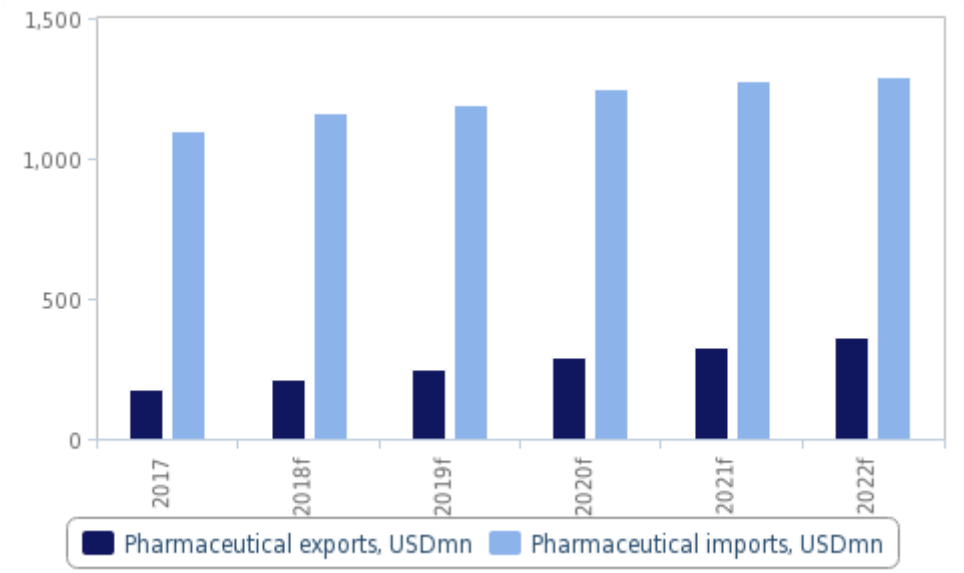
OVER-THE-COUNTER (OTC) MEDICINE MARKET INDICATORS, HISTORICAL DATA AND FORECASTS (EGYPT 2017-2022)						
Indicator	**2017**	**2018f**	**2019f**	**2020f**	**2021f**	**2022f**
OTC medicine sales, USDbn	0.364	0.395	0.410	0.414	0.426	0.433
OTC medicine sales, USDbn, % y-o-y	-41.33	8.48	3.87	0.88	3.01	1.75
OTC medicine sales, EGPbn	6.492	6.960	7.384	7.464	7.891	8.343
OTC medicine sales, EGPbn, % y-o-y	4.10	7.21	6.10	1.08	5.72	5.74
Over-the-counter (OTC) medicine sales, % of total sales	16.9	16.8	16.5	15.5	15.1	14.7

f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, local news sources, domestic companies, Fitch Solutions

Pharmaceutical Trade Forecast

Key View: *Egypt will remain heavily reliant on pharmaceutical imports despite planned improvements to domestic manufacturing capabilities. Currency instability and economic headwinds compound a challenging operating environment for drugmakers with a local presence, which poses a downside risk to the domestic medicine supply. Nevertheless, the situation for domestic and foreign drugmakers in Egypt is showing signs of improvement as a combination of higher drug prices and government intervention lies ahead.*

Pharmaceutical Trade Forecast
2013-2022 (2017-2022)



f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, Fitch Solutions

Structural Trends

We have previously highlighted the measures taken by the Egyptian government to boost self-sufficiency in the pharmaceutical sector (*see 'State Intervention To Counteract Pharmaceutical Import Reliance', March 20*); however, import growth will be supported by the limited technological capacity of the local manufacturing sector as the market relies on imported drugs in the field of sophisticated medicines. Imports are forecast to remain much greater than exports, as the Egyptian drug market continues to punch below its weight on international markets.

Egypt's pharmaceutical imports are estimated at EGP19.7bn (USD1.1bn) for 2017. We forecast this to reach EGP24.90bn (USD1.3bn) by 2022, posting a local currency compound annual growth rate (CAGR) of 4.8%, and 3.2% in US dollar terms. The devaluation of the local currency continues to have a significant impact on the market size in US dollar terms. Around one-third of Egyptian pharmaceuticals imports come from EU member states, which are likely to continue supplying much of the patented drug market.

Pharmaceutical exports are forecast to rise as well, from EGP3.1bn (USD176mn) in 2017 to a still-modest EGP7.0bn (USD362mn) by 2022, at a local currency CAGR of 17.2%, and US dollar CAGR of 15.5%. As such, export growth is forecast to increase at a faster rate than that of imports of pharmaceuticals in Egypt, albeit from a much lower base. Most exports will continue to target other Middle East and North Africa markets, with a focus on Saudi Arabia, the UAE, Iraq, Sudan and Jordan. The Egyptian health minister has announced that a number of drug manufacturing plants are still under construction, many of which will be built in industrial zones across the country. Exporting generic drugs is the main avenue to long-term gains for Egyptian firms, particularly in keeping prices

low and therefore competitive.

PHARMACEUTICAL TRADE DATA AND FORECASTS (EGYPT 2017-2022)						
Indicator	**2017**	**2018f**	**2019f**	**2020f**	**2021f**	**2022f**
Pharmaceutical exports, USDmn	176.50	215.84	249.25	290.08	328.33	362.49
Pharmaceutical exports, USDmn, % y-o-y	-26.73	22.29	15.48	16.38	13.19	10.40
Pharmaceutical imports, USDmn	1,102.22	1,166.57	1,195.05	1,250.86	1,278.69	1,292.97
Pharmaceutical imports, USDmn, % y-o-y	-41.13	5.84	2.44	4.67	2.22	1.12
Pharmaceutical trade balance, USDmn	-925.72	-950.73	-945.80	-960.79	-950.35	-930.48

f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, Fitch Solutions

PHARMACEUTICAL TRADE DATA AND FORECASTS LOCAL CURRENCY (EGYPT 2017-2022)						
Indicator	**2017**	**2018f**	**2019f**	**2020f**	**2021f**	**2022f**
Pharmaceutical exports, EGPmn	3,149.91	3,806.90	4,490.21	5,235.90	6,082.40	6,977.92
Pharmaceutical exports, EGPmn, % y-o-y	30.01	20.86	17.95	16.61	16.17	14.72
Pharmaceutical imports, EGPmn	19,670.83	20,575.37	21,528.79	22,578.10	23,687.68	24,889.61
Pharmaceutical imports, EGPmn, % y-o-y	4.44	4.60	4.63	4.87	4.91	5.07
Pharmaceutical trade balance, EGPmn	-16,520.92	-16,768.47	-17,038.58	-17,342.20	-17,605.28	-17,911.69

f = Fitch Solutions forecast. Source: United Nations Comtrade Database DESA/UNSD, Fitch Solutions

Industry Risk/Reward Index

MENA Innovative Pharmaceuticals Risk/Reward Index

***Key View**: The Middle East and North Africa (MENA) region is home to diverse opportunities and challenges for multinational pharmaceutical companies. Given the widespread regional instability and varying levels of regulatory protection, it is vital that companies appreciate the varying levels of investment risk and reward that are present in the markets in the Middle East and North Africa. Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index tool, which provides a globally comparative and numerically based assessment of a market's attractiveness for companies looking to launch a high-value drug, was established to address this.*

Middle East And North Africa: A Significant Number Of High-Risk Markets

Middle East & North Africa Innovative Pharmaceuticals Risk/Reward Index

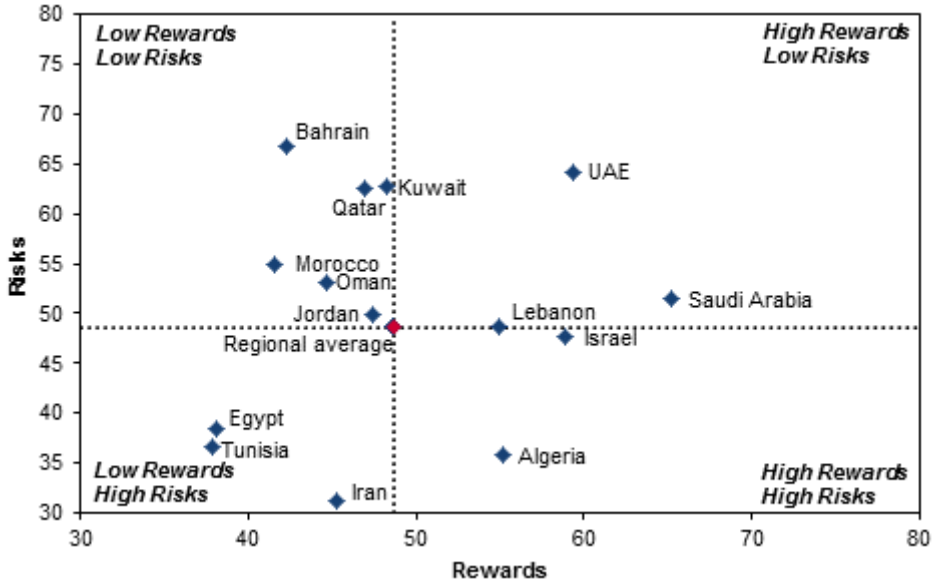
Note: Scores out of 100; higher score = lower risk. Source: Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index

Main Regional Features And Latest Updates

- The Middle East and North Africa (MENA) average in our Innovative Pharmaceuticals Risk/Reward Index (RRI) slightly underperforms the global average. The region is highly diverse, with a number of large Gulf States including Saudi Arabia, the UAE and Kuwait, scoring highly for access to, and demand for, innovative medicines. However, a number of significantly underdeveloped markets with low affordability levels, poor access to healthcare services and elevated industry- and country-specific risks drag the regional score below the global average.
- The MENA region presents a diverse mix of opportunities that generally favour the larger markets positioned in the Gulf Cooperation Council (GCC). While the oil-abundant, wealthier GCC markets are characterised by higher per capita spending on pharmaceuticals, discrepancies exist at the national level with regard to market attractiveness. Highlighting this, the larger markets of Saudi Arabia and the UAE continue to stand out as the region's most lucrative prospects for innovative drugmakers given the developed nature of their respective pharmaceutical industries. While some degree of fiscal consolidation and regional instability is set to remain the norm in the majority of the MENA region, there is a risk that many of these markets will look to advance cost-containment measures within the pharmaceutical sector.
- With regard to assessing rewards, the RRI identifies industry-specific factors, such as the size of the pharmaceutical market, and country-specific factors, such as the size of the pensionable population, which represent opportunities for potential investors. Saudi Arabia scores the highest for the Rewards component of the MENA RRI due to its large medicine market, high per capita medicine spending and rapid population growth. Meanwhile, Bahrain scores the lowest in the region.
- With regard to assessing risks, we identify industry-specific dangers, such as a country's pricing regime, as well as risks emanating from the state's political and economic profile, which call into question the likelihood of anticipated returns being realised over the assessed time period. Iran has the lowest Risk score among the MENA markets due to low levels of patent respect which are further exacerbated by considerable operational, economic and political risks in comparison to the regional average. Meanwhile, the UAE scores the highest in the sub-sector.

Middle East And North Africa: A Diverse Field Of Opportunities And Risks

Middle East & North Africa Innovative Pharmaceuticals Risk/Reward Index



Note: Scores out of 100; higher score = lower risk. Source: Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index

Outperformers: High-Reward And Low-Risk Markets

MENA markets are not considered among the most attractive globally for companies looking to launch innovative pharmaceuticals. The UAE, which ranks first in the region, is ranked 27th globally, while the region's second-ranked country, Saudi Arabia, is ranked 37th globally. Scoring in the Innovative Pharmaceuticals RRI favours larger markets with greater sales potential for multinationals. While the larger markets of Saudi Arabia and the UAE present sizeable commercial opportunities within MENA, neither market can compete with the high per capita expenditure or absolute market size of the top global markets.

The UAE boasts a wealthy population which, combined with a fast-growing private healthcare sector and strong drug approval process, serves to boost its appeal as a destination for innovative product launches. A similar situation exists in Saudi Arabia where patented drug consumption will be continually supported by the population's wealth, high demand for sophisticated pharmaceuticals, and the practice of prescribing by brand name. However, both countries suffer from relatively small pensionable populations, particularly the UAE, somewhat limiting the demand for high-value innovative medicines. This, coupled with industry risks, such as the risk of further drug price cuts and the likelihood of the government implementing further cost-efficiencies, weighs on the potential rewards for multinational firms.

- The UAE's Ministry of Health (MoH) has stated its intention to continue the 'Reduction in Medicine Prices' initiative until the prices of drugs in the UAE become the lowest across the Arabian Gulf. While the UAE has a relatively a tough stance on medicine pricing in the Middle East, it is unlikely to introduce aggressive pricing regimes as seen in some developed markets globally, including Germany, Japan and Turkey. This restraint on the issue of pricing aims to achieve the UAE's desire to attract greater foreign investment as part of its drive for innovation and technology, which international drugmakers may bring. At the same time, the UAE is becoming more accepting of new and innovative medicines, with proposed reforms to the country's drug regulatory system likely to gain traction over the coming years - upholding its appeal for innovative drug launches. The UAE Ministry of Health and Prevention (MoHP) announced the approval of Merck KGaA's innovative multiple sclerosis treatment *Mavenclad* (cladribine) – the first country to do so in the MENA region. Crucially, this is a direct outcome from the MoHP's implementation of Ministerial Decree 28 for 2018 concerning the registration of innovative medicines and orphan drugs.
- A central challenge for multinational drugmakers in Saudi Arabia is the country's patent system, as highlighted in PhRMA's 2018

report. Highlighting this, in 2017, the Saudi Food and Drug Authority (SFDA) granted marketing approval for a generic version of an innovative medicine during the patent term of that product. Despite this, Saudi Arabia's advances to promote local pharmaceutical manufacturing will continue to support multinational drugmakers expansion plans into the Kingdom. In March 2018, AstraZeneca and Saudi Pharmaceutical Industries & Medical Appliances Corporation (SPIMACO) signed a Memorandum of Understanding (MoU) during the Saudi Crown Prince Muhammed Bin Salman's state visit to the UK. This agreement confirms the intention for an investment, development and technology transfer initiative to Saudi Arabia's local pharmaceutical sector, including the launch of a contract manufacturing operation arrangement between the two companies. The initiative will focus specifically on the local production of innovative medicines targeting cardiovascular, diabetes and gastrointestinal areas.

Underperformers: Low-Reward And High-Risk Markets

Tunisia and Iraq sit at the bottom of the MENA Innovative Pharmaceuticals Risk/Reward Index. Both are characterised by a combination of high political, economic and industry-specific risks and low rewards.

- Opportunities for innovative pharmaceutical firms in Tunisia will remain limited for high-value medicines. The country is ranked 80th out of 110 markets globally in the Innovative Pharmaceuticals RRI, with a small market size and low per capita spending on medicines acting as significant headwinds to patented drug sales. Besides a high degree of industry-associated risks, Tunisia's location, particularly its proximity to Algeria and Libya, is the source of the country's greatest operational drawbacks. The Tunisian government's drive to reduce regulatory uncertainty and improve investor sentiment will yield benefits for the pharmaceutical sector over the long term; however, this will be predominantly in the generic medicine segment due to the lack of affordability of innovative medicines.
- Iraq will remain an unattractive market on both a regional and global level for the foreseeable future. It is ranked 82nd out of 110 markets in the Innovative Pharmaceuticals Risk/Reward Index. Reflective of its underdeveloped pharmaceutical market, Iraq suffers from amongst the lowest per capita pharmaceutical spending in the region, well below the regional and global average. From a Country Risk perspective, sustained political and security risks will continue to weigh on the country's potential appeal to investors, including within the pharmaceutical sector.

REWARDS AND RISKS SCORES

	Industry Rewards	Country Rewards	Rewards	Industry Risks	Country Risks	Risks	RRI	Regional Rank	Global Rank
UAE	67.5	38.3	60.2	77.7	72.8	75.7	65.6	1	27
Saudi Arabia	72.8	48.6	66.7	37.2	58.9	45.9	59.4	2	37
Kuwait	47.7	46.6	47.4	68.3	55.9	63.3	53.0	3	51
Qatar	41.0	45.4	42.1	68.9	63.3	66.7	50.7	4	53
Lebanon	55.9	47.2	53.7	48.3	25.1	39.0	48.6	5	59
Morocco	41.8	46.1	42.9	68.2	44.3	58.7	48.4	6	61
Algeria	62.9	51.8	60.2	24.1	24.2	24.1	47.6	7	63
Jordan	47.5	47.5	47.5	51.0	40.1	46.6	47.2	8	65
Bahrain	34.4	49.8	38.2	74.3	43.3	61.9	46.5	9	66
Oman	40.3	42.9	40.9	57.4	49.6	54.3	45.6	10	68
Egypt	46.4	39.7	44.7	28.7	24.6	27.1	38.6	11	74
Iran	49.3	45.2	48.2	15.1	23.7	18.6	37.9	12	76
Tunisia	39.6	50.5	42.3	24.1	28.3	25.8	36.5	13	80
Iraq	43.1	43.6	43.2	28.6	9.3	20.9	35.4	14	82
Global Average	50.0	50.0	50.0	50.0	50.0	50.0	50.0	~	~
Regional Average	49.3	45.9	48.5	48.0	40.3	44.9	47.2	~	~

Note: Scores out of 100; higher score = lower risk. Source: Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index

INDUSTRY REWARDS SCORES					
	Market Expenditure, USDbn	Spending Per Capita, USD	Sector Value Growth, %	Industry Rewards	Rewards
UAE	64.2	73.4	69.7	67.5	60.2
Saudi Arabia	82.6	63.3	42.2	72.8	66.7
Kuwait	40.4	65.1	39.4	47.7	47.4
Qatar	29.4	62.4	46.8	41.0	42.1
Lebanon	48.6	72.5	49.5	55.9	53.7
Morocco	46.8	27.5	55.0	41.8	42.9
Algeria	70.6	45.0	70.6	62.9	60.2
Jordan	42.2	52.3	65.1	47.5	47.5
Bahrain	18.3	66.1	35.8	34.4	38.2
Oman	31.2	55.0	50.5	40.3	40.9
Egypt	56.0	18.3	73.4	46.4	44.7
Iran	55.0	22.0	96.3	49.3	48.2
Tunisia	33.9	37.6	79.8	39.6	42.3
Iraq	50.5	29.4	40.4	43.1	43.2
Global Average	50.0	50.0	50.0	50.0	50.0
Regional Average	47.8	49.3	58.2	49.3	48.5

Note: Scores out of 100; higher score = lower risk. Source: Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index

COUNTRY REWARDS SCORES					
	Urban/Rural Split	Pensionable Population, %	Population Growth, %	Country Rewards	Rewards
UAE	83.5	0.0	69.7	38.3	60.2
Saudi Arabia	78.9	18.3	78.9	48.6	66.7
Kuwait	97.2	10.1	68.8	46.6	47.4
Qatar	98.2	0.9	81.7	45.4	42.1
Lebanon	86.2	50.5	1.8	47.2	53.7
Morocco	36.7	42.2	63.3	46.1	42.9
Algeria	56.9	36.7	77.1	51.8	60.2
Jordan	79.8	19.3	71.6	47.5	47.5
Bahrain	88.1	5.5	100.0	49.8	38.2
Oman	68.8	3.7	95.4	42.9	40.9
Egypt	17.4	30.3	80.7	39.7	44.7
Iran	61.5	33.9	51.4	45.2	48.2
Tunisia	49.5	48.6	55.0	50.5	42.3
Iraq	53.2	13.8	93.6	43.6	43.2
Global Average	50.0	50.0	50.0	50.0	50.0
Regional Average	68.3	22.4	70.6	45.9	48.5

Note: Scores out of 100; higher score = lower risk. Source: Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index

INDUSTRY RISKS SCORES					
	Patent Respect	Pricing Regime	Protectionism	Industry Risks	Risks
UAE	78.0	71.1	81.7	77.7	75.7
Saudi Arabia	38.5	39.0	33.9	37.2	45.9
Kuwait	66.1	71.1	70.2	68.3	63.3
Qatar	78.0	71.1	52.3	68.9	66.7
Lebanon	49.5	39.0	52.3	48.3	39.0
Morocco	89.4	39.0	52.3	68.2	58.7
Algeria	21.6	39.0	18.3	24.1	24.1
Jordan	55.0	39.0	52.3	51.0	46.6
Bahrain	78.0	71.1	70.2	74.3	61.9
Oman	66.1	71.1	33.9	57.4	54.3
Egypt	38.5	19.7	18.3	28.7	27.1
Iran	3.7	39.0	18.3	15.1	18.6
Tunisia	21.6	39.0	18.3	24.1	25.8
Iraq	21.6	61.5	18.3	28.6	20.9
Global Average	50.0	50.0	50.0	50.0	50.0
Regional Average	50.4	50.7	42.2	48.0	44.9

Note: Scores out of 100; higher score = lower risk. Source: Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index

COUNTRY RISKS SCORES							
	Long Term Economic Risk Index	Short Term Economic Risk Index	Long Term Political Risk Index	Short Term Political Risk Index	Op Risk Index	Country Risks	Risks
UAE	58.7	60.6	60.6	89.9	83.5	72.8	75.7
Saudi Arabia	68.3	62.8	32.1	67.4	61.5	58.9	45.9
Kuwait	56.9	57.8	52.8	70.6	48.6	55.9	63.3
Qatar	43.1	42.2	58.3	91.3	72.5	63.3	66.7
Lebanon	44.0	32.6	18.8	7.3	23.9	25.1	39.0
Morocco	31.2	26.1	61.5	55.5	45.9	44.3	58.7
Algeria	37.2	36.7	22.0	14.7	17.4	24.2	24.1
Jordan	18.3	6.0	64.2	39.9	56.0	40.1	46.6
Bahrain	23.9	12.4	29.4	56.9	68.8	43.3	61.9
Oman	10.1	17.0	56.9	79.8	67.0	49.6	54.3
Egypt	22.9	31.2	20.2	16.5	28.4	24.6	27.1
Iran	15.6	18.8	21.1	35.3	25.7	23.7	18.6
Tunisia	9.2	2.8	55.0	33.0	34.9	28.3	25.8
Iraq	13.8	39.4	0.9	0.0	0.9	9.3	20.9
Global Average	50.0	50.0	50.0	50.0	50.0	50.0	50.0
Regional Average	32.4	31.9	39.5	47.0	45.3	40.3	44.9

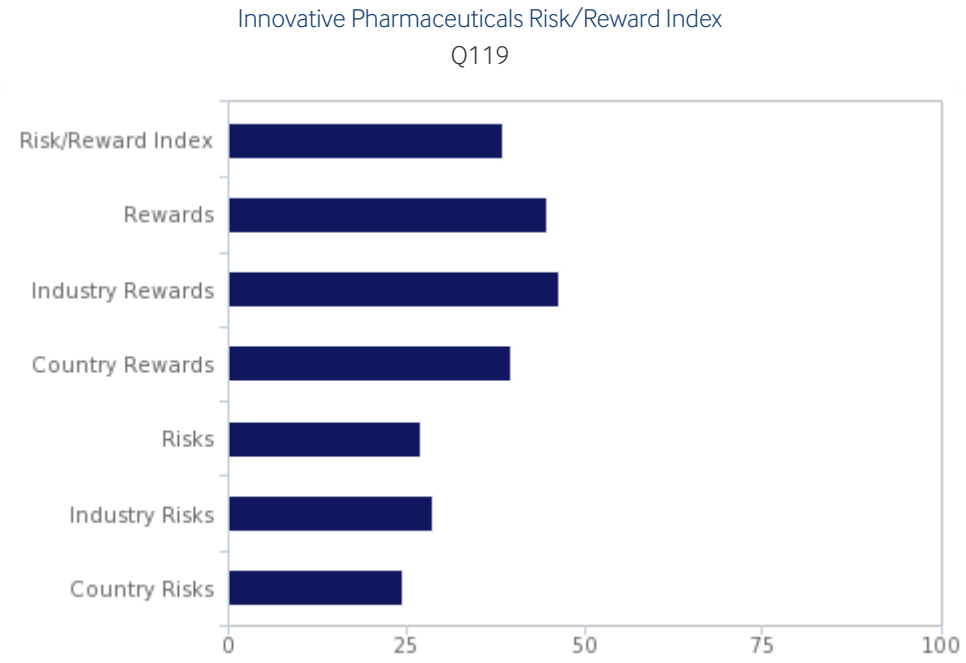
Note: Scores out of 100; higher score = lower risk. Source: Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index

Egypt Innovative Pharmaceuticals Risk/Reward Index

Key View: *Egypt will remain a highly challenging pharmaceutical market for innovative drugmakers, with low per capita medicine expenditure and persistent market access barriers Egypt has scored 38.6 out of 100 in our Innovative Pharmaceuticals Risk/Reward Index. Increasing political instability poses upside risks for market entry opportunities, with the country's restrictive market further hindering innovative drugmakers.*

Egypt: Innovative Pharmaceuticals RRI - Global And Regional Rank

- Regional Rank (out of 14): 11th
- Global Rank (out of 110): 74th



Note: Scores out of 100, higher scores = lower risk. Source:Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index

Industry Rewards: Egypt scores 46.4, below the regional average of 49.3. The attractiveness of Egypt's pharmaceutical market to innovative drugmakers is weakened by the low level of drug expenditure per capita, which is one of the lowest in the region. The country cannot draw on oil wealth in the same way as its Arab peers in order to boost income levels, and low affordability levels have prompted the Egyptian government to ensure that pharmaceuticals are affordable on a national scale. This will reduce the rewards for pharmaceutical drugmakers producing high-value innovative products.

Country Rewards: Reflective of its unfavourable demographic profile, Egypt's score of 39.7 is below the regional average of 45.9. Egypt has a relatively young population and a very high birth rate, which is regarded as a disadvantage as ageing populations tend to show a higher demand for pharmaceuticals and healthcare services. However, population growth is high, which is advantageous as this should translate into a growing pharmaceuticals market. A downside risk for innovative drugmakers stems from Egypt's unfavourable urban/rural split. Egypt is sparsely populated in some areas, with the Western Desert covering large swathes of the country where access to healthcare services is limited - reducing the demand for innovative pharmaceuticals. Still, in others it is extremely densely populated - Cairo accounts for around 11% of the population - raising the country's score in this category.

Industry Risks: Egypt scores 28.7, well below the regional score of 48.0. Intellectual property laws are markedly below international standards - data protection and enforcement being major concerns to innovative drugmakers. Reinforcing our views,

Egypt has recently been included on Pharmaceutical Research and Manufacturers of America's 'Watch List' Special 301 Submission, with restrictive pricing and approval delays cited as key issues for concern. Medicine prices are among the lowest in the region - an unattractive feature for innovative drugmakers. This has encouraged the use of discounted pharmaceutical pricing as a market access strategy for innovative drugmakers looking to exploit opportunities in Egypt. A non-transparent, outdated regulatory system has also been noted as leading to unnecessarily long review periods, depriving patients of access to innovative pharmaceuticals.

Country Risks: Egypt's unstable economic, political and operational climate reflect in its score of 24.6, below the regional average of 40.3. The country's operating environment presents a myriad of risks underscored by a rigid labour market structure, the significant threat of domestic terrorist attacks, an uncertain political outlook and currency weakness. Whilst the long-term economic outlook will get brighter as structural reforms gather momentum, Egypt's transition to a fully-fledged democracy is unlikely over the coming decade as the military retains substantial control over the political system.

Regulatory Development

Regulatory Review

The Egyptian Drug Authority (EDA) is the pharmaceutical regulatory body of the Egyptian MoH. The EDA has three sub-organisations - the Central Administration of Pharmaceutical Affairs (CAPA), the National Organization for Drug Control and Research (NODCAR) and the National Organization for Research and Control of Biologics (NORCB).

In August 2018, the Parliament of Egyptian prioritised a draft law published by the MoH on a new EDA. Speaking at the CPhI Middle Exhibition Centre in Abu Dhabi in September 2018, Sedico Pharmaceuticals' Chairman & Managing Director Dr Awad Gabr, announced that 'the reformed EDA will be inaugurated in the coming weeks; making up part of a strategic decision by the MoH to further expedite the growth of Egypt's pharmaceutical market. The jurisdiction of the new body will increase the number of product registrations and further enhance pharmaceutical exports'. Moreover, Member of Parliament Abdel Aziz Hamouda highlighted the importance of reforming the EDA to achieve medicine sustainability.

CAPA is a regulatory body in Egypt and includes the following divisions - Registration Department, Licensing and Pharmacists' services Department, Inspection and Control Department and Importation and Exportation Department. Together these departments handle licensing, registration and the import and export of drugs. NODCAR is responsible for quality control and bioavailability testing of pharmaceutical products and NORCAB is responsible for quality control and analysis of biologics.

The Egyptian Pharmacovigilance Centre monitors drugs after their release for adverse drug reactions. The reporting of adverse drug effects has been made compulsory for pharmaceutical firms, as part of a wider increase in regulatory activity in the field of pharmacovigilance in Africa, which seems to have moved up the continent's agenda in light of soaring rates of drug counterfeiting. The Egyptian Drug Authority released draft guidelines for the registration of biosimilars, whereby authorities took into account EMA, ICH and WHO guidelines, along with the draft biosimilars guidance from the FDA and India's guidelines on 'similar biologics'. The proposed guidelines aim to facilitate the registration of biosimilar products in Egypt through an abbreviated pathway. Final guidelines have since been approved.

Intellectual Property Issues

Egypt is a member of the WTO and legal provisions do exist for granting patents to manufacturers which covers pharmaceuticals. Intellectual property rights are managed and enforced by the Egyptian Patent Office. However, poor intellectual property protection remains an issue in Egypt. There are no legal provisions existing for the data exclusivity for pharmaceuticals, patent term extension or linkage between patent status and marketing authorisation. At the start of 2005, Egypt's comprehensive intellectual property rights law brought the country's legislation in line with the requirements of Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS-compliant legislation should have had a significant impact on the local pharmaceuticals industry, as the grace period allowed under TRIPS obligations for noncompliance of patent rules ended in January 2005.

Egypt has been included on the 'Watch List' of the Pharmaceutical Research and Manufacturers of America's Special 301 Submission 2018, with intellectual property protection and discriminatory market access policies cited as the key issues for concern. Despite being amongst the largest markets for pharmaceuticals in the MENA region, 2018 marks Egypt's fifth consecutive appearance on the watch list since 2014. Key issues highlighted in the submission include:

- Weak patent enforcement and regulatory data protection failures.
- Discriminatory market access policies (approval delays and restrictive pricing).

Egypt's regulatory system continues to come under scrutiny owing to its lack of regulatory data protection and ineffective patent enforcement, which allows manufacturers to obtain marketing licenses for generic products prior to the expiration of the original

patent. Egypt continually evades its WTO TRIPS obligations, resulting in a lack of patent protection and the inability to regulate newly licensed medicines.We note that Egypt has shown increasing commitment in recent years to enact greater patent enforcement. The MoH has created a committee to examine the possibility of implementing an effective patent enforcement mechanism however, since then, there have not been any notable improvements. This is likely owing to the fact that some officials have opposed putting in place an effective patent enforcement system similar to the process used in the US.

Pricing Regime

Egyptian pharmaceutical companies are subject to an unfavourable pricing system controlled by the Government's MoH. As such, the Egyptian MoH controls the prices of pharmaceutical products in order to make them affordable to the public. Egypt's current method of pharmaceutical pricing does not allow for price increases to compensate for inflation, and the pricing policy has failed to adjust for the rising costs of importing raw materials. In certain cases, state intervention is necessary. The decision by the Egyptian MoH to raise the price of a number of medicines in 2017 will provide some relief to domestic drugmakers in the country who are suffering from the lasting effects of the devaluation of the Egyptian pound. However, despite the MoH's pledge to implement the second phase of price adjustments in August 2017, to date this is yet to be implemented. We expect that the government will be hesitant to significantly raise the price of a large numbers of medicines as their commitment to affordability will remain the top priority.

Reimbursement Regime

The MoH compiles 'essential' and 'non-essential' drug lists, with the former including 26 categories and medicines such as insulin, antibiotics and cardiovascular treatments, but the authorities are under pressure to establish a universal reimbursement system as the vast majority of healthcare spending in the country is currently out-of-pocket spending. If this were to happen it would require the introduction of a system that demands higher payments for wealthier individuals to replace the current system, in which pharmaceuticals companies bear the expense of making drugs affordable to the poor, through forced price restrictions.

Regional Harmonisation

The Arab Union of the Manufacturers of Pharmaceuticals & Medical Appliances - covering major industry players across 15 Arab countries, including the UAE, Egypt, Saudi Arabia, Tunisia, Morocco, Algeria and Jordan - is trying to develop a regional drug registration process in the region. Meetings have taken place, but we are not aware of any ongoing regional drug registration processes.

Market Overview

Multinational pharmaceutical and healthcare companies will find Egypt an attractive, yet challenging investment destination. Increasing efforts to develop the pharmaceutical and healthcare sector offers some promise at a time when currency issues and an uncertain economic future threaten drugmakers' revenue-earning capabilities. Over the long term, private investments will drive health expenditure in Egypt and lead to an improvement in the delivery of specialised healthcare services in hospitals.

Egypt's pharmaceutical market is among the largest in MENA region, valued at EGP38.3bn (USD2.1bn) in 2017. However, given its large population of nearly 90mn, per capita pharmaceutical expenditure is just USD22, which is one of the lowest regionally. Prescription medicines dominate the market representing 83% by value, with patented medicines accounting for just under two-thirds of prescriptions in value terms.

As of 2017, healthcare expenditure in Egypt is valued at EGP134.5bn (USD7.5bn), with the private healthcare market leading the way representing 70% in value terms. Healthcare spending represents just under 4% of GDP, with per capita spending at USD77. Government health expenditure accounts for 30% of overall healthcare costs, demonstrating the current lack of health insurance coverage. As it stands, Egypt's current public health insurance system is reported to cover less than half of the population and is funded through contributions from a citizen's salary and from their employers. Given the current lack of coverage, well over half of healthcare expenditure in Egypt is paid for out-of-pocket by patients. However, as the government looks to raise its allocation towards the healthcare sector, the state's contribution to healthcare expenditure will increase, albeit at a slow pace.

Egypt's disease profile represents that of a developed country with non-communicable diseases accounting for over three quarters of all deaths in 2017. Similarly, our Disease Database demonstrates that non-communicable diseases are the greatest burden in Egypt, accounting for around 20mn lost disability-adjusted life years (DALYs) in 2017, compared with 3mn lost to communicable diseases. Cardiovascular diseases (51%), cancers (10%) and communicable diseases (7%) are amongst the leading causes of death, according to the WHO.

Egypt's domestic pharmaceutical manufacturing industry is strong, with the main players being Egyptian International Pharmaceutical Industries (EIPICO), South Egyptian Drug Industries (SEDICO), Medical Union Pharmaceuticals, VACSERA and Amoun Pharmaceuticals - recently acquired by Canada-based Valeant. Multinational drugmakers hold the greatest market share in value terms, with notable players including GlaxoSmithKline, Novartis, Sanofi, Pfizer and Merck & Co.

Healthcare Sector

The Egyptian healthcare system is centrally operated. The state holds executive responsibility for the provision of healthcare, with a predetermined level of free care universally available. The private sector plays a major role in Egypt's healthcare provision, with the public/private split emerging largely as a result of the declining standard of public sector care. However, the challenges facing Egypt's private healthcare sector, largely stemming from the high cost of treatment, are creating a significant degree of uncertainty in the sector for foreign investors.

HEALTHCARE RESOURCES (EGYPT 2016-2018)			
Indicator	**2016**	**2017**	**2018f**
Hospitals, total	1,679	1,697	1,716
Hospitals, private	1,017	1,032	1,047
Hospitals, public	662	665	668
Hospitals, beds	126,595	128,869	131,184
Hospitals, beds, per '000 population	1.32	1.32	1.32

Source: Fitch Solutions

HEALTHCARE PERSONNEL (EGYPT 2016-2018)			
Indicator	**2016**	**2017**	**2018f**
Physicians, total	125,250	137,339	150,595
Physician, per '000 population	1.31	1.41	1.52
Dentists, total	21,902	23,513	25,244
Dentists, per '000 population	0.23	0.24	0.25
Pharmacists, total	205,596	221,014	237,589
Pharmacists, per '000 population	2.15	2.27	2.39
Nurses, total	205,596	204,174	202,762
Nurses, per '000 population	2.15	2.09	2.04

Source: Fitch Solutions

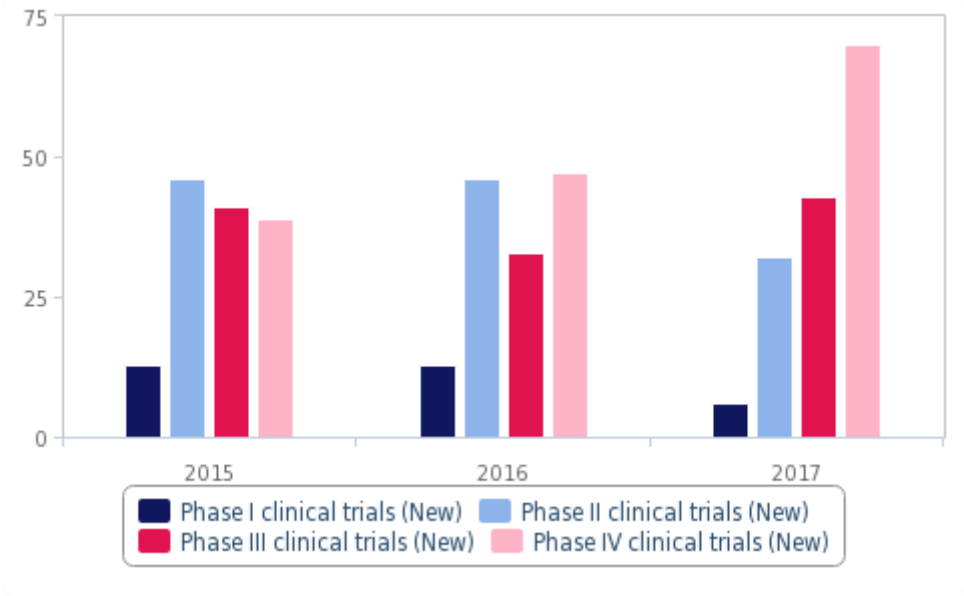
HEALTHCARE ACTIVITY (EGYPT 2016-2018)			
Indicator	**2016**	**2017**	**2018f**
Public inpatient admissions, '000	5,784.08	6,071.62	6,373.45
Public inpatient admissions, per '000 population	60.45	62.24	64.13
Outpatient visits, '000	100,368.33	106,619.15	113,170.19
Outpatient visits, per '000 population	1,048.90	1,092.93	1,138.81
Hospitals, average length of stay, days	4.4	4.4	4.3
Surgical procedures, '000	1,908.75	2,003.63	2,103.24

Source: Fitch Solutions

Clinical Trials

Egypt does not invest heavily in pharmaceutical product development, and this is one of the local industry's weaknesses. We uphold our view that this is unlikely to change in the medium term. Domestic firms undertake limited R&D activity due to the prohibitive cost of developing new chemical entities. Consequently, the domestic industry remains based on the formulation of legal and illegal generic drugs and the production of under-licence products.

Clinical Trial Registrations
2013-2017 (2015-2017)



Note: Early Phase I was formerly listed as Phase 0. Sourced by date of initial registration. Source: ClinicalTrials.gov, Fitch Solutions

Clinical trials activity will be boosted by the demographic profile of Egypt and large numbers of treatment-naive patients, as well as low research and labour costs. Also, a number of firms (eg, Roche) have conducted trials in the therapeutic area of infectious diseases, and hepatitis C in particular. There are no legal provisions requiring authorisation for conducting clinical trials by the Medicines Regulatory Authority in Egypt Additionally, there are no legal provisions for GMP compliance of investigational products. National Good Clinical Practices (GCP) are not published by the government and inspection of facilities where clinical trials are performed is not permitted.

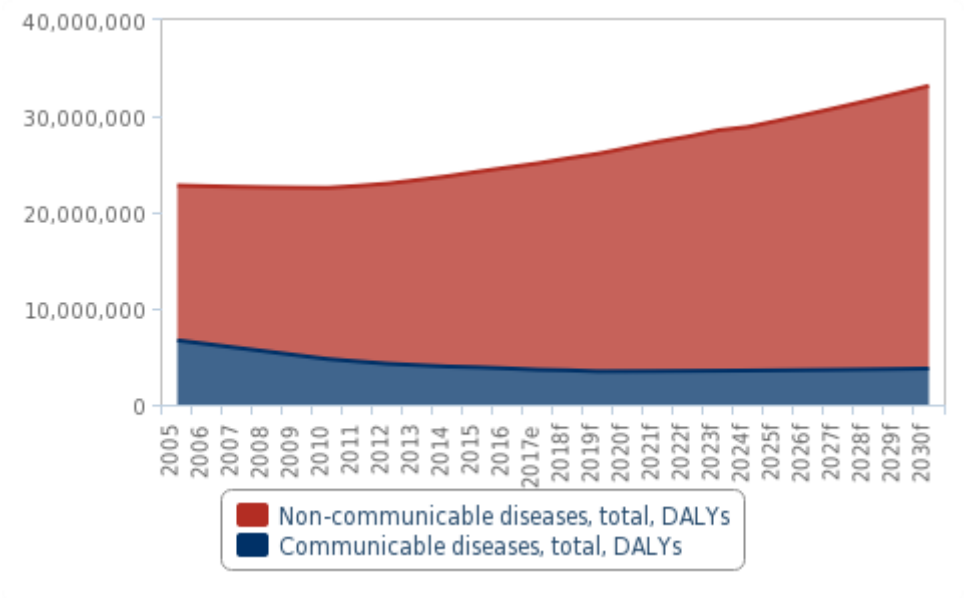
Epidemiology

Non-communicable diseases account for approximately 89% of deaths and were responsible for the loss of 20mn DALYs in 2017, according to our Disease Database. These diseases pose a considerably higher burden than communicable diseases which contributed to 3mn DALYs. By 2030, the burden of communicable diseases is forecast to marginally increase to 3.7mn DALYs with non-communicable diseases increasing at a much faster rate - forecast to rise to 29.4mn by the same year. This evolving epidemiological profile reflects the increasing prevalence of lifestyle-related diseases in Egypt, as well as improved healthcare provision going someway to alleviate the communicable disease burden.

Epidemiological studies by the WHO suggest that non-communicable diseases - such as cancer, cardiovascular disease (and ischaemic heart disease in particular) diabetes and mental health disorders - are the main causes of morbidity and mortality in

Egypt. Egyptians have a shorter average life expectancy, compared to other North African countries, with men and women averaging 69 and 74 respectively. The health issues associated with young people are increasingly mirroring those in more developed countries, such as the prevalence of psychiatric disorders.

Burden Of Disease Projection
(2005-2030)



Note: DALYs = disability-adjusted life years; e/f = Fitch solutions estimate/forecast. Source: Fitch Solutions' Disease Database

Communicable Diseases

Hepatitis C

Egypt continues to report amongst the highest incidence of Hepatitis C (HCV) in the world, estimated at 10-15mn sufferers in 2017. Secondary problems associated with HCV include cirrhosis of the liver, which was responsible for around half a million DALYs lost in Egypt in 2017.

The Egyptian government is upholding its pledge towards reducing the HCV burden in the country. The MoH recently announced its plans to strengthen the national campaign against the virus, largely through greater cooperation with pharmaceutical manufacturers of antivirals. In 2015, the Egyptian government successfully negotiated with US-based Gilead Sciences' in importing its Hepatitis C treatments of *Sovaldi* (sofosbuvir) and *Harvoni* (ledipasvir/sofosbuvir) at heavily discounted prices. Gilead Sciences' agreed to sell *Sovaldi* in Egypt for 1% of its price; people with health insurance and/or being treated at state expense can purchase the drug at EGP2,200 (USD301) compared to the original price of EGP200,000 (USD28,000).

Non-Communicable Diseases

Diabetes

Diabetes and obesity are MENA's biggest epidemiological challenge. The rapid societal transition to a more urbanised lifestyle with little exercise and westernised diets has caused a huge increase in obesity, which in turn has seen huge increases in diabetes mellitus rates. Diabetes prevalence in Egypt is high compared to global levels, but low compared with some MENA countries, particularly the Gulf Cooperation Council. According to the latest data from the IDF, there were over 7.8mn cases of diabetes in Egypt in 2016, with diabetes related deaths reaching a value of 78,184. The IDF estimates that 14.9% of the adult population in Egypt is currently diagnosed with diabetes and that USD219 was the mean annual diabetes-related spending per person in 2016. The IDF estimates that in 2016, there were 3.2mn cases of diabetes in adults that were undiagnosed. This is a concern, as there are numerous medical complications from diabetes, leading to considerable indirect healthcare costs. In 2016, diabetes accounted for 481,031 DALYs in Egypt, which is set to increase by 2030 to 879,976.

Cancer

According to Globocan, the number of new cases of cancer in Egypt will increase from 108,611 in 2012 to 167,376 by 2030. The majority of these new cases will come from females over the age of 65. Liver cancer is the most common cancer in males, followed by bladder, lung and non-Hodgkin lymphoma. Breast cancer is the most frequent cancer in females, followed by liver, non-Hodgkin lymphoma and brain cancer. Many cases are often undiagnosed or misdiagnosed, which is partly due to the widespread lack of awareness regarding the disease.

Competitive Landscape

Research-Based Industry

Domestic Industry

Leading local producers include Egyptian International Pharmaceutical Industries (EIPICO), Amoun Pharma, Pharco, Medical Union Pharmaceuticals (MUP) and South Egypt Drug Industries (SEDICO). Few local drugmakers in Egypt are wholly state-owned, with the remainder either partially or fully privatised. Public production is represented by state-owned Holding Company for Pharmaceuticals (HOLDIPHARMA).

Egyptian pharmaceuticals demand is mostly met by domestic production, in terms of volume. Foreign companies are responsible for about two-thirds of this figure, in the form of local manufacturing output and contract manufacturing outsourced to Egyptian firms. Domestic producers are mainly small- to medium-sized firms that manufacture generic drugs, with many being copies of patent-protected drugs owing to the country's weak patent law. Most active pharmaceutical ingredients (APIs) are imported, leading to cost pressure in times of currency fluctuation. Over the long term Egypt has the potential to become a major manufacturing hub - although to achieve this, the government may have to improve regulations, notably those covering the intellectual property regime.

The Egyptian government has previously offered research grants for innovative projects that result in the development of pharmaceutical products using domestic expertise, production of pharmaceutical raw materials, manufacture of interferon, insulin and early identification of viral ailments such as hepatitis. The licensed manufacturing of products from foreign drugmakers is common and has helped local firms to develop GMP standards, which has in turn led to improvement in the competitiveness of exports. However, more activity is needed to achieve internationally acceptable standards across the industry.

Foreign Industry

Leading multinationals such as Pfizer, GlaxoSmithKline and AstraZeneca are planning to expand their local operations. The current market leaders with production facilities include Bristol-Myers Squibb, GlaxoSmithKline, Novartis and Pfizer. Other leading multinationals present in the market include France-based Servier and US-based Johnson & Johnson, Eli Lilly and Merck & Co. Despite the fact that a number of multinationals are active in the Egyptian market, latest reports show few have a direct manufacturing presence. Many will import drugs or license production to local manufacturers. Multinational companies supply about two thirds of the market through direct local manufacturing or through licensing agreements. Due to the great diversity of products, local and foreign companies tend to specialise, making the Egyptian pharmaceuticals market highly fragmented.

MULTINATIONAL MARKET ACTIVITY

Company	Operations
Novartis	Novartis operates in Egypt through its subsidiary Novartis Pharma. Based in Cairo, Novartis employs approximately 1,750 associates at its manufacturing site, including in its scientific office for OTC and prescription pharmaceutical products.
Pfizer	Pfizer operates in Egypt through its 100% owned subsidiary Pfizer Egypt. The company currently has around 70 drugs on the Egyptian market and seeks to introduce six additional innovative products for the treatment of breast cancer, blood thinning, tumours and mental illnesses over the coming years.
Roche	Swiss drugmaker Roche has a scientific office in Cairo but does not manufacture locally. The company has a manufacturing licence agreement with Egyptian International Pharmaceutical Industries (EIPICO). Roche has an agreement with the Ministry of Health allowing differential pricing, allowing the local branded medicine to be available at a significantly reduced price to the government in order to enable greater public access.
Sanofi	Sanofi, operating through its local affiliate Sanofi Egypt, is among the largest pharmaceutical firms in Egypt. Sanofi Egypt has a plant and four offices, employing more than 800 people. The company's manufacturing capacity is 50mn boxes and 20mn packs per annum. Sanofi markets the following medicines in Egypt: Plavix (clopidogrel bisulphate), Aprovel (irbesartan), Tritace (ramipril), Actonel (risedronate), Depakine (sodium valproate), Amaryl (glimepiride), Lantus (insulin glargine), Eloxatin (oxaliplatin) and Taxotere (docetaxel), among a number of other products. Sanofi has also provided the vaccines used in mass polio immunisation programmes in the country.
Merck & Co	US major Merck operates in Egypt through its fully owned subsidiary Merck Sharp & Dohme Egypt. Until 1984, the company imported its products through a public sector distribution company Egyptian Pharmaceutical Trading Company (Egydrug), or manufactured them locally through a government-owned manufacturer (Al-Kahira Co) and private sector company Egyptian International Pharmaceutical Industries (EIPICO). RAMCO, SoficoPharm and EGYDRUG are the main distributors of Merck Sharp & Dohme products in Egypt.
Johnson & Johnson	The company does not have a direct manufacturing presence in Egypt; products are imported.
GlaxoSmithKline	GlaxoSmithKline operates in Egypt through its 91%-owned subsidiary GlaxoSmithKline Egypt, which employs around 1,500 staff. The subsidiary principally manufactures ethical drugs, but also markets and distributes other pharmaceuticals products and toiletries. In July 2016, GlaxoSmithKline announced plans to build a new EGP60mn (USD5.1mn) manufacturing facility in Cairo, making up part of its commitment to invest EGP400mn (USD34.1mn) into Egypt's pharmaceutical sector by 2017. According to GlaxoSmithKline officials, a large portion of the investment will be used to develop existing production units in accordance with the newest manufacturing technologies. GlaxoSmithKline's latest investment in Egypt should assure the production of pharmaceuticals at an affordable price and is in line with the company's global initiative to improve medicine access in developing nations.
AstraZeneca	AstraZeneca's production in Egypt was previously contracted out to a local manufacturer. AstraZeneca has since built a pharmaceuticals production facility near Cairo, which produces a broad range of the company's products including cardiovascular and cancer treatments. The decision by AstraZeneca to focus on three product lines in Egypt - cardiovascular, cancer and psychiatric drugs - follows local epidemiological trends. AstraZeneca has become one of the few multinationals with a direct manufacturing presence in Egypt. Some of the output is destined for exports to Middle Eastern, European and African markets.
AbbVie	AbbVie opened a scientific office in Cairo in 2015. Products are imported into Egypt.

Source: Pharmaceutical companies, Fitch Solutions

Generic Drugmakers

Domestic producers in Egypt mainly manufacture generic drugs. Although multinational drugmakers operate in Egypt, we believe the market is increasingly shifting in favour of generic medicines, thus favouring domestic production. Price is a major barrier to accessing healthcare in Egypt and rationalising prescriptions to reflect purchasing power therefore bodes well for generic drugmakers.

Pharmaceutical Distribution

The leading wholesalers in Egypt are United Company of Pharmacies (UCP), Egyptian Pharmaceutical Trading Company (Egydrug) and Pharma Overseas. Public drug manufacturers are required to distribute a considerable percentage of their products through public wholesalers, namely Egydrug, which claims to be the largest trading and distribution company for pharmaceutical products in the Middle East. Private sector companies are also required to distribute their products through the two public players, both of which are 100%-owned by HOLDIPHARMA, but to a lesser extent.

Pharmaceutical Retail Sector

Pharmacies deal with both foreign companies and state-owned local players, as well as with wholesalers. The majority of pharmacies are publicly-owned, although a handful of chains have emerged. For example, El-Ezaby - established in 1975 and part of the Multipharma Group - aims to become a leading pharmacy chain in the Middle East region. Other chains include Misr Pharmacies and Seif Pharmacies, part of the Seif Group, which targets higher-income groups.

Company Profile

APC

SWOT Analysis

Strengths

- One of the leading pharmaceutical producers in Egypt.
- Contract manufacturing for foreign players.

Weaknesses

- Low per capita incomes constraining discretionary spending on pharmaceuticals, especially given the modest reimbursement coverage.
- Stringent drug registration policy, with restrictions on the number of drugs available on the market per indication.

Opportunities

- Regional modernisation.
- Rising demand for healthcare and pharmaceuticals in line with demographic and epidemiological trends.
- Egypt serving as a gateway to less penetrable Middle Eastern, Asian and African markets.
- Rising prices of some pharmaceuticals.

Threats

- Rising competition from imports and multinationals operating within the country.
- An increase in cheap generic drug imports.
- Local currency weakness to increase costs and reduce profitability.
- Egyptian government is keen to keep drug prices low.

Company Overview

Amoun Pharmaceutical Company (APC) was established as a drug import and distribution firm in 1976. The company currently operates three production facilities and exports to a number of countries throughout Africa, Europe and the Middle East, with sister companies in the US, Romania, Russia and Kenya.

APC was acquired by Canada-based Valeant Pharmaceutical in 2015 for approximately USD800mn. APC is the largest domestic drugmaker in Egypt and is the top domestic company in terms of revenue, and third overall. The company currently has five branches in Egypt manufacturing human and veterinary pharmaceuticals products and nutritional supplements. APC was the first private drug company founded in the country to import and distribute drugs.

Strategy

APC's product portfolio includes anaesthetics, analgesics, gastrointestinal drugs, medicines for the endocrine system, topical preparations, cardiovascular drugs, vitamins and minerals. The company manufactures more than 150 products across 18 therapeutic classes. As such, APC covers quite a few therapeutic areas that are prominent in terms of Egypt's disease profile.

APC's contract manufacturing deals will allow it to continue performing well in the local market, although it will also increasingly target exports, as domestic prices continue to be an issue. APC is also aiming to increase its exports, aiming to become 'the leading Egyptian pharmaceuticals exporter'. The company's mission is based on 'quality and trust'.

EIPICO

SWOT Analysis

Strengths

- Strong focus on generic drugs, which comprise the majority of its portfolio (the remainder being accounted for by in-licensed products).
- Contract manufacturing projects for foreign partners.
- Sales and distribution network covering most of the MEA region, and also parts of Europe and Asia.

Weaknesses

- Lack of strong financial capabilities.
- Stringent drug registration policy, with restrictions on the number of drugs available on the market per indication.

Opportunities

- Trade agreements giving a boost to Egyptian exports.
- Government policy more inclined towards local producers.
- Increased focus on generic drugs, driven by cost containment.
- Egypt serving as a gateway to other emerging and less penetrable Middle Eastern, Asian and African markets.
- Investment in biotechnology research to take advantage of increasing demand for such products, nationally and internationally.

Threats

- Low per capita incomes constraining discretionary spending on pharmaceuticals, especially given the modest reimbursement coverage.
- Persistence of the unsettled political situation reducing investment potential.
- An increase in cheap imports could threaten EIPICO's marketplace.
- Failure of government to fully revise its overly opaque and discriminatory pricing policy.
- Local currency depreciation to increase costs and reduce profitability.

Company Overview

Egyptian International Pharmaceutical Industries (EIPICO) started production in 1985 and is now one of the largest domestic drug manufacturers in Egypt. It exports medicines around the world, accounting for a significant share of Egypt's total pharmaceuticals exports, according to the company's own figures.

EIPICO also owns a majority share in Egyptian International Ampoules Company (EIACO), which produces some 800mn units annually. EIPICO also holds shares in Universal for Pharmaceutical Production based in Saudi Arabia, having invested EGP27.7mn. EIPICO has its own R&D laboratories, including one for chemical control and the Biotechnology Centre.

Strategy

EIPICO manufactures more than 300 prescription and OTC pharmaceuticals, covering 23 therapeutic groups. This includes all known pharmaceutical forms, either traditional or non-traditional dosage forms such as soft gelatin capsules, spansules, lyophilised products, gels, sprayers and effervescent tablets. The company also manufactures high-value drugs such as anaesthetics and analgesics. EIPICO caters for the local and African market by producing anti-parasitic drugs against infections and schistosomaisis. This includes antibiotics, anti-fungals, anti-dysenterics, antihistamines, anti-malarials, blood substitutes, anti-hypertensives and cardiovascular medicines and central nervous system (CNS)-acting drugs, dermatological treatments, endocrine and ophthalmological therapies and steroidal anti-inflammatories.

EIPICO has a number of licence agreements with a group of international pharmaceutical companies to produce their specialities.

These include US-based Allergan; UK-based Riker; Germany-based Dolorgiet Arzneimittel, Hek Pharma and Dr Willmar Schwabe; Switzerland-based Ginsana Products Lugano (GPL) and Roche; Denmark-based Biogena; Italy-based Angelini And Menarini; and South Korea-based Shin Poong.

In line with the government's aim to reduce its medicine import reliance, EIPICO selects which pharmaceuticals it is able to produce based on replacing imported versions. To this end, it also liaises closely with multinational drugmakers regarding licence agreements. Through such agreements, the company also stands to gain from knowledge and technological transfer, which will ultimately make it more competitive within Egypt and the Middle East and Africa.

Medical Union Pharmaceuticals

SWOT Analysis

Strengths

- Sizeable product portfolio across few therapeutic areas.
- Contract manufacturing for major multinational drugmakers reflects strong quality control.

Weaknesses

- Sizeable counterfeit activity in the country impacts on brand.
- Rising competition from imports and multinationals operating within the country.

Opportunities

- Regional modernisation.
- Rising demand for healthcare and pharmaceuticals.

Threats

- Government keen to keep drug prices low.
- An increase in cheap generic drug imports.
- Low per capita incomes constraining discretionary spending on pharmaceuticals, especially given the modest reimbursement coverage.

Company Overview

First established in 1984 through the cooperation of the Professional Syndicates Union, Medical Union Pharmaceuticals was listed on the Egyptian stock exchange in April 1997 and has since gone on to become one of the largest domestic drugmakers in the country. Medical Union Pharmaceuticals also has a representative office in Kazakhstan, indicating its ambitions for the Commonwealth of Independent States.

Medical Union Pharmaceuticals is engaged in the manufacturing and distribution of medicines, cosmetics and special food products within Egypt and abroad. The company's product lines consist of its own specialties, as well as licensed products, covering more than 30 therapeutic areas.

Strategy

Currently, Medical Union Pharmaceuticals is mainly focused on the local Egyptian market, generating the majority of its sales in the local market and somewhat less via public sector tenders. The company's position is strengthened through contract manufacturing for major multinationals, which reflects strong quality control. In recent times, Medical Union Pharmaceuticals has reported a greater international position in Africa, Eastern Europe and the MENA region.

SEDICO

SWOT Analysis

Strengths

- One of the more prominent local companies.
- Focuses on generic medicines, but it also has three patented products in its portfolio.
- One of the leading producers of insulin.
- Contract manufacturing for foreign players

Weaknesses

- Stringent drug registration policy, with restrictions on the number of drugs available on the market per indication.
- Low per capita incomes constrain discretionary spending on pharmaceuticals, especially given the modest reimbursement coverage.

Opportunities

- Trade agreements giving a boost to Egyptian exports.
- Access to foreign capital.
- Recent medicine price hike has had a positive impact on sales over H217.

Threats

- Failure of the government to revise its overly opaque and discriminatory pricing policy.
- Rising competition from imports and multinationals operating within the country.
- An increase in cheap generic drug imports.
- Currency volatility to affect margins.

Company Overview

South Egyptian Drug Industries (SEDICO) started production in 1990 and its facilities are GMP-certified. The company focuses on generic medicines, but also has patented medicines. SEDICO is engaged in the production of some biotechnology products, in partnership with foreign players.

Strategy

SEDICO's product portfolio includes analgesics, antihistamines and nasal decongestants, antidepressants and cardiovascular drugs. As such, the company is well placed to continue taking advantage of the country's disease profile and its growing population. SEDICO manufactures its own products and those under licence from various multinationals, including AstraZeneca UK, as well as other foreign players, such as Trenka (based in Austria).

SEDICO's official strategy is based on two objectives, namely to create a strong R&D-driven manufacturing base and to collaborate with existing players in a variety of therapeutic areas. The benefits of the inclusion of biotechnology products in its portfolio are likely to be realised in the medium to longer term, as the healthcare modernisation initiatives continue and as public and private funding for pharmaceuticals becomes more readily available. The company manufactures biotechnology products including insulin, streptokinase, angikinase, Follicle Stimulating Hormone (FSH), somatropin and erythropoietin.

At the same time, SEDICO is aiming to increase its export activity. Its products are already available in Eastern Europe (including Russia, Romania and Moldova); Africa (including Sudan, Ethiopia, Tanzania and Kenya); the Gulf region (including, among others, Kuwait and Oman); and in Arab countries (including Yemen, Iraq, Morocco and Jordan).

SEDICO is one of the most technologically advanced pharmaceuticals producers in the MENA region. For example, its sterile areas are environmentally controlled, and thus able to utilise filtered air. Its water purification system supplies the company's production lines with demineralised and distilled water.

VACSERA

SWOT Analysis

Strengths

- In-house R&D capacities.
- One of the main blood banks in the country and the only vaccine producer in Egypt.

Weaknesses

- Lack of strong financial capabilities.
- Stringent drug registration policy, with restrictions on the number of drugs available on the market per indication.
- Low per capita incomes and modest reimbursement coverage.

Opportunities

- Trade agreements giving a boost to Egyptian exports.
- Rising demand for healthcare and pharmaceuticals.
- Egypt serving as a gateway to other emerging and less penetrable Middle Eastern, Asian and African markets.

Threats

- An increase in cheap generic drug imports.
- Difficulties in overcoming corruption allegations.

Company Overview

VACSERA, the Holding Company for Biological Products & Vaccines, is a vaccine producer, comprising five subsidiaries. VACSERA's plants manufacture blood and biotech treatments and vaccines. The company also has solid R&D infrastructure, an area that management is looking to fully utilize.

Strategy

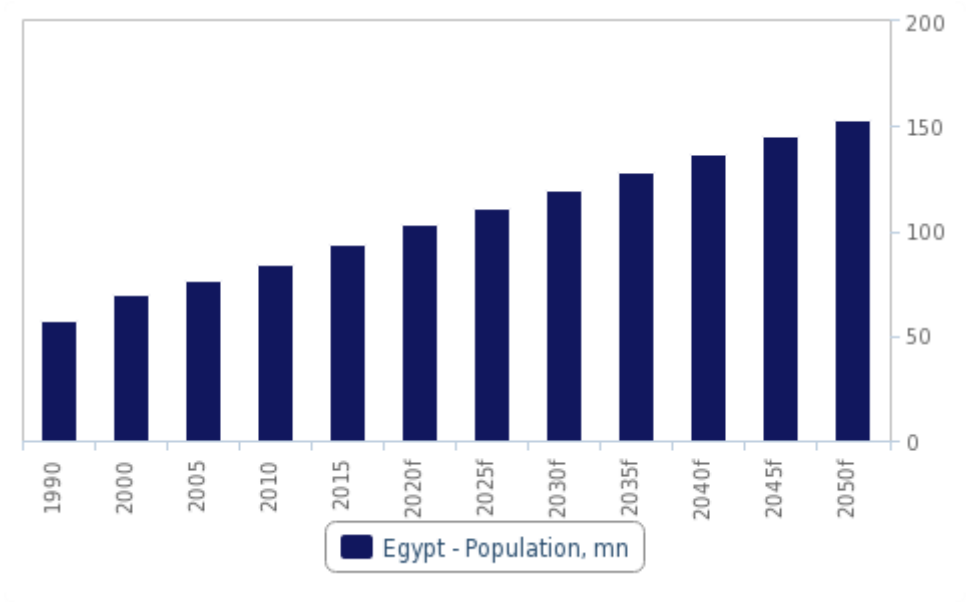
In addition to building on its existing R&D capacities, VACSERA is also looking to expand sales abroad, providing the capital to complete its unfinished projects. The most important of these is a plan to produce retractable syringes. In the long term, VACSERA is looking to become the top vaccine supplier in the MENA region. According to the list of registered vaccines, the company supplies vaccines in Egypt that include those for Bacillus Calmette–Guérin, measles, cholera, typhoid, rabies, meningitis hepatitis B, diphtheria and poliomyelitis.

Egypt Demographic Outlook

Demographic analysis is a key pillar of our macroeconomic and industry forecasting model. Not only is the total population of a country a key variable in consumer demand, but an understanding of the demographic profile is essential to understanding issues ranging from future population trends to productivity growth and government spending requirements.

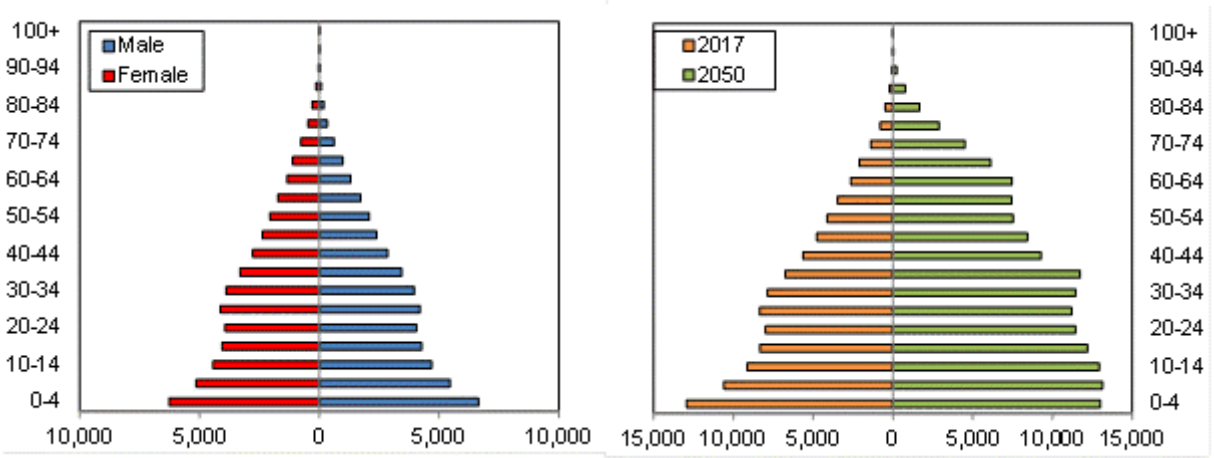
The accompanying charts detail the population pyramid for 2017, the change in the structure of the population between 2017 and 2050 and the total population between 1990 and 2050. The tables show indicators from all of these charts, in addition to key metrics such as population ratios, the urban/rural split and life expectancy.

Population
Egypt (1990-2050)



f = Fitch Solutions forecast. Source: World Bank, UN, Fitch Solutions

Egypt Population Pyramid
2017 (LHS) & 2017 Versus 2050 (RHS)



Source: World Bank, UN, Fitch Solutions

POPULATION HEADLINE INDICATORS (EGYPT 1990-2025)							
Indicator	**1990**	**2000**	**2005**	**2010**	**2015**	**2020f**	**2025f**
Population, total, '000	57,412.2	69,906.0	76,778.1	84,107.6	93,778.2	102,941.5	111,470.9
Population, % y-o-y		1.86	1.85	1.99	2.14	1.75	1.52
Population, total, male, '000	28,822.4	35,164.3	38,706.6	42,466.0	47,408.9	52,045.8	56,328.9
Population, total, female, '000	28,589.8	34,741.7	38,071.5	41,641.6	46,369.2	50,895.7	55,142.0
Population ratio, male/female	1.01	1.01	1.02	1.02	1.02	1.02	1.02

f = Fitch Solutions forecast. Source: World Bank, UN, Fitch Solutions

KEY POPULATION RATIOS (EGYPT 1990-2025)							
Indicator	**1990**	**2000**	**2005**	**2010**	**2015**	**2020f**	**2025f**
Active population, total, '000	31,281.9	40,922.9	47,429.1	53,104.5	57,954.8	63,320.2	68,959.6
Active population, % of total population	54.5	58.5	61.8	63.1	61.8	61.5	61.9
Dependent population, total, '000	26,130.3	28,983.1	29,349.1	31,003.1	35,823.3	39,621.3	42,511.4
Dependent ratio, % of total working age	83.5	70.8	61.9	58.4	61.8	62.6	61.6
Youth population, total, '000	23,542.7	25,553.4	25,604.9	26,988.9	31,075.1	34,135.7	35,948.1
Youth population, % of total working age	75.3	62.4	54.0	50.8	53.6	53.9	52.1
Pensionable population, '000	2,587.6	3,429.7	3,744.1	4,014.2	4,748.2	5,485.6	6,563.3
Pensionable population, % of total working age	8.3	8.4	7.9	7.6	8.2	8.7	9.5

f = Fitch Solutions forecast. Source: World Bank, UN, Fitch Solutions

URBAN/RURAL POPULATION & LIFE EXPECTANCY (EGYPT 1990-2025)							
Indicator	**1990**	**2000**	**2005**	**2010**	**2015**	**2020f**	**2025f**
Urban population, '000	24,961.7	29,917.7	33,035.3	36,182.3	40,451.2	45,070.9	50,121.8
Urban population, % of total	43.5	42.8	43.0	43.0	43.1	43.8	45.0
Rural population, '000	32,450.5	39,988.3	43,742.8	47,925.4	53,327.0	57,870.6	61,349.1
Rural population, % of total	56.5	57.2	57.0	57.0	56.9	56.2	55.0
Life expectancy at birth, male, years	62.2	66.2	67.1	68.2	69.1	69.9	70.6
Life expectancy at birth, female, years	67.0	71.1	71.8	72.6	73.6	74.6	75.5
Life expectancy at birth, average, years	64.6	68.6	69.4	70.4	71.3	72.2	73.0

f = Fitch Solutions forecast. Source: World Bank, UN, Fitch Solutions

POPULATION BY AGE GROUP (EGYPT 1990-2025)							
Indicator	**1990**	**2000**	**2005**	**2010**	**2015**	**2020f**	**2025f**
Population, 0-4 yrs, total, '000	9,041.1	8,272.6	9,000.9	9,868.7	12,374.4	12,071.6	11,678.5
Population, 5-9 yrs, total, '000	7,855.5	8,425.5	8,209.0	8,940.2	9,797.3	12,302.0	12,005.3
Population, 10-14 yrs, total, '000	6,646.0	8,855.3	8,394.9	8,180.1	8,903.4	9,762.1	12,264.2
Population, 15-19 yrs, total, '000	5,580.0	7,781.1	8,822.7	8,357.4	8,137.2	8,861.8	9,720.1
Population, 20-24 yrs, total, '000	4,877.1	6,482.2	7,729.7	8,696.6	8,206.0	7,990.3	8,713.8
Population, 25-29 yrs, total, '000	4,212.2	5,236.6	6,404.2	7,550.6	8,431.6	7,948.0	7,734.5
Population, 30-34 yrs, total, '000	3,659.1	4,577.0	5,176.4	6,302.6	7,389.9	8,271.5	7,792.2
Population, 35-39 yrs, total, '000	3,055.6	4,123.0	4,553.8	5,146.2	6,316.8	7,402.0	8,280.1
Population, 40-44 yrs, total, '000	2,857.8	3,624.2	4,100.9	4,530.3	5,214.7	6,379.3	7,457.7
Population, 45-49 yrs, total, '000	2,041.6	2,975.1	3,572.8	4,047.4	4,567.5	5,246.8	6,397.7

Indicator	1990	2000	2005	2010	2015	2020f	2025f
Population, 50-54 yrs, total, '000	1,868.1	2,694.7	2,864.6	3,451.6	3,956.9	4,469.7	5,138.3
Population, 55-59 yrs, total, '000	1,696.2	1,832.2	2,528.0	2,698.5	3,256.3	3,746.1	4,249.0
Population, 60-64 yrs, total, '000	1,434.2	1,596.7	1,675.9	2,323.3	2,477.9	3,004.8	3,476.1
Population, 65-69 yrs, total, '000	1,060.2	1,354.7	1,395.3	1,470.1	2,036.9	2,183.3	2,671.8
Population, 70-74 yrs, total, '000	732.2	1,012.7	1,096.8	1,133.5	1,193.7	1,669.4	1,810.6
Population, 75-79 yrs, total, '000	452.9	607.4	719.8	781.9	809.3	863.5	1,232.0
Population, 80-84 yrs, total, '000	231.7	301.8	355.3	421.3	460.7	485.5	532.9
Population, 85-89 yrs, total, '000	86.3	116.3	134.2	157.9	188.8	211.6	230.8
Population, 90-94 yrs, total, '000	21.0	31.2	36.1	41.7	49.6	61.0	71.0
Population, 95-99 yrs, total, '000	3.0	5.1	6.1	7.1	8.4	10.3	13.1
Population, 100+ yrs, total, '000	0.2	0.4	0.6	0.7	0.8	1.0	1.2

f = Fitch Solutions forecast. Source: World Bank, UN, Fitch Solutions

POPULATION BY AGE GROUP % (EGYPT 1990-2025)

Indicator	1990	2000	2005	2010	2015	2020f	2025f
Population, 0-4 yrs, % total	15.75	11.83	11.72	11.73	13.20	11.73	10.48
Population, 5-9 yrs, % total	13.68	12.05	10.69	10.63	10.45	11.95	10.77
Population, 10-14 yrs, % total	11.58	12.67	10.93	9.73	9.49	9.48	11.00
Population, 15-19 yrs, % total	9.72	11.13	11.49	9.94	8.68	8.61	8.72
Population, 20-24 yrs, % total	8.49	9.27	10.07	10.34	8.75	7.76	7.82
Population, 25-29 yrs, % total	7.34	7.49	8.34	8.98	8.99	7.72	6.94
Population, 30-34 yrs, % total	6.37	6.55	6.74	7.49	7.88	8.04	6.99
Population, 35-39 yrs, % total	5.32	5.90	5.93	6.12	6.74	7.19	7.43
Population, 40-44 yrs, % total	4.98	5.18	5.34	5.39	5.56	6.20	6.69
Population, 45-49 yrs, % total	3.56	4.26	4.65	4.81	4.87	5.10	5.74
Population, 50-54 yrs, % total	3.25	3.85	3.73	4.10	4.22	4.34	4.61
Population, 55-59 yrs, % total	2.95	2.62	3.29	3.21	3.47	3.64	3.81
Population, 60-64 yrs, % total	2.50	2.28	2.18	2.76	2.64	2.92	3.12
Population, 65-69 yrs, % total	1.85	1.94	1.82	1.75	2.17	2.12	2.40
Population, 70-74 yrs, % total	1.28	1.45	1.43	1.35	1.27	1.62	1.62
Population, 75-79 yrs, % total	0.79	0.87	0.94	0.93	0.86	0.84	1.11
Population, 80-84 yrs, % total	0.40	0.43	0.46	0.50	0.49	0.47	0.48
Population, 85-89 yrs, % total	0.15	0.17	0.17	0.19	0.20	0.21	0.21
Population, 90-94 yrs, % total	0.04	0.04	0.05	0.05	0.05	0.06	0.06
Population, 95-99 yrs, % total	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Population, 100+ yrs, % total	0.00	0.00	0.00	0.00	0.00	0.00	0.00

f = Fitch Solutions forecast. Source: World Bank, UN, Fitch Solutions

Pharmaceuticals & Healthcare Glossary

Terms Used In Datasets, Daily Analysis And Reports

Pharmaceuticals, medicines, drugs: synonym terms used interchangeably.

Pharmaceutical market/sales: the sum of revenues generated by generic, patented and over-the-counter (OTC) drugs through hospitals, retail pharmacies and other channels. Unless otherwise stated, market value is reported at final consumer price including mark-ups, taxes, etc.

Prescription drugs: patented and generic medicines regulated by legislation that requires a physician's prescription before they can be sold to a patient.

Patented drug: an innovative medicine granted intellectual property protection by a patent office. The patent may encompass a wide range of claims, such as active ingredient, formulation, mode of action, etc, giving the patent holder the sole right to sell the drug while the patent is in effect.

Generic drug: a bioequivalent medicine that contains the same active ingredient as an originator drug. The originator drug is an innovative medicine that no longer has intellectual property protection due to patent expiry. The definition for generic drugs includes off-patent originator medicines.

Over-the-counter (OTC) drug: a medicine that does not require a prescription to be sold to patients. Also known as non-prescription medicines.

Biosmilar: a drug that is similar to a biological reference product, and which is manufactured by a company other than the originator. Regulatory approval of biosimilars is technically possible following patent expiry of the reference product. There are several terms used to describe these drugs in various markets, including 'similar biologics' (India), 'similar biological products' (Singapore) and 'subsequent entry biologics' (Canada). However, biosimilars is the official name given in the EU pharmaceutical directives, and that was adopted in the 2010 US legislation.

Healthcare expenditure: government and private spending on medical products and services. This includes the purchase of healthcare services and goods by public entities such as ministries and social security institutions; government purchase of new assets including investments into buildings, machinery (capital expenditure); or by private entities such as non-profit institutions and households. The inclusion of this factor in our forecasts necessitates taking into account the essential attributes of country-specific healthcare sector characteristics such as comprehensiveness, consistency, standardisation and timeliness. The inclusion of this factor in our forecasts necessitates taking into account the essential attributes of country-specific healthcare sector characteristics such as comprehensiveness, consistency, standardisation and timeliness.

Government healthcare expenditure: (includes capital healthcare expenditure): refers to current healthcare expenditure which includes healthcare goods and services used or consumed during the year, capital expenditure on assets, restoration or enhancement paid by government entities such as a ministry of health, other ministries, parastatal organisations and social security agencies, including transfer payments to households to offset medical care costs and extra-budgetary funds to finance healthcare provision.

Private healthcare expenditure: spending on health by private entities such as commercial or mutual health insurance providers, households, non-profit institutions serving households, resident corporations and quasi-corporations not controlled by governments.

Medical devices: equipment and products used for diagnosis or therapy in patients. Whereas pharmaceuticals achieve their principal action by pharmacological, metabolic or immunological means, medical devices act by physical or mechanical means. Medical devices include a wide range of products, including syringes, thermometers, blood glucose tests, prosthetic limbs, ultrasound scans and X-ray machines.

Clinical trials: for the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include, drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes and preventive care. This definition includes Early Phase I to Phase IV trials.

Hospitals: health facilities larger than clinics, including general hospitals, specialised hospitals, public hospitals and private hospitals.

Hospital beds: a piece of furniture for recovery from illness, available at all facilities classified as hospitals by the relevant national statistical office.

Public inpatient admission: a person receiving medical treatment overnight in a hospital as defined by the relevant national statistical organisation. Excludes outpatient (non-overnight) visits. Units: thousands of visits.

Outpatient visit: a person who is not hospitalised overnight but who visits a hospital, clinic or associated facility for diagnosis or treatment.

Physician: a skilled healthcare professional trained and licensed to practice medicine.

Proprietary Tool Terminology

Disease Database: a fully country-comparative interactive tool that provides dynamic forecasts of the burden and number of deaths of 268 diseases and injuries in 178 countries, from 1990 to 2030. Fitch Solutions' disease database incorporates WHO, World Bank, IMF and Fitch Solutions data to create a proprietary dataset. The data is quantified as the sum of disability-adjusted life years lost to a disease in a particular country.

Disability-adjusted life years (DALYs): the sum of the years of life lost (YLL) due to premature mortality in a population and the years lost due to disability (YLD) for incident cases of the health condition. The DALY is a health gap measure that extends the concept of potential years of life lost due to premature death (PYLL) to include equivalent years of 'healthy' life lost in states of less than full health (broadly termed 'disability'). One DALY represents the loss of one year of equivalent full health.

Communicable disease: an infectious disease transmissible (as from person to person) by direct contact with an affected individual or the individual's discharges or by indirect means (as by a vector).

Non-communicable disease: also known as chronic diseases, non-communicable diseases are not passed from person to person. They are of long duration and generally of slow progression.

Innovative Pharmaceuticals Risk/Reward Index (RRI): quantifies and ranks a country's attractiveness in terms of its pharmaceuticals industry; it balances the Risks and Rewards of launching innovative medicines in different countries. It should be emphasised that the RRI broadly assess the rewards and the risks that a company will face when looking to launch an innovative drug in a market. For example, we do not differentiate between drugs that are part of different therapeutic groups or whether the drug being launched is the first to be launched in the market or will be one of the many different drugs of the same therapeutic class that has been launched in the market.

Rewards: this component of the RRI is composed of an evaluation of an industry's size and growth potential (Industry Rewards),

and also macro industry and/or country characteristics that directly impact the size of business opportunities in a specific sector (Country Rewards).

Risks: this component of the RRI is composed of an evaluation of micro, industry-specific characteristics, crucial for an industry to develop to its potential (Industry Risks) and a quantifiable assessment of the country's political, economic and operational profile (Country Risks).

Acronyms

CAGR: compound annual growth rate

WHO: World Health Organization

LHS: left-hand side

RHS: right-hand side

EUR: euro

USD: US dollar

Pharmaceuticals & Healthcare Methodology

Pharmaceutical Expenditure Forecast Model

Historic pharmaceutical market data is collected from a range of sources, including:

- regulatory agencies;
- pharmaceutical trade associations;
- company press releases and annual reports;
- subscription information providers;
- local news sources;
- information from market research firms that is in the public domain.

Currently available data varies in confidence levels, so it is calibrated by **Fitch Solutions'** Pharmaceuticals & Healthcare analysts. In the absence of a complete time series of numbers, intermediate years are calculated from secondary sources. This 'composite' approach is used to ensure the accuracy and consistency of historic data, which is crucial for reliable forecasts.

To remove the effect of inflation, real pharmaceutical expenditure figures are then calculated by removing the annual average consumer price index (CPI).

Real per-capita pharmaceutical expenditure numbers are calculated by dividing by population figures.

A linear regression (see Note 3 for explanation) is then performed on five years of real per-capita pharmaceutical expenditure against real per-capita final consumption (see Note 4 for explanation). From analysis of the top 130 economies, **Fitch Solutions** has established a strong statistical relationship between pharmaceutical expenditure and final consumption expenditure ($r = 0.985$).

Healthcare Expenditure Forecast Model

Historic government and private healthcare expenditure data is sourced from the World Health Organization (WHO)'s Global Health Expenditure Database, which contains the National Health Accounts (see Note 1 for explanation). This methodology has been used for a few markets including Hong Kong, Taiwan, Somalia, Puerto Rico, Kosovo, Burkina Faso, Cuba and North Korea. This is due to elements of healthcare sector-financed expenditures being omitted in the System of Health Accounts 2011 methodology, owing to lack of appropriate methods and data sources.

For the remainder of the markets, historic government and private healthcare expenditure data is sourced from the World Health Organization (WHO)'s Global Health Expenditure Database, which contains the System of Health Accounts 2011 (see Note 2 for explanation). In December 2017, WHO released estimates of health expenditures through an updated framework called the System of Health Accounts 2011. The new classification now captures more accurately the health financing reforms taking place in member states, and enables more insightful and policy relevant analysis to be conducted. Each country's health expenditure estimates are available in absolute amounts in national current units (NCU) and common currencies including US dollars (USD) and international dollars at purchasing power parity (PPP).

To remove the effect of inflation, real healthcare expenditure figures are then calculated by removing the annual average CPI.

Real per-capita healthcare expenditure numbers are calculated by dividing by population figures.

A linear regression is then performed (see Note 3 for explanation). This is first on five years of real per-capita public healthcare expenditure against real per-capita government final consumption expenditure (see Note 4 for explanation). This generates a 10-year forecast of future real per-capita public healthcare expenditure figures from 'known' projected real per-capita government final consumption expenditure figures. Another linear regression is simultaneously performed on real per-capita private healthcare expenditure against real per-capita private final consumption expenditure.

To generate the nominal public healthcare spending forecast, population and CPI numbers are returned to both real per-capita public healthcare expenditure figures and real per-capita private healthcare expenditure figures.

The overall healthcare expenditure forecast is then calculated by combining public and private healthcare expenditure.

Notes On Methodology

Note 1: National Health Accounts methodology. The global health expenditure database that WHO has maintained for the past ten years, provides internationally comparable numbers on national health expenditures. WHO updates the data annually, taking, adjusting and estimating the numbers based on publicly available reports (national health account reports, reports from the Ministry of Finance, Central Bank, National Statistics Offices, public expenditure information and reports from the World Bank, the International Monetary

Fund, etc). The estimates are sent out to the Ministries of Health for validation prior to publication but users are advised that country data may still differ in terms of definitions, data collection methods, population coverage and estimation methods used. This database is the source for the health expenditure tables in the World Health Statistics Report and the WHO Global Health Observatory.

Note 2: System of Health Account 2011

In response to the pressing need for reliable and comparable statistics on health expenditure and financing, the OECD, in co-operation with experts from OECD member countries, developed the manual, A System of Health Accounts (SHA), releasing the initial 1.0 version in 2000. Building on SHA 2000, the OECD worked with the World Health Organization (WHO) and Eurostat to publish A system of health accounts 2011 edition (SHA 2011). The formal process of producing SHA 2011 started in 2007 as a co-operative activity of health accounts experts from the OECD, WHO and Eurostat, known collectively as the International Health Accounts Team (IHAT). The resulting manual has been the subject of an extensive and wide-reaching consultation process aimed at gathering inputs from national experts and other international organisations around the world.

This year, the WHO reported healthcare expenditure data using the framework of System of Health Accounts 2011 (SHA 2011). The macro-economic variables were also updated to calculate some indicators. At present, National Health Accounts (previously used methodology) are at different stages of development in various countries and may not only differ in the boundaries drawn between health and other social and economic activities but also in the classifications used, the level of detail provided and in the accounting rules.

The SHA 2011 framework makes health accounts more adaptable to rapidly evolving health financing systems, further enhances cross-country comparability of health expenditures and financing data, and ultimately improves the information base for the analytical use of national health accounts (NHAs). SHA 2011 reinforces the tri-axial relationship and the description of healthcare and long-term care expenditure – that is, what is consumed has been provided and financed. The framework provides an approach that better reflects the complex and changing systems of healthcare financing, eliminates ambiguities regarding some of the financing categories, provides new approaches for country-specific analysis and is sufficiently flexible to accommodate future changes. The framework also allows middle and low-income countries to provide a more transparent picture regarding foreign assistance.

In summary, the SHA 2011 financing framework increases the transparency of health financing systems, creating the possibility to monitor changes, compare health expenditures across countries and over time, as well as providing better information for analysis of the performance of healthcare financing systems. This is due to the clear distinction between the following four elements: financing schemes, financing agents managing the schemes; revenues of each scheme and the institutional units providing those revenues.

Note 3: Linear regression equation.

y = mx + b

Where y = unknown variable, m = slope of gradient, x = known variable, and b = where the line crosses the y-axis.

Note 4: Final consumption is the sum of government final consumption expenditure and private final consumption expenditure. Government final consumption expenditure is the sum of expenditure on final goods and services made by the government. Included in this are investments into healthcare infrastructure, buildings, machinery, public sector salaries, but it does not include transfer payments such as unemployment benefits or pensions. Private final consumption expenditure is the sum of all private consumption of goods and services within the economy, including both durable and non-durable goods. Housing purchases, however, are excluded. Government final consumption expenditure and private final consumption expenditure are the 'G' and 'C' in this equation:

GDP = C + I + G + (X - M)

Where GDP = gross domestic product, C = private final consumption expenditure, I = gross investment, G = government final consumption, X = exports, and M = imports.

Innovative Pharmaceuticals Risk/Reward Index Methodology

Our Innovative Pharmaceuticals Risk/Reward Index (RRI) quantifies and ranks a country's attractiveness in terms of its pharmaceuticals industry; it balances the **Risks** and **Rewards** of launching innovative medicines in different countries. It should be emphasised that the RRI *broadly* assesses the rewards and the risks that a company will face when looking to launch an innovative drug in a market. For example, we do not differentiate between drugs that are a part of different therapeutic groups or whether the drug being launched is the first to be launched in the market or will be one of the many different drugs of the same therapeutic class that has been launched in the market.

To form a country's RRI score, we combine industry-specific characteristics with broader economic, political and operational market characteristics. We weigh these inputs in terms of their importance to investor decision making in a given industry - in this case, that of innovative pharmaceuticals. The result is a nuanced and accurate reflection of the realities facing investors in terms of the balance between: 1) opportunities and risk; and 2) sector-specific and broader market traits. This enables users of our RRI to assess a market's attractiveness in both a regional and global context.

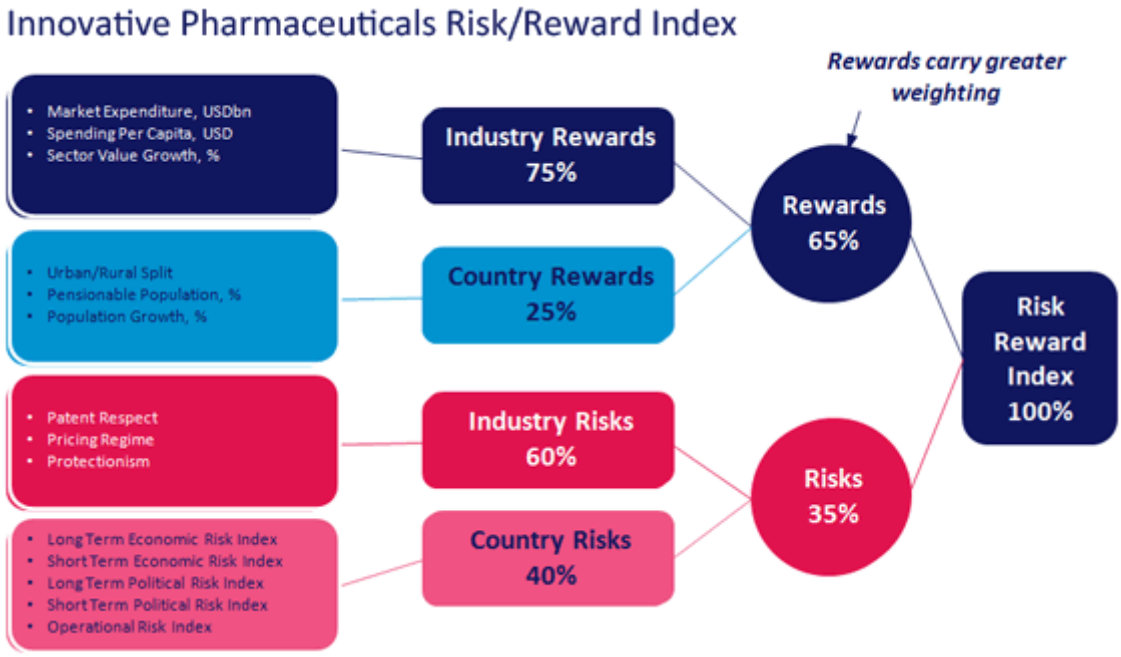
The RRI also encompasses a combination of our proprietary forecasts and analyst assessment of the regulatory climate, as well as globally acceptable benchmark indicators (eg, the World Bank's Ease Of Doing Business Scores and Transparency International's Corruption Perceptions Index). As regulations evolve and forecasts change, so does the RRI score, providing a highly dynamic and forward-looking result.

The Innovative Pharmaceuticals RRI universe comprises **110 countries**.

Benefits Of Using Fitch Solutions' Innovative Pharmaceuticals RRI

- Global Rankings: One global table, ranking 110 countries for the launch of innovative pharmaceuticals from least (closest to zero) to most attractive (closest to 100).Accessibility: Easily accessible, top down view of global, regional or sub-regional Risk/Reward profiles.
- Comparability: Identical methodology across 110 countries allows users to build lists of countries they wish to compare, beyond the confines of a global or regional grouping.
- Scoring: Scores out of 100 with a wide distribution, provide nuanced investment comparisons. The higher the score, the more favourable the country profile.
- Quantifiable: Quantifies the Risks and Rewards of doing business in the innovative pharmaceuticals sector in different countries around the world and helps identify specific flashpoints in the overall business environment.
- Comprehensive: Comprehensive set of indicators, assessing industry-specific risks and rewards alongside political, economic and operational risks.
- Entry Point: A starting point to assess the outlook for the innovative pharmaceuticals sector, from which users can dive into more granular forecasts and analysis to gain a deeper understanding of the market.
- Balanced: Multi-indicator structure prevents outliers and extremes from distorting final scores and rankings.

Weightings Of Categories And Indicators



Source: Fitch Solutions

The RRI matrix can be split into two distinct components:

Rewards: This component of the RRI is composed of an evaluation of an Industry's size and growth potential (**Industry Rewards**), and also macro industry and/or country characteristics that directly impact the size of business opportunities in a specific sector (**Country Rewards**).

Risks: This component of the RRI is composed of an evaluation of micro, industry-specific characteristics, crucial for an industry to develop to its potential (**Industry Risks**) and a quantifiable assessment of the country's political, economic and operational profile (**Country Risks**).

Assessing Our Weightings

We deliberately afford Rewards a greater weighting (65% of a market's final RRI score) and within this, the Industry Rewards pillar accounts for a majority 75%. This is to reflect the fact that when it comes to long-term investment potential, industry size and growth potential carry the most weight in indicating opportunities, with other structural factors weighing in but to a slightly lesser extent. In addition, our focus and expertise in Emerging and Frontier Markets has dictated this bias towards industry size *and* growth to ensure we are able to identify opportunities in countries where regulatory frameworks are not as developed and industry size is not as big (in USD terms) as in developed markets, but where we know there is a strong desire to invest.

INDICATORS - RATIONALE AND SOURCES

	Source	Rationale
Rewards		
Industry Rewards		
Market Expenditure, USDbn	**Fitch Solutions Forecast**	Denotes breadth of pharmaceutical market. Large markets score higher than smaller ones. Scores are based on annual average expenditure over a five-year forecast period.
Spending Per Capita, USD	**Fitch Solutions Forecast**	Denotes depth of pharmaceutical market. High-value markets score better than low-value ones. Scores are based on annual average expenditure over a five-year forecast period.
Sector Value Growth, %	**Fitch Solutions Forecast**	Denotes sector dynamism. Scores are based on annual average growth over a five-year forecast period.
Country Rewards		
Urban/Rural Split	**Fitch Solutions Forecast**	Urbanisation is used as a proxy for the development of medical facilities. Predominantly, rural states score lower.
Pensionable Population, %	**Fitch Solutions Forecast**	Shows the proportion of the population over 65. States with ageing populations tend to have higher per capita expenditure.
Population Growth, %	**Fitch Solutions Forecast**	Fast-growing states suggest better long-term demand and thus growth for all industries. Scores are based on annual average growth over a five-year forecast period.
Risks		
Industry Risks		
Patent Respect	**Fitch Solutions Subjective Indicator**	Markets with fair and enforced intellectual property regulations score higher than those with endemic counterfeiting.
Pricing Regime	**Fitch Solutions Subjective Indicator**	Markets with a free pricing environment score higher than markets where governments and private-sector payers put downward pressure on pharmaceutical prices as a mechanism to control expenditure.
Protectionism	**Fitch Solutions Subjective Indicator**	High scores are awarded to markets which have realised the economic and social benefit of pharmaceuticals, in turn modernising the provision of healthcare through reforms and essential drug lists and encouraging local manufacturing and research and development by foreign firms.

Source: Fitch Solutions

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