Interview with Israel Garcia Crespo, General Manager, Almirall Mexico

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Could you give us a brief run-down of the last few years in the Mexican pharmaceutical and how the various regulation changes such as the new drug registration process and the suppression of the manufacturing plant law have affected Almirall?

At the moment, Almirall is present through affiliates in 11 European markets, Mexico is the first and only Latin American presence for the company and we have been here for the last ten years.

Since I arrived in Mexico in 2008 there have been a lot of changes, but I think the most important milestone for the industry came in February 2010 when all sanitary registrations had to be renewed with the health authorities, and thus provoked a substantial block in COFEPRIS as an organization. I believe that since then we have been going in the right direction, especially with Mikel Arriola and his team, and things have improved greatly. Regarding the manufacturing plant law, the new regulation was approved in 2008 and is now being implemented thoroughly. Increasing the speed in this important topic is critical for the industry and for companies like us. Thirdly, I think there is a very important trend in Mexico being pushed by Felipe Calderon's government to provide sanitary healthcare for everybody in the country. As part of this healthcare, I believe it is important to give innovative drugs access to the public system, because right now the access of these drugs in the National Public Formulary is very slow. We need to accelerate the process within the institutions so that everybody has access to innovation.

With the universal healthcare you mentioned being implemented at the moment, Seguro Popular is now covering more than 50 million Mexicans. Have you seen any new

opportunities for Almirall in this institutional market?

We have one molecule called Cinitapride included in the public health system, but we compete with generics manufacturers for the tender: sometimes we win and sometimes we lose, but it is tough competition. We have submitted new requests for patented innovative drugs, and we are waiting for them to be included also. Regarding Seguro Popular, it really is the future and although it is just starting, we do have business with them already. It is a great initiative, providing healthcare coverage to a population where previously there was nothing.

Almirall registered nine new drugs in Mexico over just three years: please can you tell us more about Almirall's product portfolio in Mexico?

In the last three years in Mexico we have launched nine products, mainly focused on Gastroesophageal Reflux Disease (GERD) and Dyspepsia; Dermatology; and a product for Vertigo. Almirall also focuses on respiratory diseases, and we have just submitted two registrations with the FDA and the European market for Aclidinium Bromide for Chronic Obstructive Pulmonary Disease (COPD) treatment which will be released in Mexico after due regulatory approval, and Actikerall for which the active ingredient is 5 Fluorouracilo with salicylic acid, for the treatment of Actinic Keratosis in the dermatology area. In March 2012, we signed an agreement with the British company GW Pharmaceuticals to commercialize a new drug here in Mexico for the treatment of spasticity in Multiple Sclerosis. The name is Sativex and we plan to submit it to COFEPRIS during 2012. If as a company you go down the path of innovation, you have to be constantly submitting new drugs for registration!

Almirall has a good range of therapeutic areas on which they are working, but have you seen any particular opportunities specific to Mexico with which to increase your market share?

Our strategy in Mexico is completely aligned with the Research and Development strategy of the whole company, which is based on Respiratory and Dermatology. For example right now we are developing a new molecule for Skin Cancer with no melanoma which goes by the name LAS-41007. Although Respiratory and Dermatology are our two main R&D areas, we also have a lot of interest in Gastroenterology because we are awaiting regulatory response for Linaclotide for the treatment of Irritable Bowel Syndrome (IBS), in Europe, and Mexico is also good market for this. We launched a new combination here in Mexico last year called Clebopride + Simeticone, also for the treatment of IBS.

How does Almirall Mexico fit in with the rest of the corporate structure? You mentioned that the therapeutic areas were very much aligned, but how is Mexico seen in terms of an opportunity for the company?

We have eleven subsidiaries in Europe and only one in Latin America, so our focus is clearly Europe. Having said that, Mexico is growing very fast and we have seen double digit growth for the last four years. This makes the Mexican market very interesting for the rest of the company, and having been here for ten years already, Almirall is well established. Our aim is to continue with sustainable growth in Mexico.

Why is Mexico your only Latin American presence, and not Brazil?

When we set up our operations in Latin America, Mexico was the biggest market in the region; bigger than Brazil, which was one of the key elements behind the decision. Mexico is also seen as more of a similar country to Spain: the language is the same, and it was probably going to me much easier to enter than Brazil, for a Spanish company. Brazil is also a very internally protected market.

Does Almirall see a future in Research and Development, specifically clinical trials, here in Mexico?

Our main Research and Development center is in Barcelona (Spain) and we also have a Dermatology Research and Development center plus another one focused on Inhalation R&D both in Germany. We do drive some clinical trials here in Mexico and we usually include Mexican patients when we develop our clinical trials for our R&D products.

It is necessary to have Mexico in mind because when you register new products in Mexico, one of the requisitions is to have Mexican patients included in your clinical trials.

Congratulations to Almirall for completing 10 years in Mexico this year! Where do you see the company moving forward in the next five years? What is the next big step for Almirall in Mexico?

We are a mid-ranked company here in Mexico, but our strengths lie in Research and Development, and we will be launching more innovative drugs in the next five years, aside from the three new treatments I mentioned earlier. We are committed to the health of the Mexicans so our goal is to provide society with new and innovative drugs to improve their quality of life. I hope Almirall in Mexico continues to grow with double digits for the next five years, but our goal is not to be in the top 20, but to complete our work to a very high level of quality. We were the first European company that received CETIFARMA recognition for Ethical Promotional practices, so this is our goal- to retain sustainable growth and to continue our high level of quality.

Right now there are over 200 people working in the Almirall Mexico office, and we have managed to maintain that headcount over the last two years in an environment in which the pharmaceutical industry has actually been reducing headcount significantly. We are trying to contribute by providing not only stable, but quality jobs in Mexico. 90% of our workers have a University degree

which is a very high percentage compared to the rest of the industry, and we will continue on this path in the next few years.

On a personal note, how do you like working in Mexico?

Mexico is a very interesting country and in many ways, very different from Spain. When you arrive in Mexico you might think the two countries are more similar than they actually are in reality, and it's very interesting as a Spaniard to understand the Mexican mindset. The Mexican pharmaceutical market is also very interesting: you have two segments which are Private and Government; when usually you don't have this separation in Europe because the majority is reimbursed and it works differently to the Mexican market. I appreciate the opportunity that the Mexicans have given to me.

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