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Mexico is a key market for Ipsen to consolidate its footprint in the Americas. The recently appointed general manager and the medical director of the Mexican affiliate discuss how penetrating the market is a hard, yet not impossible mission, how Mexican patients are increasingly involved in Ipsen's global clinical trials and how the company is leveraging three strong partnerships with Sanofi, Galderma and Mayoly Spindler to pave the way to double the size of local operations within the next few years.

You have been appointed as general manager of the Mexico affiliate in July 2014. What [illegible]ou entrusted with by the headquarters in France?



François Ramognino (FR): Ipsen started local operations back in 2004 and

Mexico is a very interesting market for the Group for a number of reasons: it still is an emerging economy; it is among the fifteen largest pharmaceutical markets in the world; and it features a very large and diverse population. This said, my mission is pretty simple: continue expanding the

local business to capture the opportunity the market offers and launch all Ipsen's products, which today are not present in the country.

Ipsen is a mid-sized specialty care pharma company with a high-quality and unique product portfolio, which allows us to compete against big pharma in the market segments we focus on, worldwide as well as in Mexico. A good example is Dysport®, our prescription medication used to treat the symptoms of cervical dystonia, cerebral palsy and post-stroke spasticity which today is second in the market and can become leader very soon.

Rubens Lima, general manager at Ipsen Brazil, explained us that one of the company's global strategic objectives is to leverage its footprint in emerging markets, with a special eye at Brazil, China and Russia. What about Mexico? What is its strategic role of the market to the company's global operations?

FR: Currently the size of our local operations is relatively small. Still, we consider Mexico a strategic market on its own as well as to reach the rest of Latin America. The region is becoming an increasingly interesting hot market, as it is a huge geographic area with a population of almost 600 million with a rising access to healthcare.

We are witnessing that other emerging economies are under strain from a political and economical standpoint, as it is the case of Russia, for example, which is going through a financial crisis. On the other hand, Mexico and Latin America are maybe not hitting exceptional performance, but are definitely growing. Also, Ipsen is interested in increasing its footprint in the US and South America, so having a strong presence in Mexico is key.

Ipsen prides itself of an active policy of commercial partnerships. What are some of the partnerships the company has entered which impact operations in Mexico?

FR: Globally the Ipsen Group is divided into two completely autonomous divisions, primary care and specialty care, and everywhere Ipsen is a combination of own operations and strategic partnerships – Mexico is not the exception. We have partnerships for the complete product chain – from early stage product development to sales. In Mexico we have granted commercial rights to three companies leaders in their respective segments: Sanofi, Galderma and Mayoly Spindler.

How do you choose the partners you work with?

FR: We usually look for leading companies, which rely on strong operations in a region or market, a large sales force or expertise in a specific therapeutic area – a partner that really brings value to

Ipsen. It’s not only about licensing the products for sale, it’s about monitoring its performance, understand what can be improved, providing scientific information as well as training – it’s a very active and win-win partnership for both sides.

We chose Sanofi for its strong footprint in Latin America and its expertise in oncology, so have a regional deal for Somatuline Autogel®, our drug for neuroendocrine tumors. We chose Galderma as a global leader in dermatology to handle Dysport® for aesthetic indications, while we take care of the medical indications. Ipsen has been strong in primary care, with a specific focus on gastro-intestinal disorders and a leading position in Europe, Russia and China in this segment. In Mexico, we decided to leverage Mayoly’s expertise to market Smecta®, a drug indicated in the treatment of acute diarrhea (rebranded as Iprikene® in Mexico), as it has a sales force dedicated to this segment.

Get drugs listed in the national formularies of the different government healthcare institutions is the major challenge innovation companies face in Mexico. How do you think the process has changed over time and wh oved?



Victoria Vázquez, Medical Director, Ipsen Mexico **Victoria Vázquez (VV):** In Mexico getting a drug listed in the formulary of a healthcare institution implies a three-step process: first, the drug must be submitted to approval to the Federal Commission for Protection against Sanitary Risks (COFEPRIS). Second, it must be presented to the National Health Council, which reviews the pharmacoeconomic study to evaluate efficacy, the potential benefits it can bring to patients as well as to the institution, and, finally, its cost-efficiency. Lastly, you need to get the drug approved at each and every healthcare institution. The process can be very slow and take one-and-a-half to three years.

The big paradox in Mexico is that after the approval of the National Health Council, the highest health authority, a drug needs to be approved by every healthcare institution separately. Fortunately over the past few years the National Health Council has become much more transparent and open towards the pharmaceutical industry. Today they give us the opportunity to have a technical meeting before submitting a new drug file, where we can present a summary of the file and they give us feedback, letting us know what should be improved. It’s an excellent way

to better understand their parameters and requirements as well as to work together so that patients get access to the drug quicker. Overall, this new approach brings forward an improvement and acceleration in the entire process as well as a direct contact with the authority.

FR: After a long process three years ago we got Somatuline Autogel® approved for neuroendocrine tumors at all major institutions and this year we got Dysport® approved at the Mexican Social Security Institute (IMSS) for treatment in pediatric and adult population. In both cases we were able to demonstrate our products provided better outcomes in terms of treatment and cost-efficiency than others in the market. We are very proud of these achievements, and especially of Dysport®, as it was one of the very few new molecules listed by IMSS over the past three years.

You have used patient data from Mexico for phase III studies of Dysport® in lower limb spasticity in children and in adults. Why did you select Mexico over other countries?

VV: Our clinical sites in Mexico were among the best worldwide with regard to quality of clinical data and number of patients included – and we are very proud of this achievement, especially because Mexico presents higher rates of cerebral palsy in pediatric population when compared to other countries. This study was a good opportunity to prove we have excellent clinical sites and researchers, make health authorities aware about the problem and make sure they include this treatment in formularies. It’s a very sensitive issue, as it affects a highly vulnerable segment of the population.

AMIIF and COFEPRIS signed an agreement with IMSS to open up the largest healthcare institution in Latin America to clinical research. Do you plan to involve more Mexican patients in global clinical trials in the future?

VV: We plan to start including IMSS patients in the close future. Producing new clinical data and evidence is key and that’s why Ipsen has a long-term commitment to R&D, locally as well as internationally. It is interesting to point out that besides being a company strongly committed to R&D, with about 15 percent of sales reinvested in research and development in 2014, Ipsen is also investing in observational studies (so-called ULIS programs). We are currently running a three-stage study for post-stroke spasticity, which started with an international survey to better understand how physicians say they manage this movement disorder (ULIS I), a second stage to see how they really manage patients (ULIS II) and a final two-year observational study to comprehend how treatment can be improved by creating global guidelines and using best practices (ULIS IV).

A further interesting initiative Ipsen is fostering is using patients' goals to improve adherence to treatment. It is demonstrated that if a patient is committed to a specific objective, treatment outcomes are better. For this reason we are recommending the use of the Goal Attainment Scale (GAS), a method of scoring the extent to which patient's individual goals are achieved in the course of a treatment.

FR: Part of the strategic importance – and, actually, also success – of Ipsen in Mexico is that we have a strong medical team. We are not only here to market our drugs, but also to develop products to satisfy local needs, by creating a strong relationship with physicians and by making sure Mexican patients and researchers participate in global trials and get access to innovative drugs. Our ultimate goal is 'innovation for patient care'.

Any local CSR initiative you have launched?

FR: Since the beginning of the operations in Mexico, we have created the Candy Foundation, an independent organization that helps low-income families with children suffering from cerebral palsy by providing the company's products. Currently we have 160 children enrolled, but we are interested in including new patients. As a company we think is important to fulfill our social responsibilities.

What are your personal ambitions for Ipsen in Mexico over the next five years?

FR: Growing the business in Mexico is my most important priority. We want to consolidate local operations and double the size of the company by launching new products and leveraging the company's rich product pipeline. And, of course, bring more clinical research to Mexico.

Before being appointed as general manager in Mexico you have managed other emerging markets, namely Eurasia and the Middle East. How is your previous experience in these markets helping you navigating the Mexican market?

FR: The Mexican market is very complex. It is useful and almost mandatory to know it and all of its intricacies. My experience in each country has been very different, which proves that each market has its own way. As in other markets, in Mexico you also need to be patient, be able to adapt to the local needs, be very professional and ethical – run the organization with the most stringent international business standards adapted to local rules.

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