Amgen Mexico â?? Elvin Penn, Executive Director & General Manager

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The executive director and general manager of Amgen Mexico discusses how the company relies on Mexico as a hub for clinical research, with an investment of over USD 22 million since 2006, and strives to deliver its pipeline of innovative medicines to treat seriously ill patients in Mexico.

You have been working across whole Latin America. What aspects differentiate Mexico from other countries in the region?

First of all, the size of the country, as Mexico has a population of approximately 120 million. Second, Mexico relies on a very developed pharmaceutical market worth USD 15 billion, number thirteen worldwide and second in Latin America only to Brazil. Moreover, the country is also very interesting in terms of R&D: it has very good infrastructure, medical centers, high-quality professionals and a very diverse population, which makes it attractive as a location to conduct medical trials. Last but not least, the Mexican market currently has modest growth but is much more stable in macroeconomic terms when compared to other markets in the region, such as Argentina and Venezuela.

Amgen started operations in Mexico in 2006 with the objective of creating a regional hub for clinical trials. What role does the country play today for Amgen?

Today we have presence in Brazil, Colombia and Mexico through direct affiliates and in the rest of the Latin America region through distributors, but Mexico was our first affiliate to open in Latin America and has played a special role for Amgen. What started back in 2006 as an R&D hub intended to cover the rest of Latin America, has received over the last eight years an investment of over USD 22 million in clinical research. Today we have 21 clinical trials running in Mexico, at leading research institutions such as La Raza Hospital and the National Institute of Health Sciences and Nutrition (Instituto Nacional de Ciencias MÃ©dicas y NutriciÃ³n) Salvador ZubirÃ¡n. Moreover, we have eight products already available on the market, and among these, seven already listed in the national basic formulary. In Mexico we are moving towards fulfilling our mission: to serve patients

by making innovation available to them.

How do you use the information you collect from the different clinical trials?

The data we generate here in Mexico are used locally as well as globally for the application process, including the US FDA. R&D in the pharmaceutical industry is very strictly regulated and the complete process from the selection of the site through the implementation of clinical trials receives close supervision from the headquarters to ensure the highest quality standards are met.

A hot topic in the industry is access. According to IMS data, in Mexico it takes up to 4.3 years for a new treatment to be listed in the public healthcare sector â?? much more if compared to the two years it takes in the UK and in Japan or even the 3.4 years of Brazil. What do you think needs to be done to ensure patients can access innovation?

During the past three years COFEPRIS (the Federal Commission for the Protection against Sanitary Risk) has significantly improved the drug registration process, accelerating timing. Moreover, the equivalence agreements, which were signed with the major pharmaceutical regulatory agencies around the world, provide an excellent opportunity for companies to get the products available in Mexico in a very short period of time. However, patients sometimes have to wait more than four years to see the products listed in the formularies of the national public institutions. This indeed represents a challenge. We are currently working together with CANIFARMA (the National Chamber of the Pharmaceutical Industry), AMIIF (the Mexican Association of Pharmaceutical Research Industries) and with the different government institutions to see how Mexico can speed up the processes required. We know it is not an easy task, but reducing listing times is our key priority moving forward.

Some of your colleagues have mentioned that the biotech regulation is stuck in Mexico and they are eager to see COFEPRIS regulating so-called *biolimbos*, biotech products that have not proven their biocomparability through clinical studies, but are on the market as they were approved before the 2009 regulation was in place. What needs to be done to improve this grey area?

The industry, through CANIFARMA and AMIIF, is working with COFEPRIS to reinforce the regulatory environment for biotech products in Mexico, with the objective of defining additional specific regulations and norms to make sure the country has a strong legal environment for biotech and biosimilar drugs â?? this is currently work in progress.

Amgen is currently working on the global development of nine biosimilars, which we expect to start launching by 2017. The company has a long tradition of manufacturing biotech drugs, which puts us in a very strong position to compete in the biosimilar arena, as we rely on our vast experience and manufacturing capabilities to produce high-quality biosimilars.

What are the therapeutic areas you expect to drive most growth in Mexico?

Amgen does not disclose country-specific sales data or revenue projections. I can tell you that we currently market therapies in Mexico in the oncology/hematology, nephrology, and bone therapeutic areas. One of the fields Amgen is doing research on is cardiovascular, as Mexico suffers from a significant burden of disease, especially with regard to obesity and diabetes. We are developing a drug for high cholesterol, which is currently in the clinical trial stage here in Mexico and has significant potential to improve the quality of life of patients who suffer from this disease. Cancer is also a major focus of our R&D efforts â?? we have several oncology drugs already available in Mexico and in the very short term we hope to gain regulatory approval in Mexico for a multiple myeloma medicine.

What is the top priority at Amgen for the coming years?

The company will continue to focus on innovation and on finding new ways to treat serious diseases to make innovation available to patients in need.

What attracted you to Amgen after more than 20 years at Bristol Myers Squibb?

Amgen is a company focusing on innovation that is really making a difference in the life of patients suffering from serious diseases. It is the largest independent biotech company worldwide and is a reference for the industry in terms of biotech and innovation. Besides this, the pipeline is very attractive.

As a general manager you need to be able to deal with different stakeholders. How do you do that?

Amgenâ??s mission is very clear: to serve patients in need and make sure patients can get access to treatment and innovation. It is challenging as you need to deal with each and every one of the stakeholders, but it is very easy to make sure we are right, we just need to look at the mission of the company: everything we do must be aligned with the intention to serve patients, which is our priority. As a result, all we do is done with this purpose in mind.

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