

Interview: Nelson Mussolini - Executive President, Sindusfarma, Brazil



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Nelson Mussolini, executive president of the syndicate of the pharmaceutical industry in the State of Sao Paulo (Sindusfarma), which represents around 95 percent of all pharmaceutical marketing in the country and gathers together over 312 associate members overall, documents the exceptional growth of the pharmaceutical industry in Brazil despite the recent political and economic turmoil as well as the latest trends shaping the country's pharmaceutical sector. He also discusses some critical topics for the development of the healthcare and pharmaceutical companies in Brazil, such as incremental innovation, Brazil's pricing approach, and the evolving relationship between the public and private health systems.

Over the past three years, Brazil has made global headlines because of the political turmoil and the triggering of an economic crisis that was unprecedented in the country's modern history. What has been the impact of this difficult context on the pharmaceutical industry?

Our country has indeed been through particularly agitated times over the past few years, but the pharmaceutical industry in Brazil has always accommodated such crises. In this regard, pharmaceutical companies have been continuously developing themselves despite political and economic turmoil, while Brazil's economy is set to eventually exit this two-year recession period in 2017. As a matter of fact, Brazil's pharmaceutical market has been growing at a double digit growth rate over the past decade, and we expect that it will further grow by nine percent in 2017,

which is truly remarkable given our country's economy has been stagnating for the past four years.

The main driver behind this continuous growth undoubtedly relates to Brazil's rapidly aging population *[in 2016, 14 percent of Brazil's 207 million people population were over 60 years old and this share is expected to twofold within the next decade – Ed.]*, and growing healthcare needs have been propelling the development of the pharmaceutical sector. In the meantime, healthcare stands as a constitutional right in Brazil, and this specificity has kept our market fully active even during the economic crisis.

However, one should not overlook the impact of the economic difficulties either – especially with regards to the performance of the private healthcare market. In Brazil, private health plans are traditionally financed by the employers, and the recent economic crisis has rendered the latter more reluctant to provide their employees with a comprehensive coverage, while Brazil's jobless rate more than doubled during the recession from a record low of 6.2 percent in 2013. Looking at the second quarter of 2017, pharmaceutical sales in Brazil fell by almost five percent in comparison to last year. Nevertheless, a strong recovery has already started to materialize in August, which seems to indicate the pharmaceutical industry only went through a three-month crisis in Brazil. As a matter of fact, we see that distributors have already leveled up their stocks and, without a doubt, the pharmaceutical industry will continue to grow – probably at a high single-digit growth rate in 2017, but we do not believe double digit growth will resume in 2018.

In this interesting context where the pharmaceutical sector has distinguished itself by being the only industry that has weathered the recent crisis, what are Sindusfarma's main priorities?

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First and foremost, Sindusfarma has a clear focus on education and we aim to prepare the pharmaceutical sector workers for the new challenges of the industry. Another focus point that is very clear to us is to protect the interests of the pharmaceutical industry, regardless of the capital origin. At the end of the day, what really matters to Sindusfarma is whether investments will enable the set up of a local manufacturing capacity, create new job opportunities, generate tax revenues for the state and, most importantly, contribute to enhance the knowledge and expertise across the Brazilian ecosystem.

In this regard, Brazil has been steadily but rather slowly improving its attractiveness and capacities with regards to basic research and early stage clinical trials. On the other hand, we do see an interesting number of phase III trials being conducted in Brazil, but – given the huge potential of

our country in this regard – we consider that this aspect is still underdeveloped, mainly because of both regulatory and mental barriers. For example, in Brazil, the idea that a close collaboration between academia and the industry could be beneficial to both sides has been gaining traction over the past years, but we still hold substantial rooms for improvement.

In the meantime, Sindusfarma is advocating toward the government, universities and all stakeholders for a greater recognition of the economic significance of the pharmaceutical sector and its crucial role in fostering the development of our country. We also strive to convey the idea across the Brazilian ecosystem that operating in the healthcare field and being a profitable business does not stand as antagonistic concepts.

Finally, Brazil is still highly reliable on API imports, as close to 95 percent of the raw materials used in the country come from abroad. Such dependence can lead to dramatic situations, and Brazil was for example significantly affected by the global shortage of benzyl penicillin that occurred in 2016. As we do not hold any local production of this API, our companies were not able to supply highly needed finished products, which actually triggered an outbreak of related diseases.

But wasn't this situation also related to a pricing issue?

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The first trigger of this penicillin crisis was the aforementioned global shortage of the API. However, as final products' prices are regulated by CMED [*Brazil's pricing agencies – Ed*], we could not afford to purchase these foreign products any longer, as the global shortage made APIs prices to significantly increase – and we were left with no choice but to exceptionally change pricing regulations to tackle this issue. In this regard, Sindusfarma plays a crucial in updating Brazil's pricing policies. All countries in the world have developed their own price-setting model – especially for institutional sales – and we strive to modernize Brazil's model and address some of persisting, structural problems.

What do you identify as structural problems affecting Brazil' price-setting model?

Our current model does not reward *incremental* innovation. Let me give you a concrete example: if an existing treatment course requires taking 100mg of a given product, and a company manages to develop a dosage form that allows treating the disease with only 50mg of the same product, our price setting model stipulates that the cost of the new product should be half of that of the 100mg product. This model clearly overlooks the benefits that incremental innovation brings to the patient – in terms of side effects notably – as well as its heightened cost-effectiveness profile and therefore do

not incentivize companies to pursue their efforts in this regard.

In November 2016, you were appointed on the Advisory Board of ANVISA. What are some of the main topics you want to advocate for as part of this new responsibility?

My role as an advisory member for ANVISA is to bridge the gap between our country's regulator and the industry, bring visibility to the difficulties that our companies encounter and seek to develop joint solutions, which will never compromise the quality and the safety of the pharmaceutical products reaching the market. As part of this appointment on ANVISA board, my representative role actually goes beyond the pharmaceutical industry as I operate on behalf of the National Industry Confederation (CNI), and therefore also represents the interests of other industries that fall within ANVISA regulations, such as the food and beverage or agrochemical industries.

As part of our priorities, we consider that ANVISA still needs to reduce market approval timelines and in the meantime increase post-registration and post-marketing inspections. In the US, the FDA often performs pharmacy inspections, for example.

Furthermore, one should not forget that ANVISA's scope is actually very wide – much wider than that of the US FDA. Besides food and beverage, chemicals, medicines and other healthcare products, ANVISA also looks after these products' imports and exports and conduct ports and airports inspections. Such a wide scope of responsibilities somehow creates hindrances in the working of the agency and negatively impacts resources allocation.

What is your assessment of the government's support toward the development of the pharmaceutical industry in the country?

Minister of Health Ricardo Barros and Minister of Industry, Foreign Trade and Services Marco Pereira have already proven being greatly supportive to the development of the pharmaceutical industry in Brazil. Both Ministers acknowledge the eye-catching development opportunity that the private sector holds in the country as well as the necessity to implement incentives that will allow to fully unlocking this untapped potential.

Although tax incentives are definitely important, our approach must go beyond this limited aspect: we need to create and implement the most favorable conditions for economic development, which will ensure that the state does not have to directly subsidize our industry's maturation – whether it relates to R&D, manufacturing, or exports.

This aspect is evermore crucial for the R&D side. The state should not directly finance pharmaceutical R&D, because it does not work – no country in the world does it, apart from Cuba. In this regard, I do not support the emphasis put by the government on national public laboratories, although our members and Sindusfarma itself work with some of them. Instead of the broad scope of focus that they follow at the moment, I believe that these public labs should concentrate their resources on therapeutic and product areas that have been neglected by the industry, such as penicillin.

Although the state should not directly subsidize pharmaceutical R&D, what could be its role in fostering basic and medical research in the country and bolstering collaboration between academia, the industry, and the public sector?

Unfortunately, this holistic approach is not yet part of the Brazilian culture. Academia in Brazil remains essentially committed to fundamental research and to producing scientific literature, and we deeply need to enhance our country's capacity in terms of translational research. Brazil's stakeholders need to understand that R&D collaboration is a great way to access funding, while – to the contrary of the US – Brazil still follows the outdated model where most of universities' budget comes from public sources. In the meantime, the government has yet to come with stronger policies that would render cross-sector, R&D project easier and more attractive to establish – without integrally founding these projects either.

Nevertheless, the fact that we can today discuss R&D investments in Brazil also showcases the great pace at which our country has been catching up over the past twenty years. Brazil's patent legislation was created less than two decades ago; at that time, no one really believed that Brazil would ever have a effective and recognized IP framework as we do now. The same applies to ANVISA and to the Generic Drug Law, which were both set up in 1999 – less than twenty years ago. Brazil has made huge progresses over the past two decades and all stakeholders across the Brazilian pharmaceutical ecosystem are committed to keep up this pace of development.

In this ongoing, ascending trajectory, what should be the strategic next step to be targeted by the country's pharmaceutical industry?

I believe that Brazil will soon get to the point where the critical importance of incremental research and innovation will be fully acknowledged. To reach this objective, we must create world-class regulations for clinical data protection – as they already exist in the US or in Europe. In the meantime, new product formulations must be entitled to patent protection for a certain period of time – a regulatory update that is strongly protected by both local and international companies.

Looking forward, I believe that ANVISA will be focused on strengthening this area over the next five years, while Brazilian companies will continue to rapidly increase their R&D investments.

Brazil's Sistema Único de Saúde (SUS) proudly stands the only universal health system in the world covering a population of over 100 million inhabitants. The recent economic crisis and limited budget availability have however led the government to take a stance on public spending, which will imply in the mid-term to refine the relationship between the country's public and private sectors. What is your take on this fundamental situation?

This is a very interesting subject. Our 1988 Constitution guarantees the equality, universality and integrality of healthcare access to our entire population, but – on the other hand – Brazil still stands as a developing country that does not hold the financial resources to guarantee this constitutional right. In this regard, I deeply believe that the SUS should concentrate its resources on providing basic, critical treatments to Brazil's 207 million citizens, while the private system would alleviate part of the overall pressure by taking care of more sophisticated healthcare needs.

There is room in our legislation for the public health sector to be integrated to the private system and vice-versa, but some policy makers strongly defend the idea that SUS should remain entirely state-funded. This drastic approach will not favor the emergence of a sounder relationship between the private and public sectors – although reaching this equilibrium stands as an indisputable necessity moving forward. In this regard, I believe that the private system will gain in importance in the upcoming years and we will see the implementation of a co-payment system, just like it happens in some European countries like Italy and Spain. Co-payment is a good way to regulate the system and avoid the exploitation of the system by the user: once the individual is helping with the payment of treatments, misuses tend to be tremendously reduced.

What would be your final message to our international readers?

I am utterly convinced that Brazil's pharmaceutical and healthcare sectors will continue to grow in the upcoming years. Brazil's population is rapidly aging and our country's 207 million citizens display soaring healthcare needs. In this regard, Brazil undoubtedly stands as an eye-catching market opportunity, being one of the few fast-growing markets among the global top 10.

Looking forward, I consider that the future growth of our country's pharmaceutical industry will largely depend on Brazil's capacity to further attracting foreign investments. In the meantime, importing pharmaceutical products to Brazil is becoming less and less attractive from a cost perspective, especially given our country's huge local needs make it particularly interesting to

localize product manufacturing.

Spanning the global economic landscape, Brazil emerges as a country of great interest for international investors. Despite political turmoil, our economy has proven being relatively stable and exceptionally resilient. In this regard, I do not think any other countries in the world would have managed to keep their pharmaceutical market growing at a sustained pace through the two-year economic crisis that we just experienced. This specificity truly showcases the strength of our country's pharmaceutical sector. Finally, Brazil has been able to gain the trust of international companies and investors when it comes to IP protection, and we do offer the same guarantees and rights as any other developed countries in the world. In the meantime, our regulatory framework is perfectly aligned with those in force in the US and in Europe, which clearly eases business development for foreign companies.

Overall, all the conditions have been met to allow Brazil becoming the third or fourth largest pharmaceutical market in the world. I am confident that this will happen one day, and those companies that will have been able to build strong operations and a long-standing presence in Brazil will indisputably reap the rewards of their commitments.

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