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Amr Seif outlines Astellas' progress into becoming a focused oncology speciality player in the Middle East and Africa, in line with the company's global Corporate Strategic Plan 2021 (CSP2021). He also touches on key market trends in MEA, including regulatory developments, the rise of private insurance, and the growing importance of national cancer plans.

Can you give us an update on Astellas' activities in the region?

Astellas has been undergoing a significant transformation in the region. In 2018, we began shifting our overall strategy as a company, and in 2020, we began an initiative to increase our presence in the Middle East and Africa (MEA). This transformation has been twofold – we have been expanding our presence in countries where we are already established, such as Saudi Arabia, Egypt, the United Arab Emirates (UAE), and South Africa while withdrawing from some other markets in East Africa where the existing healthcare infrastructure is not currently suited to accommodating our pipeline of highly innovative gene therapies and oncology specialties, yet ensuring options for alternative supply solutions for live-saving products.

In terms of expanding our presence in established markets, we have established new affiliate offices in Egypt, Saudi Arabia, and the UAE. Previously, the region was an export market, with most of our activity focused on supporting business partners and distributors across the region. Now, we

have started to take steps towards establishing a stronger and more focused footprint across key markets.

In terms of our commercial strategy, we have been divesting our legacy products, such as dermatology and antibiotic medications, to focus solely on becoming an oncology specialty company, at the same time providing alternative supply solutions for life-saving products. Our flagship oncology treatment has been well-received across the region, and we have been working hard with key healthcare stakeholders to ensure patients have access. Additionally, we have launched a new therapy for the treatment of acute myeloid leukaemia, which has been registered in several countries across the region. We also have another molecule for urothelial cancer that was recently launched in the UAE and in the registration process in other markets. Our goal is to pioneer first-in-class healthcare solutions including ground-breaking medicines in oncology and medical specialties, and we have been building the necessary capabilities internally to support this. We have been investing locally in market access, government affairs, public relations, and communication capabilities to ensure Astellas will be positioned as a leader in this field.

Unfortunately, the past couple of years have been challenging due to external factors. Economic and political situations in Lebanon, Egypt, and other countries have impacted patient access to medication, and the post-COVID economic challenges have also affected our operations. However, we remain committed to the region and are continuing to work hard to ensure patients have access to our innovative medications.

You have mentioned a certain level of volatility in MEA and yet Astellas still chose to open subsidiary affiliates here. What would you say is the strategy behind this decision?

Operating in the MEA region does come with uncertainty and volatility, but Astellas is willing to deal with these challenges to ensure patients have access to ground-breaking therapies.

As an example, Astellas has been operating in Egypt for over 20 years and has witnessed cycles of currency devaluation multiple times. However, despite these fluctuations, we continue to see that there is a strong long-term prospect for growth in the region.

One of the key factors in determining which countries to operate in is the healthcare infrastructure that can support our future portfolio. This includes development opportunities, physician experiences, and the dynamics of healthcare payers. Additionally, the size of the market is also a

consideration, particularly for specialized therapies that treat a small number of patients. Smaller countries may have an equally small patient population, but in larger countries like Egypt with a population of 100 million or more, the number of patients is relatively high.

While some countries may be more stable than others, we believe that the region as a whole offers a solid long-term growth trajectory. Ultimately, the decision to operate in this region is based on careful consideration of various factors, including the healthcare infrastructure and market size.

Oncology is a very competitive therapeutic area in the industry with many other players aiming to lead the way. Given that this is a newer focus area for Astellas with some of your leading assets having been acquisitions, how challenging has it been to build your internal capabilities in this space?

To be able to compete in oncology, we have been working on two dimensions since 2014 to acquire talent with the necessary skills and then further develop these capabilities. We did not launch all our products in one go, rather we started with extending our talent pool by acquiring experts in commercial areas. Furthermore, we began developing internal capabilities and bringing in foreign colleagues on international assignments to the UAE. However, there are still some areas, such as market access and government affairs, particularly in countries like Saudi Arabia where local expertise is essential for success. In such cases, the talent pool is small, and the competition is high, making it challenging to acquire talent. Nonetheless, I have been impressed by the level of homegrown local medical talent and commercial sales teams in the region.

Having been in this region for the past decade, how have you seen the regulatory environment of the Middle East and Africa developing?

I can confidently say that MEA has undergone tremendous positive progress, particularly in Saudi Arabia and the UAE over the past five years. This progress has been marked by the establishment of regulatory pathways for oncology and other innovative products, as well as policies for pricing such products. In particular, the UAE has implemented fast-track registrations and abridged registrations, which have shortened the time it takes for innovative drugs to be registered. In fact, drugs can now be registered in the UAE just two to three months after they are registered in the US or Europe. This has made the UAE an attractive hub for innovation and has led to a significant influx of multinational pharmaceutical companies. Saudi Arabia has taken a slightly different

approach and is pushing for parallel registration, which allows manufacturers to file for registration simultaneously in both Saudi Arabia and the US or Europe. This approach promotes faster access to life-saving therapies for patients.

Another important pillar of the regulatory environment in the MEA region is patent protection and data protection. In 2020, the Ministry of Health & Prevention in the UAE implemented an eight-year Data Exclusivity Period from the date of marketing approval for innovative pharmaceutical products. This provides multinational pharmaceutical companies with an environment that is conducive to innovation and attracts them to the region.

The regulatory environment has also been shaped by private-public partnerships that have emerged in the region over the past decade. These partnerships have significantly reduced the number of unilateral decisions that are made without consulting stakeholders and have created an environment in which stakeholders are encouraged to engage in open dialogue with regulatory authorities. This has enabled the pharmaceutical industry to work closely with the Saudi Arabian, UAE, and Egyptian authorities in shaping a healthy regulatory environment. While there are still some grey areas, there has been a significant positive development in the region.

Overall, the regulatory environment in the MEA region has come a long way during my time in the industry. The private-public partnerships that have emerged and the various policies and incentives that have been put in place to attract innovation to the region have created an environment that is conducive to the growth of the industry and access to therapies for patients.

How do you manage the Health Technology Assessment process and the need for localized data?

There is a consensus among healthcare authorities in MEA countries about the importance of the HTA process when making informed decisions on reimbursement of new medications and technologies. HTA has been evolving amidst many MEA countries with Saudi Arabia and Egypt progressing quickly.

The pharma industry is working collaboratively with healthcare authorities to support the establishment of HTA systems. The industry understands the need for local data generation and is supporting such initiatives considering several factors like capacity, feasibility, and relevance.

Speaking about health insurance, there seems to be a trend of growing importance for the privatization of insurance in the region. How is this reflected in the countries you oversee?

I agree there is a growing trend of privatization in the region, with the UAE leading the way followed by Saudi Arabia. The prerequisite for privatization is digitalization, which both UAE and Saudi Arabia have been focusing on. They have both taken steps to digitize health records and connect the whole healthcare system, which is crucial for success.

We don’t know what privatization will look like definitively, but there is a good level of consultation and openness for discussion among stakeholders to ensure that it works. The UAE government has a vision of being an innovation hub within the region and globally, and they are taking steps towards this goal. The healthcare system here is among the finest in the world, with a high number of hospitals and physicians and a high life expectancy. There are also world-renowned institutions like John Hopkins, Cleveland Clinic, and MD Anderson being brought in to build the necessary capabilities. This is all part of a public-private partnership that will help to drive innovation and excellence in our healthcare system.

It seems there is a race in the region to get access to the most innovative products, especially in cancer. However, simply granting reimbursement to all the available treatments can create a significant economic burden. Do you expect to see the emerging importance of creating strategic, comprehensive cancer plans rather than utilizing medicines as standalone treatment components?

One of our main priorities is to work closely with government affairs teams in different countries to support the development of cancer plans. We aim to highlight the high unmet medical needs and ensure that patients can benefit the most from available treatments. This is a major focus in both Saudi Arabia and Egypt. In Egypt, there are presidential initiatives for cancer plans, starting with breast cancer and now working on including other cancers. In Saudi Arabia, there are also cancer plans in place, and we are similarly partnering closely with authorities to support them.

It is a positive sign to see that cancers are being prioritized as a top healthcare issue in the Middle East. Previously, diabetes was the biggest health problem, and efforts were focused on prioritizing diabetes. In Egypt, HCV was a major concern, but with public-private partnerships, there is now a greater emphasis on oncology and niche diseases. Orphan diseases and medications are also taking more of the frontline and focus from authorities.

As an industry, we are working on an initiative called ‘Headroom for Innovation’ through our local pharma association. We want to collaborate with healthcare regulators and payers to spare budgets to support innovative medications, as we know that resources are limited. We are exploring ways to allocate budgets from areas that are not innovative and channel them to areas where greater value exists.

While there is room for improvement in the portion of GDP being allocated to healthcare, we also need to be realistic. For example, let’s consider the demographic differences of the population and age distribution between MEA and Europe. Countries like UAE and Saudi Arabia have 40 percent of the population under 30 years old, which is different from Europe’s aging population. We are a young population in MEA, and this presents a different set of challenges that we need to consider when making informed decisions about allocating resources to healthcare.

Do you expect the MEA region to be able to keep pace with the kinds of cutting-edge innovations that Astellas is planning on launching in the coming years?

I expect the Gulf countries, particularly Saudi and UAE, to be able to keep up with innovation, as they are ahead of the curve in building the necessary infrastructure to make specialty medicines available for patients quickly. The trend is positive, and the pathway is clear, with the government’s clear goal to support their people with the best technologies and treatments. However, in countries where the economic situation is challenging, it may be more difficult to provide access to medication. Astellas works closely with healthcare systems and authorities to ensure that the regulatory framework supports innovative initiatives that create access for patients. We plan to focus on specific disease areas and strategic markets in the MEA region where we can add the most value for patients and healthcare systems.

Two years ago, we announced our Corporate Strategic Plan 2021 (CSP2021) with the aim of further enhancing the execution of our focus area approach in oncology, accelerating and expanding our primary focuses, and ensuring that the realized value for patients is maximized. We also have new management in the company that joined the executive board in the CEO and CCO roles. Now that we are in the middle year of the CSP2021 with highly motivated leaders, I am confident we are heading in a good direction to reach our goals globally and in the MEA region.

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