Interview with Paul Miller, Vice President and Managing Director, Mylan SA

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Mr. Miller, you have been Vice President and Managing Director of Mylan's operations in South Africa since 2008. What mission were you assigned back then, and in those three years, what have been your main achievements?

Mylan entered the South African market in 2008 through its acquisition of Merck KGaA's former generics business. This acquisition gave Mylan a global footprint. The group moved from being the third largest generic pharmaceuticals company in the US to the third largest generics and specialty pharmaceutical company in the world with a presence in more than 140 countries and territories at that time.

On a local level, it allowed Mylan to establish a presence in the South African market. Before the acquisition, there was no clear generic strategy. Mylan was positioned 18th in the South African generic market. Since then, we have grown over the last four years, placing us at number 8 by value in the generic market.

We have been the fastest growing pharmaceutical company in South Africa in the last 18 months, if you use schedule 3 to 7 as the assessment. We have been showing growth of close to 60% in 2011.

In order to achieve this, our initial starting point was to define which direction we wanted the business to take, and understand exactly how we are going to build it and transform it. We have been mainly focusing on three aspects: the pipeline, the marketing strategy, and local

partnerships.

First, we focused on fixing the pipeline, as we are expecting to see a lot of traction at the Medicines Control Council (MCC). Four years ago, we were submitting close to 12 dossiers a year and securing between zero and two approvals out of the MCC. That has been transformed now, as we have been accessing the Mylan pipeline. Today, we have over 100 dossiers awaiting approval, and we have now moved up to 20 approvals on an annual basis.

Moreover, we decided to see how we could transform the business strategies. We were previously focused on a ‘push strategy’ via the wholesale distribution channel. We soon shifted our focus to building a sales organization which can call on the pharmacists: we established a team and grew the business from 12 people to over 50 people to give us that commercial expertise and scale required.

Thirdly, we signed agreements with local companies to leverage on a first to market advantage. One of these companies was specialized in oncology. Through this partnership, we have launched nine new products in the oncology sector, most of them are injectable-s such as cytotoxic chemotherapy; but they also include three oral oncology products. That has given the business a significant growth.

We are one of the late entrants into the South African generic pharmaceutical market. We have been working on the short term, as well as putting our aim on the long term sustainable business.

What are the main growth drivers in South Africa?

It has been specialty care.

Our primary care business has grown by 32% whereas our specialty care business has grown by 126% over last year. We have put a special focus on speciality care because we feel that it requires a different set of generic promotional skills. It differentiates the typical generic companies from those who have strong commercial skills

Our team of staff is highly skilled and experienced; most of them have post graduate degrees. We put a lot of focus on training. The opportunity for good quality sales with reasonable profits is a lot higher in the speciality care business. We have noticed that the specialty care area is a core focus for initial short term growth.

Since South Africa joined the BRIC grouping last year, it is interesting to compare the South African market overall with its BRIC counterparts. How would you compare South Africa with China, for

instance, where you spent two years as Marketing Director, in terms of the business environment it offers to a generic player?

The dynamic in both those markets is incredibly exciting. Both markets are full of opportunities and fairly unpredictable in their nature, which are the basic characteristics of any emerging market.

In order to establish a strong presence in this kind of market, you need to find a local organization ready to take advantage of the market opportunities and at the same time, you need a long strategic commitment. It takes time to get through all the barriers, the complexities and dynamics of the local market, along with the approval processes.

While there are a lot of short term gains, we have got to be in it for the long run. China has proven that. The country is incredibly competitive: innovative companies and generic companies compete in very similar spaces. The morphing of the innovators to the generics has progressed more and more in China, and I expect this might happen more and more in South Africa, where the innovators are going to move into the generic space more aggressively, and the generic companies will transition back into the innovators space.

Oncology is a perfect example, where Mylan in South Africa is competing toe to toe with companies with similar skills sets, similar expertise, and similar approaches. You cannot stick to your typical generic or innovative approach. You have to be able to operate in both spaces.

Generics are a tool for the government to drive down the cost, but at the same time, the innovative industry is needed to create the pipeline for generics to exist; incentives are needed for both. How to balance up a right environment for the two to coexist?

The dynamic in the South African market is that the MCC is suffering a significant backlog in approvals, and the problem could get a lot worse before it gets better. This dynamic creates barriers to entry. As a result, competition is not that steep; you are not getting a typical flood of generics in the market place. Research-based companies manage to hold on to their market share for longer, past the patent cliff, because they do not face the volume of generic competitors .

In South Africa, generic companies tend to hold on to commoditized brands and grow them for longer. The dynamic created by the MCC is reducing generic competition and creating artificial barriers to really drive the generic business more aggressively and to become more commoditized and more price-sensitive.

Furthermore, a lot of innovative companies are introducing pseudo generics to circumvent any future competition.

Ultimately, the patients are not benefitting from this reduced competition.

Despite the fact that there is already a high generic penetration in South Africa and that there has been a lot of new entrants recently in the market in the generic space, competition has not been felt yet because of this registration time, but it surely will soon. How you preparing yourself for upcoming competition?

The most important element is to have market share. Last year, we have grown by 60% and we have been maintaining the fastest growing generic company locally for over 18 months. Market share is critical, as we need sufficient volumes to increase our price competition.

Furthermore, we need to move as much manufacture to our global sites, so that we can leverage the volume. Mylan is one of the largest producers of Active Pharmaceutical Ingredients (API) in the world, and one of the largest manufacturers of finished dosage form products. We believe that the combination of those two is going to put us in a very strong position.

We also need to make sure that our pipeline is more aggressive, that when the MCC becomes more efficient, which we believe it will, we will be in a strong position to take advantage of a better regulatory environment.

At the moment we are sourcing products from our Indian operations – Mylan Laboratories Ltd. – as well as from the US and from Europe. We know that our timelines in terms of patent offs are very aggressive – America's patent off has gone ahead of Europe – therefore outsourcing products from America means that we are a little ahead of the competition.

In that context, we are incredibly confident for the future.

Although South Africa does not show the same level of comparative advantages as India, to develop manufacturing operations, could we see Mylan invest in the country in production facilities?

First and foremost, 50% of all of our supplies come from local suppliers. In that respect, we do support local manufacturers. Secondly, while the government has put some incentives in place, which are financial in nature -the biggest incentive would be to expedite approval from the MCC. If we are going to have manufacturing locally, we cannot rely upon our old commoditized products to support local manufacture. We need to have new differentiated products, with opportunities for large volume.

The company is also actively exporting to bordering countries such as Namibia, Botswana and Swaziland. What is the importance of the African region for your revenue and development, and to what extent can South Africa be used as a gateway to Africa?

Mylan’s business in South Africa is part of the Company’s export markets business, which includes our Africa business.

Historically, our sales out of South Africa in Africa were less than five percent of our local turnover, so it was not a big contributor to our sales. We have put our focus on building the South African operation as we believe it is critical to have a stable foot at the base of Africa.

What is left for you to achieve as the head of Mylan South Africa and where would you like us to see the company in five years’ time?

We constantly have to earn our future. We believe that Mylan will be among the top three players in South Africa in the next five years.

There is a very significant opportunity in South Africa: that of the generic market growing in double digits. It has sustained double digit growth for more than three years, and we do not see it slowing down. The expansion of the market is a key driver as more patients enter into the private sector. The National Health Insurance (NHI) also offers opportunities for volume. The other aspect is that we have invested very heavily in our pipeline, and we believe we have one of the richest pipelines in South Africa.

Looking at the forecast of those drugs, it will put us in the top three slot; which will then allow us to rival against the two largest local competitors.

What keeps you motivated in the industry, and after a long assignment in China, how does it feel to be back in South Africa?

The home aspect is a strong motivating factor; it is good to be home. It is familiar and very unfamiliar at the same time. In the seven years I have been gone, South Africa has gone through dramatic changes. It is almost as if I moved to a new country.

I try to leverage on all my learning, understand the dynamic of the local market and really see what we can make out of this local business.

I am very result orientated; I like to take on competition; I have aspirations and visions. To take a business and drive it to the top is what wakes me up every morning. It is great to see the organization sharing that same vision and being committed to meet our global ambition to…. At

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