Egypt's Pharmaceutical Sector Following Bold Economic Reforms:
CHALLENGES AND OPPORTUNITIES
Abstract

Egypt's bold economic reform measures present new opportunities as well as risks for the pharmaceutical sector, which has witnessed a series of challenges in previous decades. This report will present a multilayered analysis of the sector in Egypt, shedding light on both short-term trends and challenges following Egypt's currency floatation, and detailing new avenues for expansion through legislative reforms that would enhance the sector's production capacity for exports in Africa and beyond.
Contents

Market Overview ........................................................................................................................................3
  Drug Sales Distribution ..........................................................................................................................4
  Foreign Trade ........................................................................................................................................5
  Competitive landscape ..........................................................................................................................6
Regulatory Environment ..........................................................................................................................6
  Regulatory Bodies in the Pharmaceutical Industry ..............................................................................7
  Roles of Regulatory Bodies ..................................................................................................................8
  Key Regulatory Issues ...........................................................................................................................9
    Forced-Pricing Mechanism ..................................................................................................................9
    Delayed Regulatory Approvals ..........................................................................................................10
    Intellectual Property Rights and Counterfeit ..................................................................................10
    Growth and Market Size .....................................................................................................................11
    Pressure to Improve Regulatory Environment ................................................................................11
    Export Potential .................................................................................................................................13
Recommendations .....................................................................................................................................13
Conclusion .............................................................................................................................................14
Arguably the region’s most promising pharmaceutical market, Egypt requires a swift overhaul of the regulatory framework for this sector so that local and foreign investors may seize its untapped potential.

Despite a turbulent half-decade for Egypt’s political and economic outlook, Egypt remains the largest producer and consumer of pharmaceuticals in the Middle East and Africa. It also maintains its position as the second largest pharmaceutical market, second only to Saudi Arabia, holding a value of EGP 35.6 bn. That said, Egypt’s recent currency devaluation, and reform-measures, such as fuel and energy subsidy cuts and the implementation of a new Value-Added Tax Law, has led to significant inflationary pressures. This has overwhelmed the Egyptian business climate, and has left the pharmaceutical industry particularly vulnerable due to an out-dated state-imposed pricing mechanism implemented when the exchange rate to the dollar was fixed.

Egypt’s pharmaceutical industry faces regulatory obstacles beyond the economic environment, including delayed governmental approvals for licensing, lax intellectual property right enforcement, and an undesirable pricing scheme. These obstacles have negatively impacted the various players in the industry.

This report aims to highlight the key characteristics of the Egyptian pharmaceutical market and regulatory framework, and capitalize on this information by offering policy recommendations that can support local and foreign investors in seizing opportunities in Egypt’s expanding market.

### Market Overview

Egypt is among the largest producers and consumers of pharmaceuticals in both the Middle East and Africa. Typified by high demographic growth and urbanization, the growth of the industry is contingent on high population growth, an expanding generic drug sector, and increased health awareness. Egypt maintains a Risk/Reward Index of 44.3 out of 100, remaining above the regional average of 40.4, making it the 4th most attractive pharmaceutical market in Africa. By 2020, the market is forecasted to expand at a compound annual growth rate (CAGR) of 8.0% in local currency terms to reach a value of EGP 48.6 bn.

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1. BMI Egypt Pharmaceuticals & Healthcare Report Q4 2016
2. Ibid.
Egypt's Pharmaceutical Sector Following Bold Economic Reforms

**DRUG SALES DISTRIBUTION**

Given the lack of a comprehensive health-insurance system in Egypt, the pharmaceutical sales are based on out-of-pocket expenditures as consumers find self-medicating to be the cheapest form of treatment. Pharmaceutical sales are divided into prescription drugs and over-the-counter (OTC) drugs. Egypt’s pharmaceutical sales are largely dependent on prescription sales, which comprised 82.5% of total drug sales in 2016 as compared to 17.5% over-the-counter products. Prescription sales are comprised of two types of drugs, generic and brand-named drugs. As shown in the figures below, sales of patented drugs will outgrow that of generic drugs due to the domestic industry’s heavy reliance on importing raw materials, which have surged in the past year. It should be noted, however, that the market could eventually shift favour towards generics, given their cheaper price tags, and the government’s willingness to maintain cost-containment measures.
FOREIGN TRADE

The pharmaceutical industry in Egypt is import-dominated in terms of volume as it imports roughly 90% of raw materials used in domestic production. This can be attributed to the market’s dependence on foreign Active Pharmaceutical Ingredients (API) due to relatively weak domestic manufacturing capabilities. On the positive side, the Ministry of Trade and Industry has pressured different industries to look for alternative manufacturing methods. This is in line with its current direction to aggressively cut down on imports as part of its plan to tackle Egypt’s trade deficit. We predict that this will trickle on the pharmaceutical industry as well, forcing it to address its limited technological capacities.

As for exports, Yemen, Saudi Arabia, Iraq, Sudan, and Kazakhstan were the top four export markets as of 2014. Pressure to explore untapped export markets in light of the recent floatation should see Egypt making strong strides in its export numbers, reaching a forecasted USD 306.16 mn by 2020.
COMPETITIVE LANDSCAPE

Egypt’s domestic pharmaceutical industry is strong, with a presence of around 120 pharmaceutical companies, of which fewer than ten are multinationals with local production bases. In the 1990s, the Holding Company for Pharmaceuticals (HoldiPharma), was established with 12 subordinate state-owned companies. There are 17 private sector players in the industry, along with nine multinational pharmaceutical companies. EIPICO is perhaps the largest private sector company in Egypt with a market share of 10-12%. Amoun and Pharco are two other key players in the industry.

On the 17th of January 2017, the Prime Ministry issued a decree that grants the Egyptian Military’s National Agency for Military Production a license to partake in the founding of a company named the Egyptian National Company for Pharmaceuticals. The decree was justified with the need to address drug shortages in the short and medium-term.

Regulatory Environment

The pharmaceutical industry’s regulatory environment has proven to be a constraining factor to players operating in the country, with the fixed-pricing scheme, regulatory approval delays, and insufficient IPR enforcement being the key domains of the problem. That said, the Egyptian government has recently taken initiative, or has at least given direct attention to the regulatory system’s flaws (explained in more details in sections below).
REGULATORY BODIES IN THE PHARMACEUTICAL INDUSTRY

In 2008, the Egyptian Drug Authority (EDA) was established by the Ministry of Health in the aim of having an independent regulatory body responsible for all pharmaceutical-related activities, similar to the function of the FDA in the United States. This was seen as a landmark restructuring in the pharmaceutical industry as there had yet to be an independent and organized body to manage pharmaceutical regulatory affairs beforehand. In addition, people responsible for pharmaceutical legislation tended to be MoH employees who have not had direct experience in the industry, which is more likely to change when the EDA is established as its own body. Albeit criticism that the body remained under the Ministry of Health and does not have financial and structural independence, the tentative establishment of the institution gives a positive indicator for pharmaceutical investors. On the 20th of October 2016, the Egyptian Parliament’s Health Committee reported that it is studying a draft bill launching the EDA as its own entity.

Three primary bodies stem from the EDA: 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 Biologicals (NOCB)
## ROLES OF REGULATORY BODIES

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<th>EDA</th>
<th>CAPA</th>
<th>NODCAR</th>
<th>NORCB</th>
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| • Protecting people’s health by regulating the safety and quality of pharmaceutical products  
• Monitoring the regulation and legislation of pharmacy practice  
• Ensuring the availability of high-quality medicines at affordable prices  
• Conducting strategic planning and policy making for the pharmaceutical sector | • Finalizes the approval for market entry  
• Provides licenses for factory operations  
• Issues pharmacy licenses  
• Inspects production facilities  
• Includes Drug Policy and Planning Center (DPPC)  
• Reviews the documentations and registration application  
• Provides price recommendations  
• Provides its approval for raw materials to be used, packaging materials, supplements and biological products, medical appliances | • Carries out quality testing of products through laboratory analysis | • Ensures the safety, quality, and efficacy of all imported and domestic biologicals, and checks to see if the products are in compliance with WHO & and international standards |
KEY REGULATORY ISSUES

This section aims to shed light on the history and current status of regulatory issues related to the industry.

FORCED-PRICING MECHANISM

Medicine in Egypt has been strictly regulated by the state since the 1950s in the aim of maintaining its affordability for lower-income segments of the population, allowing it to enjoy among the lowest retail drug prices in the region. Yet, regardless of the number of amendments in the pricing policy to help accommodate for rising costs on pharmaceuticals, there has yet to be a sustainable scheme that accounts for inflation and a changing economic climate.

After years of a pricing policy based on mark-up regulation and profit control related to the production cost of the medicine, a significant amendment was made to the policy in 2009. The government introduced the external reference pricing system (ERP), whereby a guiding list of 36 countries is used to price medicine. This system was once again amended in 2012 with decree 499, which rearranged the distribution of profit margins to different beneficiaries.

Timeline of Pharmaceutical Pricing Regulations

- **1991**
  - Ministry of Health issued Decree No.314/1991 to establish the cost-plus pricings.
  - Under this system, prices of products manufactured locally, either brand name or generic drugs are set based on the production cost.
  - A price ceiling was set to pharmaceutical companies. Generic drugs were priced at 80-90% discount rate compared to branded drug prices.

- **2008**
  - In November, an increase in prices took place after pressure from multinational corporations that suffered from the cost-plus pricing system.

- **2009**
  - Ministry of Health issued Decree No.373/2009 in early September to set a new pricing system for new companies that will register branded and generic drugs. Branded drugs were made subject to a 10% discount rate relative to the cheapest retail price found in the 36 selected reference countries. Generic drugs were priced based on 3 categories of fixed percentage markdowns of the brand-name versions of the drug. Only two of the 36 reference countries were developing countries.
  - The Decree went into effect as of 25th of September
  - In October, the Egyptian Initiative for Personal Rights (EIPR) filed a case against the Ministry of Health regarding Decree No.373/2009

- **2011**
  - The government enforced price reductions based on public demands
  - The Supreme Administrative Court ratified a Decree to tie local drug prices to international rates. The decree shall only apply on new registered patents, and not generic drugs.

- **2012**
  - The Ministry of Health issued Decree No.499/2012, which replaced decree 373/2009.
  - The decree maintained the same external reference pricing model, however it changed the distribution of the profit margins for the different beneficiaries in the medicine’s supply chain, increasing the profit margins for pharmacies, and decreasing the margins of pharmaceutical producing companies.

- **2016**
  - As a result of widespread drug shortages due to higher manufacturing costs, the Cabinet agreed to raise the prices of medicine that cost less than EGP 30 by 20%, in order to address the shortage of around 4,000 low-price medicines in the market.
  - This came as a consequence of heightened manufacturing costs after Egypt’s currency devaluation.

- **2017**
  - After strenuous negotiations with pharmaceutical companies, the Ministry of Health and Population increased the prices of 3,010 individual medicines by 30-50%.
  - Domestic products in the EGP 1-50 category rose by 50%, the EGP 50-100 category rose by 40%, and those costing more than EGP 100 rose by 30%
  - As for imported products, 20% of all imported goods witnessed a price hike, with products falling under EGP 50 increasing by 50%, and those higher priced increasing by 40%
Pharmaceutical companies have lobbied heavily for price hikes after deteriorating economic conditions post-revolution, which resulted in a devalued currency and higher production costs. According to Amr Saad, a representative of the Ministry of Health, in 2014 around 1,200 drugs were sold in Egypt at prices less than their manufacturing cost. The lobbying efforts partially succeeded when the government decided to implement a 20% price increase on all medicines costing less than EGP 30 in May 2016. The increase led to a relative stabilization of the industry, however the situation was exacerbated after the floatation of the Egyptian Pound in November 2016, which halved the value of the Pound. Given the heavy reliance on imported raw materials, as well as higher running costs on all local manufacturers, Egypt experienced a widespread medicine shortage. This placed pressure on the government from both pharmaceutical companies and those unable to access medicine. On the 15th of January 2017, the Ministry of Health issued a decree raising the price of 3,010 medicines 30-50% under a new pricing formula.

**DELAYED REGULATORY APPROVALS**

As stated previously, the body mandated to govern the licensing and registration of pharmaceutical products is the Central Administration on Pharmaceutical Affairs (CAPA). In 2009, the MOHP issued decree No.296, which outlined the general guidelines to registering products. As per the guideline, the process is divided into 5 steps, and they are:

1. The applicant should send an email to CAPA to reserve a date to submit an application form.
2. Applicant receives an email from CAPA stating the date and time for them to submit their application form within 3 working days from their initial email.
3. The applicant submits their form and receives a receipt of application that is signed by an official state pharmacist. Processing time after the application form is signed is 15 working days.
4. CAPA informs applicants whether or not the application was accepted. In the case that it is accepted, the applicant will then be given 30 working days to deliver a pricing file so that the product is priced according to Decree no.499.
5. Applicants are to be informed of their product’s state-regulated price within 60 working days.

Despite an expected total of 105 days mentioned in Egypt’s registration guidelines to complete the process, pharmaceutical manufacturers have reported delays in regulatory approvals taking up to two or three years. According to a source from a leading pharmaceutical multinational operating in Egypt, the shortest time taken to register one of their drugs was six months. It was also stated that the time required to register a drug depends on the availability of the drug in the market, and whether or not it treats chronic illnesses, which creates a discriminatory market access climate. In addition, Egypt’s inclusion on the Pharmaceutical Research and Manufacturers of America’s (PhRMA) Special 301 Submission for a third consecutive year indicates that regulatory approval delays are a primary threat to innovative drug-makers.

**INTELLECTUAL PROPERTY RIGHTS AND COUNTERFEIT**

The Egyptian Patent Office at the Academy of Scientific Research and Technology (ASRT) manages intellectual property rights (IPR) in Egypt. After adapting a comprehensive IPR law in 2002, Egypt enforced the World Trade Organization’s Trade Related Aspects of Intellectual Property (TRIP) agreement in 2005. As part of the agreement, Egypt was obliged to suspend activities of any generic drug-manufacturing company that has not acquired a marketing license after the expiration of the original patent period. However, patent violation in the industry remains

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4 Based on key informant interview
to be substantial. The most recent high-profile case occurred in 2014 when the Ministry of Health granted five local pharmaceutical companies permission to produce a generic version of Gilead Science’s hepatitis C drug **Sovaldi**. Gilead had only allowed seven Indian generic drug makers to manufacture the drug. As for counterfeit activity, Egypt is regarded as a transit hub for counterfeit medicines coming from Asian markets to Africa. Although the number of counterfeit medicine is difficult to assess, multinational pharmaceutical companies have constantly reported that the activity strongly affects their business.

**GROWTH AND MARKET SIZE**

With global demographic growth and urbanization expected to rise in Africa, Asia, and Latin America, a 90mn consumer market such as Egypt offers opportunities for many pharmaceutical companies. Rising GDP Per Capita, supported by an increasing population, and increasing health awareness, are all attributes to an attractive market for pharmaceutical companies. Furthermore, efforts made to introduce basic universal health insurance should also help the 20% of the population that lacks public or private health insurance to participate in the prescription drug market. The Government looks to raise the allocation towards healthcare to the ambitious target of 3%. As it stands, Egypt’s public health insurance system covers less than half of the population, leaving most of Egypt’s healthcare expenditure coming from out-of-pocket patient expenditures. In April 2016, Egypt’s Minister of Health submitted his proposal for advancing the public health industry in the country through four main pillars:

I. Human capital development through training and capacity building for professionals working in MoH hospitals
II. Reform and expansion of the national health insurance, and utilizing PPP projects with the strong private health-insurance base
III. Reducing the burden of Hepatitis C
IV. Allocating more of the Ministry’s budget to upgrading healthcare facilities

**PRESSURE TO IMPROVE REGULATORY ENVIRONMENT**

As previously stated, without the necessary regulatory reforms, industry investors will continue to shy away from the market. However, there are tangible indicators to be optimistic that the regulatory environment will be improved. The MoH’s responsiveness to the lobbying efforts imposed by the local pharmaceutical industry and pressure by the government sets a new precedent for effective cooperation with relevant stakeholders in the coming period. For the first time in its history, the MoH has been forced to alter its pricing mechanism twice in less than a year in order to accommodate for these demands, and this indicates that there is at least enough pressure to break the rigidity of the regulatory system, and open the door to more profound change.
We remain optimistic that regulatory adjustments may be made in the following domains:

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| Basis of Opportunity | - The MoH’s decision to raise the price of nearly 3,000 medicines on January 2017 was seen as a lobbying breakthrough given that the Minister had maintained his rigid stance of denying a nationwide drug shortage for months. Although the price-hike has given pharmaceuticals room to “breathe”, as Managing Director of one of Egypt’s most prominent pharmaceutical multinationals stated, the Ministry of Health is required to find a more sustainable solution.  
- Furthermore, in 2016, the MoH stated on a number of occasions that it is looking towards the automation of pharmacy management to speed up procedures in the registration of drug licensing and pricing, as well as the drug supply chain project. | - A constitution that has embedded intellectual property rights indicates political will for IPR reform  
- In 2014, the MoH reportedly created a committee to establish an effective patent enforcement mechanism and to study measures to tackle counterfeiting activity. This at least shows awareness of the problem. |
| Our Recommendations | - The establishment of the EDA as a financially independent body will facilitate the study of a more sustainable pricing and registration system that caters to a constantly changing industry ecosystem.  
- However, it should also allow for the inclusion of key stakeholders from pharmaceutical industry, alongside government officials in the decision-making process. This is also the case for equivalent foreign bodies such as the American FDA, and the National Pharmaceutical Pricing Authority (NPPA) in India. As member of the Egyptian Chamber for Pharmaceutical Industries, Ossama Rostom stated, the individual stakeholders for overseeing pharmaceutical regulation in Egypt are often not from the industry and therefore are often not aware of the complex impediments it faces. Going through with the creation of the EDA and allowing industry players to take part in the decision-making process will enable the creation of a pricing system that is more sustainable, more accommodating to changing environments, and more efficient in drug registration methods. | - Incentivizing local R&D activity and obliging companies to dedicate a portion of their revenue to this will decrease the local industry’s reliance on the generic industry, and will consequently deter IPR infringement.  
- Reinforce the efforts of the Customs Authority and the Ministry of Interior’s Supply Investigations Department to crackdown on counterfeiting activity, especially in medicine given the detrimental impact on consumers’ lives.  
- Amending the Ministry of Health’s pharmacy law in order to curb unlicensed pharmaceutical sales. The amendments can come in the form of establishing a barcode system that automates the illicit drug tracking, or by adopting harsher punishments for participation in counterfeiting activity. |

5 Based on key informant interview
**EXPORT POTENTIAL**

With an ambitious target of boosting export numbers from USD $18.5 to USD $34 bn by 2020, Minister of Trade and Industry Tarek Kabil is adamant on gearing attention away from oil and gas-based exports to focus on diversifying export industries. One key advantage of the floatation of the Egyptian currency is the competitive price advantage relative to international markets, especially in untapped markets in Africa. Furthermore, the floatation allows Egypt to accommodate significantly low labour costs and a large pool of highly trained doctors, pharmacists, engineers, and skilled technicians. It is noteworthy that there are local companies already capitalizing on the opportunity, such as one of Egypt's largest generic drug producers, EIPICO, which is currently constructing a production plant with output levels expected to surpass domestic demand, and thus also leaving a sizeable portion for exports.

**Recommendations**

1. **Research and Development**

One of the main channels to significantly boost exports in the medium and long-term is to invest in the local manufacturing of APIs. This will reduce reliance on imports for raw materials thus decreasing manufacturing costs, giving economies of scale, and increasing output capacity. The only viable way of accomplishing this is developing R&D activity, which few local companies currently invest in.

2. **Diversifying export markets**

Until recently, Egypt’s target markets were significantly limited to Asia-specific countries. With changing geopolitical conditions and much better positioning to export due to the currency floatation, Egypt should capitalize on new export opportunities by optimizing the use of its promising Free Trade Agreement (FTA) memberships and optimizing the pharmaceutical industry’s trade mission activity abroad.

Egypt is currently a member of the COMESA, EFTA, GAFTA, Agadir, EU Partnership, and QIZ. In addition, Egypt has also spearheaded the Tripartite Free Trade Agreement, which should combine the three major African FTAs – COMESA, SADC, and EAC – into one. A great number of the members of these agreements are potential export markets that have yet to be tapped by local pharmaceutical companies, due to the lack of accessibility and the financial resources to study the markets.

African markets were neglected in previous times due to strained political ties between Egypt and much of the continent prior to the 2011 Revolution. Since then, Egyptian foreign policy has drastically changed and more effort is being made to utilize African markets. For instance, the Export Council of Medical Industries (ECMI), which is a council under the Ministry of Trade and Industry mandated to boost export activities for the pharmaceutical, medical device, and cosmetics industries, have started to play a more effective role in accomplishing this. Dr. Maged George, Chairman of the ECMI, placed an intensive plan to organize trade missions for these three sectors throughout the continent in order to highlight export market opportunities for smaller pharmaceutical companies that do not have the resources to explore them themselves. This is a positive indicator that more export markets could be reached in upcoming years.
3- Fast-tracking regional harmonization of registration processes

The Arab Union of the Manufacturers of Pharmaceuticals & Medical Appliances (AUPAM), a sub-organization of the Arab League, has begun the development of a regional drug registration process in the region. The organization includes 15 Arab countries, among them key pharmaceutical industry players such as the UAE, Jordan, Saudi Arabia, and Morocco. If implemented successfully, this will not only ease the penetration of undiscovered foreign markets in the region, but also attract investors in neighboring countries to Egypt.

Conclusion

If enough political will and initiative is exerted to address the flaws of Egypt’s regulatory framework, a major deterrent to pharmaceutical investors may be removed. In BMI’s MENA Pharmaceutical Risk Index, Egypt received a score of 2.8/7 for patent respect, 2.1/7 for policy enforcement, and 1.4/7 for approval expediency. These scores fare significantly lower compared to neighboring countries, and provide empirical evidence of the regulatory deficiencies in the market. By expediting the process to establish an independent regulatory authority comprised of figures well-aware of these deficiencies, incentivizing the local industry to improve R&D activity, reinforcing IPR enforcement, and improving export activity focusing on untapped export markets such as Africa, Egypt’s pharmaceutical industry may be attractive enough to exceed its growth expectations on the long run. According to a report published by BNP Paribas, Egypt retains the region’s strongest economic strength assessment in the region. Egypt’s brave fiscal and monetary reforms might have ushered a period of short-term hardship, but secured a safer medium-term economic future, with GDP expected to reach 4.5% and core inflation levels set to decrease to 14.5% by 2018. These positive indicators could in turn lead to an improved business climate, which would decrease pressure on industry players to operate. The future of Egypt remains promising for all markets, including the pharmaceutical. All that is required is patience from pharmaceutical investors, and firm action by government stakeholders for the industry’s potential to be reached.

Sources:

BMI Egypt Pharmaceuticals & Healthcare Report Q4 2016
EIU Pharmaceutical Report 2014 Q4
Observatory of Economic Complexity – Egypt Country Profile

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