Tanner Pharma GROUP

A Guide to the Key Pharma Markets in Latin America

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Introduction to the Latin American Market

For pharma companies interested in product expansion, Latin America is one of the most interesting and dynamic parts of the world in which to establish a presence. This emerging region has many opportunities for new entrants, with a high demand for specialty pharmaceuticals, supplements, and diagnostics – and some key untapped markets.

The region has a population of more than 650 million people, mostly in urban areas. Over the next 30 years, the older population (aged 65+) is projected to double.[1] This will increase the burden of chronic diseases, and with it the market for new treatments.

In 2021, Latin America displayed the fastest regional pharmaceutical sales growth worldwide, reaching 15.6%. And growth expectations throughout the region are high, with the LATAM market projected to post a CAGR of 9.7% from 2021 – 2026 (in LCD terms), outperforming other global key market expectations.[2]

What's more, innovations could stand to make a greater impact here than they might in more developed countries. A case in point is mortality rates. Over the past few decades, life expectancy throughout Latin America has increased dramatically – a change that has been credited in part to the introduction of new medicines.[1]

Aside from the impact on patients, the industry makes a significant contribution to regional GDP. It employs nearly 700,000 people, both directly and indirectly – for every job created by the pharma industry, 1.7 jobs are created elsewhere in the economy. [1]

Unfortunately, Latin America can be a challenging environment for market entrants. While certain countries have taken steps to remedy this situation by reforming their healthcare systems and improving their licensing processes, a number of barriers remain. This can hold back companies that would otherwise be interested in commercializing their products in the region.

In this whitepaper, we explore some of the advantages and challenges in accessing five of the largest pharma markets in Latin America: Argentina, Brazil, Chile, Colombia, and Mexico.

Tanner Pharma's Licensing, Acquisition & Commercialization (LAC) division was established more than 20 years ago. By licensing, registering and commercializing products, the division seeks to help international pharmaceutical and biotech companies gain a foothold in Latin America and other emerging markets, in turn making new and mature drugs more accessible to the patients who need them most.

Argentina

Although the Argentine pharma market is not the easiest starting point for new entrants, it is worth considering on the basis of its population size alone. Pharmaceutical sales in Argentina reached around $4.6bn in 2021, making it the third largest in Latin America behind Brazil and Mexico.[3] Sales that year amounted to 690 million units, with local companies accounting for more than two thirds of sector turnover.[4]

With a population of 45.4 million – around half of whom rely on the public sector for their medical needs – Argentina is notable for its health insurance coverage. Before entering the market for commercialization, most pharmaceutical companies would have already run a pharmaco-economic analysis of the new drug they want to introduce and therefore would have already demonstrated a benefit, allowing for more immediate health coverage and entrance into the public insurance system. These factors mean that Argentina's private market is smaller. In these cases, the manufacturers might not be able to charge a high price point on their drugs, but because a larger part of the population would now have access to the product, they would potentially be pushing higher sale volumes.

Margarita Chala, TannerLAC's commercial operations director, observes that Argentina product registration requirements also offer unique possibilities when compared to other Latin American countries. To start, the Argentine National Administration of Medicines, Food and Medical Technology (ANMAT) is WHO/PAHO certified, ensuring the quality, efficacy and safety of drugs meet international standards. This aligns with their efforts to improve regulatory processes and accelerate approval times of drugs, which in turn improves market access for new products. [2]

From a framework standpoint, ANMAT categorizes countries into two annexes. Countries that are deemed high-vigilance – for instance, the US and the EU – are placed in Annex I. If a product is already marketed in a country listed in Annex I, fewer documents are needed when you're looking to register a product, allowing for a quicker-to-market timeline for certain products. Additionally, Argentina's bioequivalence requirements give more flexibility for local companies to develop generic or biosimilar products in this region, offering more sales power.

Carolina Cortez, TannerLAC's executive vice president, adds: "The government supports innovation, given the important number of local pharmaceutical companies investing in research and development. Even though the country is facing economic challenges with increasing prices of pharmaceutical products to compensate for currency devaluation, doctors in Argentina are well aware of the latest treatments available abroad and are interested in trying them for their patients as early as possible."

Additionally, Argentina's more recent e-prescribing law allows for the prescription and distribution of some medicines electronically. This digitization has created more convenience for the patient in accessing products and helped to drive retail sales during the pandemic.[2] This trend is expected to continue, lending further to positive retail sale projections.

Brazil

Brazil is the largest country in Latin America, with a population of 212.6 million, and a large pharmaceutical market, too. GlobalData reports that pharmaceutical sales in Brazil reached $17.08bn in 2021.[3] For market entrants, that brings one big advantage: volume, and lots of it.

“The whole population has guaranteed access to medicines,” says Chala. “Even though in practice not all products are in formularies and of easy access to the population, something that makes the market attractive is that if patients don’t receive access to a product, they have the right by law to request coverage by legal means.”

Brazil’s unified healthcare system, Sistema Único de Saúde (SUS, is the world’s largest government-run public healthcare system in the world by number of users, delivering universal healthcare to the country. SUS spends approximately 10% of GDP on healthcare, which is predicted to rise to 12.6% by 2040. [5]

On the downside, the country is notoriously protectionist in its trade policies, and imposes a number of barriers to entry for international companies. Only 89 of Brazil's 441 pharmaceutical companies are of international origin. [6]

"Brazil can be very challenging when it comes to the regulatory side – they do have a lot of requirements," adds Chala.

The industry is also subject to stringent price controls, which can, in some cases, limit profitability for manufacturers. Essentially, the regulators will look at the prices being charged in a basket of countries around the world to determine the price that can be approved. However, Brazil is edging towards the first substantive reform of its drug pricing framework in several years, as new amendments are currently under review with Drug Market Regulation Chamber (CMED). [7]

In other positive news, a recent development may make it easier to bring some products onto the market. In 2020, Brazil's health regulatory agency, Anvisa, joined the Pharmaceutical Inspection Co-operation Scheme (PIC/S). Among other advantages, adopting PIC/S codes will reduce the number of duplicative audits required for certain products, which could substantially decrease the time to market.

Additionally, the pandemic advanced the use of telemedicine in this region, and a bill has been put into motion to authorize the practice of telehealth throughout Brazil. This act will better enable the spread of health information, as well as help to further expand specialized care and patient access to treatments.[8] This could increase the need for products in the region as more patients – including those in rural areas who could not previously access healthcare easily – receive diagnoses.

Chile

With a population of 19.1 billion, Chile doesn’t offer the same kinds of volumes as Argentina or Brazil, but its pharmaceutical industry punches above its weight in several respects. In fact, Chile is considered to be one of the easier markets in Latin America to access and do business.

Unlike many neighbouring countries in the region, Chile is known for its greater political stability, combined with increased certainty over legal requirements, and a business-friendly environment. Furthermore, Chile comes top in Latin America for countries with the highest annual healthcare spending as a percentage of GDP, according to 2019 figures, as well as having the highest out-of-pocket expenditure per capita in the region. [9]

The annual sales total of Chile’s pharma market was reported at $3.7bn in 2021, [3] and its productivity is ranked second highest of any industry in the country.[10] Chile’s ISP (Public Health Institute of Chile) is also recognized by the WHO/PAHO international standards for drugs. [2]

While the region has traditionally been reliant on imports, it has undergone a shift since the start of the pandemic, when the country doubled down on domestic vaccine production. On top of that, several foreign companies have set up operations in the country, attracted by Chile's network of free trade agreements and incentives for foreign investment. These include the Chinese vaccine manufacturer Sinovac. [10]

"It's always a good market due to its growing economy and higher purchasing power," states Chala.

As referenced in the report "Pharmaceutical and Healthcare Industry in Chile - Forecast and Analysis 2022", the pharma and healthcare sectors in Chile are expected to show long-term growth with investment interests from many multinational companies. And the Chilean Government is seeking to better manage healthcare costs by introducing new drug pricing policies.[11] The CENABAST law (passed in January 2020) is a good example of this. The law has allowed private pharmacy chains and independent pharmacies to purchase drugs through CENABAST, reducing drug acquisition costs by nearly 70%.[11]

"The timeline to enter the market could be more promising than in other countries in LATAM for certain products," adds Chala. "In particular, some supplements and diagnostic products don't require registration – so as long you have the correct documentation, you'll be able to start commercialization in the market more quickly."

While the market may be relatively easy to deal with at the moment, this could change in future as the Chilean congress considers a 2015 bill called Ley de Farmacos II. This may result in extra regulations for pharmaceuticals and medical devices in Chile, and extra costs in certain areas.[12]

Colombia

Colombia is another sizeable market, with a population of 50.9 million – the third highest population in Latin America – and a growing economy and healthcare market. In 2021, its pharmaceutical sales reached $4.95bn, with digestive and metabolic health products leading the way across a diverse product portfolio.[3]

Following reforms over the last few decades, Colombia has achieved near-universal healthcare coverage, with 96% of its population participating in an insurance scheme that takes a 12% mandatory contribution from working people's wages. Provision is also available for those unable to afford the 12% contribution.[13] This amount of coverage is considerable turnaround from the early 1990s, when just 20% of the population had coverage and Colombia was considered to have an unreliable healthcare system. The health insurance system enables the Colombian Government to pay for the majority of procedures and treatments.

Additionally, Colombia ranks third in the region for highest public healthcare spend, reaching $21.6bn in 2019. And healthcare spending as a percentage of GDP is set to reach 7.3% by 2028 – rising 1.3% from the 6% level in 2018. [13]

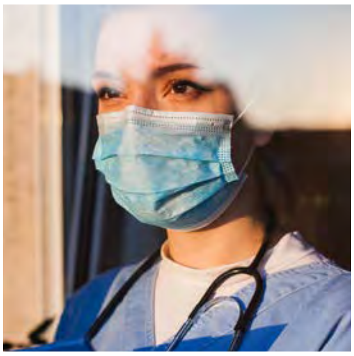
This widespread healthcare coverage coupled with government investment creates clear opportunities for pharmaceutical players looking to sell into the public system. Government health spending is fairly high here, with healthcare sales above the regional average.[14]

Brand-name drugs constitute around half of all drug sales in Colombia, with the other half consisting of generics. Broken down by prescription medicines versus OTC drugs, the ratio is around 80:20.[13]

While the regulatory system is relatively simple to navigate – making this an easier market to enter than, say, Brazil or Mexico – market entrants are still likely to contend with a lot of red tape.

"The way you submit your product registration makes a big difference in Colombia, as this can affect how the product gets classified," says Diana Mendoza, program manager at Tanner Pharma Group. "Some products take a really long time to receive registration approval, such as pharmaceuticals and dietary supplements. A long registration timeline can affect potential access to treatments for patients."

On top of that, Colombia does impose some drug-pricing controls, based on what is being charged elsewhere in the world. Its value-based pricing model broadly follows the Brazilian template, although it isn't as strict in this regard as Brazil would be.



Mexico

Mexico is TannerLAC's number one market for product expansion, and with good reason. For one thing, it is the second largest country in Latin America, with a population of 128.9 million. An estimated 90% of the population is covered when it comes to core health services, yet out-of-pockets payments account for more than 40% of the country's total healthcare spending.

Mexico has the second largest pharma market in Latin America and ranks in the top 15 worldwide.[15] Pharmaceutical sales were valued at more than $15.48bn in 2021, with a strong manufacturing base of antibiotics, analgesics, and antiparasitics. [3, 16]

Furthermore, the Mexican market retains a preference for branded products over generics, making this a good place to license innovative medicines. Because of the country's proximity to the US – the largest pharma market in the world – most doctors (and patients) are well aware of new therapies and are interested in gaining access.

“The Mexican population has a higher out-of-pocket expense than in other Latin American countries – they do have public health insurance but it’s not quite as robust as elsewhere,” says Chala. “This can be good for pharmaceutical companies because most products that are introduced to this market start out as an out-of-pocket expense. Companies can start with a higher price to the private sector which will then allow them to offer discounts to the public sector, equating to higher sales volume over time.”

That said, many companies entering the Mexican market are taken aback by the regulatory requirements, particularly when trying to register pharmaceuticals.

“Mexico’s regulatory system is second only to Brazil’s in terms of its complexity,” says Chala. “For example, when it comes to stability studies, Mexico requires more detailed information on the reports that need to be submitted for approval. There are many instances like this where the expectation from manufacturers is that registration will be similar to the US or Europe, or even other LATAM countries, and that is just not the case.”

How Tanner Pharma Group can help

The Latin American pharma market is highly varied, with a patchwork of different challenges and requirements that can catch pharma companies unaware. Regulations are variable and often complex. Even when a company knows the rules on paper, entrants may not be privy to nuances, or the different local interpretations of the law.

Without direct experience of each country's system, it can be hard to know how to proceed. Delays are common, as the company learns exactly what is expected of it throughout the process of licensing and commercialization. And as governments and healthcare systems continue to innovate, adding new healthcare technologies and processes, the roadmap to success can be wrought with new twists and turns. That's where a seasoned partner can make the difference.

With more than 20 years' experience in the region, TannerLAC serves as a single point of contact for all registration, licensing, and commercialization needs. Considering itself 'product agnostic', this division of Tanner Pharma Group works with pharmaceutical, biotech and healthcare companies across any therapeutic area to bring pharmaceuticals, supplements, and diagnostics to international regions where patient demand is high and availability is low.[17] Over time, the division has accrued an in-depth knowledge of each country's healthcare system, registration requirements, language, culture and political affairs, through experience and reliance on a network of local partners – and continues to keep up with the ever-changing pharma landscape in these unique regions.

In part, it comes down to staying well connected. In each of the countries where it operates, TannerLAC has built up an extensive network of partners and experts on the ground. This gives the company a well of up-to-date information, covering everything from regulatory changes to sourcing disruptions to sociocultural factors. [17, 18]

“We have the knowledge of what’s needed, and we have very creative ways to overcome certain obstacles,” says Chala. “That’s always been the plus of having us as a partner.”

To cite just one example, there was a company that changed the primary manufacturer of their product which was already registered with ANVISA, the Brazilian regulator, and it was required that the company conduct bioequivalence studies, which would have been extremely expensive and time consuming. But through its knowledge of the regulatory technicalities, TannerLAC was able to get that requirement waived by getting the product added to the “exceptions” list.

“The team prepared a well-supported case explaining why the product should be exempt from this requirement and presented it to the authority, and the regulator approved it,” recalls Mendoza. “That was a big win, and we definitely learned a lot from the experience and were able to help our partner.”

In collaboration with TannerLAC, manufacturers looking to gain a foothold in Latin America should not be deterred. TannerLAC is the ideal partner to license and market products in the region, with a view to ensuring medical products reach the people most in need. That means formulating the right strategies, providing the right documents, ensuring compliance, mitigating risks, and minimizing any disruptions to product supply. With its skilled, multilingual team, and deep experience in each market, TannerLAC has seen it all before. The division can handle the full array of challenges that may arise, ensuring products are launched successfully and reach their maximum sales potential. [17, 18]

The upshot? Across a 12-month period, for example, Tanner helped partner companies succeed in distributing over 221,000 product units in Latin America.[18]

"We have always been able to find a way to solve issues," says Chala. "When we have been told 'this is not possible', we have found ways to make it possible. Regulatory requirements are not always black or white, so experience is necessary to find a middle ground that allows projects to move forward."

For more information, please contact Tanner's Business Development Market Analyst Manager, Marisol Garcia at LAC@tannerpharma.com

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