Pedro Galvis – General Manager, Merck Mexico



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General Manager of Merck Mexico, Pedro Galvis, showcases the strategic importance of the Mexican affiliate within Merck's global network and explains the importance of public-private partnerships in enhancing patient access and treatment in emerging markets.

Stefan Oschmann, CEO and Chairman of the Executive Board of Merck, recently stated: "We again achieved everything we aimed for in the second quarter. Actually, our performance in healthcare was so good that we have decided to lift our forecast for 2016". To what extent is this declaration applicable to the Mexican affiliate?

We have been experiencing a solid period in Mexico the last three years, being able to grow our business in double digits year-on-year in a market that grows around 3.5 percent. Fortunately, we have identified a positive trend and we expect to maintain this growth trajectory in the upcoming years. In addition, the Mexican affiliate is a strong contributor to the region's revenues and one of

the key growth markets in LATAM.

I am proud to confirm that we have a very interesting portfolio for the Mexican and regional markets in areas such as endocrinology, fertility, oncology, neurology and immunology. We are going to continue developing those business areas where we have presence with a mix emphasis in specialty and primary care, we are very committed to developing our participation in emerging markets.

What kind of differences have you identified between emerging and developed markets?

The main difference between these markets is that the brand value is stronger in emerging countries. In mature markets people do not identify very much the difference between generics and the original brand for a specific drug. This is an important consideration, given that a large part of our portfolio is available out-of-pocket, i.e. the individual patient is the decision-maker, rather than institutions. Therefore, the way consumers perceive our value is extremely important.

Despite the regulation efforts to homogenize the parameters, there are still differences in terms of product quality. This is where Merck can take advantage, showcasing the high quality of our products.

Patient access to innovative therapies is also a big difference between Emerging and Developed markets. Limited access is one of the key challenges in emerging markets, but also one of the main opportunities for growth if we find ways to overcome this.

Merck’s portfolio displays as very good fit with the therapeutic needs of the Mexican population, as you are particularly strong in oncology and fertility, while in 2014 you were displaying double-digit growth in primary care, thanks to your coverage of diabetes and cardio-vascular pathologies. Considering this excellent portfolio, what are your key points of focus and opportunities you identify to fully maximize your portfolio performance?

There is a huge potential in all therapeutic areas we cover and we are undertaking the necessary actions to fully leverage that, strengthening our existing structure and allocating resources in a smart and targeted way. Nevertheless, the specialty care market is relatively small because of the

existing restrictive access and the fact that areas like fertility and endocrinology were seen as luxury in the past. We are working hard to overcome such barriers, communicating all the benefits and displaying the value of these treatments to institutions. While there have been certain positive advancements to date, there is still a long way to go.

It is important to take into consideration the huge potential of a country like Mexico with around 125 million people and an actual healthcare coverage of 60 percent, meaning that 40 percent of the population has only very limited access to healthcare. This represents an enormous area of opportunity and we are advancing towards enhancing our awareness and communicating the benefits of our therapies.

Specifically, we see improved market access in oncology and neurology through enhanced diagnosis capabilities and high-forming physicians. The challenge in this area is that the institutions simply do not allocate the resources to cover this type of treatments. I expect however that this situation will improve in the long run. We are currently holding several conversations with institutions about alternative models that should enhance the access for patients.

What are the upcoming product launches you are already preparing and how do you expect to expand your Mexican portfolio in the upcoming years?

We currently have some clinical trials ongoing in Mexico for some of our pipeline products in oncology and immunology. Immuno-Oncology is one of the key areas and most promising in our pipeline.

In terms of patient recruitment for local trials, we have experienced some improvements in comparison to the past and to other countries. Nevertheless, the most difficult part in Mexico are the bureaucratic processes to get the green light to actually initiate the clinical trial process. Once you get the approval to start the process, the medical community is quite keen and prepared to collaborate in developing the discovery.

In my opinion, regulators and the rest of the stakeholders should advance towards shortening the lead times in getting the approvals to start running trials in Mexico; especially considering that some companies are choosing other countries in the region such as Argentina and Peru to run their trials.

In Mexico, generics penetration is high, as they already make up 79 percent of the total market volume, and have taken the lion's share of the total market growth over recent years. Furthermore, budget constraint faced by the social security institutes in Mexico renders biosimilars a very interesting option for Mexico's public sector. How has your biosimilar division been doing in Mexico?

It is taking more time than expected to bring biosimilars to Mexico, mainly due to the aforementioned approval challenges but there is a lot of interest in developing the biosimilars area in Mexico. Indeed, we are currently running biosimilar clinical trials here due to the big potential we foresee in the future.

Some general managers told us the Mexican market could radically change in a six-month period. Over the last four years, what have been some of the market changes that might have surprised you, and what is your personal technique to best react to these?

Mexico is an interesting mix between an emerging and a developed market, having the complexities of both of them. Notwithstanding, if you are flexible enough to manage the particularities of the market you can really benefit from its local dynamism turning challenges into opportunities. It is crucial to keep your affiliate aligned to global strategy while simultaneously adapting the implementation to local trends. Mexico is one of the top 10 affiliates for Merck globally and therefore, it is important to consider the impact that any market change in Mexico can have to our global business.

One of your key projects was to start exporting Eutirox® to the US, while you were already exporting primary care products to Germany and Spain. How have you been progressing in this regard?

We are advancing but still waiting for FDA an internal approval processes in order to start exporting Eutirox to the US but most of the investments to enlarge our manufacturing capabilities and to reap the benefits of our export potential are about to be finalized. Indeed, the expectations are to triple our manufacturing capability. Meanwhile, we are using our existing capacity to export Eutirox to other countries in LATAM and Europe such as Germany and Spain.

In addition, we are also expanding our injectable manufacturing area and we will invest around USD 5.6 million in the next two years mainly for Dolo Neurobion and Neurobion drugs. In this regard, we have developed a new double-chamber device that is able to mix the different components at the exact moment of the injection which will significantly improve the quality of the product and the experience for the patient. It has been an important milestone especially considering that Dolo Neurobion is a top 3 sales products in Mexico, not only being exported to the rest of LATAM but also recently to Asia.

In November 2015, Merck decided to invest to strengthen its Life Science division with the 17-billion acquisition of Sigma-Aldrich. In addition to organic growth, the acquisition of Sigma-Aldrich lifted sales of the division by 79.7% globally. How has the Mexican affiliate been progressing in the integration of the portfolios and human resources?

We are very excited about our integration with Sigma because of its size here in Mexico. As a result of the acquisition, we have almost doubled our life science business here. In addition, the operation has given us some interesting digital capabilities in terms of e-commerce, which was one of Sigma's strengths. The process of integration is not finished yet, but its advancing rapidly and well on track, i.e. besides having already set up the structure, we are still working on the next steps in terms of legal entities and other implications. We have identified a lot of potential and enthusiasm in biotechnology and biosimilars here in Mexico, in several of our main customers, and we are willing to offer all our knowledge to speed up the development.

You worked across many different divisions in Merck during the last 20 years. Heading Merck´s operations in Mexico for all divisions (Merck Biopharma, Consumer Health, Performance Materials and Life Science as well as the manufacturing site), what are the synergies you have been working on since your took over?

Retaining and bringing in the right professionals was key to start creating and strengthening synergies between all business units. It has been an interesting journey and we have been able to manage the different areas keeping a strong link and collaboration through clear communication. Nevertheless, we are continuously exploring synergies between the different lines in terms of business and back office units and I expect to strengthen the entire affiliate moving forward.

In 2014, your vision was to remain in the top 10 and be among the top five in terms of growth in the Mexican market. What is your new vision for the affiliate, and what will be the key strengths of Merck Mexico that make you confident you can fulfill it?

We are the fastest growing MNC in the retail segment according to IMS data. In addition, we have improved in the retail channel moving from the ninth to the eight position. We are certainly advancing as well as we are currently collaborating with the different public stakeholders in order to enlarge market access in areas such as women health, which is aligned with one of our global initiatives “Healthy Women, Healthy Economies”.

I believe that this type of private-public collaborations is the future for the industry in order to enhance patient access to innovative treatments while dealing with the financial challenges facing the main government institutions. Further, we will continue working with the private sector and hand in hand with doctors and patients. We have strong fundamentals in our portfolio and in our pipeline to continue driving growth in the Mexican market.

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