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We are opening a new chapter in medicine. The early 2000s were focused on monoclonal antibodies, 2015 to 2025 is all about immune therapy, but 2025 and beyond will be the era of cell and gene therapies

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Amr Seif introduces the evolution in Astellas' MEA strategy; the adoption of innovative access models to ensure that the companies' therapies are available for all patients who need them; and the challenges and opportunities in the Saudi pharma market.

Could you begin by introducing yourself and the scope of your current role?

I have worked in pharma for over 20 years, having started out as a medical rep before then moving into product management and taking on roles as business unit head, country head, and marketing director. Prior to joining Astellas seven years ago, I spent most of my career with Roche and MSD, primarily working in specialty medicine across oncology and hepatitis.

My joining Astellas in 2014 coincided with the company establishing a presence in MEA with a legal entity in Dubai and taking back some of our business in the region, having previously worked solely through distributors here. I first spent a few years working as marketing director before becoming general manager for Middle East, North Africa and Sub-Saharan Africa (MENASSA), and now – for the last two years – have been area lead for MEA.

Having spent time in functional roles, what were the challenges you observed that country and regional managers were facing in your region and how have you implemented plans to solve them upon your promotions?

There are two main challenges for pharma in the region today. The first is access to treatment; all pharma companies are struggling with this, and some are doing better than others. Finding the right access formula differs between countries; developing nations like Pakistan, Nigeria, and Ghana have specific challenges, but the wealthy countries like Saudi Arabia, Kuwait, and the UAE have their own struggles, and all markets require very localised access initiatives.

The second major challenge is access to clinical research. There are very reputable clinical research centres and key opinion leaders in MEA which we, as multinational organisations, need to bring our research to earlier, thereby driving better education around new molecules and modalities.

Given that emerging markets only make up around 15 percent of Astellas' global business, why was the company so keen to establish a physical presence in MEA back in 2014?

Astellas has been on a real transformational journey! When I joined the company back in 2014, the vision and strategy was focused on expanding our presence across the region. We were looking at opportunities in multiple countries, including the likes of Nigeria and Ghana which have big populations but where doing business can be complex.

However, from April 2021 we have implemented a more focused strategy based on our new three-year corporate strategic plan (CSP). Now, our focus is on enhancing access to our treatments. While Astellas does not want to establish a physical presence in every country, we do want to ensure that our medicines are available for *all* patients who need them, wherever they are in the world. This is especially pertinent for our growing rare disease portfolio. Moreover, as we bring forward more gene therapies and regenerative medicines – which require healthcare systems, reimbursement systems, and payer profiles equipped to deal with them – our focus is on building up our presence in select countries.

What KPIs are in place in your region to assess the access and availability situation for Astellas' products?

Availability does not necessarily mean approval; and our aim is not to register our products in every country in the world. For example, for some of our rare disease medicines, we found that in some of the region's smaller countries we would only have been able to serve one patient in nine years. In this environment it makes no sense to register the product in that country.

However, when this patient is diagnosed, we need to make sure that they can somehow reach the medicine they need. We are therefore looking at alternative access models and multiple sources to make sure that these patients can access the treatment. In some countries, it means the fully-fledged process from registration to launch, commercialization, and medical affairs, while in others it might only mean access when needed on a reactive basis.

How fit for purpose is Astellas MEA to help create this more reactive access model in smaller or developing markets?

Our purpose is clear: adding value to patients. We need to ensure that everything we do serves this purpose, whether that is registering our product in a country with one patient every nine years or finding an alternative pathway and putting resources where there are more patients. That is why it is very motivating to see that we are not cutting resources, but rather relocating them so that we can make a difference and add value to patients who have diseases that were historically untreatable or incurable.

For example, our gene therapy for the treatment of X-linked myotubular myopathy (XLMTM) – a rare genetic neuromuscular disorder – is not yet registered and is currently undergoing clinical trials. However, through these trials, many of the children suffering with XLMTM who would otherwise be on life support machines, unable to eat or walk, and who would normally die by the age of five, are now – via a single injection – able to run, eat and live a relatively normal life. This represents a revolutionary new chapter in medicine and will change the way we treat many diseases.

Within the CSP, what else alongside access will shape the way that Astellas operates moving forward?

Innovation! Astellas is very much focused on innovation, which is a key part of our CSP. We are not looking at me-too products but only first-in-line or best in class products that are paradigm shifters for critical disease patients.

The CSP contains four strategic goals. The first is to enable patients to achieve better outcomes. The second is to translate the innovative science we have into value for the patient. Thirdly, we are looking at Rx+ and everything around the medicine itself. The final goal is around sustainability in terms of both access to medicine and the environment.

Saudi Arabia is – for most pharma companies – the MEA's most significant market in terms of size and innovation adoption, with the country's ambitious Vision 2030 plan set to further transform its domestic market. What does Saudi Arabia mean for Astellas?

Saudi Arabia is our key market in MEA without question. When Astellas began reviewing its operational model in international markets in late 2020, we looked at over 130 countries before whittling them down to six priority markets: South Korea, Turkey, Brazil, Mexico, Russia, and Saudi Arabia. In these markets we are prioritising early access to our medications and faster product launches, facilitated by strategic investments.

As our only priority market in MEA, we recently created a legal entity in Saudi Arabia, and our office will be officially inaugurated in February 2022. Astellas' Saudi strategy is based on three pillars. The first is, from a geographic point of view, ensuring that we have the right legal setup there. The second is, from a portfolio point of view, accelerating the launch of our new pipeline products. Very recently, our latest acute myeloid leukaemia molecule was approved in Saudi Arabia and we hope to launch in the next three months. The third is capabilities.

All of this is very much fits with the goals of Vision 2030. Astellas is making direct investments in the Saudi market, creating a technical and scientific office in the country, and Riyadh is also now our management hub for the Gulf countries. We also already have long-standing partnerships in Saudi Arabia for the local manufacturing of some of our molecules, for example in the form of a joint venture (Saja) with Tamer Group for our urology line. Astellas, Daiichi Sankyo, and Tamer all own stakes in this Saja facility, which allows our urology portfolio to be fully manufactured in-country and allows us to out-license certain products.

We are also working with another local company, Al Jazeera, on locally manufacturing our transplant portfolio. Our third arm is the import of our innovative molecules in oncology. Therefore, in essence, we are transferring technology, making investments, and bringing innovation.

Finally, we are looking at developing capabilities among Saudi talent. Over 60 percent of our total Saudi workforce and over 40 percent of our Saudi management team are locals today, and this percentage will expand in the next few years, in line with the Vision 2030 goals of building up the capabilities of the domestic workforce to take on more leadership roles.

Why did Astellas only decide to establish a footprint on the ground in Saudi Arabia in 2021, given the huge significance of the country to the company?

We have been working very closely with the distributors of our oncology portfolio on the ground for several years. However, it was not until the recent reprioritisation exercise that sufficient resources were moved away from less strategic countries to our six priority markets, one of which is Saudi Arabia. That is the benefit of a greater degree of focus.

Secondly, we still have the partnerships with Tamer for our urology portfolio and with Aljazeera for our transplant portfolio. Now, with new oncology products in the pipeline, the time was right to enter the market and establish our own presence. We have already one molecule available for prostate cancer and are currently finalising the registration for a second molecule for acute myeloid leukaemia, which we hope will become available to patients in Saudi Arabia in the next few weeks.

Within Astellas' six priority international markets, Saudi Arabia and the Saudi FDA stand out as relatively swift in their drug approval process. Will this lead to the firm placing greater numbers of clinical trials in the Middle East?

This is something that all multinationals will go through eventually. However, as a new affiliate just starting out with its own setup in Saudi Arabia, we first need to build up the confidence of our global management teams in the US and Japan that Saudi Arabia is a good place for clinical trials and that its clinical research centres are of a high quality and capacity. We already have some ongoing post-marketing and HTA research in Saudi Arabia, but development research will take time. This is something we will look to build and map over the next five to seven years, as Saudi Arabia has state-of-the-art facilities, highly qualified, HCPs, and a good healthcare system, which are all prerequisites for a clinical trials hub.

As the biopharma industry, including Astellas, moves towards regenerative medicines which require a lot of medical affairs, logistical, and regulatory work alongside the therapy itself, what questions are you having to ask yourself in your region?

I ask a lot of questions, foremost of which is whether we are going to send the medicine to the patient or the patient to the medicine? Many cell and gene therapy innovations also require us to rethink the supply chain; for example, our gene therapy needs to be transported at minus 80 degrees and the shelf life of many of these products is very small. This means that from the day the patient is diagnosed, there will be a completely different setup where the medication is custom-made for patients rather than taken off a shelf. That requires new supply chain capabilities and greater alignment with all the relevant stakeholders – from government authorities to key opinion leaders, treating physicians, patients, and their families – across the entire process.

The future of these medications is around patient identification. As an illustration of the importance of identification, we are only expecting four XLMTM patients in Saudi Arabia per year as it is an ultra-rare disease. That requires the right tests and diagnostic tools, the right supply chain for the medication, and the right follow-up post-medication. As an industry we are still learning, although those companies involved in areas like SMA have led the way and helped forge expedited registration pathways.

There also needs to be more liaison with payers and how they budget for such products, creating innovative access models and promoting the idea of pay-for-performance. While these medicines will come with high price tags, the value of allowing a child that would otherwise die by the age of five to live a normal life is also high.

As I mentioned earlier, we are opening a new chapter in medicine. The early 2000s were focused on monoclonal antibodies, 2015 to 2025 is all about immune therapy, but 2025 and beyond will be the era of cell and gene therapies.

There is a lot of optimism about the direction in which Saudi Arabia is moving and most global pharma players are ramping up their investments in the country. However, what do you think will be the main challenges in Saudi Arabia over the next few years?

There are multiple challenges. The first is unpredictability, although the Saudi authorities have improved significantly on that score and are now making far fewer unilateral and unpredictable decisions without consultation.

The second challenge is intellectual property (IP) and generics. Not all companies have registered their patency rights in Saudi Arabia, and the Saudi authorities have five years of data protection on any file, which is a good thing. The challenge is that this has not always been respected. A country like Saudi Arabia, which is prioritising innovation within Vision 2030, should respect global IP. I do not think that it is appropriate to see generics coming onto the Saudi market when the originator product is still patented under the US FDA and EMA. Since Saudi Arabia is taking these two authorities as references, there can be more stringent rules on IP protection.

Pricing could also be added as a challenge, although the Saudi authorities are now listening to our concerns more and looking at ways to improve access to innovative medication.

Trust seems like it will be an important component in the evolution of the Saudi pharma industry. From an industry perspective, are the multi-stakeholder mechanisms in place for this trust to be developed further?

Things are working well and improving. Most of the authorities are open to discussion and we have excellent access to multiple stakeholders via our industry group. The authorities are starting to understand that it is a two-way relationship, where multinational companies are willing to invest and expand *if* there is clarity, predictability, and IP protection.

Do you have a final message for our international audience?

Saudi Arabia has long been a priority – and will continue to be a priority in the coming years – within MEA. Astellas is now ramping up its presence in the country, accelerating access to our medications, and is looking forward to expanding our already solid partnerships to achieve our ultimate goal of better serving patients.

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