Samir Khalil â?? Executive Director, PhRMA Middle East & Africa (December 2019)

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Samir Khalil, executive director for the Pharmaceutical Research and Manufacturers of America (PhRMA) Middle East and Africa (MEA), reveals why the US industry is investing in MEA, the challenges presented by the lack of intellectual property enforcement in the region, and the shifting of focus from manufacturing to broader research and development.

Can you introduce yourself and outline how you ended up establishing the office?

I represent PhRMA in the Middle East and Africa. PhRMA represents the leading biopharmaceutical research companies and supports the search for new treatments and cures. We work with governments to advance public policies that are conducive to better patient access to innovation in the region and to improve the ecosystem so that it is able to attract more innovation. Our work is of incredible value because the industryâ??s ultimate mission is to help patients around the world, providing them with the latest innovative medicines discovered by our companies in their laboratories.

In order for patients to access those treatments, countries need the right public policies in place, either from the regulatory point of view, intellectual property, rule of law and adequate pricing systems that reward innovation. Having these policies in place will better enable countries to access the industryâ??s innovation as quickly and as safely as possible. PhRMA works with governments to

engage in public policy discussions that allow the medicines and therapies to get to patients in need. But, at the same time, having the right ecosystem encourages companies to invest in the countries. I say that we have two parallel objectives: improve patient access to medicines and foster economic growth in the region.

The biopharmaceutical industry is one of the most innovative industries in the world, investing an unbelievable amount of resources on research and development (R&D). Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone. When companies invest in R&D, they build economic growth that is based on knowledge and innovation. The economic impact is broad because of the elements required to achieve that level of innovation. That is the message that we try to convey to governments and other stakeholders.

Many governments in the region want the industry to bring manufacturing to their countries but I always tell them that the industry has transformed and their also needs to be an increased focus needs on R&D. After having more than 40 years of experience in the industry, most of it with Merck (MSD), mostly on global assignments, I was able to live that transformation, where due to new technologies, companies rationalized their manufacturing and shifted from having manufacturing in almost every major country in the world to manufacturing in a few selected countries. The value we, as an industry, bring to the countries goes way beyond manufacturing jobs; we focus on attracting clinical research and knowledge-based investment. My job has been to engage with countries in the region so they can benefit from the valuable investment that our members can provide.

Have you seen that knowledge-based investment being recognized in the region?

With Saudi Arabia, for example, we have been involved in dialogues for a few years regarding the opportunities presented by the industry. They have been keen to understand the value of clinical research, even visiting some of our innovation hubs and research labs, such as Boston in the United States. The whole 2030 vision in Saudi Arabia is about diversifying the economy and we are one of the most research-intensive industries. It can take more than a decade to bring one molecule from the lab to the patients. That is our message in the region: if you really want to benefit from us, bring innovative medicines faster to patients but also take advantage of the quality investment available.

One of the key hurdles for countries like Algeria, for example, are their localization policies; they believe they are helping the local ecosystem but are not diversifying their economy which depends on oil and gas. Nevertheless, we have seen an effort to address that situation that can be appreciated after the recent establishment of our local trade association.

It might not seem like a big deal, but the Middle East is different from any other region since there are no provisions to establish local trade associations in every country. The only countries with established local trade associations for the global pharmaceutical industry in the region are South Africa, Morocco and Tunisia and now in Algeria.

Why did PhRMA decide to open and operate a dedicated office in the Middle East & Africa?

The Middle East and Africa region is a growing region for pharmaceuticals and PhRMA decided to establish the regional hub in Dubai in order to ensure that we engage with governments in the region to improve access to our membersâ?? innovative medicines. The office has been operating for almost six years and we have engaged with countries all over the region, including the UAE, Saudi

Arabia, Egypt, South Africa and Algeria to ensure that we partner with governments to both improve access and the public policy environment. That way, the industry can increase its footprint and investment in the region.

I have seen the will from the governments to work but if you look at the percentage of global clinical trials, the region accounts for less than one percent. We must ensure that the region attracts more clinical trials because it will also have an impact on the local economies.

What are some of the public policy changes that you are advocating for?

A key issue is that intellectual property laws are clear, enforced and respected. The industry has been at the forefront of innovation and it needs to be protected by local and international laws. It is an area in which we are working closely with governments. PhRMA wants to help governments protect intellectual property, including both patents and regulatory data protection. That protection is the driving force behind continuous investment into the biopharmaceutical research and development. The region has to be up to speed in that regard.

The shift from manufacturing to R&D will not happen in one day, but the protection of intellectual property is a good start. Also, having the appropriate guidelines for clinical trials to ensure that the approval process is nationalized will have a positive impact. Countries must provide incentives for researchers and have a strong clinical research organizations (CRO) industry. PhRMA has been involved in mapping the clinical research environment to understand the hurdles and then establish working groups that can address them one by one.

What has been your strategy to help the governments apply those changes?

We have looked at the solutions from a holistic approach. Customarily, the industry has focused on dealing particularly with the ministries of health or regulatory agencies, but we have broadened that focus in the region. We approach the investment agencies and ministers of economy to explain how the industry can benefit the country as a whole rather than a particular sector. It is something that we have done in Saudi Arabia and they have established the Saudi Authority for Intellectual Property (SAIP) to work on enforcement and guidelines. The move makes the country more attractive because the industry has greater confidence that there is a central body that will look after one of their most valuable assets.

In your view, does the industry hold any particular reputation in the Middle East?

For decades, the industry in the Middle East has been perceived mostly as a supplier, as a group of companies that are limited to providing a necessary product. The reality could not be further from that. The industryâ??s business revolves around revolutionizing how we fight disease. We can improve access to medicines through market-based reforms that promote competition, modernizing the drug discovery and development process and move to a system that prioritizes results for patients. Putting the patients at the centre of any decision is a win-win. Partnerships between industry and government is the best way to find creative solutions to difficult problems.

Stephen Ubl, global president and CEO of PhRMA told PharmaBoardroom that we are on the onset of a new â??golden eraâ?• of medicine. What should the Middle East do in order to be part of that and not lag behind?

For the Middle East, it is key to take a look at public policies that are conducive to that goal. Localization policies do not work because the world is truly global now and companies have alternatives. The industry cannot control how patients are getting their medicines; however, we can control where the research and development is conducted. The presence of the industry in any country depends on the conditions of said country.

When we visited Boston, for example, we asked the governorâ??s team about the reasons behind their success in life sciences and they mentioned those enabling factors. We were at the governmentâ??s building in One Beacon Street and he pointed out the window and showed Harvard, the Massachusetts Institute of Technology (MIT) and the industryâ??s laboratories in Kendal Square, all just meters away from each other. They have created a physical connection between the three main elements of the ecosystem (academic institutions, industry and government), but also have provided the right incentives. They developed the ecosystem.

I am optimistic about the Middle East in that regard. When you look at the United Arab Emirates, they have attracted regional hubs by having good policies and incentives. 90 percent of PhRMAâ??s members have established regional offices in Dubai.

What has motivated you to work in the industry for more than four decades?

I joined the industry right out of college, and I have witnessed the unbelievable impact that the industry has. At certain points in my career, I was responsible for public policy for HIV/AIDS in Europe Middle & Africa for Merck. It was during the time (the 1990s) that HIV was a still mystery; companies such as Merck were trying to develop new molecules but there was no clear infrastructure to bring those treatments to patients. Africa was one of the places affected more severely by HIV/AIDS and I was part of the team that was tasked with finding a solution to the access and infrastructure problem. We entered into a partnership with the Bill & Melinda Gates Foundation and the Government of Botswana to develop a model for access in the continent. After months of deliberation, we decided to do it in Botswana, the country with the highest levels of infection and the political will to address the issue. We established the African Comprehensive HIV/AIDS Partnership and we made tremendous progress. We built the infrastructure, brought doctors, nurses and an awareness program, educated professionals, and developed a treatment program. Today, Botswana has the highest level of patient treatment for HIV/AIDS in Africa. The industry has a big heart and has contributed to patients and economies all around the world in these and other ways.

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