Interview: Ahmed Zaghloul – CEO, October Pharma, Egypt

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You were last interviewed by Focus Reports in 2006; how would you compare the economic context for the Egyptian pharmaceutical market today to that of 2006?

In 2006 economic growth was accelerating, per capita incomes were increasing, and people were starting to invest in things outside their basic needs for survival, such as health and education. The government had shared a clear vision to increase public funding for healthcare and education, and they had clear intentions to carrying out financial and limited political reforms which they began before the January 2011 revolutions. From the pharmaceutical perspective, the market was very attractive as the life expectancy of Egyptians was rapidly increasing and thus the proportion of the population belonging to older age groups was steadily increasing, which is very important for pharmaceutical companies who seek to treat oncology or chronic diseases.

Today, the basic demographic trends and market fundamentals are still very attractive and the population is growing by roughly two million people per year. We are seeing predictable double-

digit growth in local currency, with reasonable USD growth of 8.3 percent in 2014 and 5.5 percent in 2015, with the potential to be much higher if the wider economic situation were to stabilize. That said, these growth figures are somewhat misleading as roughly 4 or the 5.5 percent growth was realized within one therapeutic segment; antivirals such as sofosbuvir which are used to treat hepatitis C.

The downside is that the Egyptian economy is currently in a precarious situation. Tourism generated the majority of foreign currency for Egypt in the past, and this industry does not appear to be on the path to recovering to pre-revolution levels. This has created a significant deficit in Egypt's current account, which has caused significant shortages of hard currency and prompted multiple currency devaluations, with more expected to occur in the coming months.

How do you expect to see the situation evolve in the coming months?

My primary concern is not the current economic situation, but rather the fact that there does not appear to be a clear vision for how Egypt can overcome these challenges and set the economy on a stronger growth trajectory. The current government has not shared any clear plans for economic reform with the business community. Moreover, the president and his cabinet are so isolated from existing politics that it is unclear whether liberalization or further regulation of the economy can be expected. Given the current trade deficit there is a clear need for Egypt to drive export growth and to attract foreign investment, yet there has been very limited guidance in this regard.

This situation has particular implications for the pharmaceutical industry, as we have excess production capacity and can easily produce pharmaceuticals for the export market at competitive prices. Moreover the industry has a strong base of skilled and knowledgeable professionals, well-trained individuals with a wealth of experience. However, there are certain barriers that we would need the government to help address if this is to become a reality, and the government has not made its stance clear on the matter. The government has not shared a political vision for the Egyptian pharmaceutical industry, and most likely one does not exist; it is impossible to say whether the authorities intend for the pharmaceutical industry to generate foreign income into Egypt. In fact, current regulatory policies do not support the growth of the pharmaceutical industry, exports, or incentivize investments in this area.

If the government were to formally incorporate the pharmaceutical industry into its economic vision for Egypt, what policy changes would be necessary?

For the pharmaceutical industry to grow pricing reforms are absolutely necessary as costs of imported raw materials have increased significantly while local currency prices have remained

fixed. Secondly, regulatory reforms are necessary to support exports; currently, the Egyptian Ministry of Health does not recognize bioequivalence studies performed outside of Egypt, even when conducted at highly accredited facilities certified by the EMA. Thus, to develop a product for the export market currently we must carry out bioequivalence studies in Egypt as well as abroad, as there are no internationally accredited facilities in Egypt, and there won't be any until parliament passes a law formally regulating clinical trials. The Ministry of Health is also not particularly supportive of even incremental innovation in Egypt, as officially we cannot register products that don't have an exact reference product registered in one of our 23 officially recognized reference countries; an October Pharma product was recently rejected because we wanted to package 30 tablets in each box, whereas the reference product only contained 15 per box. There are ongoing discussions to create an Egyptian Drug Authority independent from the Ministry of Health, but unless new people with new ideas, experience and capabilities are brought in, then its formation would have a limited impact.

With respect to attracting investments, the policy changes needed are not specific to the pharmaceutical industry. The government must introduce explicit incentives that make Egypt a competitive investment destination when compared to other markets globally. An essential first step would be for the government to make clear and credible assurances to potential international investors to build confidence in the security of investments in Egypt, as several investors saw the contracts that they signed with the Egyptian government before the revolution treated as invalid following the revolutions; such situations must be resolved first before we can attract substantial new investments.

Given this lack of vision, what is your current strategy for October Pharma?

Last year in 2015 we set the internal goal for October Pharma to be in the Top 15 Egyptian pharmaceutical companies by 2025. We achieved our first round of targets for 2015, and so far we are on track to achieve this larger goal.

When I developed our current strategy and presented it to the board, I was very clear that, given the fragmented nature of the Egyptian market, it would be extremely difficult for a company of October Pharma's size to capture significant organic growth. For any given generic our competitors like EIPICO and MUP can put far more marketing personnel in the field. To realize significant growth under these circumstances, inorganic growth may be much more profitable and as such I have been searching for acquisition opportunities of companies up to the same size as October Pharma. This could also include the acquisition of specific product lines; in fact we acquired a few products from Hikma three years ago.

At the same time however, growth in Egypt is quite difficult at present due to the pressure on prices and strong competition. In fact, it appears that given our position it may be much easier to grow in export markets; 10 percent of October Pharma's turnover currently comes from export sales and we have products registered in markets not usually targeted by Egyptian companies like Russia, Thailand, and Vietnam amongst others. In many such markets we only have a single product registered, so we are currently working to build upon such toeholds and develop a strong export business; we aim to grow our export business such that by 2025 exports account for 50 percent of our total revenue.

What changes and investments will October Phamra need to make?

To do this, we must make October Pharma competitive and attractive on the international market, so we are working towards getting a GMP certificate issued by a recognized EMA authority. However, the current hard currency shortage and aggressive pressure on our margins makes it challenging to finance the necessary investments. It is not clear how long it will take to bring our facility into EMA compliance, although it will certainly take longer than a year or two; it is very likely that I will retire from my position as CEO before this process is complete, but I hope I can make enough progress that getting an EMA GMP certificate will be achievable for my successor. Already our internal standards and capabilities are higher than those required by the Egyptian government, as we are aiming to meet global standards.

We are also working to overhaul and upgrade our portfolio to better match with the current strategy of the organization. This means that we are developing some products with the needs of our export markets in mind, and we also see a space to create a line of pure generic products for the tender market, as opposed to branded generics. Finally, we have begun to change all of our product registration files over to the ECTD format and are carrying out bioequivalence studies at EMA or GCC certified facilities to prepare them for registration in foreign markets; this is part of a wider effort to develop a powerful regulatory department that will be able to meet the requirements and demands of regulators in markets worldwide.

How much progress have you recently made?

Over the last year we have been able to register one product in Morocco and our facilities have been audited and certified by the authorities of Uganda, Kenya and Nigeria. We have also established a relationship in Ethiopia – we expect to be audited by their regulator soon – and plan to enter the French speaking countries in West Africa via Morocco after we solidify our presence there.

Several other opportunities depend largely on the political situation. For example, we still have many connections in Yemen and we continue to pay our representatives there to support them through this dangerous and unstable time, in the hopes that the situation will soon stabilize and allow our business to resume. We are actually building an internal team to focus on the Yemen and Oman market at present.

The other very high potential market, one that could determine our company's growth potential as a whole, is Russia. We already export products to Russia and have a presence on the ground via a local agent and currently we are studying the possibility of establishing a legal entity of our own in Russia. Studies are still underway and it may turn out to be prohibitively costly, however the Russian market is quite large and strong and we are determined to leverage our current presence in the Russian market to drive our growth. In recognition of this markets potential, we have already dedicated one full time employee to the Russian market, as well as another to our objectives in French speaking West Africa.

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