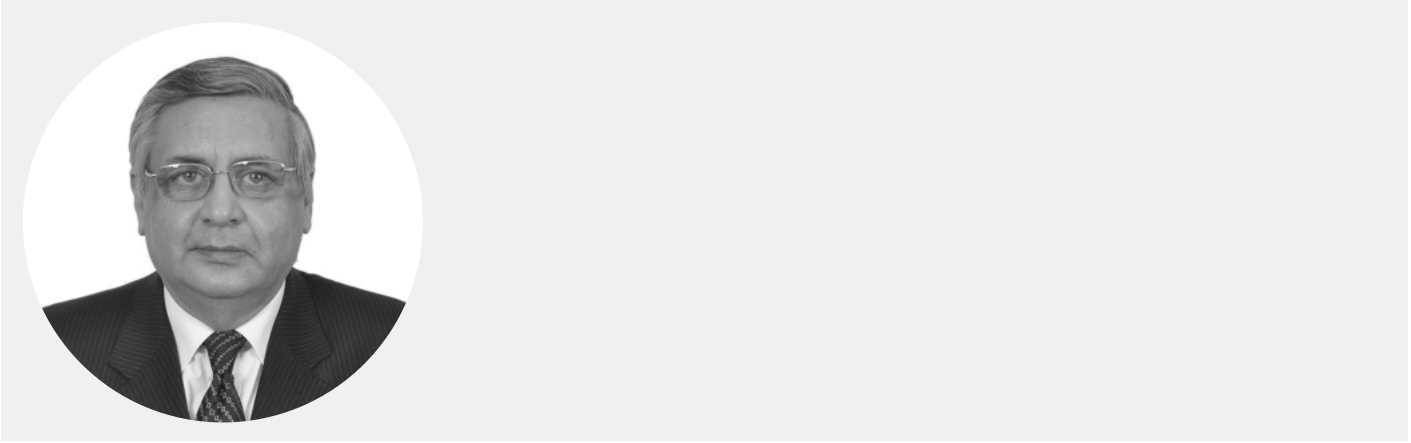
Interview: Prof. Dr. Mohamed Awad Tag Eldin – Chairman, Arab Company for Drug Industries and Medical Appliances (ACDIMA), Egypt



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The chairman of Egypt's largest holding company for pharmaceutical manufacturers, ACDIMA, shares his vision for how Egyptian manufacturers can enhance their competitiveness in the coming years, and extend their activities further up the value chain into API production and R&D activities.

How well prepared are Egyptian companies to compete in the current pharma market?

There is still room for improvement in the Egyptian industry and we have some ambitious goals for the coming years to increase the competitiveness of our companies, but overall I would say many of our companies, certainly the largest Egyptian manufacturers, are very well equipped to compete for the next few years. The entire Egyptian industry complies with rigorous GMP requirements and many Egyptian companies manufacture products for multinationals and are thus held to global manufacturing standards by their foreign partners. These partners carry out regular inspections of the various production lines and in general very few issues are encountered. Moreover, the Ministry of Health and Population has implemented strict regulations and carries out regular inspections along the entire pharmaceutical value chain, including at the final point of sale in pharmacies, and this has driven a marked improvement in quality and reliability compared to some years ago.

Of course, there are competitive challenges. Since the vast majority of medications are well established, competition from newly developed molecules is not a major threat to the business of Egyptian manufacturers today. Instead, we are facing a much greater challenge from products that utilize new methods of delivery. The most popular example is insulin, where a few years ago the standard for administration was a simple vial and syringe, while the multinational companies are now transitioning to injection pens, which many patients prefer. These pens represent an increased level of complexity and expense, the same goes for the new types of inhalers, and ACDIMA is currently supporting efforts to develop Egyptian products that feature new delivery technologies, to compete more effectively with the innovators.

What investments need to be made for the Egyptian industry to remain competitive in the coming years?

Egyptian companies must increase their level of technical sophistication and begin some upstream operations. Our first goal is for some of the larger Egyptian companies to develop API production for a few of the most commonly used compounds in Egypt. It is certainly not practical to produce most APIs domestically, but developing dedicated API production facilities that can manufacture some ingredients for the local market and for export will enhance the industry’s competitiveness and capability as a whole. Selecting the right APIs to produce is both critical and challenging, and we are now carrying out detailed cost-benefit analysis and investment studies. As an example of an API that doesn’t make sense, while cephalosporins are commonly used antibiotics, with over 300 kg used in Egypt each year, an investor must be confident that they can sell a minimum of 500 kg for the investment to make sense; to capture just the 300 kg local market you must be able to compete with Indian and Chinese producers on price, and significant infrastructure would be required to be able to export the remaining 200 kg.

The second goal in this regard is to develop more technologically advanced manufacturing operations, including biosimilar production, and licensed production of products that depend on sophisticated technologies. We have similar goals for the production of medical appliances, and of course the aim to produce products with advanced delivery mechanisms, on both the formulation side, and in terms of the medical appliances; already there are insulin injection pens being made in Egypt.

A third objective is to increase investment in R&D, and thus to increase the scientific capacity of Egyptian pharmaceutical companies. In one respect this overlaps with the previous goal; for example, developing R&D capacities pertaining to bioengineering will be critical to a companies ability to move into biosimilar development and manufacturing. Taking a longer view however, we

would like to look towards the day that an Egyptian company might develop a molecule on its own to bring to the global pharmaceutical market. As such, we are encouraging our companies to invest more in research projects, to work with research centers and universities, and to aim to develop some products featuring incrementally innovative features.

Finally, Egyptian pharmaceutical manufacturers need to export more. We are currently focusing on developing exports, and have even established foreign operations in Sudan, Ethiopia, and Libya. In general, African markets represent a huge potential for Egyptian companies in the future, and it is important that we establish stronger relations in these countries and begin investing in the African pharmaceutical industry. Of course, we must also work to expand our exports to other Arab countries as well as Eastern Europe.

Some companies have expressed a willingness to invest more in R&D in Egypt but cite the current lack of a clinical trial law and an FDA or EMA approved bioequivalence study center as a major hurdle.

Egypt already has very strong regulations for clinical trials, however these regulations have taken the legal form of Ministerial Decrees. Many multinational companies require that such regulations be set in Egyptian law before investing significantly in clinical trials in Egypt, and we recognize that such laws already exist in neighboring countries like Jordan and Saudi Arabia. At present, we are working with the Ministry of Scientific Research to finish a draft law for clinical trials, and now that our new parliament is in session it will be possible to get such a law passed soon.

For Egyptian companies that need to carry out bioequivalence studies at an EMA approved facility, they will soon be able to do so within Egypt. ACDIMA is an investor in the International Center for Bioavailability, Pharmaceutical and Clinical Research (ICBR), and this is a brand-new state-of-the-art facility located in El-Obour City that has been developed according to international standards and complies fully with EMA requirements. ICBR recently hosted the inspectors from several Gulf Cooperation Council countries, and the process of receiving gulf area accreditation should be completed in the next few coming weeks. The next step will be applying for accreditation by the EMA.

Regarding early stage research, ACDIMA has already begun funding two early stage drug discovery projects that are being carried out jointly between several different university research groups, government research centers and R&D departments in a few of the larger Egyptian pharmaceutical companies. By funding projects of this type ACDIMA serves the larger Egyptian pharmaceutical community and leads by example, as ACDIMA has a broader purpose to lead the industry and

contribute to society outside of supporting the companies in our portfolio.

You are a former Minister of Health, a professor of medicine, now a pharmaceutical executive; given these different experiences, what are you personally aiming to accomplish today?

First, I would say that it is impossible to demarcate my past roles from one another clearly, and thus I have different perspectives. Before serving as Minister of Health, I was the president of Ains Shams University, and before that I was the Vice President responsible for running the all of the healthcare related activities at the university. From the time I became a professor of medicine, I always had a strong relationship with the Ministry of Health, so I have always worked in healthcare within the public sphere, collaborating with the government. Later I became a member of parliament and then minister, so I began dealing more directly with politics, but I was still a physician who had worked in the field and knew the reality of healthcare in Egypt, so my goals didn’t really change. My objective today is the same as it always has been: to support and help improve the healthcare sector in Egypt. Today, I am doing this by running ACDIMA and influencing the course of several large pharmaceutical and medical appliance manufacturers and thus I am striving to improve the quality and efficiency of pharmaceutical and medical appliance production in Egypt.

Now, Egypt is trying as hard as possible to implement universal medical insurance. This has been a very long story, but I genuinely believe that at this point the Ministry of Health is working as hard as it ever has before to make this a reality and it is clear that there is high level support for this goal within the Egyptian government. We are now approaching a point in time where large changes will be possible. We already have public medical insurance, but only about 52 percent of the population is covered, while our goal is to cover the entire population.

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