Driss Chaoui – Managing Director, Afric-Phar

Afric-Phar's commitment to supporting rare disease patients is deeply rooted in our guiding philosophy to 'leave no one behind'

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Driss Chaoui outlines recent milestones in Afric-Phar's over 50-year history, including the launch of its first in-house developed generic, and discusses the firm's unique focus on orphan and rare diseases and the challenges facing the field in Morocco. He also reviews the opportunities presented by the transformation of Morocco's regulatory authorities, such as the potential for aligning with other international health agencies for mutual recognition of marketing authorizations (MAs) beyond Morocco.

The last time we spoke, you mentioned the new developments that were underway at Afric-Phar, including the opening of an R&D centre in 2017. However, a lot has transpired between 2020 and 2023, not least the COVID-19 pandemic. Could you discuss how these changes affected your plans and what kept you busy during this period?

COVID-19 essentially acted as a catalyst, accelerating various processes. We fully embraced the digital realm, simplifying meetings and procedures.

During this transformative time, our commitment to product formulation remained strong. In 2021, we achieved a significant milestone by launching our first-ever generic medication, a product that was entirely developed within our own R&D centre. We also introduced the market’s first generic version of Rivaroxaban, a direct oral anticoagulant medication. This accomplishment considerably expanded access to oral anticoagulants in Morocco marking a significant step forward in our

development and market position.

Furthermore, we have expanded our presence in the cardiology field, where we are now the leading laboratory in the country, offering a comprehensive range of around ten products. This consolidates our position as the premier cardiology laboratory.

Beyond product innovation, we have ventured into business-to-business collaborations, specifically through ‘MA bis’ partnerships. In these arrangements, we manufacture the product while another laboratory takes charge of marketing and sales under their own brand. This approach streamlines the registration process and expedites approvals, allowing us to maintain steady production levels.

Simultaneously, we are enhancing our subsidiary, Pharmis, which stands as an independent pharmaceutical laboratory as well as a Contract Manufacturing Organization. This dual role enables Pharmis to provide a wide range of specialized services to various laboratories, in addition to registering and marketing its own products. Or instance, during the COVID-19 pandemic, Pharmis was the first to bring a generic version of Merck’s Molnupiravir to the Moroccan market, even before other pharmaceutical solutions, such as Pfizer’s, became available in the country. We are actively coordinating efforts between Afric-Phar and Pharmis to optimize both production and distribution activities. This symbiotic relationship enriches our flexibility and capacity for innovation.

Could you provide an update to our audience on the business model and strategic positioning of these different lines of business?

Our strategy can be categorised into four primary pillars. The first pillar centres around the development and marketing of our generic medications. We accomplish this through our in-house R&D laboratory, with an emphasis on becoming increasingly autonomous in this space.

The second pillar is built on partnerships with multinational corporations, specifically in therapeutic areas that complement our portfolio. We have alliances with companies such as Gilead for hepatitis B and C treatments, liposomal amphotericin B or AIDS medications, and Baxter for peritoneal dialysis and parenteral nutrition products. While we focus on producing generics for medications that can be genericized, we also seek specialized, value-added products, including those in the field of oncology.

Our third strategic pillar is particularly unique, as it targets rare and orphan diseases. This involves distribution on a smaller scale, targeting niche markets that require specialized medications. Due

to the registration complexities associated with these types of products, we often navigate under Named Patient procedure or the ATU temporary authorization for use process.

Lastly, the fourth pillar is our expansion into B2B services, specifically contract manufacturing and aforementioned MA bis partnerships.

In essence, these four pillars underpin our holistic approach to pharmaceuticals, balancing innovative products, generics, partnerships, specialized drugs and B2B solutions.

What are the main challenges you see in the field of rare diseases in Morocco in terms of the environment and access to therapies?

The challenges in the field of rare diseases in Morocco are both environmental and related to access to therapies. One example lies in enzymatic deficiencies, conditions requiring lifelong treatment. While we can provide medications to act as enzyme substitutes, there are ancillary challenges, particularly nutritional, that are not yet fully addressed.

Consider phenylketonuria (PKU), a condition that requires a specialised diet. This is similar to the needs of individuals with gluten intolerance who require gluten-free products. Currently, these special dietary requirements are not subsidized or covered by insurance, leaving patients to manage these additional expenses out-of-pocket.

The Ministry of Health is certainly cognizant of these challenges. While they have made commendable strides in addressing rare diseases like haemophilia and tyrosinemia, there is still a gap when it comes to comprehensive treatment that includes specialised diets. The introduction of generics in some cases has been beneficial, bringing down the overall costs of managing these conditions. However, there is more work to be done to create an environment where all aspects of rare disease management, including nutritional needs, are covered.

Can you expand on Afric-Phar’s commitment to supporting rare disease patients?

Certainly, Afric-Phar’s commitment to supporting rare disease patients is deeply rooted in our guiding philosophy to “leave no one behind.” This is not just a company slogan; it is a shared ethos that resonates deeply with me as a medical professional and extends throughout our entire team at Afric-Phar. Our collective goal is to meet the healthcare needs of every individual, regardless of the rarity or complexity of their condition.

To elaborate, even if there is just a single patient requiring a specific treatment, we go to great lengths to ensure they receive their medication. We also assist in navigating the reimbursement process by providing all the necessary documentation to help patients substantiate their treatment needs. In many cases, we supply the medication upfront and wait for the reimbursement to follow. This approach exemplifies our commitment to social welfare and solidifies our role as a pharmaceutical laboratory that is genuinely dedicated to patient care.

In many different countries, we see programs being implemented to facilitate access, often through public-private partnerships, especially in the context of rare diseases. Could you provide insights into the programs and actions in place to facilitate access and support for these patients?

In Morocco, we have initiated several programs to improve access to treatments for conditions like haemophilia and hepatitis C. Although hepatitis C does not necessarily meet the criteria for a rare disease, its long-standing lack of treatment made it a priority. Now, patients can access various therapies, including generic options.

For enzymatic deficiencies, existing programs are generally managed at the regional level by University Hospital Centres (CHU). These centres operate with budgetary autonomy, enabling them to directly oversee the treatment needs of their patients. The procurement of necessary products for these treatments is often conducted through regional tenders.

We also handle a specialised product used for renal transplants, known as organ preservation solution. This product is used to preserve a donor’s kidney until it can be transplanted into a recipient. While kidney transplants are less common in Morocco than in Europe, this solution is indispensable when such procedures do occur. Occasionally, hospitals reach out to us on short notice to check the availability of these kits as they prepare for an imminent transplant.

While there are programs to facilitate access to treatments for rare diseases and other specialized conditions, these are often regional rather than national initiatives. At Afric-Phar, we play an essential role in ensuring that these specialized treatments and products are available when needed, reinforcing our commitment to comprehensive healthcare solutions.

What therapeutic areas do you see as your focus moving forward?

Moving forward, our primary focus will be on chronic conditions, spanning therapeutic areas like cardiology, the central nervous system, rheumatology, metabolic disorders, and diabetes. These are areas where continuous treatment is a necessity, underscoring the importance of expanding the availability of generic medications. Take diabetes as an example: despite numerous advances, there remain many medications in this field that have yet to be offered in generic form. Considering that roughly ten percent of Morocco's population is affected by diabetes, the demand and the potential impact are substantial. Our aim is to fill these gaps by offering more affordable and accessible medication options.

We are currently witnessing a major healthcare reform in Morocco, covering aspects like universal healthcare and the creation of a new medicine agency. Given your experience in the market, what is your take on this reform and what opportunities do you see for Afric-Phar?

The ongoing healthcare reform in Morocco presents a valuable opportunity for improvement, especially considering the country's low average annual healthcare spending per person of around 600 Dirhams or approximately USD 60. The Moroccan healthcare system is generally under-medicalised, and the establishment of new clinics indicates a significant potential for growth. However, it is crucial to establish a financially sustainable model to support these improvements.

One of the challenges lies in the reimbursement process under the mandatory health coverage (AMO). Patients currently have to pay upfront for medications and seek reimbursement later, which can be a hurdle for those unable to afford the initial cost. There's a third-party payment system in place for some high-cost medications, but it's not uniformly applied, leading to complexities in affordability and access.

In terms of opportunities for Afric-Phar, the regulatory authorities' transformation from a pharmaceutical direction to a medicines agency adhering to international standards is incredibly promising. This structural change could enable Morocco's new medicine agency to engage with other international health agencies. The exciting aspect here is the potential for mutual recognition of marketing authorizations (MAs) not just within Morocco, but potentially across Africa. Similar to how the European Medicines Agency (EMA) operates, a product registered in Morocco could potentially gain recognition in countries like Senegal, Gabon, and Ivory Coast, among others.

Challenges will certainly continue to exist, but the healthcare reform in Morocco opens up an array of opportunities for better access, improved infrastructure, and broader regional influence, all of

which align well with Afric-Phar’s strategic focus and capabilities.

What are your thoughts on the current state of access to medications and the regulatory processes for bringing drugs to market? Can you identify areas for improvement?

The current state of medication access and regulatory procedures for introducing new drugs into the market is undoubtedly complex. Starting a lab and importing medications involves navigating a multitude of regulatory hurdles. While our supervisory authorities are making strides to streamline these processes, there is still much room for improvement, especially when it comes to human resources and the digitalisation of various processes.

The recent MA decree specifying particular timelines is a step in the right direction. It outlines a two-month period for an initial assessment of acceptability, followed by approximately 45 days to arrive at a preliminary agreement. After the application is submitted, there is a 90-day window for providing samples. This then leads to a series of steps including sample testing, compliance evaluations, and price studies, which in theory, should total around 15 months as per the decree.

However, the reality often diverges from this 15-month theoretical window, and delays are not uncommon. Efforts are being made to address these issues, and I am optimistic that we’ll see improvements in the regulatory timeline.

The COVID-19 pandemic added another layer of complexity by causing significant delays and creating a backlog in the regulatory processes. These challenges further underscore the need for optimizing the existing frameworks to ensure more efficient and timely access to medications.

So yes, there are clearly defined regulatory procedures in place, but there are also areas where efficiency can be enhanced. This includes striving for a more rational and predictable timeline for drug approvals.

Many local companies are expanding into international markets, particularly in Sub-Saharan Africa and the surrounding region, with some considering entry into the Middle East. How does Afric-Phar approach international expansion?

When it comes to international expansion, Afric-Phar employs a dual-pronged strategy. First, we focus on exporting our own registered products, predominantly to French-speaking African nations.

Second, we work closely with our partners to broaden our territorial footprint, as seen in our representation of Baxter in countries like Senegal. Leveraging our in-house expertise, we handle the registration of products in these foreign markets ourselves.

Operationally, we opt for a direct-to-wholesaler approach in these countries, sidestepping the need for local subsidiaries or distributors. To facilitate this, we maintain a medical promotion office that is tasked with local product promotion, ensuring our offerings are well-understood and widely adopted.

At present, exports contribute to about five to seven percent of our total revenue. Our goal is to escalate this figure to around ten percent, highlighting the importance we place on African partnerships.

We are also actively engaged in tender processes in our export markets, which provide unique opportunities. These tenders frequently focus on specialized products, offering us a chance to leverage our expertise in niche areas. For example, in Senegal, we have participated in tenders specific to peritoneal dialysis, an area that aligns well with our specialized product offerings and commitment to comprehensive healthcare.

We can say that our international expansion strategy is a mix of direct exports and partnerships, with an aim to deepen our foothold in sub-Saharan markets and reinforce our African presence.

What distinguishes Afric-Phar from the other 56 local pharmaceutical producers in Morocco?

What sets Afric-Phar apart from other local pharmaceutical producers in Morocco is multifaceted. One of the key differentiators is our unparalleled expertise in rare diseases, a relatively unique emphasis in the Moroccan market. This positions us as a go-to provider for essential treatments in areas where options are otherwise limited.

The certifications we hold are also a testament to our commitment to quality and best practices. We were the first Moroccan laboratory to achieve the ISO certification in 2004, and we have made a conscious effort to continually align with the evolving standards, offering stakeholders added assurance of our dedication to excellence.

Another cornerstone of our particularity is the integrity and ethical standards of our teams, notably in regulatory and compliance matters. Trust is vital in our industry, especially when laboratories

entrust us with their MA dossiers. This trust is not just given; it is earned over time through our consistent performance and professionalism.

Furthermore, our African Hub and established presence in the region amplify our strategic growth perspective. Our ability to holistically manage our partners' operations in Africa speaks to our operational effectiveness, expanding our influence beyond Morocco's borders.

Ultimately, it is the relationships we have with our clients that speak for us, and the enduring relationships we've cultivated with our partners underscore our standing. Through our reliability and consistent delivery of high-quality solutions, Afric-Phar has emerged as a distinguished entity in a competitive market.

How has Afric-Phar been performing within the Moroccan market and what are your hopes and expectations for the coming years?

For over 50 years, Afric-Phar has remained steadfast in its commitment to promoting patient well-being by developing high-quality products. We proudly stand among the top ten pharmaceutical laboratories, and we are setting our sights on maintaining a double-digit growth trajectory. We offer a diverse portfolio of products, with many of our brands currently leading sales in their respective classes.

I would be remiss if I did not highlight the exceptional work of our marketing teams. They have been nothing short of remarkable, spearheading our success on the sales front. Yet, it is essential to underline the continuous support they received from our supply chain team and regulatory department. Together, they formed an unbreakable trio, with the regulatory team ensuring compliance and swift approvals and the supply chain team adeptly forecasting and managing market demands generated by the promotion team, even when they surged unpredictably.

As we continue our journey, we remain dedicated to our motto of "leaving no one behind."Addressing rare diseases is not just a part of our DNA; we see a beacon of hope and anticipate the most profound societal impact. At the same time, we harbour high expectations for our B2B engagements, which are vital to our mission. With the backing of our R&D initiatives, our goal is to introduce premium products tailored to the needs of our clients and the broader market's demands.

Lastly, we aim to strengthen our presence in the export market, expanding our product range and boosting our export sales to surpass the ten percent mark. Africa, deeply ingrained into our

identity, is a prominent international focal point. We aspire to extend our network throughout the continent, building upon established partnerships and cultivating new alliances.

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