Shire Mexico – Dr. Raul Vivar, Head of Mexico / Central America and Caribbean

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The general manager in charge of Mexico, Central America and the Caribbean is on board with the corporate mission of doubling Shire's product sales to USD 10 billion by 2020 and explains how Mexico and the rest of the region will contribute to this achievement.

You were appointed head of Shire Mexico, Central America and Caribbean in March 2014. What is the overall corporate mission of the company and how does it translate in the region you are in charge of?

At Shire we have the aspiration of becoming a leading global biotech company to deliver innovative medicines to patients with rare diseases and other specialty conditions and doubling our product sales to USD 10 billion by 2020. Locally we are absolutely aligned with these objectives. We have been in Mexico since 2008 and, for the past five years, our compound annual growth rate has been of 75 percent, focusing up to date on lysosomal storage diseases therapies. In the near future we plan to provide a therapeutic option to patients with hereditary angioedema in the public market. In addition, we got registration of what will be the first product of our neuroscience business unit, indicated for ADHD (attention deficit hyperactivity disorder).

Today Latin America represents only 4 percent of Shire's total products sales but with a very interesting annual growth of 25 percent. What role does Mexico play in this scenario and what are the main challenges you are facing in the market?

Mexico is the second largest market after Brazil and the growth we have delivered in the past five years has been outstanding. Today marketing authorization is not the biggest issue, as orphan drugs in Mexico do not require a registration number, but only a special sanitary authorization. Since 2013 we have noticed much more openness from the General Health Council towards the treatment of rare diseases. In the past when filing any kind of drug you were requested to submit a complete pharmacoeconomical analysis; however, this kind of analysis does not apply to orphan drugs. Recognizing this, one year ago the Council changed the regulation, requesting only a budget impact analysis and an economic evaluation only when sufficient clinical and economical data is available.

As you can imagine, challenges mainly lie in patients' access to drugs, as products need to be included in the formularies of each and every public healthcare institution in an additional step after the inclusion in the national formulary. Fortunately our products for lysosomal diseases are all available at the different public institutions. However, the situation is different at every healthcare provider. At *Seguro Popular* we face two main challenges. First, as per today the public insurance scheme only covers patients, who start treatment before the age of ten. Indeed, the institution is evaluating the option to cover at least all pediatric affiliates (until the age of 18), however budget is a constraint. Second, lysosomal diseases included in the Fund for Protection against Catastrophic Expenses can only be treated at certified hospitals, which are very few, implying a huge burden in terms of commuting costs and time for patients as well as for caregivers. At IMSS (the Mexican Social Security Institute), on the other hand, the main problem is time between diagnosis and beginning of the treatment. Physicians have first to confirm the diagnosis according to the clinical guidelines published by CENETEC (the National Center for Health Technology Excellence) and need the patient to undergo a number of tests, for which waiting times are very long. Once the diagnosis is confirmed, the physician creates a clinical record, which is sent to a central committee of medical experts in Mexico City. The central committee reviews each clinical record on a case-by-case basis, discusses the diagnosis, may request further tests or even ask to see the patient before deciding the start of the treatment. What we are seeing today is that the average time between diagnosis and start of treatment is twelve to eighteen months – way too long. The whole process to make sure a patient is correctly diagnosed before starting the treatment is terrific, but it just takes too much.

What is Shire doing to raise awareness and facilitate diagnosis?

Because of the nature of the diseases, which are rare and of very low prevalence, there are a lot of challenges in terms of awareness. Physicians do not normally have these types of diseases in mind

and their procedures and testing are not always adequate. A problem of this magnitude has not an easy solution and should be addressed by different stakeholders such as physicians, patient organizations, education institutions, public healthcare providers, among others. In this regard, we see ourselves as an additional stakeholder that can help. Of course there are several organizations and NGOs that make it their own mission to increase awareness and we always support them.

From our perspective, it is all about education: our mission is to facilitate medical education on these rare diseases and their symptoms to make sure patients are diagnosed in an adequate and timely manner. To make sure we can raise the necessary awareness we are starting collaborations with different parties such as AMIIF (the Mexican Association of Pharmaceutical Research Industries) and other drug companies focusing on rare diseases, such as Alexion and BioMarin. Partnerships are definitely starting in Mexico and we hope to see much more in the future.

So far Shire has mainly focused on HGT (Human Genetic Therapies) in Mexico, with the neuroscience business unit about to be launched. What product launches can we expect in Mexico in the coming years and what are your plans for expansion in Central America and the Caribbean?

We currently have three products available in the Mexican market, but future growth will definitively also be driven by new launches. In the next few years we want to concentrate on increasing our portfolio and are very excited about entering the HEA (hereditary angioedema) market with the inclusion of our first product in this therapeutic area in the national formularies. We are currently in the process of registering a second one in that area, which comes from the acquisition of the biotech company ViroPharma. Both products are already available in the US and match the disease very well, as one product tackles acute attacks, while the other is for prophylaxis. This means we can provide a complete solution to HEA patients.

As for Central America and the Caribbean, every single country has a different healthcare system with different entry requirements. Today, we are pursuing a registration in Panama and exploring Guatemala, Costa Rica and the Dominican Republic.

What is your vision for Shire in the coming five years?

In five years time we would like to have a larger product portfolio and our neuroscience franchise up and running with ADHD. With the recent news of IMSS opening to clinical trials, we see important developments for the area we operate in, mainly for lysosomal diseases. We had never considered the institution for R&D before, but today it is a terrific scenario we have in front of us. We currently do some clinical trials in Mexico but so far the number of patients was very limited, as

most patients were within the IMSS. We have had Mexican patients involved in international multicenter trials, however recruitment was not as easy and speedy as we wanted to. We really look forward to having more trials running in the country, as Mexican patients and investigators will definitely benefit from them.

You come from the medical side of the pharmaceutical business. How do you think your past experiences are helping you in your current position as general manager?

I started my career as clinical research manager at Bayer, then was appointed medical manager at Roche to later move into marketing. Having this medical background has been very useful to me in many aspects: you have the ability to talk to the medical community very directly, you can understand the business in a deeper way and you can be much more empathic with physicians as well as with patients. I value very much my background, as my current decisions as general manager take in consideration all these past experiences. Today I am only a facilitator: my first priority is to make sure all employees have the means to do their job at their best. My role is to facilitate the team, which is Shire’s most important asset.

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