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Loic Galmard discusses the opportunities and challenges of setting up local production in Algeria, and the best strategies to increase market access and create a dialogue with the regulatory authorities.

What are your first impressions of the local market in the 10 months that you have been here so far?

My first impression is that Algeria represents an unprecedented opportunity within Africa for international pharma companies like Janssen. Firstly, the scope of medical coverage is extraordinarily high, reaching some 85 percent of the entire population. This is not at all common in African countries, which are almost always high co-payment markets where the patient must pay for treatment out of their own pocket.

Secondly, the government is a staunch advocate of strengthening the local pharma manufacturing base, meaning there are considerable incentives to investing deep into the market and building up in-country manufacturing capabilities. MNCs have a lot to gain from taking this bold step and conversely much to lose if they donâ??t. By the looks of things, given the scale of import-substitution and protectionism for local manufactures, Algeria is well on the way to becoming a production hub that could potentially service a large chunk of the African continent and even some of the Middle

Eastern markets.

Given that analysis of the state of play of the market, what are your immediate priorities?

As a new country manager, one of my first priorities has been to evolve our organizational model here in Algeria, better reflecting the changing operating environment. Traditionally Janssen possessed a very balanced portfolio that catered more or less equally to the retail and the hospital markets. However, the global portfolio of Janssen has shifted over the past decade, pivoting more towards cutting-edge innovation and the hospital segment.

Our primary therapeutic areas today constitute oncology, neuroscience, immunology, and virology. Thus, I felt it was imperative to bring the local structure in Algeria up to date to reflect this transformation and to be better equipped to respond to future challenges. There is almost always a delay in the introduction of innovation to emerging markets by around 2-3 years. Consequently, I firmly believed that Janssen Algeria needed to be rendered â??*fit for the future*â?•, and that is what I have been focusing my energies upon. We are simultaneously reforming the internal organizational structure of the company, such as bolstering the government affairs and market access departments, both to cope with handling the highly complex disease and therapeutic areas, where we now have a strong presence, and to overcome challenges related to access to innovation, the new reality of the pharma market over the world.

I also have two other key priorities. The first is a local manufacturing strategy to bring this to the next level and leverage on it to build a business backbone. A further priority is to Evolve and reinforce our legal presence in Algeria by designing a new operating model, cohesive with government guidelines and recent health law. The objective is to better position Janssen to achieve its long-term ambition within the country.

How are developments at the global level tricking down? For instance, what is the impact of the Actelion acquisition, which introduces an entirely new portfolio for treating hypertension into the mix?

It very much depends on the operating model that was originally chosen by Actelion. Every affiliate will therefore likely have its own specific configuration. Here in Algeria, Actelion was represented by a distributor. This is an excellent opportunity for Janssen to expand on this new therapeutic area, and ultimately to localize and extend out our footprint. Nevertheless, Algeria is a sluggish market where it takes a certain amount of time and patience to achieve things. Currently there are quite a few products that havenâ??t yet been registered and this is often a cumbersome and lengthy process. Despite the excellent opportunities locally to capitalize on having gained the Actelion business, it is realistically going to take quite a bit of time to integrate those operations. The business will be formally handed over in 2019, and we will work hard to shorten the timelines and make this business running out before 2021. Actelion is a leader in PAH and patients canâ??t wait.

Janssen recently announced plans to commence local manufacturing, initially with psychiatry products and then moving incrementally into onco-hematology. What is this all about?

Localization has been my second priority after the completion of the restructuring project. We began localization back in 2014 through a contract manufacturing agreement between Janssen Pharmaceutical in Belgium and a local CMO called Prodiphal to produce 3 SKUs. The initial agreement was small scale but laid the groundwork for eventual local production. We have now extended local production to include psychiatry, historically an important therapeutic area for Janssen. In 2019, we will add our highly successful schizophrenia therapy, RisperdalÂ®, to the Algerian market.

We are also leveraging one of our legal entities. We are represented here in Algeria by both a representative office and through a legal entity, Janssen SPA, which is a trading entity dedicated to importation and distribution.

We also have a plan in the works to extend local production to including oncology products, specifically for the treatment of prostate cancer. However, we, like many multinational companies, are facing the limitations of local manufacturing within Algeria. While in-country manufacturing is extremely developed for basic drugs, it is markedly less so for high potency product such as many oncology drugs. To overcome this, we must invest heavily in tech transfer. There are essentially two alternative ways: either you invest directly into upgrading the plant or you sign a commercial agreement, where a CMO is handed the opportunity to update their facilities and integrate fresh know-how and technology in the short to mid-term. Both options are considered as a concrete investment by Janssen, even if it is not always considered as such by the authorities.

You mentioned how the government is striving to build up a homegrown pharma production base. Have you considered setting up your own proprietary plant as an alternative to hiring CMOs?

We are certainly exploring the possibility of investing directly. Algeria needs to reach the next level in terms of a manufacturing strategy and we, for our part, respect that ambition. Much of the governmentâ??s focus, to date, has been about getting local production to the level by which it can assure 70 percent of the drug needs of the national population. When we are talking about â??easy to makeâ?? drug forms such as chemically synthesized small molecules then the local industry is more that capable of stepping up to the plate. The issue, today, however is that this part of the market is now reaching saturation point and the model is touching its limit. As an innovative drug developer, we cannot expect to extend this model and reap any benefit. If we are considering the impact of the exchange rate and the importation of APIs, the cost of production is clearly increasing, but the prices of these classic drugs have been plateauing and staying constant for around 5 years. Even when the prices are revised, it tends to always be in the face of downward pressures. Nor will the Algerian patient benefit either from yet another Paracetamol.

As a company, we need to have a real think about the type of manufacturing model that would play to our strengths and simultaneously benefit the country in the sense of orientating the local production base away from low-value forms and more towards high-value add, sophisticated products. The solution may well be opt for direct investment and our own proprietary facilities, but this has yet to be properly conceptualized.

We stand at a crossroads. Local CMOs are eagerly awaiting fresh investors to bring in new production contracts and drug categories. On the other hand, MNCs like Janssen are aware that localization in Algeria is only viable if the production volumes are sufficient. For drugs like Paracetamol with millions of units this is easily viable. Conversely, this is not necessarily the case for hematology drugs for example due to a limited patient pool. Take the example of prostate cancer treatments, which represent one of the broadest markets in terms of number of pills. This will represent only 1 or 2 days of production per year. Hence, building a new production line for 1 or 2 days of production is not possible. The lack of usage of the plant also risks losing the â??know howâ?• and future improvements.

Would the solution not to be to move to an export strategy?

We are in Africa, and unfortunately the needs in the market are skewed towards primary care medicines, rather than hematology. Prostate cancer or virology drugs could work in the future, but it requires further assessment drug by drug to determine the true potential.

Your current portfolio is quite broad. What aspects are generating the most revenue and performing the best?

Onco-hematology is the leading therapeutic area in Algeria for us currently. We possess old products such as EprexÂ® dedicated to nephrology and we have been able to forge a strong business in treatment for prostate cancer. This is because the diagnosis and patient pathway are already quite well settled, and our therapies have mustered a good reputation amongst clinicians. Looking forwards, I identify an excellent opportunity to build a backbone in oncology, though CNS could also conceivably prove to be a growth hotspot in the long run.

Market access is always going to be simpler when you can build a bridge to state health priorities. In oncology we already benefit from our participation in the National Cancer Plan and on the 10th September, we signed MoU with the authorities to also assist with the National Plan for Mental Health, which is an equivalent nationwide program. This is part of our 60 years commitment in psychiatry at Janssen and given our sturdy portfolio of innovative injectables for the management schizophrenia and promising psychiatry pipeline. Moreover, the competitive environment for this segment is not yet mature which means, at least in the short term, we wonâ??t be having to face down cheaper alternatives to our products in that space.

What is your assessment of the ease of market access, given your ambitious target of introducing 10 products within 3 years?

For the last 2-3 years, market access for three products in the pipeline was locked. Our dossiers were delayed. The products had been reviewed by the expert committee, but not by the economic committee. This sort of slow follow-up is unfortunately relatively common out here. Nonetheless, the priority of the government is clearly orientated towards oncology. Within the 10 products we wish to launch, we have a good balance of oncology, immunology and CNS, all of which we can expect to be fast-tracked given their alignment with the Ministry of Healthâ??s core policy aims.

At the same time, we are striving to introduce other key products and innovation in rheumatology, gastroenterology, and conditions like Crohnâ??s disease, which is debilitating for those with no medical options. Unfortunately, these are not especially high up on the government agenda so need to raise the awareness on patient unmet need. Often dermatological diseases are viewed more as a cosmetic issue rather than real ailments, so they can be especially difficult to navigate through the regulatory process.

One of the bottlenecks is clearly that the regulatory apparatus is not structuredell enough to be able to handle the complexity of many latest generation medicines. Though we sense a strong desire on the part of the authorities to introduce HTA methodologies to be able to gain better visibility around the value of specific biologics, the existing capabilities are not sufficient to perform this function. Meanwhile the oversight structures are simply not efficient because responsibility for this task has not been concentrated within a single authority.

A new drugs agency has been formed. Will this likely speed up the registration process?

I think it is a good vision. Unfortunately, the agency was built two years ago and was created in the image of the former inefficient structure, so it didnâ??t work in practice. Now a new director has been appointed to head up both entities: the new agency and the responsible department within the Ministry of Health. Any attempt to streamline and simplify the processes is obviously very welcome. What industry stakeholders like Janssen would like to see is an empowered agency that operates according to clear and transparent norms, which are mutually understood. However, the most formidable challenge for this agency and the local life sciences sector in general, especially when discussing innovation, is to be able to incorporate new models of integration of latest generation

medicine. We donâ??t yet really possess any kind of meaningful HTA yet and that is impeding drug accessibility.

How can you become a real partner of the government and get the message across that the medicines that can really generate cost savings are the innovative ones that deliver targeted and efficient treatment?

Firstly, the onus is on industry to educate the authorities about different types of Management Entry Agreement (MAE) and how these arrangements can mitigate economic risks for both the payer and the drug developer.

There are countless models that can be set that include pay-per-performance and risk sharing elements. We also need to provide showcase examples of success from other countries, like in Italy and France by way of demonstration.

Secondly, we need to assist policymakers in drawing up a legal framework that can accommodate these types of contracts. Currently this doesnâ??t exist. Right now, even if we can come up with an agreed risk-sharing model, the contracts cannot be implemented because they are outside of the scope of the prevailing law.

Thirdly, we need to build local HTA capabilities. This is admittedly very complex. Even mature markets are still grappling with this issue. Today the assessment tends only to be based on the immediate direct impact. Consider if there is a patient who needs a drug which will cost X amount for two years of added life expectancy. The reality of a drugâ??s impact is clearly much broader than that, but the lack of tools for properly calculating value are leading to poor decision making.

Pharma companies can help advance the cause of HTA by generating and sharing data on epidemiology in Algeria, which is not well known. More detailed data will give a better assessment of the impact. By collecting and interpreting the data at our disposal and then sharing the findings, we can help, for example, to define the cost of a day of hospitalization to treat cancer. Currently no one really knows how much it costs for a patient to receive one day of treatment for prostate cancer or for schizophrenia. That, in turn, makes it very difficult for companies to compile pharmaco-economic evidence and calculate how a drug can generate savings. Having local data is essential, so these gaps need to be filled.

In which case, just how strategic is this market for Janssen?

Considering the emerging markets, Algeria is amongst the top 5. The potential is obvious. If our localization and innovation strategies are successful, the company could grow extremely fast and be twice its current size. Our current revenues are close to 60 million dollars. We could double that in the next 5 years.

However, there are substantial hurdles to overcome to succeed. The IP framework is very weak. As a leading innovating company, we need to drive the debate in this regard. Building the business in the short term is great, but security in the long term is imperative.

Finally, how would you define your leadership style? And how do you inspire your employees?

My leadership style naturally is transparency and authenticity. People are often trying to spin things too positively. For me, it is necessary to be clear in any situation. My mantra is persistency and resilience. For me this summarizes the two key success factors for a GM, or an organization in a country like Algeria. Our duty is to reveal the real healthcare potential despite hurdles and fight for patients.

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