Interview: Roberto Alvarenga – General Manager Latin America, Biotronik



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30.11.2017

Tags: Brazil, Biotronik, Medtech, Strategy, Latin America

Roberto Alvarenga, general manager Latin America at Biotronik, the leading company globally for cardiovascular and endovascular medical technologies, documents how he has been leveraging on his long standing experience among prestigious pharmaceutical companies in order to implement pioneering processes in Brazil's medtech field and ultimately increase Brazilian patients' access to innovation.

You undoubtedly stand as one of the most experienced executives in the country's pharmaceutical sector, having honed a long-standing expertise at the head of the Brazilian affiliates of Ferring, Shire, and Merck Serono. What motivated you to move to the medtech side?

After having spent twenty-five years in the pharmaceutical industry, I was looking for an opportunity to challenge myself. In this regard, moving to the medtech field emerged as the perfect occasion to fulfill this objective: although the stakeholders involved are relatively similar, business models differ significantly from the pharmaceutical sector to the medtech industry. Don't get me wrong: I never considered that I was at the end of the line in the pharmaceutical field or that I had nothing to learn anymore – far from that; however, I really wanted to get exposure in another part of the healthcare value chain.

In the meantime, moving to the medtech side has enabled me to leverage the expertise honed by working among leading pharmaceutical companies. When it comes to the complexity of market approaches implemented, I do consider that the pharmaceutical ecosystem has reached a higher level of sophistication than the medtech field, although the latter has been rapidly catching up over the past years.

Could you elaborate on this point and provide insights into the processes that you strive to translate from the pharmaceutical sector into the medtech industry?

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Over the past few years, the medtech industry has been moving away from the commodity approach historically used. Whether it relates to pacemakers, stents, defibrillators or any other devices, showcasing the added value of our innovative products has become paramount in order to ensure that our stakeholders do not perceive them as commodities roughly equivalent to any other products on the market. To develop our marketing capacity accordingly and ensure we can become frontrunners in this area, we therefore inspired ourselves from the processes developed by pharmaceutical companies when designing market approval and reimbursement dossiers for innovative drugs.

Market access has truly become the name of the game for innovative pharmaceutical companies – and the affiliates' capabilities in this field are widely considered as crucial value drivers. At Biotronik, we are now implementing this "access concept" in both the private and public sectors to ensure our products are included in their guidelines. For example, we decided to develop a fully fledged reimbursement dossier for Biotronik's Home Monitoring®, a pioneering and award-winning remote cardiac monitoring system which automatically collects data from the patient's device and is capable of detecting and alerting physicians to relevant changes in patient health and the device status, bringing enhanced efficiency for clinics and peace of mind for patients. After reviewing this value-based dossier, the technology of Home Monitoring® was accepted by CONITEC and integrated into the SUS *[brazil's public health system – Ed]*, marking the first time that such technology is incorporated in our country's public sector. While this product's precise guidelines still need to be clearly established, we want to expend our partnerships with the government and ensure that this technology is available to patients that truly need it. Overall, we expect that Home Monitoring® will be available to Brazilian patients in the public sector during the first semester of 2018.

In the meantime, we see that stakeholders' expectations have led pharmaceutical companies to tremendously heighten and upgrade their compliance processes – to a level that has not yet been equaled by medical devices companies. This does not mean that medtech companies do not comply with their own regulations, but only that pharmaceutical companies have been faster in aiming to exceed stakeholders' expectations. As a result, we also hold the ambition to lead the medtech industry in this area by significantly enhancing our ethics and compliance processes, therefore establishing Biotronik Brazil as a true frontrunner in Brazil's medtech industry.

In all aforementioned areas, Biotronik Brazil today stands at the forefront of the Brazilian industry, but we do not plan to rest on our laurels moving forward. As general manager for Latin America, my objective is to ensure we remain ahead of stakeholders' expectations in the long term. The Brazilian ecosystem is rapidly evolving, and we have to continuously adapt ourselves to the opportunities and challenges bolstered by our country's rapidly aging population, the increasing focus on cost containment and the heightening of compliance and regulatory requirements.

Despite the recent, unprecedented economic crisis that hit Brazil over the past three years, the country's healthcare sector has remarkably weathered the crisis and still emerges as a strategic market for most international companies. What is the importance of Brazil within the global operations of Biotronik?

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In terms of revenues, Brazil proudly stands as the sixth largest affiliate within the Biotronik group. Biotronik's regional headquarters are located in Brazil, and the country makes up around 70 percent of all Latin America revenues. In this regard, I want to highlight that Latin America has become the fastest growing region for Biotronik, although we are still in the process of consolidating our regional footprint. For Brazil, which stands as a cluster in itself within Latin America, we plan to grow our revenues by at least ten percent in 2018. Additionally, we just opened an office in Argentina, a country that now operates as our hub for the Southern Cone (including Chile, Paraguay, and Uruguay), while we are currently assessing the opportunity to open a marketing and sales office in Mexico, from where we could oversee the North LatAm area.

In Brazil, Biotronik is the market leader for products and solutions targeting cardiac rhythm management, vascular intervention, and electrophysiology. We are also able to offer coverage and a quality of service that are absolutely unrivalled in the country. As a matter of fact, we are the only company offering technical assistance across the entire territory of Brazil, which is the world's fifth largest country. These investments made to ensure that patients and physicians can rely on

qualified technicians – whether they are based in Recife, Manaus, Sao Paulo, Porto Alegre or any other regions of our vast country – truly contributes to strengthen the long-standing trust awarded to Biotronik by both the patients and the medical communities in Brazil.

As I said earlier, our fundamental objective is to ensure that we will continue exceeding the expectations of our partners in the next three, five, and ten years, and we plan to continue investing in the country. For example, we are currently evaluating the opportunity to establish a manufacturing footprint in Brazil, which would stand as a historical milestone for both our company and Brazil's healthcare ecosystem. So far, Biotronik holds manufacturing plants in Germany, Switzerland, and in the US, while we opened a new facility in Singapore just a few months ago. As a reminder, Biotronik also stands as one of the only medtech companies in the world that does not rely at all on manufacturing outsourcing and solely assumes all parts of this strategic process.

Two years into the job, what would you highlight as your key achievements in Brazil?

First, we comprehensively redefined our commercial approach and pricing strategy based on profitability and growth opportunities, especially for the customers in the private market. These efforts have already born fruit as the Brazilian affiliate now displays a very satisfactory profitability.

In the meantime, we do not want to limit our value-based efforts to Brazil's public sector. In parallel to the aforementioned integration of Home Monitoring® into the SUS, we recently managed to include our products into the guidelines of a leading HMO, by following a similar value-based approach than in the public sector. Moving forward, we want to continue expanding this pioneering access model in both the public and private sectors, for an increasing number of Biotronik's products and solutions.

In the grand scheme of things, we hold high ambitions for Brazil, especially as our country is finally exiting a two-year recession period. Building on the heightened growth prospects that this economic recovery could entail, we will launch new products in the upcoming months and expand our sales force accordingly.

Talking about product launches, one of the distinctive features of Biotronik is that we launch our latest products in all markets we operate in, regardless of the sales potential. This is extremely important for patients, as it means that products available are the same all around the world. If a patient is travelling abroad and – unfortunately – encounters a technical problem with his device, physicians and technicians in all countries will be familiar with this patients' device. Finally, we submit market approval dossiers almost simultaneously in all our markets – so the delay in terms of product access only depends on the pace at which regulators approve a new product.

Cardiovascular disease (CVD) has been the leading cause of mortality since the 1960s and still accounts for more than a third of all deaths in Brazil, with ischemic heart disease (31%) and cerebrovascular diseases (30%) being the leading CVD causes. How would you rate the level of investment of the Brazilian government in the CVD area and what are the rooms for improvement that you identify in order to improve the level of care available in the public sector?

From a medtech perspective, the level of investment in CVD is relatively satisfactory, although healthcare spending in general is always perfectible. After having been through intense price and value negotiations, all our pacemakers, stents, and defibrillators are fully reimbursed in Brazil's public system. In the meantime, we see that the Brazilian government has been continuously investing in prevention programs, which is absolutely crucial when it comes to CVD.

I believe that Brazilians should take pride on our public health system, especially given that it covers over 208 million inhabitants. In this regard, Brazil is the only country in the world with a population over 100 million inhabitants that has embraced universal healthcare coverage.

On the other hand, Brazil's SUS system is far from being perfect. Moving forward, we must strengthen collaboration across the entire ecosystem and ensure that all stakeholders – including the government, the industry, the private sector's payers, and patients' organizations – are provided with the opportunity to sit down at the same table and discuss crucial matters together. This endeavor should notably encompass more frequent reviews of the technologies and added value accessible through the SUS, as well as regularly updating our public system's guidelines to ensure they are aligned with Brazil's epidemiological and demographic transitions and the latest innovations developed by the industry.

In this regard, it makes no doubt that the public and private sectors have to further coordinating their efforts in critical matters such as prevention and reimbursement – or the healthcare situation in the country will soon become unbearable as our population keeps aging.

Overall, we hold significant rooms for improvement, but I believe Brazil is definitely moving to the right direction. The main bottlenecks are clearly identified, and we can concentrate our efforts on the most urgent matters. As a country, we already hold a sound healthcare basis on which we can build on and I personally have the tendency to see the glass half full rather than half empty.

This optimism truly embodies the Brazilian way to see things…

As Brazilians, we have to be resilient. I grew up at the time when Brazil experienced inflation of 2.000 percent per year, or 80 percent per month. Looking at the ups and downs that our country has experienced over the past decades, Brazilians of my generation were left with no choice but to become resilient and to learn how to navigate through the storms.

Where do you want to see Biotronik Brazil in the next five years?

We want to become a top five market within the global operations of the group. In the meantime, we want to further expanding patients' access and tirelessly increasing the speed to market for our new product launches. Finally, I want to ensure Biotronik continues investing in Brazil.

In this regard, we recently initiated our very first clinical trial in Brazil, while a new trial has already been approved by our company's HQ and should begin during the first quarter of 2018. In the grand schemes of things, I would like to see at least three new clinical trials being conducted in Brazil over the upcoming years. As mentioned earlier, we are also working on potential business plans to evaluate the opportunity to set up a manufacturing footprint in the country.

You mentioned that your decision to join the medtech field was notably driven by the desire to challenge yourself. What have been some of the key learning since the beginning of this exciting journey?

The first aspect relates to the enhancement of my understanding of the medical devices field as well as the subtleties of the business models used in this sector. In the meantime, a large share of my learning stems out from my ambition to implement new processes, which has required tackling the medtech ecosystem's resistance and – at the personal level – implied being resilient and patient.

In this regard, it is sometimes impossible to strictly replicate access models that have proven themselves being successful in the pharma industry; you then have to take a step back and identify which intermediary steps would allow you to successfully fulfill your vision.

Finally, running our first clinical trials in Brazil was also an extremely interesting experience, as most medtech companies are still not used to conduct such investments in Brazil.

What is your final message to our international readers?

Continue investing in Brazil! Our country has recently faced several challenges, but I deeply believe that the worst of the crisis is now behind us. Brazil and its economy are recovering, and it would be a terrible mistake for any multinational companies to reduce its investments to the country,

whether it relates to the pharmaceutical or the medtech industry.

From an executive standpoint, my message is that it is paramount to believe in what you've learnt throughout your career while remaining eager to further enrich your skills and expertise. In fast changing and innovative industries, the only way to stay relevant and successful is to continuously challenge yourself.

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