Interview: Sameer Savkur – Country Manager, Biogen Brazil



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Sameer Savkur, country manager of Biogen Brazil, provides insights into the key specificities of the Brazilian pharmaceutical ecosystem and documents the great successes of Biogen affiliate in working hand-in-hand with all key public and regulatory stakeholders in Brazil, as recently illustrated with Biogen's innovative treatment for spinal muscular atrophy (SMA), a groundbreaking product which received all regulatory and pricing approvals in a record time.

You headed Biogen's affiliate in India between 2011 and 2014 before taking over the company's Brazilian operations in February 2015. Which similarities between the two countries have facilitated your transition from India to Brazil?

First of all, both Brazil and India are BRICS countries, these developing or newly industrialized countries that distinguish themselves by large economies and a raising influence on the global stage. In the meantime, both countries are among the largest countries in the world – in all aspects; India is the seventh largest and second most populous country in the world, while Brazil stands as the world's fifth largest country and the most populated Latin American nation.

In this context, both countries have become extremely relevant to any companies with global ambitions, and this assessment also applies to the healthcare sector. As a matter of fact, Brazil and India respectively emerge as the sixth and the eleven largest pharmaceutical markets in the world, and one can expect these rankings to further improving in the upcoming years.

Both countries also share strong similarities with regards to their epidemiological profiles, which are characterized by a persisting significance of communicable diseases as well as the rapidly growing prevalence of non-communicable, chronic diseases.

Both multinational and domestic companies are well implanted in India and Brazil, although the industry structure slightly differs between the two countries: in India, domestic players hold a dominant share of the overall pharmaceutical market, while the Brazilian market is almost equally split between domestic and multinational companies.

What are some of the main specificities of the Brazilian market which you had to adapt to?

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From our perspective, one of the most striking specificities of the Brazilian market relates to the significance and the strength of the country's public health system *[called "SUS" – Ed]* as Brazil proudly stands as the only country in the world with a population over 200 million inhabitants to have implemented publicly funded, universal healthcare.

In India, most of the medicine spending comes as out-of-pocket expenses, which means that products' affordability emerges as a defining parameter in terms of access. In Brazil, healthcare stands as a constitutional right, which implies that the government has to ensure that all Brazilian patients can access the treatments they need.

From a personal standpoint, moving to Brazil therefore implied to embrace a completely different market approach, as around 95 percent of our sales in the multiple sclerosis (MS) area come from the public sector in Brazil. In this context, the impact of public policies as well as our relationship with regulatory and reimbursement agencies take on a greater importance in Brazil than in India, where where the private market makes up most of our sales.

Biogen remains the global leader in all three segments of the MS market: oral, high-efficacy, and interferons. What is the market position of the company in Brazil in this strategic therapeutic area?

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Biogen Brazil is perfectly aligned with the global position of the group and we are market leader in Brazil's MS field too. AVONEX® (interferon beta-1a) and TYSABRI® (natalizumab) are approved by the National Commission for the Incorporation of Technologies (CONITEC) and therefore are

available to all Brazilian patients through the SUS.

We are also extremely proud to announce that our oral therapy TECFIDERA® (dimethyl fumarate), which initially received market approval in Brazil in 2015, was integrated in the SUS very recently and will be available to all Brazilians at the beginning of next year. MS is an extremely competitive therapeutic area, and CONITEC's decision to integrate our oral solution highlights the sheer innovation that sets Biogen apart as well as the great efforts conducted by our teams over the past two years to reach this critical objective.

In 2016, even in the face of growing competition, our company continued to increase the total number of patients around the world treated with one of our products, and 38 percent of all MS patients in direct markets were treated with a Biogen medicine overall. In Brazil, our 2017 data show that 32 percent of all MS patients were treated with our products. With the recent inclusion of TECFIDERA® (dimethyl fumarate) in the SUS, we expect this share to further increasing and getting closer to that of Biogen at the global level.

Leveraging on your leadership in the MS area, how do you ensure that the Brazilian healthcare ecosystem fully benefits from Biogen's global expertise?

Throughout the registration and reimbursement process of our MS portfolio, we have been working in a very collaborative and transparent way with dedicated patient advocacy groups. Overall, Biogen Brazil has put a special emphasis on sharing with the Brazilian stakeholders all data and information we hold about the disease.

In the meantime, it is absolutely paramount to us that we strictly comply with all regulations framing pharmaceutical companies' relationships with external stakeholders. Within this stringent regulatory framework, there are still some opportunities for global, innovative companies to foster knowledge transfer, raise awareness about the disease and provide insights into the challenges and solutions experienced by patients all around the world – and we have always been utterly committed to ensure that the Brazilian ecosystem can fully leverage Biogen's expertise in the MS field.

Biogen recently launched the first and only approved treatment for spinal muscular atrophy (SMA), a genetic disease affecting the part of the nervous system that controls voluntary muscle movement. How has been your experience in working with the country's regulatory stakeholders for this product' approval?

First of all, I want to highlight that spinal muscular atrophy (SMA) unfortunately stands as one of the largest genetic causes of deaths in infants– both globally and in Brazil. We are truly talking of a disease area with unmet medical needs, as there was no treatment option available to patients before the release of Biogen's SPINRAZA® (nusinersen).

In this context, getting this life-changing product approved in Brazil as swiftly as possible was an absolute priority for us. As a matter of fact, SPINRAZA® (nusinersen) was approved by Brazilian Health Regulatory Agency (ANVISA) within only 85 working days, which proudly stood as an industry record in Brazil, and subsequently received its reference price from the relevant agency (CMED) within only 36 working days, which was – again – an unprecedented timeline for Brazil.

This eagerness of Brazil public and regulatory authorities to render these life-changing therapies available to Brazilian patients showcases that Biogen is targeting unmet medical needs. It also proves that we have been able to establish a great working relationship with Brazil's government, ANVISA, and CMED, which contributed to further accelerating the approval process of this life-changing product.

In this regard, Brazil is often considered as a bureaucratic country, where working closely with the government can reveal itself being a challenging and lengthy process. However, Biogen's experience in the approval of SPINRAZA® (nusinersen) has been extremely positive, which proves that it is possible to get a swift market approval and reference pricing in Brazil by working closely, transparently, and ethically with public and regulatory stakeholders.

Looking forward, our key objective is to continue this successful collaboration with Brazil's public stakeholders at CONITEC level. We received our reference pricing only a few weeks ago, and our teams are already fully focused on working closely with the Ministry of Health to ensure SPINRAZA® is integrated in the SUS.

How would you define success for the affiliate under your tenure?

I personally believe that the first and foremost mission of any general manager is to build and enhance enriching work relationships – both at the internal and external levels. From my perspective, the most rewarding legacy is to feel that I contributed to develop the great talent that we have in our organization.

In the meantime, we want to play a significant role in improving Brazil's standard of care in the MS and SMA areas. Leveraging on our recent and aforementioned successes, we are in a privileged position to positively shift the treatment paradigm in these critical therapeutic fields. If Biogen

Brazil is able to provide patients and their families with a swift and satisfactory access to our life changing treatments, I consider that we would have fulfilled an important part of our overarching mission in the country.

What is the importance of Brazil within the global operations of Biogen?

As mentioned earlier, Brazil already stands as the sixth largest pharmaceutical market in the world and one of the most populous countries in the world, while it also proudly emerges as the largest economy in Latin America and a top 10 economy overall. In this context, it makes no doubt that Brazil stands as a very important market for Biogen, especially as we are expanding our portfolio. A few years ago, Biogen was essentially focused on MS products, where the prevalence is significantly higher in the US and in Europe than in Latin America. However, the context is completely different for SMA as well as other neurodegenerative diseases, a field in which Biogen has been investing huge R&D resources over the past years.

As a matter of fact, we hold six compounds in our R&D pipeline that are targeting Alzheimer's disease (AD). The latter could benefit to Brazil's significant AD patient population *[according to the Alzheimer's association in Brazil, over 1 million Brazilians are affected by some sort of dementia – Ed]* while the Brazilian population is moreover aging at a rapid pace.

Looking forward, we see Brazil's importance within the global operations of Biogen further gaining in importance over the upcoming years as our company continues to expand its portfolio. As a matter of fact, we expect to double the revenues of the Brazilian affiliate in 2018 as we launch our groundbreaking SMA product into the market.

In 2017, Biogen is celebrating its ten years anniversary in Brazil. How do you want the company to be perceived among the Brazilian ecosystem?

We want these stakeholders to see Biogen as a trustworthy, reliable, and valuable partner aligned with our company's motto of "caring deeply, working fearlessly, and changing lives". At the end of day, as an innovative company focused on healthcare, our objective is to change the outcomes of life-threatening diseases and improve patients' lives – this is the fundamental mission guiding us in our daily operations.

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