Interview: Tarek Salman â?? Deputy Minister of Health for Pharmaceutical Affairs, Ministry of Health, Egypt

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Deputy Minister of Health for Pharmaceutical Affairs Tarek Salman discusses how pharmaceutical regulation in Egypt is taking a leap forward, with the introduction of new legislation with parallel registration process that will bring approval timelines under 21 months, and the imminent establishment of the Egyptian Drug Authority, which will merge three key regulatory bodies into a single agency.

Could you please introduce us to the Egyptian pharmaceutical market, and the current developments taking place in terms of pharmaceutical regulation?

Egypt has approximately 160 pharmaceutical manufacturers, with another 40 plants under development, and 15,000 pharmaceutical products registered to 1,100 different companies with ndividual product registrations. We try to limit the number of imported generics for a single molecule manufactured and registered in Egypt, and thus for each original product we allow one imported generic, and up to 10 locally manufactured generic brands to be registered for a given active ingredient. The price of the original product is determined based on a reference pricing system that takes the lowest price observed amongst 30 reference countries; the first five generics are priced at 65 percent of the original product, with the next six priced at 60 percent of the original price.

Registration timelines for new products have been quite long in the past, taking up to four or five years, however we have accomplished a significant reduction of the time it takes to process registration applications. Last year a ministerial decree mandated that registration timelines be shortened to a maximum of 21 months, less than two years. Already we have been able to effectively apply a fast track system for products of particular importance for the Egyptian people, as when we were able to finalize the registration and approval of Abbvieâ??s new all oral hepatitis C treatment Querevo, so that Egyptian patients got access at roughly the same time as patients in the

US.

Under this new, faster approval system we are now carrying out different core processes in parallel. For example, pricing and pharmacovigilance procedures are now being carried out simultaneously. Next, pilot R&D tasks, analysis of first batches, and inspections of certain products that need additional assessment and validation will be carried out. The challenges of implementing the new system are still being carried out, for example we are currently implementing new processes to automate the process of naming new products. Furthermore, the Central Administration for Pharmaceutical Affairs (CAPA) is leading the way in terms of regulatory processes in Egypt, and has achieved full automation of registrations inside CAPA. This is in part an implementation of the Good Governance for Medicine in Egypt initiative; automated registrations eliminate opportunities for corruption, which can cause significant delays and failures of regulatory processes. We are currently cooperating with the rest of the Ministry of Health, the Ministry of Communication, and the Ministry of Planning to further automize processes to prevent corruption.

Also of note is that Egypt was the first Arab country to develop guidelines to combat counterfeit products, and we have recently began the discussion regarding the implementation of a national serialized track and trace system, like many countries. Based on our study of similar implementations in other countries, such as Saudi Arabia where it took three years, we are currently finalizing our plans for implementation. In two weeks we will be presenting our implementation strategy to the rest of the pharmaceutical sector, and we expect that the implementation process will begin in 2016.

What structural changes will be required to further these developments within the Ministry of Health?

The Ministry of Health is finalizing a final plan to create an Egyptian Drug Authority (EDA), loosely modeled on the FDA and other similar organizations. Unlike the FDA, the EDA will focus solely on pharmaceutical products, and will not oversee the market for food. This decision was made following a joint study with the National Food Safety Agency and discussions with the entire pharmaceutical sector, including the Pharmacists Syndicate, various ministries, pharmaceutical manufacturers and distributors. The conclusion of this consultation process was that due to the wide variety of distribution channels for food products, it would be more effective to limit the EDAâ??s focus to pharmaceutical products.

This new centralized body will bring together three separate bodies; the Central Administration for Pharmaceutical Affairs, the National Organization for Drug Control and Research, and the National Organization for Research and Control of Biologicals, under a single umbrella organization.

Plans for the EDA have been underway for over a year now, and we have had regular meetings to prepare for this development since October 2014. At present, the Ministry of Health owns land in two areas just outside of Cairo, in Badr City and Sixth of October City, and one of these will likely be the site of the new Egyptian Drug Authority. We already have communications material developed and ready to implement, and an engineering and construction office hired to plan and build this new facility. Now that the Ministry of Health has finished developing plans for the formation of the EDA, it is time to begin a final consultation and negotiation process with the other important stakeholders in the Egyptian pharmaceutical sector.

Are there any unique features or challenges in Egypt which require different regulatory processes than seen in other countries?

Earlier I mentioned that we have begun automation of the naming process, which is particularly important in Egypt. The old system was quite slow and tedious, not to mention inefficient, and

automating the process of analyzing and revising names will help to accelerate registration timelines. In Egypt, because a certain portion of our population cannot read, it is essential that different product names are distinct and not easily confused, otherwise the potential for miscommunication between pharmacists and patients can create significant risks for medication errors. This is particularly important because pharmacists play a critical role in Egyptian healthcare, recommending many important medical products to patients when getting a prescription from a physician is not feasible. As such, the Central Administration for Pharmaceutical Affairs seeks to ensure that products are named such that the spelling, sound, and visual appearance of product names are such that the risk of miscommunication is minimized, and going forward, this process will be enhanced by the use of automated methods that will increase both our efficiency and effectiveness.

Separately, food supplements are required to be registered in Egypt, although in many countries around the world they are not. Since the constitutions of such products are very complex, the registration process takes a long time.

What are the key areas of collaboration between the Ministry of Health and other stakeholders?

In August I had the pleasure to meet with the executive director of the American Chamber of Commerce while he visited Egypt as a part of American Secretary of State John Kerryâ??s delegation. During this visit we planned a formal meeting between the American Chamber of Commerce and the Ministry of Health to discuss collaboration between our two countries on the topics of pharmaceuticals and healthcare, and were lucky enough to have another follow up meeting with them in November 2015.

Here in Egypt, we work closely with the association for innovative pharmaceutical companies, PhRMA, and its members, who provide a variety of educational courses for our staff here at the Ministry of Health, as well as support for the ministry in the areas of information technology, including our adoption of the Electronic Common Technical Document. The Ministry of Health is currently collaborating with the Ministry of Higher Education and Scientific Research to develop a comprehensive regulatory framework to regulate and organize all clinical trials in Egypt, which will help Egypt to be involved in global clinical trials for innovative medicines. This initiative is very important, as participation in global clinical trials will help increase the access of Egyptian patients to innovative drugs, and the exposure of Egyptian physicians to the latest medical developments.

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