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Mexico is improving its regulatory framework for orphan drugs. The general manager of Alexion Mexico explains how the company is working with the authorities to ensure adequate regulation is put in place

, and how Alexion is communicating with patients' associations and medical community to raise awareness about ultra-rare diseases.

What is the history of Alexion in Mexico and what have been its key milestones so far?

The story of Alexion in Mexico started back in 2010, when the company signed a joint agreement with a firm that had the orphan drug designation in the country. In 2011 they started operations hiring a regional vice president and a small team to oversee Mexico and the region. In 2012 there was the first commercial sale of Soliris.

Since I joined the company in October 2013, I have tried to make sure we adapt the structure to keep growing in the marketplace. Today we distribute the drug only for PNH (Paroxysmal Nocturnal Hemoglobinuria), but we are ramping up for the launch of three new indications coming out within the next three-to-four years. Moreover, Alexion is also developing a drug for the treatment of another ultra-rare disease, HPP (hypophosphatasia), and we are conducting the market analysis to prepare this launch.

Alexion has been working closely with COFEPRIS (the Federal Commission for the Protection against Sanitary Risk) and government authorities to make sure orphan drugs are regulated in Mexico. What is the current regulatory status of such medicines in the country?

In the past there was no product regulation for orphan drugs in Mexico, as it is the case for example with the FDA in the US and the EMA in Europe. We had documentation, but not an official product registration number. In the past years we have worked closely with COFEPRIS to make sure orphan drugs have this number. To do so we have submitted a large amount of documentation to the regulatory authorities including results from Phase I, II and III studies. The final draft of the norm and the regulation, which will provide the registration number, was approved by COFEMER (the Federal Commission on Regulatory Improvement) in December 2013 and is currently being evaluated by the Ministry of Health in regards to economic impact; it should be published in the coming months.

What is the awareness in Mexico about rare diseases?

There are a couple of patients' NGOs that are very active in regards to rare diseases: they are working with patients to raise awareness, along with the National Public Institute of Health, to make sure patients' cases are tracked and with the Ministry of Health to ensure an appropriate legislative framework is developed for such conditions.

How would you rate the awareness of the medical community?

Early recognition of ultra-rare diseases is still a challenge. We need to build bridges with the medical community to help them understand the nature of the conditions, and how to treat them. One out of ten patients suffers from diabetes; in case of rare diseases we are talking about five out of 10,000 people. But in case of ultra-rare diseases it's five in a million. The probability for a physician to meet such a patient is very low. It's something, which is not their everyday, so we need to make them think out of the box. They are so focused on other pathologies that they may easily miss these, and by the time they are diagnosed it might already be too late.

How are you working to bridge this gap at Alexion?

We are collaborating with several medical institutions in Mexico, such as the Mexican Hematology Association, which has a special group of approximately 20 physicians focusing on PNH. We are working very closely with them in order to promote training within the medical and scientific community for how to identify and treat a patient with PNH.

A dramatic change I am experiencing compared to my previous jobs, is that whereas previously in an educational program with physicians you would probably spend up to 30 percent of time discussing patients' cases, now you spend 90 percent of the time discussing them, because each case is different. The scientific approach changes, as you do not discuss the theory, you discuss a patient's unique and real case.

Where would you like to see Alexion in Mexico in five years?

I would like to see a company that has been growing at a triple-digit growth rate – which has already happened for the past four years– and with five products and new indications for Soliris in the marketplace. Our footprint will probably stay the same, but I'd like to see a fast-paced and energetic organization impacting the market with regard to rare and ultra-rare diseases and making a difference to patients suffering from life-threatening diseases.

After working for Novo Nordisk and Stendahl before Alexion, what attracted you to the company?

The ultra-rarity of the business. During my professional career I have tried to get familiar with different business environments. On the one hand you have large multinationals, which have a huge portfolio but are not really specialized in one field. On the other hand, you have companies, which focus on a specific therapeutic area, such as Novo Nordisk with diabetes or Stendahl with multiple sclerosis and HIV. And then, you have the ultra-specialized companies, such as Alexion, whose business goes at a different speed and follows a different path. What attracted me was understanding how to do a sale of such a specialized drug as Soliris, which really changes patients' lives. It's a different market proposition, a different product concept, a different way of doing business and a different distribution scheme – a completely different challenge! And I really wanted to learn how such a business model works.

Many CEOs in the Mexican pharma sector say that their most difficult task is to deal with stakeholders – patients, employees, the government and patients' associations, among others. How do you do that?

The key is balancing the short and long-term objectives. It's not always only about immediate goals, such as quarterly results and operating margins; it's also about envisioning an organization and a business model, which can be sustainable in the long term. Nobody teaches you and it's always changing, so the only thing is to adapt.

This is your third time as a general manager. What would you like your tenure at Alexion to be remembered for?

First and foremost, we need to make sure that patients suffering from ultra-rare conditions are diagnosed, have access to drugs and are treated. Next, it is important to have a strong and committed organization that likes what they do and can fulfill a purpose, rather then doing just a job – and that's something Alexion offers. At Alexion, diseases, patients and the socio-economic environment is unique; this makes you develop skills, which you would not have in a different environment, and makes you change as a person. You eventually get to meet the patients, and they will tell you how the drug changed their life. Your work becomes something very tangible and even emotional. What I would like to achieve is being able in 20 years to look back and see we have made an impact in the marketplace.

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