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What matters most, both for Brazil and for international partners, is local production, manufacturing and innovating within the country.

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Brazil's pharmaceutical sector is undergoing a quiet but significant transformation. Once dominated by multinationals and focused largely on generics, a group of leading domestic players is now charting a different course, towards innovation, manufacturing sovereignty, and strategic influence. Speaking on behalf of Grupo FarmaBrasil, a coalition of the country's top national companies, Executive President Reginaldo Braga Arcuri offers a compelling perspective on how policy alignment and industrial strategy are reshaping the landscape.

How does Grupo FarmaBrasil position itself within Brazil's complex pharmaceutical ecosystem, and what distinguishes its role from other industry associations?

In Brazil, there are around seven or eight entities representing the pharmaceutical sector. Among the most prominent is Sindusfarma, a trade association that brings together both national and multinational companies of all sizes. It operates much like a traditional union, focusing on labour negotiations, wage structures, and sectoral agreements.

Interfarma, by contrast, represents only multinational companies and primarily advocates for their interests in innovation, regulation, and intellectual property.

Grupo FarmaBrasil occupies a distinct position. We represent a group of 12 leading national pharmaceutical companies that are not only among the largest in the country, but also among the most committed to investing in innovation. The group was established 14 years ago by companies that were, at the time, and continue to be market leaders in generic medicines by volume and revenue. Even then, they had already set their sights on moving beyond generics toward the development of innovative therapies.

Today, that transition is well underway. Companies like Bionovis and Libbs, for example, are already producing monoclonal antibodies, marking a clear evolution in the technological capacity of Brazil's national industry.

What is driving the shift toward innovation among domestic pharmaceutical companies in Brazil, and how do you respond to perceptions that this trend reflects a nationalistic or protectionist agenda?

Just like in many other countries, Brazil did not allow patents on medicines until the early 1980s, when they were still considered a matter of national security. This policy was a cornerstone of the military dictatorship that lasted until 1985. As the country transitioned toward democracy and aligned with global trade frameworks – such as the Uruguay Round and the creation of the WTO – it became necessary to adopt agreements like TRIPS. Brazil subsequently enacted its industrial property law in 1996, established its regulatory agency ANVISA, and implemented a generic medicines framework in 1999.

This led to a fundamental shift in economic logic. Multinational companies, which had long maintained local operations due to production requirements, began to scale back. A series of fiscal crises and currency instability in the 80's and 90's made Brazil less attractive for innovation-driven investment. R&D efforts increasingly moved abroad to hubs like Boston, France, the UK, or Switzerland.

This shift opened space for domestic players to step in. National companies began producing generics, supported by ANVISA's increasingly rigorous quality standards. As generics gradually displaced branded products, it was the national firms that invested in capacity and grew stronger. The outcome was not driven by protectionism but by state decisions that allowed market forces to reward local investment and adaptability.

In 2010, Brazil had virtually no footprint in biotech. Today, two companies are producing seven or eight monoclonal antibody products. This progress was made possible by a coordinated alignment between public policy and the investment capacity of domestic industry.

Brazil is also unusual in having a public, universal, and free healthcare system that serves over 200 million people, a model inspired in part by the British NHS. While not without challenges such as underfunding and inefficiencies, the system does function. And with Brazil undergoing a demographic transition, marked by a shrinking base and an ageing population, the burden of chronic and complex diseases is increasing rapidly. These conditions, including cancer, rheumatoid arthritis, psoriasis, and pulmonary diseases, are primarily treated using monoclonal antibodies and high-potency synthetic drugs, most of which are still imported.

To address this, the Ministry of Health launched a programme aimed at leveraging the purchasing power of the public system (SUS) to drive local production.

How does Brazil’s public-private tech transfer model for high-cost therapies operate, and what outcomes has it delivered so far?

The Ministry of Health identifies high-cost therapies, such as adalimumab or rituximab, that are already procured for the SUS. It then selects a public laboratory and partners it with a private Brazilian company, typically of national capital, to form a development alliance.

The private partner is responsible for securing the technology transfer, initiating industrial-scale production, and ultimately transferring the know-how to the public lab. While the public facility may not manufacture the product in full, due to the scale of investment required, it retains control over the process and the capacity to utilise the technology. This model is effective because the Ministry guarantees a pre-agreed purchase volume, which significantly reduces investment risk. In return, the public system gains access to cutting-edge therapies, priced in Brazilian reais rather than US dollars.

This framework has already enabled the local development of biosimilars, and we are now entering a longer-term effort to develop New Molecular Entities (NMEs). Its success rests on three mutually reinforcing pillars: a robust regulatory agency in ANVISA; a strong domestic generics industry; and public procurement strategies directly linked to technology transfer.

Importantly, this is not a protectionist framework. If a company holds a patent, it can sell directly to the SUS. There is no restriction preventing market access based on manufacturing location.

How is Brazil's pharmaceutical market divided between the public and private sectors, and how have these dynamics evolved?

Brazil's public healthcare system (SUS) serves the entire population, but around 25% of Brazilians, primarily from the middle and upper classes, also hold private health insurance. This enables them to bypass wait times and access private healthcare facilities. However, for highly complex procedures such as heart transplants, even wealthy individuals often rely on SUS.

In terms of market composition, national companies lead in the volume of public purchases, particularly in basic components and generic medicines. By contrast, multinational companies dominate in terms of value, given that high-tech therapies – such as oncology treatments and biologics – are still largely imported.

When we focus on the Brazilian GDP, all expenditures in health account for 9.7% of the total, from which 5.7% represents private expenditures and 4.0% represents public expenditures.

Given Brazil's significant trade deficit in medicines and APIs, is there a realistic path toward reducing dependency through local production?

Brazil once produced over half of the active pharmaceutical ingredients (APIs) it consumed. However, in 1990, shortly after Brazil's return to democracy, President Collor de Mello implemented a rapid trade liberalisation programme aligned with the principles of the Washington Consensus. As a result, domestic API production collapsed virtually overnight, including the entire upstream chain, from petrochemical feedstocks to fine chemicals and intermediates.

Today, around 95 percent of APIs are imported. China and India dominate in volume, while OECD countries lead in value. Attempting to re-establish broad-spectrum local production is neither economically viable nor strategically necessary. Only five or six companies continue to manufacture APIs in Brazil, and although some domestic pharmaceutical firms have their roots in this legacy, they remain few.

Given the industry's continued focus on generics, importing APIs from China and India remains the most cost-effective approach, particularly as most of these products are purchased directly by consumers in pharmacies, where affordability is essential.

However, a new discussion is emerging, focused on high-potency synthetic oncology drugs. These medicines offer high added value, are produced in small volumes, and may represent a viable niche for local production, especially as new technologies enable smaller-scale manufacturing.

Nevertheless, challenges persist. Many raw materials still stem from petrochemical derivatives, and viable upstream production would require integration across multiple industrial sectors, including petrochemical processing, fine chemistry, and alternative value chains.

Brazil is not seeking to replicate or compete head-on with China and India in API manufacturing. This is neither the industry's focus nor the government's. Instead, efforts are concentrated on strategic niches—particularly high-value, low-volume segments such as synthetic oncologics. The goal is not complete self-sufficiency, but greater resilience built through well-targeted industrial policies.

How would you characterise the relationship between the Brazilian government and domestic pharmaceutical companies, and where do you see the most impactful areas of collaboration?

Brazil has a longstanding tradition of strong state involvement in industrial development, even if there have been exceptions, such as during the previous administrations. The country's approach is still influenced by CEPAL (Economic Commission for Latin America and the Caribbean) concepts of import substitution, which helped build the largest industrial base in Latin America, surpassing those of Mexico, Argentina, and others. I come from government myself, having held several public roles. What we have always done at Grupo FarmaBrasil is work closely with public institutions in the design and implementation of industrial policy. Since the later years of the Fernando Henrique administration, the pharmaceutical sector has been a consistent focus of government action.

Brazil also has some distinctive tools for supporting industry, many of which date back to the 1950s. Chief among them is BNDES, the National Bank for Economic and Social Development, which is larger than the Inter-American Development Bank. Beyond financing, BNDES plays an active role in shaping industrial policy, funding R&D, and supporting long-term strategic planning. FINEP is another key institution, offering support for technological development through both repayable investments and non-repayable grants to private companies and research institutions. We also benefit from advanced infrastructure like Sirius, a globally recognised particle accelerator used for medical research, among other applications. Together, these elements form a national support framework that, while not without its flaws, fosters regular dialogue and coordination

between the public and private sectors.

This ecosystem is inclusive by design. The Brazilian constitution defines local industry based on operational presence rather than capital origin, which means that multinational companies operating within Brazil have equal access to government support. Associations like Interfarma benefit from this in the same way that we do.

Ultimately, the real differentiator is not ownership, but local manufacturing. That's the key question: who is producing in Brazil? Even in the United States, current policy increasingly favours local production. This is part of a broader global trend, especially in healthcare, toward strengthening national manufacturing capacity.

What is your assessment of Brazil's current economic environment, and how do you see the pharmaceutical and healthcare sectors evolving over the next two years?

Brazil's pharmaceutical market is substantial and has posted double-digit growth rates for several years. That trajectory is expected to continue, with projected compound annual growth between six and ten percent. While there have been global disruptions, such as the 2008 financial crisis and the COVID-19 pandemic, the underlying momentum remains strong.

Brazil also remains one of the most unequal countries in the world. As a result, any improvement in the purchasing power of lower-income populations tends to trigger a sharp increase in demand for essential goods, including medicines. This points to considerable untapped potential in the internal market.

From a broader macroeconomic perspective, Brazil is facing a paradox. The Central Bank has maintained interest rates at 15%, even though inflation is around 4.5%. In theory, such high rates should suppress investment, but in practice, that is not happening. The country is close to full employment, with an unemployment rate of approximately six percent. Although informality persists, people are working. GDP has grown by roughly three percent for three consecutive years, supported by a strong trade surplus and over USD 380 billion in foreign reserves.

Of course, the picture is not without its challenges. Brazil faces serious fiscal constraints, and the government is working hard to maintain equilibrium. At the same time, the country has a broad social safety net. In addition to the SUS (Unified Health System), there are direct transfer programmes such as Bolsa Família and subsidies for electricity and cooking gas for vulnerable populations.

Despite deep inequality, these mechanisms provide a minimum standard of living. People are not dying in the streets, but many live in precarious conditions. Maintaining this social support is costly, and the tension between fiscal responsibility and inclusive growth contributes to the Central Bank's conservative monetary stance.

Given their scale and resources, why are Brazil's leading pharmaceutical companies not more visible on the international stage?

There are two main reasons. First, Brazil is a vast country. Much like the United States, we tend to look inward. There is still enormous growth potential within the domestic market, particularly when it comes to addressing social inequality. Any improvement in income distribution creates new demand and market segments locally.

Second, international expansion requires innovation. Competing in generics abroad – say, in Colombia – offers limited strategic value when the same APIs are used across markets. That is why, around 15 years ago, our member companies collectively decided to continue generating cash flow from generics but simultaneously begin investing in innovation. It is a long and complex process, but it is progressing.

Some of our members have already made inroads internationally. Eurofarma operates seven manufacturing facilities across Latin America. EMS, Brazil's largest pharmaceutical company, owns a biotech firm in the United States and has acquired Serbia's former state-owned laboratory, Galenika, which now manufactures peptides for its liraglutide injector. BIOLAB established an R&D centre in Ontario, Canada. Other members are also pursuing international expansion.

Nonetheless, the domestic market remains our primary focus. Competing globally requires innovation, which is why we are actively involved in efforts to reform Brazil's regulatory and pricing frameworks, particularly through CMED, the government body responsible for pharmaceutical price regulation. The aim is to foster incremental innovation by enhancing off-patent molecules to develop differentiated products. While this approach may not be revolutionary, it offers a credible and sustainable pathway to access international markets.

What advice would you offer to international companies looking to enter the Brazilian pharmaceutical market, and are there any final reflections you would like to share?

The most efficient path into the Brazilian market is to partner with local companies. Brazil is a complex environment, our regulatory standards are high and continue to evolve, but our tax and pricing systems are also highly intricate. Geographically, the country is vast; for example, a flight from Porto Alegre to Manaus takes nearly four hours. These factors add significant operational complexity.

Some foreign firms have been present in Brazil for over a century and have invested in building local manufacturing capabilities. For newcomers, however, forming alliances with Brazilian partners remains the most strategic and effective approach.

More broadly, I would highlight that Brazil is undergoing a structural shift toward innovation. In addition to domestic companies, many multinationals are now participating in public-private initiatives such as the Partnerships for Productive Development (PDPs). What matters most, both for Brazil and for international partners, is local production. Whether through joint ventures or independently, the goal is to manufacture and innovate within the country.

Brazil also offers untapped opportunities in areas like biodiversity. Some of our members are developing medicines based on native natural resources, but this is only the beginning. The potential is considerable, and while there are no formal barriers to entry, it is far more sustainable to invest and produce locally than to rely on exports alone.

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