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Our success can be attributed to one word: focus

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Kamel Ghammachi and Karim Smaira are the co-founders of Genpharm, an entrepreneurial success story that now provides market access and marketing solutions for rare disease products across the MENA region. They discuss the impact of COVID-19 on their business; the evolving dynamics of the Saudi pharma market; and the crucial importance of building rare disease testing, infrastructure, and collaborations in MENA to raise awareness and create more timely treatment.

How would you characterise the impact of COVID on your business, especially given its entrepreneurial nature and niche focus on rare diseases?

Kamel Ghammachi (KG): For us as entrepreneurs, the pandemic was definitely a setback and a change from business as usual. However, we also saw it as an opportunity to do things differently. The technology available today was not around ten years ago when we started the business and we were able to utilise new platforms to better engage with our community of healthcare professionals (HCPs) and key opinion leaders (KOLs) and disseminate information around rare diseases and their diagnosis. The pandemic actually led to more opportunities to make contact with them.

As an example, pre-pandemic most physical congresses tended to have around 300-400 specialist attendees from a particular area. However, virtual congresses can have thousands of attendees,

creating more frequent touchpoints. We have even managed to hold our advisory boards digitally. Because of the smaller financial impact, we were able to hold these meetings three times a year instead of once.

In 2020/21 there were no setbacks on a business level in terms of turnover or hiring. We even hired more staff and although they do not come into the office every day, they work as hard – if not harder – than before.

Karim Smaira (KS): It took us a couple of months to adjust as an organisation, but after that we never looked back. In fact, we engaged in more activities than we would physically because the costs were less. Recently, we sponsored a disease awareness event with the Saudi Paediatric Neurology Society with over 3000 participants – the maximum allowed – meaning that many doctors were not able to join. At a traditional congress with a booth it is impossible to reach 3000 people. These are CME credit-associated, meaning that doctors can listen, learn, and participate from the comfort of their own homes. The hassle of travel, airports and hotels check-ins are no more, although we do miss it from time to time.

Rare disease stakeholders in the US and Europe worried that the rare community was deeply impacted by the pandemic, with fewer diagnoses and restrictions on access to doctors and hospitals. Has this not been the case in the Middle East?

KG: It is important to note that patient groups in our region are not as well developed as their counterparts in Europe and North America and in many geographies do not even have a legal framework for their existence. It is unclear whether there has been a significant impact on diagnosis, but patients living in remote areas with limited transport infrastructure have found it more difficult to travel and access care. We have not seen a big impact for patients living in major cities.

Karim Smaira (KS): There has been a bigger impact on patient-physician interactions than on us as a business because many hospitals no longer allowed visits and switched to virtual consultations. For rare disease patients, psychological support is especially important; they often have more than one caregiver and many of their treatments are multidisciplinary with the need to visit several doctors. Therefore, the switch to virtual was a significant challenge for patients. At certain instances this impacted some prescriptions that we expected to be renewed being delayed due to patient meetings being delayed or postponed.

Genpharm has now been operating for ten years; what have been the defining principles that has got the company to where it is today?

KS: The ten-year anniversary of the company comes with a sense of vindication for me. When we started, many people thought that our business model was not sustainable and that we were crazy to invest our own money. There are always more naysayers than supporters but, like any new business, it took a few years to get established and become profitable. As entrepreneurs the priority was to create value for the company, so we worked for the first three and a half years without salaries.

Over the past few years, we have seen several people trying to emulate Genpharm, from the way we built our website to how we communicate. Some have even tried to enter the niche and underserved rare disease space we initially targeted. With what we have learned over the past ten years, we believe we have gained valuable expertise and an edge that differentiates us; Despite our growth we remain very agile and flexible which helps when competing with large companies or multinationals attempting to enter the region.

KG: Our success can be attributed to one word: focus. As Karim noted, the first two or three years were tough, but from year four onwards we had a lot of business requests. As a small organisation, it took courage and wisdom to be able to turn down opportunities and maintain our focus on orphan drugs and rare diseases, but it was something we had to do.

Some of the companies attempting to emulate us do not have such a long commitment to rare diseases and while some can now be seen as potential competitors, we do not feel threatened. 70 percent of the opportunities we take on are successful, a very good margin in our business.

What are the company's specific areas of focus within this wider emphasis on rare diseases and what capabilities has it built to support them?

KG: Both Karim and I have experience working in neurology at multinational companies before moving into neurology-linked rare diseases. Our first two to three companies were predominantly focused on neurological and neuromuscular diseases such as multiple sclerosis (MS) and Duchenne Muscular dystrophy (DMD) and our relationships, network, and know-how within the neurology space made this an obvious choice when choosing which rare disease areas to focus on initially.

KS: Our experience has been multinational, working across senior management positions at a global level. When we transitioned to Genpharm, we brought this skill set across; It is another key differentiator from some of the regional and local companies we compete with.

Many businesses here were traditionally built on a trader's mentality. We have taken the long route, investing today to become profitable in the future. That is why we never went directly into physical distribution; we did not think we would add any value there. We have brought that international mentality to a regional company and set up the way that any pharmaceutical company would, with the different departments and support functions.

At the beginning, we looked at what type of company we wanted to create, how we could differentiate ourselves, and what niche area we wanted to compete in. Rare disease has such a personal impact on patients and their lives; 80 percent are of genetic origin and affect paediatric patients. There is a high level of genetic disease in this region, where 50 percent of marriages are between inter-family members. Having a strong sense of purpose to improve quality of life and save patients' lives has been crucial, not least in attracting in the right talent with multinational experience to join a start-up. So far, we have been quite successful, bringing in talent from most large Pharma companies.

There is an ongoing trend where rare disease companies such as Shire and Alexion have been swallowed up by large MNCs which have global presence and can therefore unroll the portfolio without the need for intermediaries. What effect does this have on the sustainability of your business model?

KS: There is risk in our model in its very nature. However, treatments currently available cover only around 200 rare diseases, while in total there are over 7,000. Most R&D investments today are geared towards rare diseases because of fast-track approval, higher prices and commercialisation pathways. Therefore, while there is a risk of losing some partners due to M&A, over the last ten years we have gained a lot more than we have ever lost. In general, we are gaining at least two to three additional partners annually, thereby mitigating our risks. We are confident that breakthroughs will come every year and that new, smaller companies without the local knowledge, financial or human resources to do so on their own will reach out to us to try to penetrate the Middle East.

How far away is the Middle East from implementing the testing, infrastructure, and collaborations necessary to raise awareness and create more timely treatment?

KG: The Middle East is a very fragmented environment with many patients on private healthcare plans and others covered by public institutions and governments. Barring Saudi, Gulf markets have relatively small local populations, meaning that there is not enough volume for governments to conduct large and comprehensive epidemiology studies. Nevertheless, three programs have now been launched – in Qatar, UAE, and Saudi Arabia – to screen their populations and create a genomic database which can be used in the quest to eradicate certain genetic diseases.

However, the diagnostic situation is far from ideal. Many samples taken locally, even from public hospitals, are still sent to commercial and university research labs in Europe and the US for genetic screening and sequencing. A lot of our investments go into education, working with geneticists and to raise disease awareness and with scientific societies and physicians that connect with patients to reduce the time taken on diagnostics.

We do this through a focus on early signs and symptoms, as in our project with the UAE Ministries of Health and Education, working in local public schools speaking to teachers through a physician about the early signs and symptoms of Duchenne muscular dystrophy. On average, patients in the Middle East are being diagnosed at the age of eight for this disease while in Europe the diagnosis happens at the age of four; meaning that there is a four-year window of opportunity to treat being missed, which has a huge impact on mobility and life expectancy. On average, these children end up in a wheelchair at the age of 11, an age that can be significantly delayed with earlier diagnosis and treatment.

Without education and local diagnosis, we will not be able to close that gap. In Duchenne we have managed to do so and are now working with CAPA-certified local lab in the UAE to cut down cost and turnaround times for diseases such spinal muscular atrophy (SMA) diagnosis.

How important is it for Genpharm’s future development that there is a ramping up of infrastructure in your region?

KG: Very important. However, in general only locals can get funded for expensive rare disease treatments and there are often budgetary constraints linked to the price of oil. Regardless, there are always more diagnosed patients than the number of patients that are actually treated. A significant difference between healthcare systems in the Middle East and those in the US and

Europe is that if approval and funding for a product is granted there, it is a blanket approval and any patient that is identified gets the treatment. Here, it is done on a case-by-case or hospital-by-hospital basis; if the hospital has the budget, the patient will get the treatment, which then needs to be renewed. If the hospital does not have the budget, then we must find a different hospital or a charity, but in many cases the patient does not get access to the therapy.

Presumably you have had to engage significantly with governments to explain the importance of paying for rare disease treatments. How challenging was this journey and how do these governments perceive the cost/benefit ratio of orphan drugs?

KS: It has been an extremely difficult journey. When a case is identified and there is a prescription, there is no way of knowing for sure if that patient is going to get on treatment or not. There are so many variables that no one process guarantees access to therapy. Therefore, there a lot of hard work and follow up that needs to happen.

In the region's biggest market, Saudi Arabia, there is a move to establish a health technology assessment (HTA) approach, but this is still in its infancy. The MoH intends to move from being a provider to being a regulator. Today it is still a provider, paying for most medicines in the country. The HTA department conducts its own analysis on pharmacoeconomic data studies, before they deciding if a patient is eligible and under which criteria. This is still at a formative stage although we are convinced this will be the trend for the future of reimbursement.

How many patients are Genpharm's medicines reaching across the Middle East today?

KS: While we cannot give a specific figure, we can say that, through our work, patients are being diagnosed and treated earlier. We are also working with authorities and doctors to expand the new-born screening for treatable diseases. There is no point putting in place expensive screenings for diseases that do not have treatments, but many treatable diseases today are not on the new-born screening program.

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One such disease is spinal muscular atrophy (SMA). Through one of our strategic partners, Genpharm is the first and only company to introduce a gene therapy to the region. SMA Type 1 is a fatal disease in which patients' average life span is just two years. Without early identification of SMA via new-born screening, patients can be diagnosed at a later stage when they are no longer eligible.

Diagnosing patients at a very early stage is very challenging, but potentially lifesaving. Diseases like SMA, Duchenne, and monochromatic leukodystrophy (MLD) now have treatments, and should be included in expanded new-born screening programs.

Saudi Arabia seems to be in a period of great change as the country pivots towards the ambitious goals of Vision 2030. How has this change impacted the way in which Genpharm operates in the country?

KG: Today, the impact is more on society than on business. Issues like allowing women to drive are taken for granted in other countries but represent a major change in Saudi. We will see an impact on business over the next decade, but for now the fundamentals remain the same for Genpharm.

We have our own medical science liaisons (MSLs) on the ground who are in touch with HCPs and charged with raising diagnosis awareness among other tasks. Then we also work with two local sub-distributors on the commercial side which collect orders, get import permits, follow up with the Ministry, clear the goods, and deliver them to the institutions.

While this system of working remains in place, there is a growing feeling of optimism that – in the long run – Saudi will become an easier place to do business with a more open society and market. For example, while there are still visa issues, the process is much more straightforward than when I began working there in the 1980s.

By the time that Vision 2030 is implemented in full, I am sure that there will be an impact on business more broadly. Greater opening up and liberalisation could mean that potential international investors no longer need to partner with local companies and could even think about establishing regional hubs in Saudi. Currently, Dubai has such a status having eliminated the need for local partners and rolled out a 10-year golden visa initiative, I am sure Saudi will follow overtime with similar measures.

KS: Additionally, the pace of regulatory change in Saudi over the past two years has been tremendous, analogous to when the countries of Central and Eastern Europe joined the EU and had

to rapidly update all their regulations on competition and pricing etc. The Saudi FDA is implementing new regulations very swiftly, centralising procurement through NUPCO, putting in place an international referencing pricing system, encouraging local production to decrease dependence on expensive imports, promoting local industry through preferential policies around tenders, and creating more transparency in the tendering and procurement processes. All these changes keep everyone on their toes as the pace of change is quite rapid.

How would you characterise the HCP community in Saudi and its approach to treating rare diseases?

KS: Most experts holding key positions within Saudi have been trained abroad in Canada, the US, and the UK. There is an agreement to send doctors to study in Canada, where they undergo their residency before returning to Saudi and taking up key positions within public hospitals. In rare diseases especially, one important difference between Saudi and US or European experts is that Saudi doctors see much more rare disease patients due to the genetic composition of the population, the tribal structure, and the consanguinity. A rare disease specialist in Europe may see a few cases per year, while his equivalent in Saudi might see a few cases a month. This creates a high level of expertise, combining Western training with a lot of practical experience in Saudi.

There is, however, a gap on the access side, with more patients diagnosed than treated. This is an area that should really be looked at; if there is an available therapy for a patient, how can it be justifiable that that patient is not treated? We understand that there is a budget dimension that is quite important but one should not forget that there is also an ethical consideration.

There is a lot of excitement about the growth of the Saudi market, how is Genpharm planning to capitalise on it?

KS: We are growing in Saudi year-on-year, always driven by the fact that there are more patients diagnosed due to increased disease awareness. We have only seen the tip of the iceberg. To illustrate, the remote eastern provinces of Saudi – where there is a major lack of tertiary healthcare institutions – are those with the highest levels of consanguinity and thus the highest rates of diseases such as sickle cell anaemia, haemophilia, and thalassemia. Most cases are treated in Riyadh or Jeddah but originate in the east of the country. However, transportation across what is a very large country by plane is difficult and these families do not necessarily have either the

finances or education to know which doctor to see or hospital to visit. That is why a lot of our work is focused on awareness.

What do you see as Genpharm's role in building up the rare disease community in the Middle East, a region without the legal framework for patient associations that exist elsewhere?

KS: Genpharm was the first company in the region to create a patient advocacy position. We have reached out to the National Organization for Rare Disorders (NORD) in the US and the European Organisation for Rare Diseases (EURORDIS) to propose a translation of some of their material into Arabic, especially given that many patients in our region had already been in contact with them. Those translations can be then published on their websites.

We also became a member of the Global Genes RARE Foundation Alliance, through which we plan to organise a workshop for parents interested in becoming advocates and engaging in lobbying. In terms of advocacy, the Middle East still lags far behind Europe and the US, where patient associations have input into legislation around access and are funding clinical trials. Up to this point, patient groups in our region have been limited to WhatsApp chat groups or social gatherings on the global day of a particular disease. To highlight the gap that exists here, in our outreach work we were shocked to find that Rare Diseases International (RDI) did not have a single member organisation from the Middle East.

Genpharm has actually been pushing for greater numbers of clinical trials in the region, especially given the large amount of rare disease patients here. We are willing to support patient advocates to create more formalised societies, which would be mutually beneficial for all stakeholders.

On a personal level and having built up the company over the past ten years, what would you both like to achieve with Genpharm over the next ten?

KS: We are a private company, so continuing to keep the business profitable and sustainable is our intention. At the same time, our purpose is crucial. We take great pride in having a major impact on people's, especially children's, lives. Our aim is continue driving growth while retaining that purpose, contributing to patients being diagnosed and treated earlier and improving understanding of the management and eradication of rare diseases through education. Based on the number of new rare disease treatments coming online, it is clear that there are still many people who have

not yet been touched. The more patients we treat, the better; in terms of both business and the human impact.

KG: We really believe in the future of the company and are even beginning succession planning. Karim and I cannot lead indefinitely; I would love to take a step back in the next four or five years and put the next generation in the driver's seat. There are good people already within the organisation who – while they bring their own ideas to the table – share our values and priorities and can take on these leadership roles in the future.

Is there a final message that you would like to share with PharmaBoardroom's global audience?

KG: If you believe in something, focus on it and do it. If we had listened to the naysayers at the beginning of this journey, we would not be sitting here today.

KS: I fully agree. Having passion and drive for what you do is key to success. When you do something that you really enjoy, it becomes more than just a job.

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