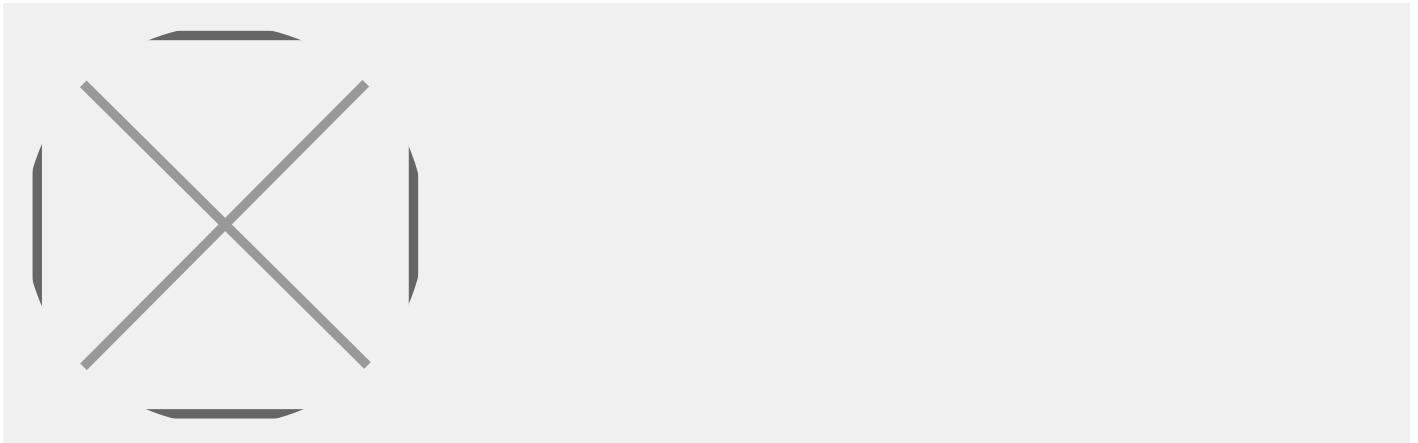


Interview with Edwin Harvey, Managing Director, Biogen Idec Argentina



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Biogen Idec's arrival in Argentina has been very recent. Could you explain to our readers why the time was right to take back your licences and to set up in Argentina?

Biogen Idec has a worldwide expansion strategy. Two years ago, the company decided to establish its own affiliates in Latin America. Previously, Biogen had a distribution agreement with Abbott for Latin America, stretching from Mexico to Argentina, for our main product, Avonex. Ten years after launching and commercialising the product throughout Latin America, the company went back and started to establish our own affiliates, starting in 2007 in Brazil, followed by Argentina in 2008. This is part of the strategic expansion of the company, together with the development of markets in other areas in the world such as China, India, and Eastern Europe.

What is the relative importance of Argentina for Biogen Idec worldwide, and to what extent is the country and region a priority for the group?

Latin America is an excellent place for developing a pharmaceutical business, and part of that attractiveness is due to the fact that Mexico, Brazil and Argentina have well developed pharmaceutical industries in place.

Argentina is important for Biogen Idec because it is the third largest country in Latin America in terms of sales. This fact, combined with the high quality of the professionals located in Argentina, influenced the decision for it to be the second step in Latin America for the company.

Biogen Idec's expansion includes not only commercial activities, but also R&D activities. Argentina is recognised worldwide as having very high scientific level for clinical studies, because the country has very well-trained physicians, at least 20-25 years of experience in clinical studies, which have formed part of both EMEA and FDA dossiers and submissions. ANMAT works very closely with investigative activities, and that has lead to a very good clinical practice in Argentina and a platform for future development.

To what extent do you intend to use your Argentinean operation as a gateway to the smaller countries of Latin America?

We currently have two employees dedicated to supervising the activities of our distribution agreements throughout Latin America. We have three distribution agreements for more than twelve countries in the region, excluding Brazil and Argentina which have their own operations. Biogen Idec uses Argentina as a platform to access the markets in the rest of Spanish-speaking Latin America. Biogen produces only in the US and Denmark, and worldwide affiliates import finished products from these centralised locations. The company established a Quality Control lab for biologics in Argentina, according to the country's regulations: Argentina is the only country in the world other than Japan that has this high standard of regulation. We dedicated 2008 to establishing our lab, which operates to both local standards, and Biogen Idec's own high level of internal regulations.

We have not only invested in this QC lab in Argentina, but in other commercial activities, particularly the area of clinical studies. The Argentinean operation is currently developing three clinical studies, but we have 21 potential clinical studies that could be developed in Argentina, depending on suitability and therapeutic areas.

How did Biogen Idec's operations start here, and what role have you played in their development?

Biogen Idec contacted me through a worldwide Human Resources Consultant, based in Switzerland. After a difficult and competitive selection I was chosen to lead the start up. It was a very enjoyable challenge: starting from scratch, and having to manage all financial activities, regulatory activities and recruiting. The Argentinean operation now has 20 staff, and we plan in the following two to three years to start developing new therapeutic areas, not only in neurology, where we are now focusing with Avonex and Tysabri. These new therapeutic areas will need different business units, not only locally but throughout the whole of Latin America.

Argentina is renowned for its great quality professionals. What do you think attracted your staff to come and work here, and what attracted you to Biogen Idec?

The main attraction for the people that started at Biogen Idec in Argentina was the start up process. We are the founding fathers of Biogen Idec in this country, and for Latin America. The company is very attractive because it is one of the leading companies in biotechnology, the leaders in massive production of biologics, and it is only 30 years old. Two Nobel prize winners in science were involved in the founding of Biogen Idec, and one of them is still on board today. The company began as a scientific start up, and then migrated and amplified through the commercial area and started to expand throughout the world. In this company you will find the future of pharmaceutical biotech developments, combining cutting-edge science with a commercial aspect.

The deciding factor for me in joining the company was the challenge, and the combination of a scientific based company with a commercial orientation. I am a biologist from the University of Buenos Aires, with an MBA as well, and this combination is my dream job: not only to start a company with such a suitable profile for my experience, but to start it here in Argentina.

How much of you is still a biologist, and how much a businessman?

You have to be able to understand both areas in this job. You have to be a scientist in order to understand the business because it's so based in science. Biogen Idec has 4,000 employees throughout the world, and half of them are scientists. We will be developing at least 21 programmes in the coming years, and the transition from the development area to the commercial area needs a leader who has a good understanding of the science going on around them. Biologics are not very simple to sell: it takes an understanding of the foundations, the mechanisms of action and the future implications of the product, so scientific knowledge is vital. We have recruited a combination of people here at Biogen Idec Argentina – half of them are based in science and the other half in business. Most of them combine both backgrounds. We have pharmacists, chemists, biologists, physicians, and then we have accountants, and business administration people. In marketing, we have a molecular biologist who has a combined MBA in marketing. The Associate Director also combined science with administration.

How do you intend to compete in the Argentinean market? Local companies dominate the market – are there any key strategies you are developing that are different to the Biogen strategy as a whole?

As an international company specialised in biotech products Biogen bases its marketing strategy on giving the best education and service for physicians in Argentina. We also give a lot of support to patients, because MS sufferers will need our products for the rest of their lives. We already have one product in the market and we will launch another one at the end of this year, and both of them are very complicated – they are biologics: one is a protein and the other is a monoclonal antibody. Multiple Sclerosis is a very complicated disease that needs patients to be supported by the company. That is a strategy that local companies do not have.

This year was the first time that World MS Day was declared as a day of importance, and we supported 14 MS patient organisations from across the country, by inviting them to visit us. We gave them information on medicines and treatments, and also on fundraising and networking. We gave them a lot of information that they need in order to be successful NGOs. They were very happy to establish interaction between the different national groups. It was the first time that they had made contact and to develop a common interest towards the quality of life of people with MS.

This is the type of reputation that Biogen Idec wants to establish in Argentina: caring people with MS, and in the future with other oncological or neurological disorders. We will help patients not only through our effective treatments, but also through the counselling and psychological support they need for their non-medical needs. For example, we have a patient support programme, and the quality of professionals that work there is excellent. They have 15 years of experience in helping patients with MS, so they understand the disease and the experience, they give information about the pathology and they help people to deal with the disease, right from the initial diagnosis.

As we introduce new treatment options for neurology and oncology, we will help physicians and NGOs to develop their scientific activities. We are in close contact with these societies in order to help them develop academically, through symposia and interchanges.

You've already mentioned clinical trials and we know that Biogen Idec is investing a lot of money in R&D in general in Argentina. What do you believe are the advantages, both for Biogen Idec and for the population, of your R&D activities here?

The benefit is that our patients have access to top quality medicines for unmet medical needs. Biogen Idec is very pleased about this, because Argentina has a lot of underdeveloped areas, and this type of clinical trial gives the population the possibility of having access to first-world healthcare.

We see that a growing trend in Argentina is that companies are starting their own biotech divisions: Sidus and Elea locally, and MNCs as well. How will they compete with well-established biotech companies like Biogen Idec ?

All Biogen Idec products have clinical support, which is very important. If these companies want to develop their biotech products to the same degree of excellence, they will need to have clinical support. Today, local companies that commercialise biological similars do not have the support of clinical trials for products that are already on the market. If they have that support that international companies have for their products, they will be able to compete with us. For example, Bio Sidus has an interferon-beta product for MS that is similar to those of international companies, but in their submission dossier for the product they did not present any clinical studies for that particular molecule. The way that companies can compete locally is having that support first.

How do you expect the biotech sector in Argentina to develop in the years to come? Do you believe that Argentina has the potential to position itself as a clinical trial hub in Latin America?

In Argentina, I believe that the intelligent local companies will make a breakthrough in the launching of biologics, probably supported by international companies that will help them to have the clinical trials to support their product. However, the real developments will come when they will start looking outside the Argentinean market. Argentina has a small market for production of biosimilars for the US and Europe, so the local companies will have an excellent opportunity to show that we have good scientists in Argentina, and good products. Argentina is one of the only countries in Latin America that has had three Nobel prize winners. We have a high quality of scientific research and development in Argentina, and the fact that the government is supporting the biotechnology sector will prove to be a big help.

This is the right moment for Argentina to start consolidating in this area. Although the country has a lot of economic ups and downs, the companies that have maintained a presence here have seen strong growth. Examples of companies that never left include both Roche and Novartis, and their positions in the rankings reflect this.

Biogen Idec made an excellent decision in choosing to enter the Latin American market. As a platform for Latin America, Argentina is the best. A lot of companies have their headquarters for Latin America in Brazil, but the language barriers and resulting relationships with physicians can often lead to problems. On top of this, Brazil is very large, and multinationals based there often spend a disproportionate amount of time focused on their own market, and not enough time on the other countries in the region.

We've heard that one of the biggest challenges facing biotechnology companies in Argentina is working alongside ANMAT, and educating them about these new areas and products. How have you found this challenge so far?

It's been one of our most difficult tasks. The standards that were set for Biogen Idec's QC lab through ANMAT were very high, and we accepted the challenge and overcame it. Ricardo Martinez recently asked me if the regulations that ANMAT had set had been too strict. The challenges are very gruelling for companies, both in this area and in the field of clinical studies, but the company prefers that. Biogen Idec is involved in cutting-edge science, and so our quality control and clinical trials also have to be done to this high standard. We just hope that all other companies involved in biotech in Argentina, national and multinational alike, are made to pass the same tests, and that companies that are already established here are made to pass them too. If the tests are made equivalent for everybody, then we would be even happier.

Our company has very strict codes of business conduct. We manage our Argentinean operation in the same way as our first world operations. The company is represented in CAEMe, and we support, act and implement the same code of business conduct that we use in the chamber.

How do you intend to lead the company in the years to come? What is your management style?

I have worked in both multinational and local companies, and so understand the culture in both, which is a big advantage. My management style is people oriented. I believe the biggest successes are based in people. The attitude of a company's employees can make an enormous difference, whether the company is big, small, national or multinational. All the people recruited to work at Biogen Idec Argentina have an attitude of entrepreneurship, and they like a challenge. Some of them came here from big companies, and they selected Biogen Idec because of the project, sometimes working here for a lower salary than in the other companies. The opportunities and things that they will learn here far compensate for this. They will be the founding fathers of Biogen Idec in this country. We are moulding the image of the company in Latin America on a daily basis: we don't yet have a history with the physicians, so we are starting from scratch, and that is very interesting, because you can imagine the ideal relationship between a company and its stakeholders, and then start to build it.

What is your biggest objective over the next five years?

Immediately, we have the challenge of 22 projects that are spread between Biogen Idec's different therapeutic areas. We have to build the business in those areas. We also have a big challenge getting clinical trials active in Argentina for all these projects, which will take at least five years. On top of this, the Argentinean operation will be supervising and synergising all our activities in Latin America. We feel that Biogen Idec Argentina is more than up to the challenge.

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