Renato Porto – President, INTERFARMA

Innovation saves lives – and lives are non-negotiable

02.12.2025

Tags: Brazil, LatAm, Interfarma, Association, Innovation, Access

Brazil's push to modernise its health system has put Interfarma at the centre of the region's biggest access debate. Since taking over the presidency in 2023, Renato Porto has steered the association – which represents the innovative pharmaceutical industry in Brazil – through a period of regulatory reform, political uncertainty, and rising demand for faster, fairer access to innovation. In this conversation, he lays out why Brazil's greatest bottlenecks now sit beyond regulatory approval, what the country must do to convert scientific potential into real-world access, and why valuing innovation is the only path to a sustainable health system.

You took over the presidency of Interfarma in 2023. Since then, what have been the main priorities guiding the organisation?

It has been both an honour and a major responsibility. When I assumed the presidency, the central mission was clear: expanding access to innovative medicines for the Brazilian population. To do this effectively, Interfarma built a new strategic plan grounded in accelerating the arrival of innovation to patients, modernising the regulatory environment, and strengthening our engagement with the health ecosystem. Everything we do focuses on shortening the journey from scientific discovery to patient access. This means reducing approval timelines – not only at the point of regulatory authorisation but also throughout post-approval stages that determine whether a product actually reaches people. The goal is to support policies and develop models that allow broader incorporation of therapies into both the public and private health systems, without

compromising financial sustainability. At the same time, we are focused on building a more qualified dialogue with the government and institutions. This strategic consolidation, while reinforcing the value of innovation, has been the core of my work since 2023.

The W.A.I.T. indicator shows that, across Latin America, it takes about 5.6 years for new treatments to reach patients, and only 36% of innovations become available. How does Brazil compare?

It is essential to distinguish between regulatory timelines and access timelines. Interfarma insists on this because they involve different bottlenecks and therefore different solutions. Brazil is actually a regional leader in regulatory quality. ANVISA is a technically strong agency, and the regulatory environment is robust. With recent improvements, regulatory approval now takes around two to three years. However, the time for that same medicine to reach the population is closer to five years, similar to the broader Latin American reality. Because Brazil is the region's largest market, this heavily influences regional averages.

We also saw an 18% increase in access timelines from last year to this year, which raises questions about whether the delays disproportionately affect those populations with the greatest needs. Oncology therapies face the longest delays, whereas treatments for rare diseases tend to be incorporated more quickly. The real bottleneck today is not regulatory performance – it lies in incorporation processes and the steps that follow market authorisation.

When we talked with Rolf Hoegner of Roche, he pointed out that financial mechanisms are critical, since payers ultimately determine whether innovation reaches patients. In your view, what kind of partnerships should Brazil develop to accelerate access?

The starting point is to recognise that access to high-quality health technologies is not a cost – it is an investment. A country cannot grow economically if its population does not have adequate health. The COVID-19 pandemic demonstrated this with absolute clarity: every day that people were unable to work resulted in enormous economic losses. Access policies must be seen through this lens.

Brazil already has important mechanisms in place, such as Productive Development Partnerships (PDPs) between public and private laboratories, which strengthen national manufacturing capabilities. These collaborations should continue to evolve. Beyond that, we must expand the use

of managed access agreements – risk-sharing models, outcome-based contracts, and real-world evidence frameworks that align value, affordability, and long-term sustainability.

These tools are essential for enabling responsible access to breakthrough therapies. Clinical research should also be seen as a strategic partnership. With Brazil's new Clinical Research Law, we now have a much more attractive environment capable of generating significant investment and accelerating access at the same time.

With local companies beginning to scale the value chain and move into biosimilars and even innovation, how should Brazil balance the role of generics with the need to accelerate innovation?

Our greatest challenge is creating an environment that nurtures the full cycle of innovation in Brazil. This goes far beyond importing innovative products – it requires strengthening every stage: academic science, applied research, development, manufacturing, and incorporation.

Interfarma's mission in this regard is to value the entire innovation cycle. Brazil possesses all the ingredients: a solid academic base, a large pharmaceutical market, a strong health-solutions ecosystem, and increasingly sophisticated manufacturing capabilities. What is missing is greater coordination and long-term policy stability. The government's perspective matters greatly.

Innovation must be treated pragmatically, free from ideological biases. Clinical research conducted in Brazil follows the same rules and protections as research anywhere in the world; it should be seen as a strategic asset. If we value innovation today – even when it is introduced by multinational companies – we equip our national industry to innovate tomorrow. Innovation is cyclical: today's patented therapy becomes tomorrow's generic. Learning from innovation is what ultimately enables a local ecosystem to produce it.

Beyond the broader incentives you mentioned, is there any specific support for clinical research in Brazil? How does the country position itself regionally?

The greatest incentive we can offer is legal certainty, regulatory clarity, and economic stability – all essential when developing a medicine takes ten years or more. The new Clinical Research Law has been a major turning point. It brought clear timelines, harmonised requirements, and greater predictability to how studies are conducted in the country.

Brazil has natural advantages: a population of 200 million, high urbanisation, excellent universities, strong regulation, and competitive research costs. Interfarma recently created a comprehensive global-Brazil comparison database of all open clinical trials worldwide. One striking finding was that Brazil lost around 694.000 clinical trial participants over the past four years. These were trials open in the country in which we did not attract enough patients.

The majority of Brazil's studies are phase III. For the ecosystem to mature, Brazil needs to attract more phase II studies – where innovation is truly shaped. The new 30-day approval rules will help. The fundamentals are there; now we must convert potential into participation.

As we approach the end of 2025, and given the political context, will your priorities remain the same next year?

Our focus will remain on reducing the time it takes for patients to access treatments in both the public and private systems. Today, Brazil can take as long as four years to incorporate a medicine, and in some cases, an additional four and a half years to purchase it. This means that patients wait far too long for therapies that are already considered global standards. Access timelines must be dramatically shortened. Another priority is improving the environment for the supplementary (private) health sector, which covers roughly 25% of the population and must work within a more predictable regulatory framework. These two pillars – access time and regulatory quality – will dominate our planning for the coming year.

Brazil is seen as the most attractive market in Latin America, yet many executives describe it as far more complex than expected. What message would you share with international industry leaders entering the Brazilian market?

The first message is to rely on data. Our sector is built on evidence, outcomes, and rigorous analysis. Investment decisions must reflect that. Second, we must reiterate that without health, there is no healthy economy. Brazil does struggle with medium- and long-term predictability, but we must collectively adopt a resilient mindset for planning horizons across all timeframes. Third, we must avoid the illusion of "magic solutions". This is a deeply complex sector; maintaining focus is essential. Innovation teaches us discipline: you need a clear endpoint, a clear target. And in Brazil, that target must always be expanding access to the best available treatments for the population.

The industry increasingly relies on data to justify policies. But when the data exposes massive unmet needs – with thousands still waiting for treatment – how does data actually help? And how do you navigate that tension between evidence and reality on the ground?

We must rethink sustainability through the lens of value. Some medicines have high upfront costs but generate enormous downstream savings by preventing complications, reducing hospitalisations, or avoiding loss of productivity. Sustainability must be assessed in terms of clinical benefit, patient outcomes, long-term savings, and the overall utility of a technology to the system. Early diagnosis, appropriate treatment, and well-structured care pathways are essential.

Brazil still needs stronger care lines and a more strategic use of technologies at the right point in the patient journey. According to FIFARMA, Brazil loses significant economic value each year due to delays in incorporating effective treatments. These losses are real and measurable. Contrary to the narrative that Brazil lacks resources, there is still ample room for better use and greater efficiency before scarcity becomes an insurmountable problem.

Finally, what message would you like to leave for our international readers?

Innovation saves lives – and lives are non-negotiable. Brazil has the science, the talent, the market, and the ambition to become a global force in health innovation. What we need now is coordination, stability, and a shared commitment to value innovation at every stage of the journey.

See more interviews