Interview with Markus Krenzlin, Country Manager, Shire Pharmaceuticals

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Please can you give us a rundown of Shires activities in Mexico in the last four years, and the key achievements and milestones along the way?

Shire started operations in Mexico in 2008, a similar story to Brazil. There are very few people working here in Shire Mexico but we have had huge growth rates- actually a compound growth rate of almost 100 percent per year. We are doing this by focusing on a segment of the market that has always been there, but only now are people actually receiving the treatment, hence the growth.

In terms of the Mexican market, I think that Mexico has a great attitude towards orphan drugs. The Mexican authorities are very conscious of the various niche problems that exist for patients across the country and have been very open in making orphan drugs available to them. Mexico is a very conscious market in this respect which is why Shire has been able to establish itself here and make treatments available to patients. Over the past two years we have been able to get four products onto the market, three of which are available in the public health system: one for Hunter’s Disease, another for Fabry Disease, and the third that was approved last year is for Gaucher´s Disease. Those are huge milestones, not just for us, but for the Mexican authorities in being able to include these treatments.

This Mexican public sector consciousness is the reason why we have been able to provide patients with new treatments, it truly is fantastic.

You said that Shire has had three drugs accepted in the public health system over the last two years. When did Shire realize that the Mexican government was so open about orphan drugs?

Authorities all around the world are trying to figure out how to deal with orphan drugs. Here in Mexico we achieved awareness and availability of the orphan drugs through a cooperative approach with the authorities. The pharmaceutical industry, COFEPRIS, and the Ministry of Health all sat down together some two years ago and decided exactly how they would deal with the situation which essentially opened up market access.

In addition, I have to say that one of our competitors had an issue with their production and supply which obviously had an important impact for Shire. More importantly for the patients, however, it was the government who made our products available so that we could step in and provide the products for those patients having problems in receiving their therapies from our competitor.

The situation in Mexico seems different from Brazil where some patients have had to fight in court in order to receive their treatment. Has this ever happened in Mexico?

We know there are patients in Mexico that have legally fought for access to their drugs, but now there is no need to take legal action. Together we made access possible for orphan drugs simply through dialogue with the authorities.

A great example is Seguro Popular, which provides one of our treatments – for Hunter Disease – to patients under 10 years of age. These are very poor patients whose families would never be able to afford a biotechnology drug in order to be treated privately.

There was actually a change to general health law in Mexico published on February 29th. Article 224 has been amended so that it both recognizes that there are orphan diseases, and that there are orphan drugs to treat them. In essence it means that the Ministry of Health has to support the development of the diagnosis and treatment of these diseases. I think this opens up considerable possibilities, and if you look at the social issues in Mexico then you can see this is a huge step forward. We have now cases with people living in very poor and remote areas that are getting treated with a biotechnology product.

But doesn’t Seguro Popular just cover the basic needs of the population. How did you do manage to get the orphan drugs under the umbrella?

The Seguro Popular covers basic needs but it has also very important programs for catastrophic diseases such as certain type of cancers. It’s true that our products are not cheap, but they are providing great value to patients and their family and the society overall by really enabling people

with life threatening diseases to lead better lives. In addition to the authorities' awareness on the problem, there are also a number of very active and well organized patient organizations who, through dialogue, have been able to open up the doors to get these approvals. Shire is basically all government business. We do have a few patients covered through private insurance, but these are high value treatments so I believe covering these diseases must come out of the solidarity of society.

What other products do you have included under Seguro Popular?

Officially lysosomal storage diseases (LSD) are included under Seguro Popular. However, they are only included in the "Insurance for the next generation" program which means there is an age limit. For example, Fabry Disease and Gaucher's Disease are usually not detected at a very young age, so they are often taken out of the age range. But if the patient was under 6 years old, they would also be able to have their treatment covered by Seguro Popular.

Hunter's Disease is detected relatively early, at about four or five years of age, and sometimes a little bit earlier. The Seguro Popular right now covers patients who have been diagnosed up to six years of age under the 'next generation' insurance, and up to 10 years of age under the catastrophic diseases scheme. Recently, a patient aged 13 was able to get access to our Hunter's Disease treatment through Seguro Popular, which was great. In fact I know that the authorities at the Seguro Popular are sensitive to that issue and along with other stakeholders are looking into that matter.

How does Shire in Mexico fit in compared with Shire's global operations?

Because Shire started in Mexico in 2008, it is quite young within the company's global structure. It is clearly a market seen by our regional and global structures as one where there is a lot of potential to do more in providing our treatments to more patients, in order for them to live better lives. In Shire we are focusing a lot on the region of the Americas, and Mexico is one of the central points. We are also planning to expand our geographic reach to Central America, out of Mexico.

What do you think awareness for the diseases you are treating in Mexico, amongst both the public and the physicians?

Awareness is definitely a problem: if you look at prevalence or incidence data and how many patients have been either identified or are on treatments, you will find figures indicating that only 10-15 percent of the theoretical disease population have been diagnosed. This means there are a large number of patients in need of our treatment but not receiving it.

Even though there is not a high level of awareness, it is difficult to do any big campaigns because these diseases are so rare. There are maybe 250 cases in the whole of Mexico, so we need to deal with awareness differently. We supported a patient association last year which did a specific awareness campaign on Hunter's Disease, and it turned out to be very effective as a lot of patients were identified through the initiative.

We usually manage awareness through supporting medical education programs or through supporting the patient associations because they really do know the families and the patients, which helps them to handle the problem more effectively. We are also doing continuous support to physicians for diagnosis, but even though we are trying to play our part it is very difficult as many of the patients live in extremely rural areas, and Mexico is a huge country.

Will the growth of healthcare from the government aid this awareness issue?

Yes I believe so. We are already in discussions with the authorities on how we can support them and provide training and information to the parties involved. At the end of the day it is really about patients, and Shire is a company that enables patients with difficult and life-threatening diseases and their families to live much better lives.

Angus Russell, the CEO of Shire worldwide said what makes the company different to other companies is that the employees actually care about what they do and what they are working for. How has that corporate philosophy shaped Shire Mexico?

It is all about people, and it starts with hiring the right people who come to us for the right reasons. Shire is a company attractive to a certain breed of employees who are really looking to make a difference in patients' lives, so hiring the right people to come to Shire is what makes the difference. People come and work with us with the expectation of truly helping people, and here they will have the opportunity to do so from the very beginning.

This might sound slightly strange, but sometimes it is not really about business, it is about getting people onto treatments. The impact for the patient is so huge, not just physically, but for their entire social environment which exactly is what drives us to overcome any difficulties along the way. That is how our corporate spirit affects the way we do things here.

How difficult is it to attract the right talent and successfully recruit in Mexico?

Finding the right talent is very difficult in any market, and Mexico is especially a complicated market in terms of talent. On top of that we need to find the right talent with the mindset I just described, which makes it even harder. You need to put in a great deal of effort and resources to

identify the right people, and after being 10 years in the market here I've seen that there is a huge pool of young, very well prepared, and very well-oriented professionals who are the right people for Shire. We do our business in a different way, and when finally we find the right people it is very refreshing to see young, professional and prepared people who want to come in and start making a difference to the patients.

Where can we expect to see Shire in five years' time?

At the moment we just do Human Genetic Therapies (HGT) here in Mexico, but there are two more business units one of which specializes in Attention Deficit and Hyperactivity Disorder (ADHD) and Gastrointestinal (GI) which are about to be launched here rather soon, and the third business unit is regenerative medicine. So we expect establishing full Shire operation in the country in the mid term; even though HGT treatments and our existing portfolio have enough potential with untreated patients to sustain our current growth rates, adding these two business units will contribute even more.

We also have our pipeline products, which will be very interesting for Mexico thanks to the very positive country environment, and I expect that we will be among the first markets to receive the products from Shire.

What kind of products are in the pipeline?

There is an additional disease in the LSD range called Sanfilippo syndrome which is very rare, and the product for this is progressing very well in the clinical trials. We also have a new Hunter's disease product in the pipeline. The problem with Hunter's Disease is that there are neurological affections and our current enzyme replacement does not cross the blood brain barrier. We are developing an enzyme replacement therapy that will be applied intrathecally and which we hope will help patients in the neurological progress of the disease. These projects are quite advanced in the clinical development stage and should be on the market in a few years.

Do you have a final message about Shire for the readers of Pharmaceutical Executive?

We at Shire are committed to delivering value to all our stakeholders and that is not just a corporate phrase. Shire in Mexico is dedicated in becoming a partner to the authorities, to the patient associations, and to all stakeholders in the market segment. Shire globally has a BRAVE culture, and we strive to do better every day. We are patient-orientated and that is the reason I am working here. What we do is for the patient, we feel it every day, and you cannot imagine the impact of knowing that a patient gets treatment and a transformed life because of you.

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