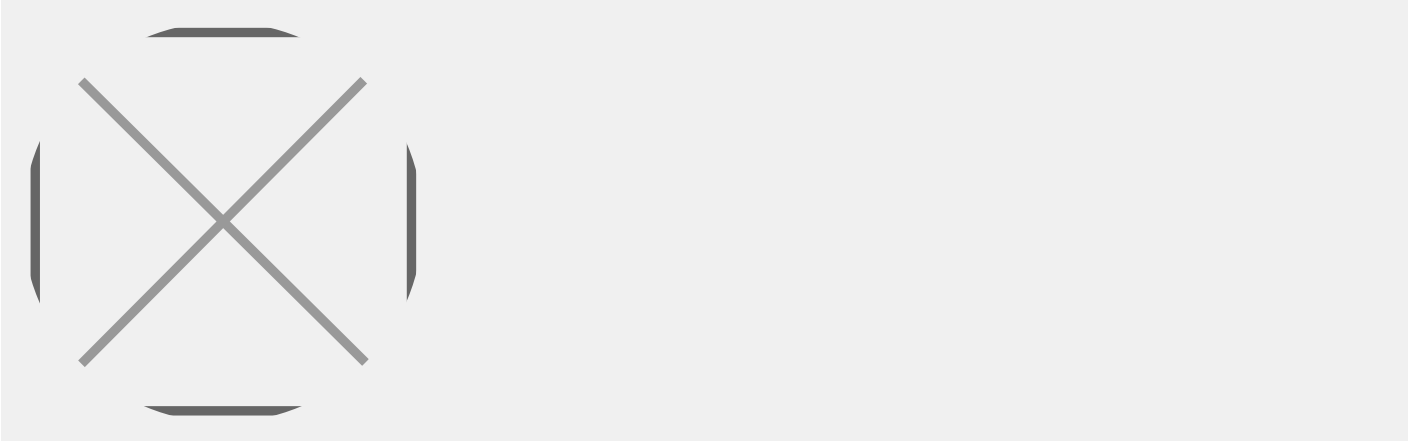
Interview with Claudio Santos, MD, MBA, General Manager, Shire HGT Brazil, Shire Brazil



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We asked Mr. Santos regarding his recommendations to help the government innovate, compete, and grow in the pharmaceutical industry here in Brazil on the Human Genetic Therapies side. Is there a different approach required in the specific area of HGT?

For HGT, one very important element is the basic regulatory framework, because there is none for orphan drugs or rare diseases. Today, the rules are the same for orphan drugs as with blockbuster drugs targeted to GPs, which means that there is significant investment and development that still needs to be done to improve the infrastructure and regulatory framework around orphan drugs.

Despite a lack of official frameworks, it's interesting to note the case of a company like BioMarin, for instance, whose entire business in Brazil is composed of some 150 MPS VI patients, some 85% of whom are covered under legal injunctions.

The Brazilian constitution, as you say, ensures each and every citizen universal rights, to health, education, etc., which means the courts when challenged by the patients determine the authorities to pay for the therapies. Not all the orphan drugs must be covered via court injunctions; there are some exceptions. Gaucher Disease is already covered by the official health system. But what we intend to foster is the development of official clinical protocols for MPS II, Fabry, etc. – not only for Shire`s therapeutical alternatives, but for all therapies available for Lysosomal Storage Diseases. Today there are clinical protocols for Gaucher and Hereditary Angioedema, in this case only for prophylactic, not acute, treatment, therefore we must move ahead and include acute treatment. There is only one phrase in one of the regulations in Brazil that says orphan drugs should have a

fast-track review, and there is no kind of special benefits in terms of special patent protections or other incentives. We are working along with Interfarma because there is not a single focal point in the MOH or ANVISA to discuss orphan drugs and. It's hard for us – because it simply doesn't make sense.

Take Hereditary Angioedema, for example. Firazyr is a synthetic drug, not biological, and as a result must be imported and fully tested for quality control. If we import 1,000 syringes, 200 must be retained for retesting. This might make sense when importing hundreds of thousands of boxes of diabetes medication, but effectively destroying 200 of a one-year supply of 1,000 syringes through retesting doesn´t make sense. We need to see these orphan drugs as very particular therapies and manage them in a different/particular way.

On the HGT side of Shire's business in Brazil, what have been some of the main milestones and achievements since its startup?

HGT began in Brazil in the end of 2007 with six people. I've been here for one and a half years, since April 2010. When I began, there were 35 people, and now, altogether, we have nearly 100. We sometimes say that the organization went from being a string quartet to a full orchestra! In three years, the business growth has been truly amazing, and this year we will grow 70% over 2010, on track to become the third HGT operation by 2015.

What do you see as the most marked differences in strategy compared to a US, Europe, or Asia?

Access is the most important difference. The business model in Brazil is different because the access for orphan drugs, as we discussed, is not well-established. In the majority of cases, patient associations use the constitution to get access to drugs. Therefore, there is a difference in the importance and strength of patient associations in Brazil compared to Europe or the US. Shire must work very closely with the government, at both the central and state levels, as the only payer we have for HGT, while putting pressure to develop the clinical protocols like with Gaucher for all diseases, in concert with Interfarma, the academy, and the medical society, which are all stakeholders in terms of guidelines.

Brazil is an underdeveloped market. The most mature market is Gaucher, followed by MPS, but Fabry is still growing, there`s low disease awareness, even among physicians, they simply don't know about the disease. And, even if doctors are aware of the disease, they may not be aware of the existence of an effective treatment, because it's new, unlike in the US or Europe. Another important issue is providing diagnosis facilities – because there are only two centres in all of Brazil with the capability. It's not a simple task. There are enzymatic assays, and DNA analysis, both sophisticated processes, and the bottom line is that we need to support reference centers in order to assist physicians with diagnosis as well.

How does the Shire HGT portfolio in Brazil compare to other countries? Has there been a strategic delay or fast-track for any products?

Shire HGT has four products in its portfolio, all of which are registered in Brazil: Elaprase for Hunter, Vpriv for Gaucher, Replagal for Fabry, and Firazyr for Hereditary Angioedema. Brazil is the only country in Latin America with all four drugs approved. Although I said before one of my recommendations was to establish regulatory frameworks for orphan drugs, I must admit we had no problems submitting dossiers for reviews and having the licenses granted.

What's at the top of your priority list right now at Shire HGT?

The focus is to get our diseases included in the official clinical protocols. That's the main objective. We're working a lot with stakeholders to include MPS, Fabry, and acute treatment for Hereditary Angioedema. The constitution may guarantee access, but it's a long way from diagnosis to treatment, often about one year. Because much of the time we are dealing with children, to have these diseases included in the clinical protocol and have that timeframe shortened to one month would be a dream.

The fact is that diagnosis, access, treatment compliance – everything is difficult for those patients. At Shire, our mission is to "help people live better lives", as so we assist the patients and treating physicians at all stages of the disease management. Furthermore, for diseases not covered by the clinical protocols, the government is not supposed to support the treatment centres. They pay for the treatment but they do not support the whole system behind it, and the only way to get this support is by inclusion in the official clinical protocol.

Where do you want to take Shire HGT side of the business in Brazil?

Our slogan for 2015 is "four, three, three": be leaders in the four markets we are playing today; triple revenues; and be the third HGT subsidiary in the world.

Shire will continue developing the pipeline – we have in our pipeline treatments for other types of MPS including MPS III A, also known as Sanfilippo Syndrome A, and a version of Elaprase that is administered not intravenously, but directly into the CNS, called IT or Intra Tecal currently in phase I/II, and others such as MLD or Metachromatic Leucodystrophy. Shire is bringing these products to market in the coming years, consistent with its commitment to develop products for other orphan diseases and supporting these patients who are indeed very brave. At Shire we wake up every day to work for those patients who need support for everything. Brazil is unlike mature, developed countries, which count on the full support of a robust health system. In Brazil, companies must work together with the authorities, government, patient associations and medical societies to support the patient from A to Z.

What is your final message to Pharmaceutical Executive readers about Shire's HGT business in Brazil?

Latin America, and Brazil in particular, represent great opportunities for HGT – mostly because of the population. In Brazil alone, we're talking about 190 million inhabitants. Latin America as a whole has almost the same population as Europe, but is still underdeveloped. Take for instance the Andean region, it is untouched, with 100 million inhabitants just now being served by a new Shire office in Colombia. It's a huge opportunity, and a nice place to be.

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