

Interview: Norberto Prestes - Director of ABIQUIFI, Brazil



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Norberto Prestes, director of the Brazilian Pharmaceutical Manufacturers Association (ABIQUIFI), provides insights into the main dynamics that have been shaping Brazil's pharmaceutical and API sectors over the past few years, while highlighting his main priorities to further strengthen the country's pharma industry both inside and outside Brazil.

What would you highlight as the main dynamics that have been shaping the domestic industry over the past few years?

First, we saw that fierce international competition combined with the government's limited budget availability for healthcare expenses have prompted local producers to further improve their productivity. In this regard, ABIQUIFI was the first sponsor of the Pharmaceutical Institute of Operational Governance (IFGO), a private initiative that helps pharmaceutical manufacturers to measure and compare (on an anonymous basis) their effectiveness gains according to 24 strategic KPIs. Overall, we also noticed that many domestic companies invested significant resources to upgrade their production capacities and equip themselves with the latest manufacturing technologies, leading international observers to highlight that Brazilian manufacturers are now as advanced as their European counterparts from a technology standpoint. Over the past six months, the Brazilian government has moreover substantially relaxed labor laws, which greatly contributed to improve the cost-effectiveness profile of local companies and should incite them to further increase their workforce and conduct new investments.

On the regulatory side, ANVISA officially became in November 2016 a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), alongside the US FDA, the EU EMA, Japan's PMDA, Swissmedic, and Health Canada. ANVISA is now entitled to appoint experts in ICH working groups and jointly develop ICH guidelines with its prestigious, international counterparts. We now expect this ICH membership to nurture the continuous harmonization of ANVISA's processes with the best international standards, which will ultimately benefit the Brazilian population by providing our patients with a greater access to new pharmaceutical products in a timely manner. Furthermore, ANVISA's membership to ICH has undoubtedly strengthened its international reputation, which will in turn broaden the export prospects of Brazilian manufacturers.

With regards to our country's international reputation, another important aspect to mention relates to Brazil's remarkable expertise in development and production of generics drugs. The Brazilian pharmaceutical industry has now reached a level of maturity and savoir-faire that can benefit many high-potential developing countries, in Africa for example – a region that so far does not stand as a priority in Big Pharma companies' strategies.

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In the meantime, the industry's interest around natural products has been rapidly picking up over the past few years, as pharmaceutical companies look for new development models to overcome the innovation bottlenecks they face at the early drug discovery stage. In this regard, Brazil's unrivalled biodiversity can truly emerge as an untapped asset for our country's pharmaceutical and pharmaceutical industries, while regulatory updates that aim to ease research projects leveraging Brazil's biodiversity were recently implemented by the country's authorities.

Finally, Brazil, as the world's fifth most populous country, undoubtedly holds the potential to establish itself as one of the leading markets in the world for clinical trial investments. Although regulatory updates are still required to further incentivize foreign pharmaceutical companies to increase their R&D spending in the country, I expect Brazil to rapidly catch up in the upcoming years.

As you just mentioned the recent efforts of Brazilian companies to increase their productivity, what should be the next steps to target in order to further improve Brazil's attractiveness in terms of manufacturing?

One of the key areas to tackle undoubtedly relates to the comparatively higher tax burden weighing on local producers' shoulders. For example, in Mexico, the production of pharmaceutical

products aimed to the domestic market is tax free, while – on the other hand – Brazil displays one of the highest tax rates among the world's top 20 countries involved in pharmaceutical manufacturing.

In the past, Brazil's customs laws were also particularly constraining, which prompted several multinational companies to move their production capacities to countries boasting more welcoming customs regulations. We see that the Brazilian government has released several regulatory updates specifically targeting this problem, which is extremely positive; however, further easing the imports and exports of raw materials and pharmaceutical products should still be considered as a priority.

ABIQUIFI represents Brazilian producers of APIs, excipients and other pharmaceutical and healthcare-related raw materials. What are your strategic priorities to propel the development of the association's members?

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Looking at the pharma chemical side of the value chain, local producers only make up five percent of the Brazilian market, as 95 percent of raw materials used in the country is imported – mostly from China and India. In the meantime, it is particularly risky to let the vast majority of our country's pharmaceutical production rely on foreign raw materials, especially when these products are necessary to manufacture life-changing treatments for chronic diseases, such as diabetes, HIV/AIDS, or cardiovascular diseases.

As ABIQUIFI, we are now working closely with the government and regulatory authorities to change the country's paradigm in this regard and – for example – provide finished products using locally manufactured raw materials with a priority access to the Brazilian market. Nevertheless, this still stands as a challenging endeavor, as pharmaceuticals manufacturers implanted in Brazil, be they multinational or domestic companies, are opposed to the implementation of any regulatory changes that would favor local APIs. They argue that domestic raw materials producers would need too much time to set up the heightened manufacturing capacity needed (which, according to them, would disrupt medicine delivery) and claim that new norms should not prevent them from importing very cheap raw materials from China or India, in order to guarantee finished products' low prices.

In parallel, we strive to operate at a high political level, with the objective to establish the pharma chemical industry on top of the government's agenda when forging new bilateral trade relationships with foreign countries.

In the meantime, local API producers will continue to tirelessly increase their innovation-oriented efforts and further broadening the product portfolio offered by our domestic industry, with a focus on complex, difficult-to-make APIs. In terms of new development options, domestic producers' strategy could also encompass the manufacturing of APIs for new products, as Brazil undoubtedly has the technical and scientific expertise to fulfill this objective.

What is the positioning of Brazilian raw materials vis-à-vis Indian and Chinese manufacturers, which have been tremendously scaling up their production capacities in order to offer particularly affordable products?

Looking at the 42 warning letters sent by the FDA's office of Manufacturing Quality in 2016, India-based facilities were issued nine and Chinese companies received 14. On the other hand, we see that all Brazilian API manufacturers have been officially GMP certified by the EMA since 2015, while Brazilian companies have to comply with the requirements of ANVISA – one of the most advanced regulatory authorities in the world.

Furthermore, Brazilian companies follow labor laws and quality standards that are absolutely aligned with those of the most advanced countries, which has incited North American, Japanese, and European companies to increasingly integrate Brazilian APIs within their manufacturing strategies. As a matter of fact, by June 2017, Brazilian exports of pharmaceutical chemicals and excipients have increased 15.7 percent year-on-year, and we see that this sustained growth has been mostly driven by a soaring demand coming from mature pharmaceutical markets.

In parallel to your responsibilities at ABIQUIFI, you also operate as the international manager of Brazilian Pharma Solutions (BPS), an export-oriented platform jointly created by APEX, Brazil's foreign trade and investment agency, and ABIQUIFI. Could you elaborate on the main missions of this organization?

ABIQUIFI indeed stands as the coordinating organization of this ambitious program covering the entire pharma chemical and pharmaceutical value chain, from raw materials, excipients, to pharmaceutical and biopharmaceutical products for human and animal health, while BPS is moreover supported by all industry associations operating in the industry. In this regard, all these associations' members are free to join and benefit from BPS' initiatives.

As part of our main objectives, we first and foremost help domestic pharmaceutical companies propel their internationalization strategies by attending world-class industry events such as the BIO International Convention or CPhI Worldwide, where they can promote their remarkable capacities, find new customers and develop cross-border technology transfers. In the meantime, we also

provide our members with business and market intelligence and conduct prospecting activities in various countries on their behalf.

Finally, we also hold a more inward-looking mission, as we strive to convince international manufacturers to maintain and/or increase their production footprint in Brazil. As you know, Brazil proudly stands as the largest market in Latin America, the second pharma emerging country after China, and the world's sixth most important pharmaceutical market. Given the sheer size of our market and our strategic geographical location, international pharmaceutical are truly reluctant to divest and relocate their Brazilian manufacturing facilities. Nevertheless, Brazil's market attractiveness should not lead us to overlook the regulatory and manufacturing hurdles that these manufacturers might still face when operating in Brazil. In this regard, we are working with some of these companies to meticulously identify the bottlenecks and regulatory barriers they face and how we could steadily solve them.

What will be your final message to our international readers?

I do not want to make sweeping, broad promises; as I believe that our country above all needs strategic plans to further propel its development. Nevertheless, my assessment is that Brazil's pharmaceutical industry, whether it relates to APIs, new drug discovery, clinical trials, emerging biotech companies or ambitious domestic powerhouses, has been evolving to the right direction for many years already.

In this regard, our industry could truly inspire and drive other sectors of the country's economy, while, Brazil's pharmaceutical industry, by its proven capacity to continuously improve and thrive despite political and economic turmoil, has clearly established itself as a high-tech sector of reference in our country.

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