

Interview: Gaetano Crupi - President and General Manager, Bristol-Myers Squibb Brazil



"In Brazil, BMS displays a profile and a vision that is perfectly aligned with the global level."

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Gaetano Crupi, president and general manager of BMS in Brazil, leverages his long-standing experience at the head of prestigious pharmaceutical companies' affiliates to provide an insightful overview of the key success factors to consider in the Brazilian market. He also documents BMS' commitment to being a frontrunner in the medical, access, and commercial areas and his vision to tirelessly partner with the country's healthcare stakeholders and entrench BMS' leadership in the biopharmaceutical area.

Based on your long-standing experience honed heading MNC affiliates both in Brazil and abroad, how would you describe the importance of Brazil in the global strategy of multinational companies?

There is no doubt that Brazil stands as a 'must win' for all companies with international operations, and multinationals cannot afford to neglect this strategic country. The crucial importance of our country on the global map stems from several structural factors: first, size matters in our industry – and Brazil's 210 million inhabitants stand as a number that cannot be ignored. In the meantime, I believe that some external observers still do not fully realize that Brazil is no longer a *young* country, as Brazil's age structure is actually pretty similar to that of European countries.

Healthcare has always been one of the main priorities of the Brazilian people. Moreover, Brazilians are particularly inclined to spend money on taking care of themselves – both from a cosmetic and

healthcare perspective. This cultural aspect has been driving the continuous and eye-catching growth of Brazil's retail market while accelerating the development of this part of the value chain, including distributors and pharmacy chains.

From a public healthcare system perspective, healthcare has been a constitutional right since 1988, which – on paper – undoubtedly emerges as a great asset to build on, Brazil being the only country with a population over 100 million inhabitants that has embraced universal, government-backed healthcare. However, in reality, there is no way in which Brazil can fully deliver on this expectation when taking into account the sheer size of Brazil's population, the extreme difficulty of controlling public spending across the SUS [*Brazil's public health system – Ed.*] and the disruptive impact of the fast growing judicialization of health [*patients leveraging on their constitutional rights to sue the state and access treatments. According to the Ministry of Health, judicialization of health has generated a total cost of over USD 2 billion in 2016 for the state– Ed.*].

Despite those limitations in the public sector, Brazil emerges as a priority for both local and multinational companies, which therefore have to cope with our country's idiosyncrasies and must learn how to develop winning strategies in this complex market.

What are some of the country's key specificities that should draw the attention of multinational companies and require specific adaptation efforts from these companies' general managers?

[Featured_in]

Overall, Brazil is a country where multinational companies and their senior executives must pay attention to detail.

While Brazil holds one of the most complex tax systems in the world, there is furthermore no other country globally that applies such a high tax rate to pharmaceutical products. In this regard, we see that the amount of money received by the state through pharmaceutical products' taxes roughly corresponds to the resources invested by the Ministry of Health in providing healthcare access to the population through the public sector.

In the meantime, senior executives must always keep in mind that Brazil is a federal country comprising twenty-six states plus the district capital, which all display different specificities – including for tax and fiscal matters. While these discrepancies might emerge as an additional source of headaches for GMs – especially when it comes to moving products across this huge country – they also entail great opportunities as fiscal incentives and tax rates significantly vary

from one state to another. In this regard, we saw that several acquisitions conducted by multinational companies during the boom of the BRICS were based on top-line figures that did not truly reflect the true size and the strength of these targets, while the complexity of Brazil's fiscal system was at times overlooked. In this regard, I believe that the situation has been improving and multinational companies have learnt from their mistakes.

With almost 50 million Brazilians having access to private health plans, Brazil holds the world's second largest private healthcare market by population – second only to the US – but we still lag behind the latter in terms of label enforcement. Looking at BMS' PD-1 immune checkpoint inhibitor nivolumab which has already been approved in five indications in Brazil, our country's HMOs do not automatically add this ground-breaking product into their guidelines, although it has been approved by ANVISA and received its price from CMED. In contrast to the US, we therefore have to negotiate on an individual basis with HMOs and showcase this product's benefits to ensure they really allow physicians to prescribe nivolumab and reimburse it to their beneficiaries. In the meantime, Brazil is also characterized by one of the slowest market uptakes for innovative products in the world. Combined with another BMS oncology product, ipilimumab, uptake in Brazil still hovers around 40 percent in this product class, while it reaches over 75 percent in the US, Canada or leading European markets.

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On the SUS side, the fact that Brazil holds one of the largest public health systems in the world [*by population covered – Ed.*] entails that the value and volume of centralized tenders are absolutely mind blowing. As a matter of fact, the Brazilian Ministry of Health frequently stands as the world's largest single buyer of products included in the SUS. In areas that have been prioritized by the government, such as HIV or HCV, Brazil boasts takeover rates of almost 100 percent. After we launched BMS' leading HCV treatment daclatasvir (to be used in combination with sofosbuvir), the government swiftly showed its interest to shift the country's treatment paradigm in this area and move – almost overnight – from the decade-old interferon to the latest, most innovative HCV treatment that can cure the disease within twelve weeks. In this regard, BMS's HCV treatment was the first product of its kind to be approved in Brazil and we were the first company to enter into a strategic agreement with the government in this product category. The same applies to HIV, a therapeutic area where Brazil has truly developed one of the best public health programs in the world. As a matter of fact, the public sector makes up 100 percent of the sales of BMS' flagship HIV product, atazanavir, which means that our country's entire population is able to access the exact same level of care in this field.

Unfortunately, investment in the public sector is not equal in all therapeutic areas, and I regret that oncology has been particularly neglected over the past decades – for almost all cancer categories.

New general elections will be held in 2018. Although we still face a very unpredictable scenario at the moment, what are your expectations regarding the upcoming government when it comes to improving the country's healthcare?

In December 2016 a constitutional change was enacted, capping public spending increases to inflation rates for the next 20 years, including for healthcare and education budgets. However, when looking at the details of this constitutional change, we see that education and healthcare budgets will actually decrease in the coming years. Although ensuring that the state does not go over budget is praiseworthy, it is particularly regrettable that both healthcare and education budgets will be so negatively impacted – especially given the crucial needs of our country in these two critical fields.

In this context, I do not expect that the level of access available in the public sector will positively change overnight. On the contrary, I foresee that cost pressures will further increase and that the upcoming government will more and more leverage on the huge purchasing and bargaining power of centralized tenders to drive prices down.

As a result, this complex context forces us to be extremely creative as pharmaceutical companies, while my experience in working with the Brazilian government has taught me that it is absolutely crucial to maintain a continuous communication with public sector stakeholders. Pharmaceutical companies and the government share a common objective: improving and extending the lives of Brazilian patients – and this fact should stand as the basis on which we can build to improve patients' access to innovation in the country.

Could you provide us with a few examples that illustrate BMS' creativeness in terms of access and the company's commitment to Brazil?

For example, BMS decided to enter into a Productive Development Partnership (PDP) with the Brazilian government, which will ensure Brazil has the capacity to become self-sufficient in the production of the HIV product atazanavir. What sets this PDP apart is its twofold technology transfer: on one part, the mixed private-public company Nortec has already received the technology transfer for the production of the raw material, while on the other hand we are rapidly advancing on the transfer of the finished product' technology to the public laboratory Farmanguinhos.

Furthermore, I mentioned earlier that the significance of Brazil's purchasing volume was a key parameter to watch, and – in the case of atazanavir – we were able to offer to the government discounts of over 50 percent.

In the meantime, we truly want to engage with the entire healthcare value chain and do not content ourselves with exclusively steering our efforts toward governmental officials. For example, BMS recently co-organized a hackathon called “Innovation Journey 2017 – #togetherforthecause” with the oncology center of the Israelite Hospital Albert Einstein [*which is widely considered one of the leading healthcare centers in Brazil and in the continent – Ed*], Microsoft and Instituto Lado a Lado (*patient association*). The priority on top of this three day meeting, which had the participation of volunteers from all the companies, was to collectively work on designing innovative access solutions or projects that contributes to leverage quality of life of cancer patients.

Over the past decade, BMS has operated a radical and successful transformation of its corporate vision and structure, with the ambition to become a true biopharmaceutical company focused on unmet medical needs. Where does BMS Brazil stand in this regard?

In Brazil, BMS displays a profile and a vision that is perfectly aligned with the global level. The most exciting challenge that incited me to join BMS in 2012 was the company's utmost commitment to turn cancer into a chronic disease – or even in some cases to cure it. At the global level, BMS has indeed been a pioneer in the implementation of the biopharmaceutical model, while back in 2007 the company still had a significant OTC portfolio (which in Brazil was sold to RB in 2012) and diabetes business (that was acquired by AstraZeneca). In Brazil, we moreover decided to leave our anticoagulant apixaban in the hands of our global partner Pfizer, as the size and complexity of our country's primary care network requires huge investments to successfully promote this leading cardiovascular product.

Looking at our portfolio in Brazil, we are extremely strong in infectious diseases, including HIV, HCV, and HBV, while we are also rapidly strengthening our leading position in immuno-science, as BMS' abatacept proudly strands as the only treatment for active Rheumatoid Arthritis (RA) that is not a TNF antagonist and it is moreover available in both intravenous and intramuscular formulations. Finally, in the oncology area, BMS' dasatinib has become the preferred option of Brazilian physicians for LMC and it perfectly complements our eye-catching portfolio in this field, alongside our immuno-oncology product nivolumab and ipilimumab.

Overall, BMS stands as a true biotech company in Brazil. This very clear focus also means that we hold a less significant footprint than innovative companies that have maintained a broader

strategy, and our priority is to gather together the most talented and committed professionals in order to navigate a very complex environment and provide patients with access to some of world's most innovative products. In this regard, I want to highlight that BMS Brazil approaches the Brazilian market in an integrated, threefold manner that equally encompass medical, access, and commercial perspectives. These three areas have their own boundaries and responsibilities, however, our affiliate's objective is to present a united front when interacting with our customers and partners.

BMS Brazil is also a millennial company with a very young profile, both in terms of age and mindset. In this regard, I believe that BMS Brazil has to offer the opportunities and the work environment that millennials are looking for, and BMS Brazil has been a pioneer in entrenching a transformative market approach across our affiliate. For example, when I am interviewing a physician for a career opportunity in the company, my first question is always "Are you willing to engage in the fight to cure cancer?" This is absolutely crucial to BMS Brazil: if one applicant is not ready to engage in a cause that is bigger than selling pharmaceutical products (i.e. the old pharmaceutical model), then BMS is not the right company for him or her. Discovering and producing a ground breaking product such as our immunotherapy drugs only stands as one part of the equation and I want to ensure that our people fully understand that establishing this new standard of care in Brazil requires changing the entire value chain, from patients diagnosis to physicians' prescription habits, without forgetting clinical protocols and reimbursement models. We must improve the patient journey's in its totality.

In this critical endeavor, we are pleased to see that our efforts are paying off, while BMS Brazil is widely perceived by government, prescribers, and HMOs and other crucial stakeholders as a company that has changed its modus operandi and fully embarked on a transformative market approach in Brazil.

What are your main priorities moving forward?

We are only scratching the surface with regards to the numbers of patients that benefit from our innovation. In Brazil, having a deep impact on the healthcare ecosystem implies having products accessible in the SUS. Since my appointment as the GM of BMS Brazil, I have closely engaged the government on access related matters. Although this commitment implied working with four different Ministers of Health within the past five years, we will never give up. What keeps me up at night is that Brazilians diagnosed with cancer face totally different survival prognoses depending on whether they are able to access the private health market or not. My fundamental mission is to ensure more people can move from one side of the treatment paradigm to the other - and it makes

no doubt that we must redouble our efforts in this regard. As a high technology, science based company, we also have a responsibility in helping the government designing the most precise protocols possible and identifying for which patients our products will be efficient, in a broader attempt to eliminate waste and rationalize healthcare investments.

From the private market perspective, we want to ensure our products are used exactly as is indicated on their labels and all eligible patients can actually access these treatments. This aspect is evermore crucial as we are in the process of receiving many new indications in Brazil over the coming years, while BMS holds one of the most exciting R&D pipelines in the industry. As a matter of fact, we are already working on the second generation of immuno-oncology products.

Finally, my responsibility is also to prepare BMS Brazil for the future, and I consider that a key success factor moving forward will be the strength of our inclusion and diversity policy. If you were at ASCO in 2015 [*when Opdivo was released - Ed.*], you would have been overwhelmed by the results announced. Our responsibility is to ensure that these scientific outcomes are conveyed across the world's sixth largest country, which implies having the best medical, commercial, and access professionals regardless of their age, gender, and race. Just to give you an example, over 54 percent of the Brazilian population is African descent, and this diversity is not yet represented at the corporate level in the country; far from it. At BMS Brazil, being a frontrunner in terms of inclusion and diversity is one of our first and foremost priorities, and we are particularly glad that BMS Brazil has been recognized for several years as both a great place to work and a great place to work for women.

What is your final message to our international readership?

Brazil is a Top Ten market in almost all sectors; hence all multinational companies must have a strong presence in the country. However, Brazil also emerges as a country where corporate social responsibility matters and should not be neglected. On the healthcare side, we have 160 million people that are excluded from the private healthcare market, and we cannot content ourselves with concentrating our efforts on the 50 million Brazilians that have the financial means to access the latest innovations and most pioneering products. Our objective, as a country and as a company, is to ensure that in the future our entire population is able to get the same level of healthcare access.

From an executive perspective, Brazil is a very fun country to work in and moreover offer bountiful opportunities, but one must be prepared to cope with our country's unpredictability. However, if you hold the right strategy, a positive spirit and committed teams, you can truly unlock Brazil's eye-catching potential.

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