Interview: Mauro Loch – President & General Manager, Amgen Brazil

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Mauro Loch, general manager of Amgen Brazil, documents the eye-catching turnaround of the affiliate since the beginning of his tenure and provides insights into the company's unique positioning in Brazil, the outstanding performance of recently launched products, as well as his main priorities to further increase access to Amgen's life-changing treatments in the country.

You hold a diversified experience forged among both the pharmaceutical and medtech sectors, as you were notably overseeing the LatAm operations of the medtech company CR BARD prior to taking over the Brazilian affiliate of Amgen. After having spent more than eleven years in the medtech area, why did you decide to come back to the biopharmaceutical field?

I indeed operated outside the pharmaceutical field for more than a decade, as I wanted to strengthen my experience in the medtech area. However, I was ultimately missing the sophisticated planning strategies and the process excellence that characterize pharmaceutical companies' business models, while the medtech industry is particularly focus on capital expenditure (CAPEX) and financial indicators.

I then decided to move back to the pharmaceutical industry and – after having held general manager positions in the medtech field – my objective was to take the helm of a pharmaceutical company's affiliate in Brazil. I had the great honor to be invited by Amgen – the world's largest biotech company – to join the selection process for this position, which proves that moving from

the medtech to the pharmaceutical field (and vice versa) is truly possible.

How would you describe Amgen's position in the market when you came in 2015 and what would you highlight as your main achievements since you took over?

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Amgen has been present in Brazil since 2009 with the opening of a clinical research branch in the country, while our products were accessible through local distributors at that time. In 2011, the company decided to strengthen its Brazilian footprint thanks to the acquisition of the domestic, generics-focused company Bergamo. Despite this significant investment, our affiliate was still at the startup stage when I took over, and it was moreover facing difficulties at the strategic and financial levels – including both top and bottom line results.

In 2015, I decided, with my management team, to refine the long-term strategic plan of the affiliate. In order to add a fresh perspective to this crucial endeavor, I decided to hire one of the world's leading consultancies to help us design the evolution of our business over the next five years. This modus operandi – based on both internal and external inputs – was totally new to Amgen affiliates. After having conducted a thorough, four-month long assessment of our organization's strengths and market positioning and taken into account the evolving dynamics of the Brazilian market and our country's economy, we started implementing our new strategic vision – unequivocally called "AMGENERATION" – and follow our affiliate's new strategic plan, summarized by these three fundamental objectives: "to prosper, to lead, and to grow".

This investment has already paid off, as we have been consistently growing at a high double-digit annual growth rate since 2015, which actually allowed us doubling the size of our affiliate and becoming profitable. Furthermore, we managed to launch five new biopharmaceuticals in 2016 alone and substantially increased our market penetration in critical therapeutic areas. To accompany this strong momentum, we also reshaped our organization and fostered a true cultural change across the affiliate, which was made possible by our great successes in attracting new and talented employees to Amgen Brazil.

The phase I of this strategic plan encompasses 13 strategic initiatives and eleven of them have already been implemented and achieved. We are now moving to the phase II of the project, which will entail the development of five new strategic initiatives.

It may be surprising for our international readers to read that Amgen – one of the most innovative companies in the world – entered the Brazilian market through the acquisition of a generics company. What is the importance of this generics portfolio in your current activities?

Brazil indeed stands as one of the only two countries in the world – alongside Turkey – where Amgen holds a substantial presence in the generics business. Our current generics portfolio mainly

comprises three product segments: growth hormones, where we proudly stand as market leaders in the public sector, as well as botulin toxin and oncology generics. In 2016, our affiliate's sales were equally shared between our generics and biologics businesses, and this breakdown actually showcases a radical change in our affiliate's profile, as generics used to account for over 90 percent of our revenues in Brazil just a few years ago.

Although this generics business is not part of Amgen's long-term strategy in Brazil, we have however been continuously investing to improve the processes of our plant, which now truly stands as a world-class manufacturing facility. In this regard, Amgen will not divest this generics asset without holding a strong exit strategy, and our approach has been to continuously working on enhancing the value of this business in the meantime.

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Given Amgen's outstanding R&D pipeline and biologics portfolio, and the substantial resources invested in the development of this area at the local level, I expect biologics to further gaining in importance in the upcoming years and making up around 70 percent of our revenues in the mid term. In 2016, our biologics portfolio encompasses products for osteoporosis, cholesterol, cancer, leukemia, multiple myeloma (MM), and palliative care, and this part of our business has experienced a strong momentum thanks to the successful launches of strategic products.

Talking about the successful launches of strategic products, how have the recently introduced Repatha® (evolocumab) and Kyprolis® (carfilzomib) been received in Brazil?

Kyprolis® (carfilzomib) was launched in Brazil less than a year ago and it has been instantly adopted by the Brazilian physician community, while it proudly stands as the first innovative product targeting MM approved in Brazil in more than eleven years. Brazil has now become the third largest contributor to this product's global sales– after the US and Germany – marking the first time ever that the Brazilian affiliate integrates the company's top three.

With the launch of our PCSK9 inhibitor Repatha® in Brazil, Amgen moreover offers an important and innovative treatment option for patients who require a medication to lower 'bad' cholesterol (or low-density lipoprotein cholesterol (LDL-C)) levels after statins. In this regard, our approach is to provide post-statin options for patients who have undergone treatment but are still at high risk and did not have a cure. In people with plaque-related heart of blood vessel problems, our clinical data actually show that Repatha® lowered LDL-C an average of 71 percent when added to a statin.

In this context, Repatha® truly emerges as a first-in-class product to lower high level o cholesterol, and establishing onto the local market such an innovative, groundbreaking treatment approach always takes time. Furthermore, market dynamics in this therapeutic area are particularly unique, as high cholesterol typically does not cause any symptoms which would urge patients to tackle the disease – although it can provoke emergency events such as a heart attack or a stroke. Despite

this specificity and the access barriers we face in Brazil, Repatha®'s sales have been consistently increasing month after month and at a growth rate that is aligned with those seen at the global level.

Could you elaborate on the main access barriers faced in Brazil?

In Brazil, private health plans do not cover treatments for chronic diseases and they moreover essentially focus on inpatient care. Therefore, 100 percent of Repatha®'s sales so far come as out-of-pocket spending, as it is not accessible through Brazil's public health system either. In this context, one of the main priorities of our access teams at the moment is to closely work with private insurers to improve the coverage of this product in the private healthcare market. Fulfilling this objective will however require completing a true paradigm shift that would see private insurers' cost assessment approach evolving from a product- to a disease-centered model. As a company, we then strive to provide our partners with detailed insights into the economic burden of the disease, the average costs associated with emergency events, as well as the savings that could be made thanks to the clinical outcomes offered by Repatha®.

In the meantime, we are also partnering with federal authorities to make this product available in Brazil's public health system, which will however take time too. Nevertheless, the remarkable clinical outcomes displayed by our product have convinced us that it definitely stands as a reachable objective.

Overall, our affiliate's portfolio is targeting both the institutional and private markets, and our Brazilian sales are equally split between the two sectors. Despite the spending freeze recently decided by the Brazilian government and its negative impact on the budget of the Ministry of Health, I expect this sales breakdown to remain unchanged in the upcoming years. As a matter of fact, we hold in our current portfolio several life-changing products which we aim to make accessible in Brazil's public market, in addition to Repatha®. For example, we just launched in Brazil Blincyto® (blinatumomab) for the treatment of Relapsed Acute Lymphoblastic Leukemia for adult patient, a product which proudly stands as the best therapeutic option available in this indication. Although our osteoporosis, hematology, and oncology have their own spaces in the private market, we do not aim to become a private market focused company, and we will remain committed to and continue exploring both segments.

After having put Amgen's Brazilian affiliate on the right tracks for sustained growth, what does the future look like for Amgen Brazil?

Beside our aforementioned priorities in terms of access, we aim in the short term to broaden indications for our recently launched products. For example, we have just submitted a new indication for pediatric patients Blincyto®, which we expect to receive by the end of next year. In the mid-term, we pan to leverage Amgen's R&D pipeline and bring to Brazil new, innovative

biopharmaceutical products.

In the meantime, Amgen probably holds the most compelling biosimilar pipeline among all biopharma companies and we recently won US FDA nod for our biosimilar of bevacizumab. Looking at the seven molecules that we have at hand in this arena, Brazil undoubtedly stands as a priority market for the company and we plan to start launching our first biosimilars by 2019.

In the grand scheme of things, our affiliate’s growth in the upcoming years will come from increased market penetration in our current product areas, the upcoming approvals of new indications, as well as the future launch of innovative biologics and biosimilars. In this context, my objective is to continuously sharpening the effectiveness of our teams and continuously improving product launch readiness, while maximizing the access of our products in both the private and public markets. Finally, being successful in such a challenging and strategic market as Brazil always comes to down to the quality of the people working across the organization, and one of my strategic priorities moving forward will be to continue attracting and developing talent in our affiliate.

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