Interview with Erich Viertel Molina, Country Manager, Janssen-Cilag Chile

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Janssen-Cilag has been investing heavily in its Latin American operations in the past years. What is the relative importance of the Chilean operations for Janssen-Cilag in Latin America and what are the major milestones and achievements since the company's establishment in Chile?

In the last five years we have been able to establish ourselves in the Chilean market with a portfolio that has been enriched and enhanced with innovative products. We have done this by targeting very niche therapeutic areas, such as oncology, virology and HIV, which are very different products compared to those you would usually sell through a doctor prescription handed out at your average doctor's visit. As a research- based company our goal is to communicate physicians all the clinical data of our medicines that will help them to take their best desicion for their patients. On the other hand, the institutional market is a lot more complex because of the different distribution channels, payers, insurance companies and entities that we must work with on a daily basis. It really has been an achievement for us to successfully establish ourselves in that market because it was a drastic change for the company. It was due to this change that we have managed to achieve our most noteworthy milestone, which is our yearly growth of 37% in the last five years. In terms of our market share our position is not so impressive, as it below 1%, but this is due to the fact that those statistics are only based on the retail market from which we have reduced our participation.

How has your portfolio developed in Chile? What therapeutic areas is Janssen-Cilag favoring in the Chilean context?

Today our most important therapeutic areas are oncology and HIV where we offer several different product lines and options for treatment. Specifically for HIV drugs we also provide treatments for people who have developed the full AIDS disease. Additionally, we still have a strong performance with neuroscience, specifically amongst our products for schizophrenia. Lastly, a therapeutic area that has been very well received in Chile is our contraceptive product in the form of a patch that women can stick onto their skin. We are the only company that produces this product that has become quite popular in Chile.

The Chilean pharmaceutical market is known for its highly competitive environment lead by generic manufacturers which produce very low-cost products. Apart from the tough competition, what would you say are the main challenges for Janssen-Cilag in Chile?

The biggest challenge for Janssen-Cilag is to successfully restructure itself internally by aligning its core activities with our strategy and mission. As I mentioned before, our focus at Janssen-Cilag is now on the institutional market and in order for us to be successful we need to constantly tailor ourselves to the needs of access for the patients of public and private healthcare systems. Due to the changes that have been occurring in the healthcare system in Chile, we need to make sure that we adapt our commercial operations to these ongoing changes, especially as regards our sales force. There are many more variables involved in selling to the institutional market, because you are selling apparently expensive products which payers are insurance companies or the government, who have to evaluate products from many perspectives such as cost-effectiveness, regulatory, etc. This process is a lot more time-consuming and requires more extensive follow-up on behalf of our commercial department. Furthermore, our medical force has the expertise to train and educate doctors about our treatments for very complex diseases, such as blood cancer. This medical force is also in charge of developing our network and establishing links with doctors, clinics, public authorities, social workers and hospitals. It is for all these reasons that the re-organization of our sales force and operations have been our biggest challenge, because even though we have been in Chile for a very long time, our new goals in the public sector forced us to start from a blank slate.

Janssen-Cilag is a company deeply committed to the innovation of pharmaceutical products and to providing the best quality. Chile, however, has seen some past issues with violations of patents. Has Janssen-Cilag experienced any violation of its patents in Chile and how has this affected Janssen-Cilag's operations in the country?

In my opinion this is no longer a challenge for the pharmaceutical companies, but rather it is a challenge for the local authorities. It is up to the government to enforce the regulations and guidelines established in the free trade agreements that have been signed by Chile, in particular the one with the United States. The issue of linkage is very controversial because the authorities have not respected what is stipulated under the agreement in terms of registering a product and

obtaining the license to commercialize it. Even though there is still much work to be done by the government in regards to linkage, I can gladly say that Janssen-Cilag has not had any of its patents violated. We have some new products that benefited from data exclusivity provisions, but luckily our company until today has not encountered any infringement of its intellectual property rights.

What is necessary for the regulatory system to be strengthened so that companies have the guarantee that linkage will occur?

There is only one thing missing at this moment, and that is political will. Without the necessary political will, these measures will never be implemented and companies will go on for years fighting for their intellectual property rights. Until now the government has actually prevented that these issues are addressed, and this is perhaps due to the fact that we have had very leftist administrations in the past. The new administration, however, is supposedly less liberal and more commercially oriented. Given this, you would expect them to be in favor of enforcing the free trade agreements to their maximum extent, but we have not seen any change until now.

The pharmacovigilance activities of ISP must be strengthened. Janssen-Cilag has developed an impressive pharmacovigilance unit which operates worldwide. In Chile, does Janssen-Cilag work in partnership with the authorities to bolster pharmacovigilance activities? What can be done to improve these efforts in the future?

Our pharmacovigilance unit located in Argentina is called SAFE and it also functions in Chile in partnership with the public authorities. Actually, the majority of pharmacovigilance activities taking place in the country are voluntary efforts by the pharmaceutical companies themselves. The government's main role in pharmacovigilance is to manage a database that registers all claims and reports. Janssen-Cilag has its own internal processes that require us to inform the local authorities of any adverse reports for any of our products, but this is entirely voluntary because there is no legal requirement for companies to report these cases. At the same time we have to report these instances to our own pharmacovigilance unit. The innovative international companies would prefer that legal requirements existed, in order that all pharmaceutical companies provide the same amount of information necessary to improve the safety and efficacy of medicines.

With a high GDP and HDI, Chile presents many opportunities to conduct clinical trials. How has Janssen-Cilag been exploiting these opportunities? What do you believe is needed to expand the number of clinical trials in Chile?

There is no doubt that Janssen-Cilag expects to increase the number of clinical trials in Chile, it has been investing in R&D activities through Clinical Research Organizations (CROs) for many years and has recently opened its own R&D unit inside Janssen´s offices. and we certainly. It must be said that apart from all the other challenges of the public health authorities, Chile has an adequate legislation for the performance of clinical trials. Of course there is always room for improvement,

but Chile already has in place a solid structure and institutions, such as ethics committees, that are reliable and organized. In terms of the regulatory environment for clinical trials, I would say that Chile is one of the more attractive countries for companies to conduct research activities in Chile than in other Latin American countries. As you mentioned, Chile offers the advantage of having very high health and economic indicators as well as low costs for clinical research. For these reasons, Janssen-Cilag is aiming to increase the number of clinical trials that we conduct in Chile.

Other innovative pharmaceutical companies have mentioned their efforts to stimulate research efforts in Chile by developing partnerships with local academic institutions. Does Janssen-Cilag have any similar initiatives to foster research in Chile?

No, unfortunately Janssen-Cilag has not developed any partnerships with academic institutions in Chile. Interestingly enough, Chile has a very rich intellectual pool, especially in the scientific community, but it is not being used to its full potential. The problem lies in the lack of investment to reap the benefits of these professionals. Chile today has one of the lowest investment rates in research at the Latin American regional level. This is indeed a pity because there is much potential for the country but is yet to be exploited. In order to further develop this area it is necessary an articulation between government and the private sector. But the private sector should be attracted to invest in research through financial and tributary incentives put in place by the government. Ultimately it has to be a joint effort, and this is the only way that we would be able to push forward.

Janssen-Cilag has a human resource management policy that aims to enhance employee satisfaction by investing in the welfare and careers of its employees. What actions does Jansen-Cilag take to attract and retain the best talent in Chile?

This is crucial to the success of any company. The most important concept to understand is that human resources and talent is a valuable asset that competitors cannot copy, because talent is unique and therefore has to be valued as such. Once this has been recognized then you have already achieved the first step in cultivating your human resources.
The second most important aspect of talent management is to ensure that managers themselves have the necessary skills and knowledge to properly manage the available talents within the company. Many times this factor is ignored, because even if I have a consistent human resources policy in place that aims to improve the careers of employees, the deciding factor is always the ability of managers to make use of the talent available. Fortunately, this is something that is encoded into the culture of Johnson & Johnson as a company, so in my 23 years working for the group, I have been able to learn the entire process of talent management – from the detection, to the development and retention of talented employees.

What is your vision for Janssen-Cilag in Chile for the next 3 to 5 years? Where would you like to take the company by then?

My vision is to establish Janssen-Cilag as a reference for pharmaceutical companies in Chile. The goal is to develop the company so that it is regarded as a standard in its ethics, social responsibility and professionalism. We want our partners to consider us a solid company to work with and our employees to see us as a great company to work for.

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