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A pro-innovation policy environment will bring access to new medicines and encourage investment in Saudi Arabia while reducing barriers for companies to expand and thrive in the market

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents many of the world's leading innovative biopharmaceutical research companies. Its executive director for the Middle East and Africa, Samir Khalil, discusses the need for a value-based pricing system in Saudi Arabia, the country's successful COVID-19 response and how the Vision 2030 initiative is helping bring more investment. In addition, he explains why countries in the region should focus less on manufacturing and more on the big opportunity presented by biopharma companies: research and development.

What has changed since the last time we spoke in the UAE? Is PhRMA's commitment to the Middle East & Africa (MEA) region still strong?

Our commitment to the region remains steadfast. MEA is a huge region so we have to prioritise our efforts; supporting our members to ensure that innovation is accessible and that government policies are conducive to research and development

Within MEA, one priority market is Saudi Arabia. Although travel is currently restricted, I used to visit Saudi often, working with our local group and governmental bodies there. Additionally, PhRMA has been active in setting up roundtable discussions in the country to find common ground with other stakeholders and increase the country's competitiveness.

PhRMA is based in Washington DC but represents the global innovative biopharmaceutical research industry, an industry made up of companies devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

Our companies back this up through their investments; since 2000, PhRMA members have invested nearly USD one trillion in research for new treatments and cures, including an estimated USD 83 billion in 2019. This level of investment requires a huge amount of risk.

How has the pandemic been felt across the region and what sort of collaborative efforts has PhRMA engaged in to ensure that vaccines arrive in the MEA?

Although I have been a part of this industry for my whole career, with many years at Merck (MSD) under my belt, what I have witnessed during the past year has truly been something to behold. The industry has been working around the clock to research, develop, and deliver new, safe, and effective treatments and vaccines to combat COVID-19. Companies felt a responsibility to step up and utilize their in-depth R&D knowledge, relying on our carefully built robust global supply chain to aid the world's population during this once-in-a-century crisis.

In terms of manufacturing, our industry has taken unprecedented steps to increase its capacity safely and efficiently. While research was still ongoing, manufacturing was already taking place; a huge risk given that receiving a regulatory green light was not assured.

There are many examples of collaboration, such as Merck helping Johnson & Johnson with manufacturing, but companies are also collaborating in the labs. The industry has worked with health authorities to support the scale of research, development and manufacturing required to deliver treatments and vaccines to patients. Our members continue to work with governments, insurers, and other stakeholders to make the treatments not only accessible but also affordable.

Looking at vaccination campaigns, Saudi Arabia in particular has been doing a great job. Saudi was the first Arab country to roll out the Pfizer-BioNTech vaccine and is currently using two COVID-19 vaccines, both from PhRMA members. Rollout has been quick, with almost four million doses having been administered as of late March 2021. These efforts in managing the infection rate are a good indicator of Saudi Arabia's commitment to transforming its healthcare system.

What are the questions that Saudi stakeholders are asking themselves at the start of this healthcare transformation journey?

During our roundtables, we asked how we can work together to create win-win scenario for Saudi Arabia as a country as well as for our companies and for Saudi patients. With MEA being such a dynamic and fast-growing region for biopharmaceuticals and Saudi Arabia being its biggest market – estimated to rise from around USD 8.5 billion in 2019 to almost USD 10.4 billion by 2024 – it has an important role to play.

However, the innovative solutions that our member companies bring require smart investment. For example, when countries start to focus on how to promote in-country clinical trials, they receive economic growth based on innovation and knowledge. I witnessed that in the US, where states compete to host clinical trials in the knowledge that they can have a big value for the health of their population and their economies.

Biopharmaceutical companies invested about USD 20 million in clinical trials in Saudi Arabia in 2016, a number that had increased by 20 percent by 2019. PhRMA is committed to working with the authorities to continue on this journey and find the gaps in clinical research in which Saudi Arabia can excel. There is an opportunity to attract even more investment, especially in early-stage clinical research, which can provide both health and economic benefits. These benefits align with the Kingdom's goal set forth in the Saudi Vision 2030.

Vision 2030 is very important for Saudi Arabia to help the country diversify its economy and achieve a world-class healthcare system. However, the country also requires companies to invest in local manufacturing and the Saudization of their workforce. How are your members approaching this situation?

Through Vision 2030 the Saudi government seeks to encourage investment in this sector. They recognize that the country needs to diversify away from oil and move to a knowledge and innovation-based economy. For the last several years, we have been working in the Kingdom to uncover opportunities and further advance policies that will attract innovation.

Our member companies' ultimate mission is to help patients by providing them with the latest innovative medicines and vaccines. Therefore, policies that protect and value medicines are essential to foster an ecosystem that promotes innovation. A pro-innovation policy environment will bring access to new medicines and encourage investment in Saudi Arabia while reducing barriers

for companies to expand and thrive in the market.

Regarding the Saudization strategy, our members are doing their best to meet the goals that have been set. I was impressed by the early efforts they made to hire and train Saudi nationals and PhRMA has worked with its members to create an academy that trains Saudi students in pharmacy schools and show them the opportunities that exist in the private sector.

Moving to manufacturing, your members have highly sophisticated products and supply chains that do not allow them to duplicate manufacturing in every single country that wants a local plant. How do they balance the demand for local manufacturing and the reality of their manufacturing process?

Companies used to have manufacturing everywhere, but technology evolved and they rationalised and condensed their global footprints. This means that today many companies can easily supply most markets for many of their products with only one or two plants.

While there are opportunities in manufacturing – particularly in generics, which make up around 90 percent of US prescriptions – I always tell government officials that the best opportunities generated by our industry are not in manufacturing. The big value we bring is in innovation through research and development; an area that is also more sustainable. The good news for the international community is that clinical trials are done globally and that means that there are opportunities for everyone.

Speaking about market strategy, what are some of the most common missteps that companies take when approaching the MEA region?

First of all, the success of multinational companies in any given market depends on some basic conditions. When you look at smaller successful countries like Switzerland or Singapore, the reason they have succeeded is because they help biopharmaceutical innovators where they most need it. Biopharmaceutical companies depend on strong intellectual property protection and enforcement, including the protection of regulatory data.

They depend on efficient regulatory systems and fair and equitable market access. With the right policies and incentives in place, companies in Saudi Arabia can bring valuable new medicines to Saudi patients and fuel the diversified economy that the Saudi authorities desire. Companies are

investing here because of the ecosystem the authorities are providing..

Since you mentioned pricing, what is the Saudi approach in this area?

We continue to make the Saudi authorities aware of the value of innovative medicines when it comes to patients and the economy. New medicines are not merely one more option, they bring in new value by reducing overall healthcare costs and allowing for longer, healthier lives.

The SFDA’s pricing guidelines set prices by comparing the prices of a basket of other markets and choosing the lowest. It is a flawed methodology that does not appropriately recognize the value of innovative medicine for the Saudi health system and patients. Additionally, the current rules are inconsistent with Saudi Arabia’s vision to establish more value-based approach, as exists in Europe, for example.

However, Saudi Arabia has been more advanced than others in the region in establishing health technology assessment (HTA), which is a good step towards a value-based assessment and pricing if executed correctly.

I want to emphasize that the current international reference pricing system is becoming obsolete and does not fit the purpose of those major trends in alignment with Vision 2030. Each country has a different healthcare system and different access to care; but Saudi Arabia really needs to think more about how their system can be more value-based.

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