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Samir Khalil, executive director for the Pharmaceutical Research and Manufacturers of America (PhRMA) Middle East and Africa, touts the USD 1.1 trillion that its member companies have invested in R&D since 2000 and analyses the opportunities in Egypt as the country moves closer to implementing universal healthcare. In addition, he underlines the importance of an efficient, transparent regulatory system that

ensures speedy patient access to high quality, safe and effective medicines; a predictable government pricing and reimbursement system that rewards innovation; and a world-class intellectual property system.

Can you begin by updating us on the organisation and its role to help the innovative pharmaceutical industry flourish in the Middle East and Africa?

PhRMA represents the leading global biopharmaceutical companies present in the region. The association is all about access to innovation and its members focus on research and development of innovation. According to the most recent data, PhRMA members, since 2000, have invested more than USD 1.1 trillion in R&D for new treatments and cures. In fact, 2021 was a record year with USD 102.3 billion in R&D investment. This is magnificent. I believe that COVID-19, along with the presence of unmet medical needs in other areas, has pushed companies further.

In the Middle East and Africa region, PhRMA's role is to work with governments and other stakeholders to advance pro-innovation public policies. PhRMA's international advocacy priority is securing patient access to innovative medicines – we need these magnificent medicines to reach patients as soon as possible – and we aim to do this by protecting intellectual property rights and removing trade barriers.

What are some specific initiatives being supported by PhRMA in the MEA region?

One of the initiatives that we have created over the last two years that is being finalised now is a study called Headroom for Innovation. The study was carried out in partnership with the London School of Economics and considers the potential for creating headroom for innovation in the healthcare systems of Egypt and the Kingdom of Saudi Arabia (KSA) to encourage governments to prioritize sustainable patient access to innovative medicines. This initiative is carried out in collaboration with local health authorities to drive policy recommendations and achieve policy changes and reforms that will result in greater coverage and access to innovative medicines. We found that savings could be made on older products, those with generic options, allowing countries to invest in new products.

Conducting the study in every single country in the region would be challenging, so we took two major markets – Egypt and Saudi Arabia – which are very different in terms of their systems, budgets and funding mechanisms. Egypt is interesting because of the size of the market and the fact that it does not have an oil-dependent economy like other countries in the region, particularly in the Gulf. Saudi Arabia spends heavily on healthcare and employs a tender-driven market while Egypt has a sizable out-of-pocket market,

Another initiative I would like to highlight has to do with regulations around registration and time to market. We partnered with IQVIA to do an assessment of access to medicines in the different countries across the region with the aim of engaging with the authorities to improve regulatory, pricing and access timelines. The study compared 10 Middle Eastern countries with developed markets in Europe and the United States. Egypt and South Africa, for example, have shown major improvements in recent years.

The Egyptian pharmaceutical market seems to be at an inflection point years after the approval of a universal healthcare law. How do you view the evolution of the market?

Egypt went through a difficult time a few years ago with the devaluation of its currency, which became a major concern for companies. Fortunately, the situation has improved, and the market has been growing by double digits. What has led to that growth? First, the government has worked to stabilise the economy and has invested heavily in infrastructure. Also, Egypt has the fastest-growing population in the region which has resulted in the country accounting for 16 percent of the region's total pharma market.

The innovative pharmaceutical industry has been working closely with both the Egyptian Authority for Unified Procurement (UPA) and the Egyptian Drug Authority (EDA), spending a lot of time and effort to help integrate the country into the global chain of innovation. Companies have invested a large number of resources.

The COVID-19 pandemic, fortunately, did not derail Egypt's efforts to raise the profile of its healthcare market. There is no question that Egypt has become a key market in the MEA region.

The creation of the EDA and the UPA in 2019 has really helped develop the nation's health system and industry. The UPA, for example, is currently planning to implement a new healthcare technology assessment (HTA) system to inform pricing and reimbursement decisions. For our part, we did a big HTA conference for authorities in the region, featuring global experts, and the message was that countries should be mindful of jumping prematurely into HTA without having reliable data capabilities.

Our members believe that the Egyptian market is quite promising as access gets better, the regulatory system improves, and overall healthcare infrastructure grows. Additionally, Egypt is making an effort to become a regional manufacturing hub. Nevertheless, to realise its full potential, Egyptian policy makers should continue to advance public policies that are conducive to innovation.

Does PhRMA MEA have any particular position about Egypt's efforts to achieve a universal healthcare system?

PhRMA has helped cultivate a local committee in Egypt which includes representatives from the EDA, the UPA and universal health insurance to drive policy changes and reform. We will continue working with stakeholders to bring universal healthcare coverage principles into the discussion, seeking the enabling factors for a proper universal system.

We must face the fact that each market has its own dynamics. In Egypt, some of our member companies continue struggling to grow their access footprint in a country with a lot of unmet medical needs, including chronic and non-communicable diseases. While Egypt has made major healthcare reforms, there are concerns and challenges that remain. Localisation policies and the clarity of regulations governing intellectual property rights sometimes hinder the ability of companies to invest and provide medicines. However, the foundation for a better system is taking shape.

What are the enabling factors for countries to foster innovation and attract investment from the pharmaceutical industry?

First, there should be pruning policies that reward innovation. Second, countries should have an efficient and transparent regulatory system which can introduce innovation as soon as possible for patients. Another key factor is having good universities that can be involved in R&D and supply the industry with talent. Lastly, there should be permanent dialogue between authorities and industry.

Is there any final message you would like to share with our audience?

I think the government should continue to support policies that both bring investment to Egypt and allow patient access to innovative medicines and treatments. Innovative medicines, as the pandemic showed, cannot be ignored because of the value they bring to the system. I had never seen such development in such a short period of time. But it was not a surprise to those who had followed companies and institutions' years of work on mRNA technology, for example. Innovation takes time and investment, but it is worth it.

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