Interview with Sergio Duplan, CPO Head & Country President Mexico, Novartis Farmaceutica S.A. de C.V. (Mexico)

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mber 2009 that 6-8% of Novartis' annual revenue comes from Latin America, and that the area is "one of the main growth engines for the company". Can you tell us how Novartis Mexico fits in with that growth strategy?

Mexico is the second biggest market in Latin America after Brazil, but the market has been stagnant for the last four years- it has either been flat or growing less than 2% year on year while other markets such as Argentina or Venezuela are growing very fast. Mexico's market has been so flat because there's been a big switch from innovative products that have now lost their patents, to generics.

Historically Mexico has been a very brand-loyal market and patients did not have a positive perception of generics therefore they continued to buy branded products even though there were more expensive. Since then there have been two changes in the perception of generics. Firstly COFEPRIS have renewed all the marketing authorizations and ensured that every generic has bio-equivalence; they have raised the bar in terms of generic quality, and they have advertised it widely. The second change has been the launch of private generic labels from trusted pharmacies across the country, which placed generic medicines in trusted sales outlets for the private market.

The decline in the market has been driven by the older, more mature brands, and most, if not all large pharmaceutical companies with innovative products have seen themselves decline.

Having said that, the market does continue to be strong if you are an innovator: in the last IMS

report Novartis is the second fastest growing company within the top ten companies in the private market. We have introduced seventeen new products in the last 10 years which is more than anybody else, and have been mentioned in Forbes as the most innovative pharmaceutical company in the world.
Mexico is also a good market if you are launching generics, but only very low-prices generics. Branded generics tend to be caught in the middle between the innovative branded products and the low-priced generics that are being pushed by the pharmacy chains.

Would that not be affected by the growing middle class in Mexico? In Brazil they are spending a lot more on branded generics, what about here in Mexico?

Looking to the future, the middle classes are growing, but not at the pace of Brazil. Brazil has had some very strong policies in order to encourage their internal market- and this is not just in pharmaceuticals- whereas Mexico has focused much more on exporting mainly to the United States. Right now, there is a lot of talk about pushing the internal consumption market in Mexico for every industry, but it is happening slowly in this political climate. That is why we are not seeing the same growth as Brazil has seen internally. There is a lot of potential to be found in the growth of the middle classes and their increasing spending power- but on innovative brands.

With this change in the perception of generics, how is this affecting Novartis' operations specifically?

There are two aspects: the first is that it has definitely damaged the mature product side of the business. Our second biggest brand in Mexico is Voltaren: a 30 year old brand with about 100 generics in the market which still continues to be very big, but its sales are declining around 13% per year. Because of this, we are shifting our resources away from the old brands and into the new ones and accelerating their growth.
The second aspect is that we have changed our business model. We used to be very focused on working with physicians but now we are partnering with pharmacy chains. In the past, patients were prescribed a medication and they would almost certainly go to the pharmacy and be given that drug, but now they are being offered generics by the pharmacies, and we want to minimize the effect it is having on our older innovative products. In the meantime, our biggest growth will come from new innovative drugs that have been patented.
After that you have the institutional market which is a whole different story. The private market is mainly made up of mass market primary care products, but now our pipelines are focused on specialty products for rarer diseases treated by high-priced biotechnology products that very few people can buy for themselves. For this strategy we need to partner with the Government and Social Security system in order to get reimbursement, and so that patients can receive the products. This market has also been struggling because of the cost pressures within the Government- they have heavily slowed down the inclusion of these therapies in Social Services

and only now are they beginning to open up and put resources into new products again.

So do you see a lot of opportunity to work with the Government in the next five years for example?

I really think so. The strategy of the Government is changing which is better for us. In the past, you would present a new therapy to the Government and they would request efficacy data, safety data, and some pharmacoeconomic data: that was enough to get the treatment into the tender. They also bought a quantity of the medicines up front based on physicians' estimates of patients that required it which resulted in a lot of product not getting used. There were a lot of inefficiencies in the system, and it was very expensive for the Government. The entrance of new products into Social Services was stopped for a period of time, and now they have opened up the door again. When they include a new product, the Government will only order the product after receiving individual requests for each patient from their doctor. If approved, the patient will receive the treatment, which means the Government can be more flexible on specialty drug inclusions because consumption is moderated.

Novartis has a huge presence in Mexico with almost 1,700 employees and sales revenues of over 7 billion MXP in 2011. On which new areas and strategies will Novartis be focusing on over the next 10 years in order to maintain and grow Mexican market share?

We still have very good growth from our newer products in primary care, including diabetes and obesity. This is the biggest concern in Mexico right now, and we have one of the most innovative treatments for diabetes. We also have products for hypertension, and we are entering the respiratory market right now, which is fast-growing and we have a whole pipeline ready to enter and become leaders. In specialty products we are very strong in Oncology; we are very strong on eye-care with a very successful bio technology product called Lucentis for the development of maculae- for which we have no competition so far. We have a strong product called Xolair that is specifically designed for asthma that is very hard to control, and we just launched our newest product called Gilenya for Multiple Sclerosis which we believe will be very big in the United States as well as here in Mexico. Gilenya is an oral treatment – one pill a day- and it delays the relapses of the disease. Usually treatments for Multiple Sclerosis are injectable or done by infusion which is not ideal, so an oral daily treatment is revolutionary for the patients.

Novartis manufactures a lot of drugs to export out of Brazil. What are Novartis' manufacturing strategies here in Mexico, and do you believe that Mexico could become the manufacturing hub for Latin America?

Yes it is definitely possible, but it is not a strategy that we are following in Novartis. In Mexico we have three manufacturing plants- one for Sandoz, Alcon, and one for OTC products, and we want to consolidate all the operations into just one plant. We are not planning on becoming a big

exporter from Mexico. There are a lot of national companies who are investing in, and expanding, their manufacturing in Mexico because there really is a great cost benefit of doing so.
In Novartis' case we are investing more in Mexican clinical research; holding many more local trials; and developing researchers. From March 22nd onwards we will have a series of training workshop for doctors who want to become researchers, in order to increase the number of local researchers here in the country.
I think there is a lot of room to expand clinical trials here in Mexico, and many international pharmaceutical companies are investing more in Mexican clinical research every day. We are also working with local authorities to strengthen the Intellectual Property and data protection because in most countries you have at least 5 years protection once you develop a new product, but in Mexico you do not have that buffer, which is something that the Government needs to look at.

Do you see the Government changing this lack of guaranteed data protection in the short-term?

I think we will get it very soon, yes. It's very important for Mexico to be able to enter the Trans Pacific Partnership that the United States is leading with the Asian countries, and we should be there, but even though our patent system is very good, data protection continues to be an issue.

What do think are the main assets of Mexico to become a clinical trial hub for Latin America?

First of all it is low cost- some trials can be very expensive so we are always looking at productivity. It is cheaper to do clinical trials here than in Switzerland or even Brazil now with the devaluation of the Mexican currency. There are also some very good technology and research centres in Mexico, and some very good researchers. The problem is that there are not enough researchers, which is why we are going to run the training workshops to develop more. The Universities are also very good, with great biotechnology programmes.

Novartis has a strong record of Corporate Social Responsibility, globally they've invested over $1 billion USD on drug-access programmes for over 70 million people. Can you tell our readers a little about the projects you have at the moment in Mexico?

We have just finalised our plans for this year! In Mexico, we have done a lot of work with our Leprosy programme, which started at the end of the 1990s and implemented globally. There were over 20,000 reported cases of leprosy in Mexico when we started and now there are less than 400 cases. We provide medicines free of charge and set up an awareness campaign for doctors in the area so that they can better identify the disease.
We also have a project called "Under the Shelter of Novartis" which is a five year project where doctors identify a specifically prevalent disease or infection in their area, and spend their free time treating it with medication and treatment donated by Novartis. Our employees also spend time in

the field on these projects, which is very important for the company culture.
We are also partnered with the Mexican Paralympics in order to help children between the ages of 5 and 15 years who want to become Paralympic athletes, to complete their compulsory health check that they are required to do before starting any kind of training. We also make a day of it here in the office- we provide the equipment; the doctors come and donate their time; our employees help with the logistics of the day, and there is food and music all round- everybody interacts!
We also want to start working more on health education in Mexico as we believe it is an area that needs a lot of improvement. For this we would have to partner with the Government in order to educate children about diseases and infections, and the importance of understanding the human body.

If we come back in 5 years' time, where will we find Novartis in the Mexican pharmaceutical industry?

In five years, Novartis will be at the very top of the market with strong growth in both the private and institutional market. If you look at how we are growing and gaining market share from our competitors, you will find us in the top 3. The sky's the limit! We are also keen to improve the social development side of Novartis, by helping to increase the number of talented researchers in the country; holding medical education workshops for the public teaching people how to differentiate between different quality medicines; and working with COFEPRIS to strengthen the pharmacovigilance system.

Do you have a final message for our readers?

Yes, that the Mexican market is still going through the last stages of a transition, and if you have innovative products, then this is a country where you want to invest: there are huge opportunities in Mexico.

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