

Luis Calderon - General Manager, Biogen Mexico



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Biogen Mexico's Luis Calderon discusses establishing the affiliate, the opportunities apparent in the Mexican neurodegenerative disease market, and the impact of the country's ongoing health reforms.

Luis, as a veteran of the Mexican pharmaceutical industry, what motivated your decision to accept the opportunity to establish Biogen's Mexican affiliate in March 2019?

My conversation with the Biogen leadership team began with a discussion of their Alzheimer's franchise. As you know, the neurodegenerative space is extremely complicated and many companies have failed. Alzheimer's disease, in particular, is very close to my heart because my father actually has Alzheimer's disease. Biogen's plan was to bring not only their commercial multiple sclerosis (MS) and spinal muscular atrophy (SMA) portfolio here but also to prepare their R&D pipeline for the market, including their Alzheimer's drug aducanumab. Based on this, it made perfect sense for me to join Biogen; their work fits completely with my purpose in life.

Funnily enough, two days before I officially started my position with Biogen Mexico in March 2019, Biogen had announced that they had, unfortunately, had to discontinue their global Phase III trials. It was a big blow to the company then and I had a conversation with the Chief Medical Officer then, who said that despite the failure, they had learned a lot from the trial. Within a few months, Biogen

was back on track with aducanumab clinical trials and as you know, we are expecting now to file with the US FDA later this year.

I have worked with a number of specialty care companies like Alexion and Novo Nordisk and in my experience, companies dedicated to particular therapeutic areas seem to be able to learn faster compared to companies with broader portfolios. Their passion and expertise in their core areas of focus bring a lot of value to their R&D efforts.

What opportunities did Biogen see in Mexico that built the case for establishing a direct affiliate?

Latin America is always a fast-paced and interesting region. There is always risk present, and companies have to deal with a lot of volatility, uncertainty and ambiguity from an operational standpoint but at the same time, it is a good place to invest and expand your footprint. Biogen was already in Brazil and Argentina, and I think it made sense to incorporate to add Mexico. Our CEO saw significant opportunities to enter more emerging markets like Mexico in 2019, Biogen was expanding simultaneously in LATAM and Asia and while our previous distribution partner was doing a good job with our portfolio, we thought that our own affiliate would perform better. Looking at the growth Biogen Mexico achieved the past year, I think we have proved ourselves.

Our full MS and SMA franchises are present here, and we are now preparing to bring our Alzheimer drug here. Looking at our MS and SMA franchises, we have been pioneers in these two therapeutic areas and the value of our products is clearly evident. This facilitates regulatory approvals because regulators understand the efficacy and effectiveness of the products we bring to the market. For SMA, for instance, we have seen wheelchair-bound patients manage to get out of their wheelchairs to walk and dance after taking SPINRAZA®. It is amazing when you are able to offer that kind of value to patients.

We have just completed our first full year in Mexico and I am proud to say we have grown the organization significantly, from fewer than three employees at the beginning to over 40 people today. We added both customer-facing and back-office roles, especially in compliance and governance, which are particularly critical in Mexico. We also have a balanced split between the public and private sector, with around 60 percent of our sales coming from the public sector and 40 percent from the private sector.

Before that, Biogen products were distributed through distributors in Mexico. How established was the Biogen brand?

Certainly, while the healthcare practitioners (HCPs) that participate in international conferences, as well as different payers and policymakers, may know the Biogen brand globally, they would not have built relationships with us locally. Globally, Biogen generally invests significantly in communication and partnership with public stakeholders, especially governments, to show that we understand the situations and problems of different countries and we want to work together with them to resolve these challenges. Generally, we have built a strong brand globally and we are doing the same in Mexico as well. We are a company that likes to partner and support stakeholders wherever we are present.

How do you assess the level of awareness and diagnosis surrounding the CNS areas that Biogen focuses on in Mexico?

In general, Mexico is behind many other OECD* countries across many healthcare metrics, and this affects the neuroscience areas as well. Looking at neonatal screening, for instance, Mexico only has six to seven diseases included in its routine neonatal screenings but some other countries in the world have nearly 50 diseases included. There are many challenges with diagnosis, awareness and treatment due to the resource limitations of the healthcare system in the country. At the same time, Mexico is also in the process of an epidemiological transition; infectious diseases used to be more prevalent and therefore higher priority but now the prevalence of chronic diseases is increasing significantly. The overall economic situation of the country also affects the situation. Mexico is trying to catch up but there are challenges it is facing.

Biogen is working with NGOs like patient associations and other stakeholders to promote better awareness through various initiatives. For instance, we are working with Funsalud to develop a National Rare Diseases Registry, and we organized a symposium together on the topic last year. We also want to strengthen and support NGOs to improve diagnosis efforts and maintain better patient registries to increase the visibility of these patients. We are working through there because it would be a conflict of interest for us to invest in better testing capabilities or to test the patients themselves as a pharmaceutical company. What we are doing instead is to push a public agenda with the help of NGOs and other stakeholders

Given the importance of collaboration with the public sector, the health reforms implemented by the government over the past two years have caused a lot of tension within the industry. What is your perspective on this?

From 2013 to 2015, I served as President of the *Asociación Mexicana de Industrias de Investigación Farmacéutica* (AMIIF), the multinational pharma association in Mexico. I was the first AMIIF President to reach out to the Ministry of Finance and start having dialogues with them because I expected that they would eventually involve themselves more in healthcare expenditures within the country.

What the government has done in the past year or so with the centralized procurement of medicines and medical supplies under the Ministry of Finance is not so different from what other governments in the world have done. Many countries have separated the entity responsible for the provision of health services and the entity responsible for the funding of health services. For me, this does not strike me as odd.

Relatedly, it also makes sense for the federal government to centralize the procurement instead of financing the states to do their procurement individually, firstly because the way the states then allocated the funds was a black box, and secondly because the consolidated procurement directly from the manufacturers instead of the wholesalers increased competition and lowered prices. Previously wholesalers were consolidating the products and quoted their own prices to the different payer institutions. Now the different payers receive quotes directly from different manufacturers, which immediately increases competition. I do not see how this can harm the country.

The problem is that the execution was a little clumsy and the industry could have been more participative in supporting a successful transition. But this is an execution issue, not a strategy issue. For me, the policy is a brilliant one.

Of course, this does mean that Biogen had to change our business model. Before we were B2B dealing with wholesalers but now we are B2C dealing with the payer institutions directly. We need to adapt our strategic plan. At the same time, we also had to recognize that there are still many things we cannot do ourselves as a drug manufacturer so we still need to engage with wholesalers and third-party logistic (TPL) providers but in a different manner. It would not be efficient for us to establish our own distribution hubs to serve the thousands of different institutions our medicines need to reach. In that sense, this policy has changed the entire structure of the organization.

In 2020, how do you expect the COVID-19 situation to affect Biogen Mexico's operations?

Personally, I still have big questions. I am more concerned about the economic impact of the situation on Mexico and how that would, in turn, affect public security and social insurance systems in general, rather than any specific concerns about our particular business. Most of our patients have chronic conditions. The issue is how to adapt to the situation and ensure that they receive their medicines in a safe and timely manner without being exposed to COVID-19 in the hospital setting. We are working with the Ministry of Health and the public health institutions closely on this topic.

In the middle to long term, we are being affected for instance by the temporary closure of the *Consejo de Salubridad General* (CSG – the General Health Council), which manages the reimbursement lists. This means that we are not able to submit our dossiers for drug reimbursement as quickly as we would want, which means patients may see deferred access to drugs.

Looking forward, what do you want to achieve for Biogen Mexico by the time it comes to hand the affiliate off to your successor?

Firstly, I would like to see broad access to our therapies – independent of the franchise – across the different institutions and markets in Mexico.

Secondly, I would like to really enhance our presence in the country and strengthen our relationships with different stakeholders, including HCPs and payers, so that they better understand the value that Biogen brings to the country.

Last but not least, I would like to see patients in Mexico being taken care of. I want the Mexican community to understand that we are here to help patients with severe and chronic conditions live easier and better lives.

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