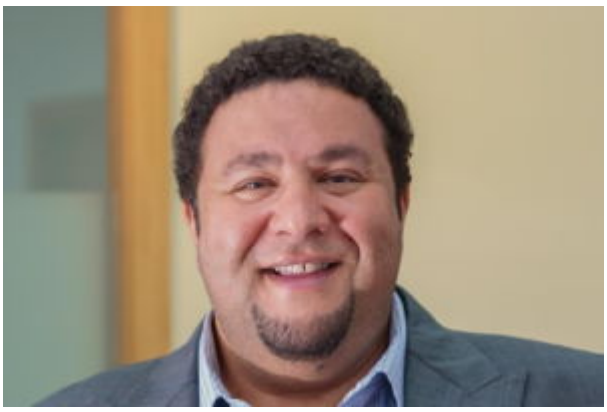
Amr El-Neklawy â?? SVP MENA FWA PAT, Emcure



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Emcureâ??s Senior VP for the Middle East, North & West Africa, Afghanistan, Pakistan & Turkey, Amr El-Neklawy, highlights the level of organizational independence given to his region, the necessity of agility and focus when competing in the generics market, and how the Indian multinational is standing out by offering its international brands to tendering bodies to look for better quality.

Can you begin by briefly reintroducing the company to our audience and the model you have implemented in the MENA region?

Emcure was founded in the 1980s by Mr Satish Mehta and has grown ever since in its domestic market, India. The company has expanded significantly by increasing its domestic product portfolio and by establishing a global presence following several acquisitions in Europe, Canada, and the United States. Today, Emcure has about 9,000 staff, a presence in 70 countries, more than 350 products across various therapeutic areas, 14 manufacturing sites and five R&D centres where it continues to develop and innovate.

According to recent data, we are ranked number 12 in the Indian market, which has been called â??the pharmacy of the world,â?• and are probably one of the fastest-growing companies in the country.

Our primary therapeutic areas of focus are oncology, nephrology, diabetes, antiviral drugs, and gynaecology. In addition, Emcure is producing biosimilars thanks to its subsidiary Gennova Biopharmaceuticals.

We are living in exciting times for the company, as evidenced by the work of our CEO, who is a reputable chemist. Our scientists are today spearheading the development of an mRNA vaccine out of India. Emcure developed its technical expertise by doing contract manufacturing for many big Indian pharma companies.

Our MENA organization is based in Dubai, but we have heads of different functions spread across other offices. The company has had a legal presence since 2010 that slowly evolved into a subsidiary. Since I joined, we have changed the physical location of the office, ramped up the hiring of talent and gained autonomy. Previously, a significant part of the decision-making process took place in India while the local organization gained a better understanding of the market and the dynamics shaping the region. We today act as a mediator with full P&L responsibilities.

Our team has fully-fledged operational empowerment to sign contracts, conduct due diligence, and engage in financial operations. Additionally, we have the personnel in place to drive the business, including on tenders, logistics, supply chain, and regulatory affairs. We coordinate these activities while the back-office work is done in India.

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At the end of the day, having a multitude of products means selecting, prioritizing, and keeping an eye on a changing environment because without that flexibility the organization will miss opportunities. Because of the fast pace and intense competition, people working in this business must have a wider span of skills than their counterparts in multinationals, they must cover more ground and are empowered to do so.

What are the different operational models that Emcure has in the markets you are overseeing and how does the company differentiate itself?

Our business is predominantly tender-driven, making institutions a key business focus. Most of our current portfolio is in the critical care area where we work primarily in injectables that supply the critical care setting in hospitals for oncology, nephrology, and haematology, among other areas.

Emcure has a big advantage in its market segment because many other players lack the sophisticated manufacturing capabilities required to produce high-quality products. However, although our current focus areas are highly lucrative, this does not mean that we will not go into the commodity sector or the private sector through pharmacy chains at a later date.

In terms of our approach to market access, we either compete in tenders or register a specific product in a specific market segment within the private area of hospitals. It is a hybrid model where we establish our brand first with a competitive price and later expand. So far, we have succeeded in our commitments to deliver with great quality to the different institutions and tender bodies that recognize the cost-effectiveness of our products.

In Saudi Arabia, cost containment measures are high on the public sectorâ??s agenda as they look to maximize resources without compromising quality. It is becoming an extremely competitive and intense market. It is an environment in which we know we can make a difference to the Saudi

Patient.

Overall, Emcureâ??s trajectory in the region looks very good. In generics, you will never be able to survive unless you have a very strong portfolio registration which requires years of planning. Fortunately, Emcure has a great pipeline of products because we challenge IPs wherever we can and conduct internal development programs, looking at different pricing models in order to offer the right products to healthcare providers and patients because, at the end of the day, it is their choice.

Our model in MENA relies on assessing greenfield projects to have a substantial business in all the markets within the region. We need to assess where we are, where we must trim, modulate or make changes, always looking to have a solid foundation from where to build with rigour. I am a great believer in process; there needs to be guiding frames, clear responsibilities, timelines, and measurable objectives. Only then can you take risks. On the other side, I encourage risk-taking and gut-feel. Passion to drive foreword is the key essence of what makes us different.

In this competitive market you just described, how complicated is it to make evidence-based decisions when market and epidemiological data is not so readily available?

This region is not Europe or the US where a lot of data is available, so we must rely on our own history, engagements, and wealth of market knowledge and data. We must be able to collect data from a multitude of points and analyze it; that is why we are here, to make decisions based on intelligence and first-hand experience, and it has been part of our fast growth. Of course, you must make some assumptions, especially during difficult moments such as the pandemic where some companies fared better than others. The struggles that some companies have faced over the past two years are not necessarily down to their portfolios, but rather their partner selection.

With such a high level of empowerment, how would you characterize the specific strategy that Emcure has defined for the Saudi market?

Saudi Arabia is recognized as the country where Emcure can have the fastest growth in the next couple of years; there are tremendous opportunities. In the last year and a half, we have been laying the groundwork by developing the right registration files, activating our networking capabilities, and gathering insights. We understand that our segment has a cycle, and we must be patient, and that is what we have done. So far, we have launched around 19 products in Saudi Arabia, most of which are unregistered. This does not necessarily fulfil what the Saudi FDA wants in terms of more registered products, more pharmacovigilance, and more responsibility to ensure that the quality is high. However, it should be remembered that, at the same time, there is a mandate for cost containment and an assessment of what companies are doing in other countries. We are aware that with such access comes a responsibility and hence product registration submissions have become a key mandate.

We applaud the Saudi authorities because they not only look where companies export but also at specific manufacturing sites to understand if they are producing for regulated markets or not. Plenty of data was requested of us, especially since we were new entrants to the market, and the authorities saw that we were providing the right products for the right needs at the right price. Since Emcure has a strong track record of quality, we were able to launch strategic products, including a biosimilar which are hard to introduce without EU or US FDA approval. We were able to do this because the originator does not have registration in Saudi but does in other regulated markets, allowing us to use real-world evidence and other data in our engagement with key institutions.

How favourable is the regulatory environment for generics in the MENA region and how does Emcure stand out in a sector that is based on the idea that its products work similarly to others?

In the Middle East and North Africa, you tend to find regulations akin to those in the US or Europe in terms of CTD format, regulatory timeframes, process, documentation, qualification, etc. Emcure and similar companies in the top tier of Indian pharma are recognized primarily as exporters to regulated markets. However, Emcure has an added value in this region because we can activate and leverage the groupâ??s businesses, using the Emcure corporate labels; we can activate the Tillomed label, which is our UK company, our Marcan label from Canada or the Avet label from the US. We are in a unique situation because we can tailor our offering to stakeholdersâ?? needs; if they want a product from the US, we can offer them at the right price. The company can capitalize on different economies of scale.

Emcure fits very well within Saudi Arabiaâ??s Vision 2030 transformation plan and the diversification of the economy by providing economic value, know-how and technology by partnering with local stakeholders.

Do you have a final message for our international readers about the Saudi Arabian market?

Saudi Arabia is an extremely important country that is undergoing a significant transformation. It is positioning itself as an attractive investment destination that will only add value to the people working in the country; it will increase the knowledge base, the technology available and help it obtain recognition as a global hub. They have the right elements in place and the question is now about diligent execution. Emcure is ready to keep the momentum going.

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