Interview: Mariano de Elizalde – General Manager, Sandoz Mexico



We want to grow twice as fast as the overall Mexican pharmaceutical market and double the size of the affiliate over the next five years

28.07.2016

Tags: Pharma, Pharmaceuticals, Generics, Biosmilars, Oncology, Management Strategy, Mexico, Sandoz, Interview, Insight, M&A, Free

Sandoz's ambitious strategy in Mexico includes aggressive product launches in biosimilars and oncology, a heightened focus on the institutional market, and an awareness of inorganic growth opportunities. GM Mariano de Elizalde reveals the key pillars that will drive the affiliate to new heights.

In Mexico, generics make up 79 percent of the total market volume, and have taken the lion's share of market growth over recent years. Cofepris' has made great efforts to ease market access for generics over the past two years and Mexico was the first country in Latin America to grant approval for Sandoz's Airflusal® Forspiro in 2014. Given this context, what is the importance of the Mexican market within the company's global strategy?

For Sandoz, Mexico stands as the second largest market in Latin America behind Brazil, while the country is particularly significant within our global strategy both in terms of sales volume and profitability. Furthermore, beside our impressive and growing sales figures in the country, Mexico stands as a market where the regulators actively and continuously look at further enhancing the penetration of generics, as part of their strategic priorities to provide patients with high-quality therapeutic alternatives at a lower cost. Over the past three years, Cofepris has been implementing fast-track market access measures to allow generics companies to bring their products to the

market more swiftly, and these regulatory improvements are clearly paying off.

The respiratory treatment Airflusal® Forspiro, which is branded IrFlosol™ Forspiro in Mexico, is a great example of how Sandoz brings innovation to the market. This product indeed associates a safe and efficient treatment for patients with asthma and/or chronic obstructive pulmonary disease (COPD) with an innovative inhaler developed by Sandoz. This brand new device notably includes multiple feedback mechanisms such as visual control features, which help reassure the patient about dosing. By developing our products in close collaboration with patients and physicians, we can bring more value to generics and come to the market with products that truly make a difference. AirFlusal has been extremely successful since it was introduced in the Mexican market, while respiratory products as a whole stand among our most important growth drivers in Mexico, alongside with governmental sales.

In Mexico, Sandoz has been dynamically growing over the past few years, and 2016 stands as a very exciting year for the Mexican affiliate. We are very proud to announce that for the first time in its history the Mexican affiliate's sales will exceed the billion-peso mark [USD 55 million]. This year we are launching seven new products in Mexico, while we are ready to bring eight new products per annum to the market over the next five years.

What is the importance of biosimilars in this development strategy?

[Featured_in]

In our very dynamic pipeline development, biosimilars play a central and increasing role, while we expect these products to steadily change our overall positioning in the generics market. In this regard, despite the overall (but relative) maturity of the generics market, we identify this niche as one of the most promising growth drivers on a mid-term horizon.

Sandoz already is the global leader in biosimilars. In 2006, we launched the first-ever biosimilar product in the EU (a recombinant human growth hormone called *somatropin*), while in 2015 Sandoz became the first company to receive approval of a biosimilar in the US. In Mexico, we launched our growth hormone treatment in 2011, while we introduced *filgastrim* to the market at the end of 2015. Leveraging these two successful biosimilar launches on the Mexican market, we are planning to introduce five new biosimilars to Mexico over the next four years.

Furthermore, it is important to underscore that *filgastrim* proudly stands out as the first biosimilar to has been approved by Cofepris since the release of their updated biotech regulation (NOM-257), which identified a brand new market access path for biosimilars. Sandoz was the first company to

successfully comply with these new regulatory requirements, and our remarkable performance in this endeavor is extremely important to us, as biosimilars and our capacity to bring them to the market will be paramount to our affiliate's development strategy.

Considering these upcoming product launches, how have you been progressing to ensure Mexico is among the first countries to receive all these new treatments?

Market access in Mexico remains challenging, particularly when it comes to making new products available within the public sector. As a matter of fact, it took us a several years to get our first biosimilar product registered by the different social security institutes. We eventually managed to register both of our biosimilars in the public sector, but we anticipate that the registration of the upcoming five biosimilar products will be more complex. Considering the importance of these products for our growth strategy, it is our responsibility to have everything prepared on time in order to meet the requirements of the regulatory agencies and social security institutes, and ensure we can register these products in the public sector as swiftly as possible.

Given the maturity of the pharmaceutical market in terms of generics penetration and the strong competition of domestic players, what makes you believe that Mexico still holds promising growth potential for Sandoz, both in terms of volume and value?

[related_story]

The Mexican generics market still holds a very interesting depth, especially in terms of value. Although generics already make up 45 percent of the total units sold in Mexico, promising and growth prospects remain, as generics only represent 17 percent of the total market value. In Mexico, the branded generics market is particularly substantial, but also very competitive. However, we see that it keeps on robustly growing year-on-year.

In this regard, our diversification strategy will be absolutely crucial. For instance, we are launching our very first oncology product in Mexico this year. This launch represents another important milestone reached by the Mexican affiliate, demonstrating that we are fully aligned with the global reputation of Sandoz as a key oncology player. Through a licensing agreement, we are also about to introduce an entire line of HIV products – an area where we were totally absent so far. In the upcoming years, we also aim to expand our existing hospital product offering a wider portfolio.

Despite the competition, Sandoz holds its core values, its product pipeline and its human expertise to make the difference. Mexican patients need access to high-quality medicines at an affordable price, and our treatments cover some the most demanded therapeutic areas in the country.

When you took over in May 2015, what did you identify as the strengths and the rooms for improvement that could further propel the performance of the Sandoz affiliate?

My assessment was that the affiliate somehow lacked of focus on its core segments. As it goes for many other businesses in this industry, we used to have a tendency to divide our efforts among too many different niches and therapeutic areas. In order to deliver an unrivalled value to our patients and Mexican physicians, we needed to operate in the areas where we know we hold a superior knowledge and the best products. In the retail sector for instance, we used to be present in four different therapeutic. Last year, we licensed out one of these therapeutic areas, to ensure we would be focused on the remaining three TAs, in which we hold a powerful competitive advantage and are reputed among physicians as a leading player in Mexico.

> One of my priorities was to foster a more aggressive business development approach among my teams

In the meantime, one of my priorities was to foster a more aggressive business development approach among my teams, to identify new growth drivers within all our TAs, be it related to organic or inorganic growth. Over the last two years, we have been extremely busy in identifying new inorganic opportunities and strategic partnerships that would complement the strengths of our own product pipeline. Our recently signed licensing agreement for HIV treatments is a perfect example of this effort. In total, we closed more than ten different licensing partnerships over the last eighteen months, which will help us to bring evermore value to our portfolio over the next five years and tremendously increase the likelihood to meet our ambitious growth objective. Our ambition is grow at least twice as fast as the overall Mexican market [which grew 5.3 percent in 2015, according to IMS Health – ed.], over the next five years. It may sound very ambitious, but I believe we are already on the right track to fulfill this objective, and with our very promising product pipeline and all the life-changing products we are about to bring to the market we definitely hold the means to consistently display such growth rates over the upcoming years.

You are active in both retail and institutional markets, how do you see the breakdown of your activities evolving between these two sectors?

> The retail market still represents around 60 percent of our sales. Nevertheless, over the last two years, our main growth driver has been the institutional market.

The retail market still represents around 60 percent of our sales. Nevertheless, over the last two years, our main growth driver has been the institutional market, in which we are successfully

increasing our market share year after year. As part of our new growth strategy, we want to ensure that new products are launched in both markets, while in the past years we mainly used to target the retail market. To capitalize on the strong growth of institutional sales, we particularly focus on treatments that cater to the institutional and hospital sectors to fully unlock the potential in these segments.

Sandoz holds a manufacturing facility in the country, but it currently operates at only 50 percent of its total capacity. Considering the importance of the Mexican market, how do you explain this underutilization of the facility?

Indeed, we hold a small manufacturing plant, which is mainly focused on packaging activities as well as it holds our quality assurance laboratories. As a result, this plant provides us with a lot of flexibly from a technical operation and a logistic point of view, especially given our ambition to diversify our portfolio in the upcoming years. Furthermore, we consider this facility as a great asset to sustain the growth of the affiliate, and we are currently defining how we want to better use this manufacturing plant and fully unlock its potential.

Considering Sandoz already holds biotech centers of excellence and state-of-the art bio-manufacturing plants in Austria, we expect to remain focused on the production of chemical pharmaceutical products in Mexico in the mid-term future. However, we see opportunities to increase the number of products that could be locally manufactured.

You took over the helm of the affiliate a year ago, how would you summarize your vision for Sandoz in Mexico?

> By delivering on our mission, I am convinced we can double the size of our business within the next five years, reaching more patients and increasing access with high quality generics at affordable prices

My vision is very clear: by delivering on our mission, I am convinced we can double the size of our business within the next five years, reaching more patients and increasing access with high quality generics at affordable prices. This does not only stand as my personal vision as general manager, but it also genuinely represents the common objective that is driving the performance of our entire team in Mexico on a daily basis. We feel confident in our capacity to reach this objective, and we know on which key success factors we need to concentrate our efforts on to be successful. We will remain focused on our strongest therapeutic areas, maintain a strong performance in the retail market and further increase our market share in the institutional market, strive to identify promising inorganic opportunities, and finally, establish Sandoz as the market leader for biosimilars

in Mexico.

See more interviews