

Interview with Ricardo Aguilar, CPO Head & Country President, Novartis Chile

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Novartis' pharmaceutical activities include innovators, generics and biopharmaceuticals. How has your portfolio developed in Chile? What therapeutic areas is Novartis favoring in the Chilean context?

Novartis is one of the Top 5 pharmaceutical companies at an international level. We have products in all the therapeutic areas inside the ethical pharmaceutical market. Novartis Chile launched in 1996 the best selling product in the local market, called Tareg and commercialized in other countries as Diovan. This drug is leader in the treatment of hypertension, reaching one of the highest market share both locally and at a Latin American level. Later on, we launched Exforge, which became the second best selling product in the hypertension market.

Also, we have introduced to the Chilean market several products in the transplants field and during the years we have earned about 50% of the market share.

But our vision doesn't consider only products: a couple of years ago we created the Vaccines and Diagnostics Division. This is a very important area for Chile, a country that has developed a consistent strategy looking for the prevention of diseases, not only their treatment.

Oncology is also a priority for us, considering the growing numbers of patients suffering some form of cancer. We launched in Chile one of our leader products on this field, Glivec, a very successful drug to treat leukemia. Glivec have been able to transform the disease from one with a very low prognosis to another that is treatable.

There are other fields where we have presence, besides hypertension, oncology and transplants. We have introduced first line products for diabetes, orphan diseases, Alzheimer's disease and

osteoporosis. To address respiratory diseases, we recently launched Onbrez for the treatment of COPD (chronic obstructive pulmonary disease). In Ophthalmology we have also launched a product called Lucentis, which is the best-selling drug worldwide for macular degeneration. Our CIBA Vision Group has also an important presence in the Chilean market with its lines of products. Finally it should be mentioned that Novartis' generics division is not present in Chile yet. I consider this as an interesting situation, given the fact that the Chilean market is highly dominated by generics companies. Even though, we do not have Sandoz division here, this is one of the things we are evaluating for the future.

When we met with your counterpart, Mr. Jim Harold, in Argentina last year, he mentioned that due to the competitive Argentine market Novartis had partnered with local companies by developing manufacturing agreements with them. Has Novartis used a similar approach in Chile to tackle competition? What are the possibilities of developing such agreements in this country?

Since the Sandoz division is not yet in Chile, we do not manufacture generics in the country. But there is a possibility that manufacturing agreements will be considered by Novartis in the future, while other possibilities will be either to create a new business division in the country or to import products for specific therapeutic areas. Nevertheless, Sandoz is an entirely separate business so, as the General Manager of Novartis Chile, I cannot tell you exactly how things are planned. Currently we do have certain Sandoz products in the market through local companies, but on a very small scale.

One of the characteristics of the Chilean pharmaceutical market is the concentration of distribution channels into the three major pharmacy chains in the country. How has this environment impacted Novartis' activities in Chile?

We do not consider this particularity of the Chilean market as an issue; it is a situation to deal with but Novartis has managed to work very well with the major pharmacy chains as well as with some of the independent pharmacies. In any case, in Chile there are two different markets for commercializing pharmaceutical products: the institutional market and the out-of-pocket pharmacy driven market, and this is the same throughout most of Latin America. In Chile almost half of our sales come through to the pharmacies, after which you have to consider that there are three major pharmacies plus a few independents. In this context, the distribution concentration in the market does not affect us that much, as for example could happen in other markets where there could exist a sole distributor.

The Chilean government strives to provide accessible healthcare to its entire population through the GES plan that favors the use of low cost pharmaceuticals. Has Novartis' portfolio been favored by the GES plan?

I think it is very important for the government to provide support for ambulatory diseases in Chile. GES is an excellent initiative that is in line with the goals of the government. The program is expected to include 80 diseases by the end of 2010 and this is an important achievement in terms of accessibility to drugs, from the perspective of the Chilean government and the Chilean population. Another goal of the Chilean government is to enhance the use of appropriate medication and to ensure that patients receive the best quality treatment.

In relation with our sales, the majority of them do not come from GES or the institutional market, therefore we have not experienced any change because of the program.

There have been a couple of patent infringements noted in the Chilean context. Has Novartis experienced any violations of its products in Chile?

As President of the committee that checks patents within CIF, I can definitely say that there are a couple of areas where further work is still needed, but I prefer to think about them in terms of future goals and possibilities. The first area to work on is the time it takes to grant a patent, which has already improved in the last few years.

Also we have to consider the issue related to the linkage between registration and commercialization as agreed through the FTA with the US. I am not saying that patents do not work in Chile but there is still work to be done in order to ensure that companies owning patents do not have to litigate to make sure the patents are respected.

There are indications that Chile's high GDP and HDI, as well as its qualified scientific community make it an ideal place to conduct clinical trials. How has Novartis been exploiting this opportunity? What can be done to expand the number of clinical trials in Chile?

Novartis has finalized around thirty clinical trials in Chile in the last ten years and we have six ongoing right now. I consider we can still improve our clinical trial activity and -as a matter of fact- we are recruiting three new employees next month to work specifically in this field. We agree that the medical and scientific communities are a very strong asset in the long term Chilean development, in addition to the economic stability of the country. All of these factors have lead to very positive experiences for Novartis in Chile. On a global scale, we have one of the largest pipelines in the industry –somewhere between 150 and 160 projects- which lead to three or four products launched every year. Once the legislation is improved in the country then we will certainly increase the number of clinical trials in Chile.

Chile is recognized for advanced universities and science research and many laboratories are working in coordination with universities in the country. How is Novartis taking advantage of the country's scientific resources to develop R&D activities in Chile?

We have developed several support programs with universities in Chile, the largest one being related to pharmacoeconomy. We also have developed partnerships for clinical trials with universities including the Universidad de Santiago and Universidad Catolica.

But Novartis has also created other programs about health and education, designed for the community. The main program is “Viviendo Mejor” (Living Better), which counts with the cooperation of the academic community to develop educational materials for patients and their families.

There are cases of biosimilar products that have been produced and approved for distribution in Chile. Additionally, major generics companies, such as Teva, which is present in the country as Laboratorio Chile, has stated that they want 25% of their portfolio to be biogenerics by 2015. Is Novartis facing biogenerics competition in Chile? What is Novartis doing to beat this kind of competition?

We are one of the largest biosimilars companies worldwide. As such, as a corporation, we believe biosimilars have a space in the market, if the appropriate regulations and controls are in place. Therefore, as a corporation, we believe that the regulation needs to be strengthened considering –in the case of biosimilar products- that there is no such thing as a generic. If we take as an example the wine as a biological product, probably the oldest in the world, there can be different types of wine depending on the processes and how they are produced. In the same way, the process itself defines the quality of biosimilar products in the pharmaceutical market. Our focus, and that of the industry, is to develop new ways to prolong and improve life. At the end our business as innovators shouldn't be how to protect ourselves from biosimilars, but it should be how to bring better and added-value medications to the population in Chile.

Novartis is known as a trendsetter in socially responsible business practices in the countries where it operates. For example, when we met with your counterpart, Ms. Alvarez in Colombia, she pointed out Novartis' new LEED-certified building (the first in the country). Does Novartis in Chile have the same environment and socially responsible standards?

Talking about CSR, I have to mention the \$1.1 million donation in pharmaceuticals and vaccines we provided to the government after the earthquake in February. We also coordinated -in our Community Day- a visit to different locations to build houses for those that had lost their homes. Also, we have a number of programs in place that allow us to provide free medications to people without access to them.

In terms of green actions, we have an internal team in the office that deals with improving our operations in an environmentally conscience way.

What is your vision for Novartis in Chile for the next 3 to 5 years and what is your final message for the readers of Pharmaceutical Executive about the commitment of Novartis to

Chile?

Regarding our pharmaceutical market in Chile, we will continue evolving from a share-of-voice driven market to a more public listing market, while at the same time improving the access to our products. I also believe that Novartis will continue growing –our objective is at least double-digit growth– and with the expected entrance of new therapeutic alternatives we expect to care and cure many patients from their illnesses.

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