Interview: Ashraf El Khouly – Executive Director, Egyptian Society for Pharmaceutical Research

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"Egypt will become the largest market for pharmaceuticals within the region in the next three years"; Ahsraf Elkhouly, Executive Director the Egyptian Society for Pharmaceutical Research (ESPR), highlights Egypt's untapped potential and explains the challenges currently being overcome in Egypt's pharmaceutical sector.

What makes Egypt the 'go to' market in the region for pharmaceutical companies?

Despite that fact that the multinational pharmaceutical industry established its production sites in Egypt in the 1960s, I identify Egypt as a virgin market. Per capita spending on drugs is very low, yet the market is growing at a double-digit rate. Egypt's economy is recovering rapidly and has stabilized from the political unrest of a couple years ago, and the population is one of the largest in the region and is growing immensely. With current spending on pharmaceuticals in Egypt at USD 35 per capita, the market can only grow, and any healthcare project however small can only contribute to and enhance the current market growth of 15 percent (in local currency), and improve the situation for Egyptian patients.

In terms of healthcare systems development, the cost needed for drastic and comprehensive reforms according to different plans being discussed in government is close to EGP 100 billion (USD

12.5 billion), still a prohibitive amount given Egypt's current economic situation, but I am convinced that Egypt will soon be taking some small steps in the right direction. For example, a draft social health insurance law is currently being discussed by authorities, and the new constitution mandates an increase in public spending on healthcare, so much of the industry considers the situation quite promising; in fact, 40 new pharmaceutical manufacturing plants are under development, in addition 160 plants that are already operational. Given these developments, Egypt will certainly become the largest pharmaceutical market in the MENA region within the next three years.

Could you give us a brief introduction to the ESPR in Egypt and the recent accomplishments of your organization?

The Egyptian Society of Pharmaceutical Research (ESPR) currently consists of 19 members, and is the legal entity which the US based Pharmaceutical Research and Manufacturers of America (PhRMA) operates under in Egypt. Our purpose is to make the pharmaceutical market in Egypt attractive for investors and beneficial for patients, in cooperation with the Ministry of Health. I joined ESPR's board of directors in 2008 and am currently the executive director of the organization. In recent years we celebrated several achievements, the most significant being reducing the registration time of drugs from between three and four years to 18 months, providing the Egyptian patient with innovative treatment much faster. Another significant success was the establishment of a committee consisting of different stakeholders in the industry that jointly reviews new laws and regulatory decrees and communicates the communal assessment to the Ministry of Health. Furthermore, this committee also submits its own proposals for regulatory changes, the latest being a proposal to restructure pharmacy and distributor margins so that higher priced products are marked up less, aiming to minimize the financial burden placed on patients who need these more expensive medicines.

What are the current issues you are working on to solve?

Currently, the ESPR is working on seven high priority issues in the Egyptian market: convincing the government of necessity of implementing a GS1 standard pharmaceutical tracking system, applying the common technical document (CTD) specifications for drug registration applications, the further acceleration of the drug registration process, establishing the right framework in Egypt in regard to biopharmaceuticals and clinical trials, solving the current pricing issues and continuing the fight against counterfeits. Accomplishing any and all of these objectives will bring invaluable improvements for local and multinational pharmaceutical companies in Egypt as well as for the Egyptian people.

The implementation of a healthcare system held to GS1 standards, in particular, will greatly benefit all stakeholders in Egypt. It will provide safety and further quality for Egyptian patients, as this will evolve the outdated payment system in place in Egypt. The CTD will improve electronic registration in Egypt and level it to global standards, in addition to providing a master file for APIs that will guarantee the quality of the end product. Furthermore, the regulatory framework in Egypt has to acknowledge current and future trends in the pharmaceutical industry and proactively encourage change; a framework for regulating clinical trials is needed, and preparations must be made to effectively regulate biopharmaceuticals, as 41 percent of all phase II and III drug candidates worldwide are biological in nature.

In all of these topics, ESPR is prepared to help, advise and support the Ministry of Health to its full capacities.

Trading of counterfeited drugs is a key issue in the Egyptian market, what needs to be done to purge the Egyptian market of counterfeits?

To effectively fight counterfeits, the full implementation of GS1 unit tracking standards to the full pharmaceutical supply chain is non-negotiable. From the start of implementation process, it will take approximately three years as all the pharmacies need to be connected to a centralized system which reports sold drugs to the manufacturer; a Herculean task. Once implementation is underway, the responsible government authorities will be able to detect and track changes and violations immediately, which will immediately reduce the trade of counterfeits in Egypt.

Next, stricter laws and penalties for the trade of counterfeit medications must be implemented in our legislative system, as current punishments are not strict enough to effectively reduce these illegal and dangerous activities. Finally, our inspectors and border control personnel need better training and equipment, as the status quo of the latter simply does not allow the effective identification of counterfeits.

How do you assess the current public-private collaboration in Egypt?

As a result of the revolution, the government started to recognize that the private sector can provide valuable input and guidance in certain areas, one of them being the pharmaceutical sector; as such, the pharmaceutical industry as a whole has been able to communicate with the authorities more effectively in recent years. This voice has and will always communicate that our main concern is the patient’s wellbeing, and I am certain that increased public-private co-operation will only bring benefits to Egypt and Egyptian patients. In this context, the public-private collaboration has improved, yet challenges remain. One of the current issues we are tackling is helping

to increase the understanding among government officials that the interests of the patients and the industry are aligned, and that they depend on one another.

Affordability and accessibility of drugs for the patient is a common goal, however, government authorities need to understand that this goal needs to be reached sustainably, and that prices should be at a level that patients and the industry both find reasonable; at present, prices are so low that certain products are no longer being produced, and that Egyptian companies are nearly unable to export, due to target markets referencing the rock bottom ex-factory prices here in Egypt.

Furthermore, a vital aspect for improving public-private collaboration is the enforcement of intellectual property rights, as guaranteed in the new constitution. At present, government policy is not only lacking in the area of enforcement, but in some cases is actually encouraging the violation of those rights; the Ministry of Health will not only registered product that infringe on valid patents, but also carries out the analysis of the first batches, effectively supporting the development of products which violate valid IP.

What is the message you would like to be heard around the world?

In my professional life I have worked in over ten countries, many of which were behind Egypt in terms of drug pricing, registration processes, quality control, and in the development of the overall industry. This has changed since I started my career, and Egypt has fallen behind. Nonetheless, I am convinced that Egypt can and will take back its rightful place as number one in the MENA region and Africa.

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