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We can improve access to medicines through market-based reforms that promote competition, modernizing the drug discovery and development process and moving to a system that prioritizes results for patients

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PhRMA MEA's Samir Khalil highlights some of the key trends at play across the Middle East and Africa's dynamic and fast-changing pharmaceutical ecosystem, including several wide-ranging national health transformation plans, the move towards health technology assessment (HTA), and the importance of maintaining robust intellectual property (IP) protection.

Could you begin by reintroducing yourself and your role to our international audience?

I represent the Pharmaceutical Research and Manufacturers of America (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 can attract more innovation. Our work is of incredible value because the industry’s ultimate mission is to help patients around the world, providing them with the latest innovative medicines discovered by our companies in their laboratories. For patients to access those treatments, different countries need the right public policies in place regarding regulation, intellectual property, rule of law and adequate pricing systems that reward innovation. Having these policies in place will better enable countries to access the industry’s innovation as soon and as safely as possible.

The biopharmaceutical industry is one of the most innovative industries in the world, investing an unbelievable number of resources in research and development (R&D). Since 2000, PhRMA

member companies have invested more than USD 1.1 trillion in the search for new treatments and cures, including USD 102.3 billion in 2021 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 we continue to try to convey to governments and other stakeholders.

2022 was a year marked by important global events, politically and economically. What have been your primary observations over the past year regarding the MENA region's resilience?

The MEA region's healthcare ecosystem and pharmaceutical market has been growing steadily over the past year and is now estimated to be the world's fifth-largest regional pharmaceutical market.

With several countries in the region rolling out healthcare reforms and healthcare transformation plans climbing the priority list on government agendas following the COVID-19 pandemic, I believe MEA will continue to increase in importance for the global innovative biopharmaceutical industry in the coming years.

What are the key topics on the 2023 agenda for PhRMA MEA's members?

We will continue to advocate for the advancement of public policies which improve affordability and access to innovative medicines in the region. PhRMA continues to partner with health authorities to advance policy changes that ensure greater coverage of innovative medicines.

Some countries in the region are moving to adopt health technology assessment (HTA) into their procurement decisions, so we are proactively engaging with them to shape HTA policies, particularly in terms of HTA governance and methods, such as cost-effectiveness assessments. At the same time, we are looking to implement partnerships with health authorities on capacity and capability building.

We continue to advance intellectual property (IP) policies, including strong patent and regulatory data protection (RDP) enforcement, in MEA markets that promote biopharmaceutical innovation and access.

Finally, we advance regulatory policies and programs that foster simplification, harmonization, and transparency to promote early access to new technologies.

The UAE is now well established as the MEA region's decision-making epicentre. How has its offering to life science companies evolved?

When it comes to UAE, we must recognize the incredible efforts made by the authorities at all levels to embrace a public policy environment in favour of innovation and attracting investments. Specifically, regarding the biopharmaceutical sector, we have an overall favourable environment for innovation led by the Ministry of Health and Protection (MoHaP) which covers the fastest regulatory approval process in MEA, predictable pricing policies, and respect for IP rights, including RDP. The continued partnership and dialogue between the authorities and industry has contributed tremendously to this favourable environment.

According to recent surveys, the UAE will continue to be a high corporate strategic priority market for our member companies. Dubai will remain the most important business hub in MEA (and its regional MEA HQ scope is gradually increasing to encompass other countries outside MEA. Dubai provided the key factors for a successful regional hub, from economic free zones to housing, schooling, and air connections to regional and global destinations.

Would your member companies like to see improvements in some areas within the UAE?

It is critical that we continue to have a constructive dialogue with the health authorities on any emerging opportunities and challenges that affect the access of patients to innovation.

Besides being a base for regional headquarters, what else does the UAE have to offer as an investment destination?

The next stage will be greater investment in innovation and R&D, as APAC hubs like Singapore have done, to propel the UAE forward. When it comes to the biopharmaceutical industry, the biggest portion of our investment is in R&D, including clinical trials. These clinical trials enable companies to develop their medicines and submit them for regulatory approval in the US and Europe. When choosing where to situate a clinical trial, industry sponsors are looking for a favourable ecosystem, which I think the UAE can work on further to attract a proportion of these

global trials. While the population is relatively small, the UAE could be a base for late-stage trials, which have a strong medical impact as well as an impact on employment and the overall economy.

Might there be greater opportunities for closer collaboration between governments in the Middle East to speed up access to innovation?

I believe that together we are more powerful. As an example of this, we only need to look to Europe, where drug registration and IP are regulated on a continent-wide level. Unfortunately, the Middle East is altogether more fractured, with countries more often looking to work independently.

A GCC Patent Office was established in Riyadh several years ago, providing important GCC-wide services on IP protection, which I see as the skeleton of our industry. However, this institution was suddenly closed three years ago, and countries moved to a national approach. Discussions are continuing between member countries to determine how the GCC patent office can be helpful for their patent filing and review.

What are some of the UAE pharma market dynamics and how significant is the market within the MEA region?

The UAE pharmaceutical market, divided between the public and private sides, is today worth approximately USD 4.5 billion, which makes it a sizable market despite its relatively small population.

Innovative companies dominate the UAE pharma market. The UAE government provided a fast regulatory approval process, including taking steps to address any delays through the implementation of a fast-track registration designation, which we hope will help bring innovative therapies to patients more quickly.

It should also be noted that the UAE is one of the best performers within MEA in terms of new medicine launches. A recent PhRMA study showed that 33 percent of the 460 new medicines launched globally between 2012 and 2021 were launched in the UAE compared to an average of just 17 percent across the MEA region. However, the UAE is still far behind the survey’s top-performing country, the US, where 85 percent of new medicines were launched.

How does the UAE's regulatory system for medicines operate in terms of registration and pricing?

MoHaP is responsible for the regulatory approval and pricing of pharmaceutical products. Prices tend to be predictable as they are initially based on the price in the country of origin. Then over the next 18 months, the UAE authorities price the treatment at the median price of a global basket of 18 countries.

After registration and pricing, a code is obtained for reimbursement either in the private sector or in the public sector. Obtaining this code is a relatively quick process.

How digitalised is the patient journey in the UAE and is the data being generated of sufficient value and well-curated enough to begin to hold conversations around real-world evidence (RWE) and real-world data (RWD) in the decision-making process?

For RWD/RWE in the UAE, frameworks and common definitions are still developing and discussions at the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) are starting. For digital health tools, this topic is emerging. But in both cases, it will be important to align on requirements globally to facilitate access for patients.

The UAE is investing massively through its sovereign funds into artificial intelligence (AI) tools. Is there a role for PhRMA members to play in this transformation?

Absolutely. AI – including predictive machine learning algorithms – is playing an increasing role in the research and development of innovative biopharmaceuticals, including screening potential candidates, assessing genomic data analysis for better management of clinical trials, and conducting computational modelling to determine personalized cancer treatments. As governments seek to promote the development and use of AI tools, it will be essential for them to engage with all stakeholders to ensure the efficient and appropriate use of those tools.

What would your final message to PharmaBoardroom's international audience be?

For decades, the pharma industry in the Middle East has been perceived mainly 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 industry’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 moving 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 are the best way to find creative solutions to difficult problems.

Beyond advocating for collaboration between countries, PhRMA also supports a “whole government approach” to attracting investment in innovation and access to these innovations by patients. We need to work, not just with the Ministries of Health and national regulatory agencies, but also Ministries of Investment, Trade and Labour to think about our industry’s impact on an entire country and its patients.

Additionally, I strongly support a proactive approach to public policy, continuously collaborating with partners to identify opportunities and challenges and work on them together.

An ecosystem that is conducive to innovation and access to these innovations by patients is critical. We need to work with governments to ensure that the mindset is shifted from thinking only about manufacturing when it comes to our sector, to an increased focus on R&D. The shift from manufacturing to R&D will not happen in one day, but protection of IP, faster regulatory approvals, and pricing systems that reward innovation are a good start and key enablers.

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