Shire Argentina – Gabriela Pittis, South Cone General Manager

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Gabriela Pittis discusses the Argentinian healthcare system's ability to diagnose, treat, and regulate rare diseases, and the country's progress in further developing what is already the region's most comprehensive system in this regard.

Is the Argentinian system able to reliably diagnose and treat rare diseases?

"Rare diseases" is a very big category, including more than five thousand recognized illnesses. There is no treatment available for many of them, and the diagnosis process is extremely long and arduous for patients, sometimes taking more than ten years. Accordingly, when we talk about rare diseases and the medical infrastructure needed to treat them – diagnostic testing, reference centers, treatment centers and all of the logistics in between – there are a lot of unmet needs anywhere in the world and there is a lot of work to do.

Argentina passed a law in June 2011 that is still being implemented, which explicitly requires the private and social insurance organizations to provide support for rare disease treatment, and which created a central committee, which includes patients as members, to coordinate activities such as neonatal screening and patient registries. There is a phenomenon unique to rare diseases, which is that through Internet research and participation in patient associations, the patients quickly come to know far more about their condition than most of their physicians, health management

organizations, and regulatory authorities, and as a result many patient organizations are working with authorities to determine what an ideal rare disease treatment system would look like. For real progress in this field, meaning better solutions for the patients foremost, all of the stakeholders must collaborate and share their experience and expertise in the issues. Here at Shire, we invest a lot in medical education to play our part in informing physicians so that the diagnosis process can move more quickly, which is of course better for the patient, but also important for the healthcare system so that expenses related to hospitalizations, symptomatic treatment, and fruitless diagnostic tests.

How would you describe the progress in this area?

There certainly is progress, but it is slow. The perceived speed changes depending on your perspective, so from a regulatory or governmental position things are probably moving at a reasonable pace, but at Shire we always try to put ourselves in the patients' shoes since they have the most interest in the healthcare system's treatment and things move much more slowly when you are the one affected by the disease. That said, the progress in Argentina is moving more quickly than in many other countries in the region, and current treatment standards are very high, so in this regard the Argentinian healthcare system is evolving and innovating strongly.

Compared to other Latin American countries such as Brazil, is the regulatory environment better designed with respect to rare diseases and orphan drugs?

In general, yes. In Argentina the Res.4622/12 regulates the process to approve orphan drugs. This resolution considers rare diseases as diseases where the incidence is 1:2000. Moreover, for all drugs marketed, full quality control testing is officially required, however ANMAT has been very open to discussing the meaning and significance of technology transfers and the burden of fulfilling the standard testing requirements for some of our products.

What is the scope of Shire's current business in Argentina?

When Shire acquired TKT in 2006, they acquired TKT's Argentinian office that had previously been licensed to distribute Shire products in the country. This marked the company's official entrance into Argentina and the business has since grown from less than ten people to about fifty. We localize all of Shire's rare disease products, which means that we register our products with ANMAT instead of just getting approvals on a per patient basis and have full quality control testing facilities in Argentina. At this point, we have not brought any of our other product lines into Argentina or most of Latin America, save for some of our Neuroscience line in Brazil and Mexico. We are assessing the opportunity for Neuroscience products in the South Cone cluster.

Major milestones since you joined in 2007?

Changing our commercialization model from a patient-by-patient system to full-scale local commercialization was very significant. Shire made material investments in people and capital here, and as a result we are able to maintain strong relationships with local insurers, regulatory authorities, physicians and patients. This permanent presence is very important, as it allows us to increase access to treatment for currently undiagnosed or untreated patients through educational outreach and ongoing dialogues with the other local stakeholders.

Could you give us an overview of Shire's R&D activity in the Argentina?

Our R&D activity in Argentina is limited to clinical research, as our NME investigation is centralized mainly in the USA, but we have been running clinical trials here for several years. Currently, we are running trials for four different drugs. The regulatory environment here is very good for clinical trials as the regulations are very clear, the standards are very high, and the infrastructure is very high quality and comparable to facilities in the U.S. and Europe. The approval process for new biological products is predictable if somewhat slow at times, usually 12-18 months, although there have been occasional delays due to evolving approval standards, and there is no fast track option in Argentina like there is in some other countries, such as Chile.

Where do you see Shire in Argentina and Shire Latin America in five years, in view of the likely acquisition by AbbVie?

Shire's footprint of rare-disease is very strong worldwide, including Latin America. AbbVie is very interested in our leadership position in rare diseases. For the company as a whole, and for other pharmaceutical companies, the Argentinian market presents a great opportunity for growth as the healthcare system is robust in general, and give patients good access to innovative and high quality products, such as our own. There are still a lot of unmet needs in the region that present further opportunities for those who are able to bring effective solutions to the market.

What is your academic and professional background, and how did you come to lead Shire's business in the South Cone?

I have a PhD in molecular biology and have several years of experience doing academic research in the field of biotechnology. Eventually, I moved from the academic research environment to the pharmaceutical industry, focusing on rare diseases. Since then I have been exposed to a variety of areas across the pharmaceutical business; I started in the medical affairs office at Shire as a medical science liaison and eventually worked my way up the ladder until I became the Associate

Director of Medical Affairs for Latin America. Next, I spent some time on the commercial side performing a variety of roles until I was made the interim country manager in August 2010, and the permanent country manager in November 2010. When we reorganized our regional operations in 2011, I took responsibility for all of our business in the South Cone.

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