Ashraf Mallak – Managing Director GCC, MSD (November 2021)



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After almost two decades with MSD, Ashraf Mallak, managing director for the company in the GCC region, dives into the often-overlooked healthcare capabilities of the Gulf countries, including the fact that certain products approved by the US FDA can sometimes be available in the region in as little as one week. Mallak also speaks about the bold efforts to maximize the use of data in the region, the performance and future of Keytruda, how Saudi has become a growth driver for the American giant, and exciting news regarding its upcoming COVID-19 treatment.

What has motivated you to remain working with MSD after almost 20 years with the company?

The biggest motivation for me has been our company's mission and commitment to saving and improving lives. Being part of an organization that is invested in adding years to people's lives and improving their health is something that is very personal to me and that I have always wanted to be part of. Combining this with the ability to build and develop a career with MSD has been an added bonus.

Over the past two decades, in my various roles, I have had the opportunity to work across markets. In these capacities, I have maintained a consistent focus on delivering upon a science-led strategy, which has proven to benefit patients and customers.

What is the rationale behind grouping the six GCC countries you manage (Saudi Arabia, UAE, Kuwait, Qatar, Bahrain, and Oman) together? Is it because of their socioeconomic similarities or the way MSD operates?

It is a mix of both. Before MSD restructured its operations in the region, the country-specific markets used to operate differently; Saudi Arabia worked as a standalone affiliate and the other GCC countries were grouped together. Over time, we began to understand how connected those markets were in terms of pricing structures, insurance, tenders, and other business areas. The organization believes that it can create better synergies if it works with them from one centre, and it appears to be working well. Personally, I understand the region well because of my time as managing director for the Bahrain, Qatar, and Oman cluster, as well as the Saudi affiliate. It might change in the future but bundling the GCC together is proving to be successful so far.

What are the specific advantages of having that prior management experience in several of the GCC countries? And what are the learnings that really translate from one country to the other?

The main advantage of having worked in many of these countries for many years is that, over time, you build a deeper understanding of the needs of patients, customers and other stakeholders such as governments insurance companies, policymakers, physicians, and other partners. The accumulated experience becomes a tool that helps you deliver strategic programs. For example, in my previous role, a regional position for the EMEA market based in Switzerland, I had the chance to work with over 50 countries. I acquired a broader perspective and learned from many different healthcare systems which will help me add more value in the GCC region.

What are the main trends in the GCC region that stand out from other markets you have worked in?

The main trend is clear: it is about innovation. Most of the markets in the GCC are trying to adopt innovation as fast as possible, even faster than in big European countries in many cases. The authorities are involved in a healthy competition to be the first to provide innovative health solutions for their populations.

Another trend is the uptake of digitalization and data science to give patients better solutions. In addition, countries are aiming to apply more localization as they move to become true partners of pharmaceutical and healthcare companies, going beyond a vendor-consumer relationship.

Is the high GDP per capita of most GCC countries being effectively translated into innovation across different therapeutic areas?

The GCC economies have clearly defined strategies that are being supported by necessary allocations within budgets. Driven by a vision, GCC countries have been building an integrated healthcare system for years. They do not only focus on bringing in new products. Analyzing the last 10-15 years, you will observe the creation of best-in-class healthcare infrastructure and a world-class cadre of healthcare practitioners. Moreover, health insurance has expanded greatly in the last ten years; today, almost every citizen or resident has insurance.

What is your perspective on the hybrid model between public and private healthcare being implemented in the GCC?”

Currently, there is a lack of a standardized approach among the countries in the GCC. For the most part, the common approach was to have a healthcare system where the government took care of everything, and all patients went to government-run institutions for treatment. Over time, there has been a shift towards privatization, first in the UAE and now in Saudi Arabia. Those countries are beginning to outsource medical services to the private sector. For example, in Saudi, citizens went to public hospitals and received their medication from that hospital, but they can now acquire them from private pharmacies.

Do you believe that governments will play a role in introducing a cap on costs to avoid skyrocketing prices?

More and more we see governments taking on the roles of both regulator and healthcare provider. They are bringing together the different pieces of the healthcare system, providing healthcare insurance, pharmaceutical products and other services. For example, Dubai Healthcare City has autonomy when it comes to licensing and bringing in their own medical teams, and other areas in Dubai have other policies. That approach is giving different healthcare entities the flexibility to

have their own regulations.

As a company with such a diverse portfolio – ranging from vaccines to oncology and acute care products – how challenging is it to coordinate with the different stakeholders involved in each category?

That is exactly what the latest major shift in the company has been about. Five to ten years ago, MSD's portfolio revolved around primary care, providing treatments for pain, cholesterol, and diabetes. Healthcare providers were our main customers, a huge target audience.

Today, our value proposition has evolved, having new medications for hospital acute care, oncology and vaccines, . Our focus has broadened to include policymakers, regulators, and a reduced number of physicians. The Organon spin-off has facilitated this transition; the new MSD will work with this different operating model around oncology, specialty products and vaccines. Activities are directed focusing on policymakers, insurance companies and different stakeholders.

Is the whole MSD portfolio of medicines, vaccines, biologic therapies, and animal health products present in the GCC region?

We have the full portfolio. For the time being, our focus areas are vaccines, oncology, specialty care, and diabetes. Diabetes is a big part of our business here; we have the number one selling product for that category in the UAE. Oncology is gaining ground and we are making progress towards market leadership.

One of the most interesting characteristics of this region, which is why we have most of our portfolio present here, is the rapid approval pathway. Most of the time, we launch new products in GCC countries right after the US and, in some cases, before Europe. These markets are always on the priority list for MSD. The regulations here allow products to be available in the market as soon as they are approved by the US FDA and the registration process is very fast, especially in the UAE and Saudi Arabia.

Another reason why we have almost the full MSD portfolio present in these markets is their respect for intellectual property, they make sure that patents are enforced, making them great partners for innovative pharmaceutical companies.

Given the strong interaction between regulators in the GCC and the US FDA, is availability of products keeping pace with approvals?

In the UAE, for example, if you have a product approved by the US FDA, it can be available in the country sometimes in one week. For non-life-saving products, availability can take from three to six months. Once a product is registered, it can be shipped with the regular process that usually takes a few weeks. This is extremely important for ensuring patients here have quick access to our most innovative medicines and vaccines.

In the case of vaccines, one of MSD's main businesses, the pandemic has put the spotlight on vaccination programs across the world. What is the situation in your region in terms of awareness, public policy, and inoculation rates?

The region has experienced a sharp increase in vaccination rates in the last few years. National immunization programs (NIPs) are the cornerstone of the vaccine market and require strong government support in the shape of smart regulations and budgets. Fortunately, GCC governments have all adopted NIPs. A bright spot in the GCC is their work on cervical cancer. MSD has Gardasil, a vaccine that protects against infection from the two types of human papillomavirus (HPV) that cause most cervical cancers worldwide.

GCC countries were lagging in that area but have now included the vaccine in their NIPs. The governments have understood the importance of the vaccine to prevent cervical cancer. Saudi Arabia included the vaccine in its NIP this year, Kuwait and Qatar are following, and soon Bahrain and Oman should too.

How did that change of mind regarding the cervical cancer vaccine come about? Was more scientific evidence presented to the authorities?

Cervical cancer is not a particularly popular topic to discuss here, however, continuous education and advocacy from key scientific leaders has made all the difference. New evidence from countries that have adopted the vaccine have proved the benefits over a period of years. Our role as MSD is to keep working, sharing the evidence until the value is transferred to patients.

How are the GCC countries leveraging their world-class infrastructure to collect and leverage healthcare data?

That is one of the key trends in the GCC region. Different countries are at different stages of maturity in terms of data banks, but the big countries – Saudi Arabia and the UAE – now have national data centers where government officials can access and process the data to draw conclusions. In the UAE, data analytics are very advanced and this trend will not stop anytime soon. On the contrary, countries like Oman, Kuwait, Qatar, and Bahrain are following that path.

MSD is committed to working with governments to support the effective use of the data. We are trying to create local data, for example, instead of sharing data from a clinical trial done in Japan or the US, we work early on with the government to involve them in the global study. There is a push towards localizing data so that different officials can make good use of it.

Ideally, the data being generated in all GCC countries should be standardized, but is that the approach they have taken?

To answer your question, there is a national data centre operated by the GCC council. We have not yet arrived at the stage where we can use it for healthcare, but it is there. The regulations to protect data privacy are quite strong in the region.

Having worked as managing director for MSD's Saudi affiliate a few years back, how do you evaluate the evolution of Vision 2030 and how it is shaping the industry in the Kingdom?

Saudi Arabia can become a good case study about real transformation. The country used to have different healthcare systems operating simultaneously across its territory, one run by the Ministry of Health, other by the Minister of Defense, the Minister of National Guard, and other by the private sector. As part of Vision 2030, they began regulating all the systems under a unified central service. Once enacted, things will change in terms of centralized insurance for the people on the private sector and centralized procurement. The most important thing is data, because the government is relying on the idea of learning from the data to make better decisions.

Saudi's Health Sector Transformation Program in 2021, part of its Vision 2030, depends on the principle of value-based care, which the government says ensures transparency and financial sustainability by promoting public health and preventing diseases. What is your view on this approach?

Saudi Arabia is looking to implement a health technology assessment (HTA), a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. In practical terms, HTA means that a medication can be covered by a system based on the value it provides to patients.

However, when we talk about specialized medications and therapies based on the genetics of a patient, there will not be an identical response across the entire population since people with different genetics and disease progression will respond differently.

For example, our immunotherapy Keytruda can be included in the protocol as standard of care for breast or lung cancer but not for other types until more data is made available. It is about evidence, which is positive, but it is also related to the local data situation.

Since Keytruda is MSD's best-selling product by far, generating USD 14.3 billion in 2020, its performance in the Saudi market might be a good indication of the opportunities present for the company there. What can you comment on that?

Keytruda is available in Saudi Arabia and is a leading immunotherapy product. Most indications approved globally are also approved in the Kingdom with a few exceptions; this is the case in every country in the GCC, as well. Keytruda has become a cornerstone in cancer treatment, prolonging and saving lives.

One aspect of Keytruda's success up to this point has been its combination with other therapeutic regimens. Is this trend also taking place in your region?

Again, Keytruda is becoming the standard of care for cancer treatment. As standard of care, the only way to provide more value for patients is to work with different partners to study how clinical pathways can be improved in combination with other therapies.

How I envision the future of Keytruda is that it will be the platform for cancer, and we need to work with other companies to create combinations that can save even more lives.

Will you take this approach of collaborating with other companies to clinical trials in Saudi?

Definitely. We are currently about to launch a new collaboration with another company for the combination of Keytruda and their product.

Since companies have already nationalized their entire salesforces in Saudi, there is the possibility that new quotas might come for other departments such as market access or regulatory affairs, provoking a tougher competition for talent. How is MSD ensuring that it remains attractive in the eyes of talent?

As I mentioned in the beginning, the new MSD is more focused on building different capabilities to make sure that we have a high caliber of focused functions. The capabilities we are looking to provide to our employees are part of that effort to be the most attractive company for talent. We want them to learn about access, affordability solutions, health technology assessment, outcome data, public affairs, communication, and policy. Their capabilities in the past were mostly limited to commercial activities but we are confident that more tools will improve their careers and the company in parallel. Moreover, we are also promoting capabilities in data and digital tools; in the last two years, around 15 percent of our hires have been in digital, data and affordability solutions.

Talent in any market is not easy to come by, not only in Saudi Arabia. Particularly when it comes to data specialists because of the intense competition from the tech industry and others. Mobility could be part of the answer to continue attracting good talent.

Do you foresee the MSD Saudi organization growing more or have you reached a sustainable size for the time being?

Saudi Arabia is a very important market for MSD, one that we see as a growth driver. There will be significant growth in vaccines and oncology.

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

We’re continuing to do our best to bring our most innovative solutions to solve the biggest healthcare challenges in this region. We have just received exciting news regarding our investigational anti-viral therapy for COVID-19 and we hope to be able to bring this treatment to the GCC once we receive regulatory approval for it. This will be a major milestone in helping to reduce hospitalizations and deaths due to COVID-19 and potentially help to get our lives back to normal.

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