

Federico Prince â?? GM & CEO, Laboratorios Kener

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Federico Prince, general manager and CEO of Laboratorios Kener details the family-run branded generics companyâ??s changing of hands and the rocky patches it went through before becoming the second-largest company in Mexicoâ??s injectables market. He also relates Kenerâ??s â??Mexico plusâ?? approach aimed at expanding reach beyond Mexico while maintaining a strong base there, the firmâ??s distribution channels, and its strong hospital business that covers 80 percent of the private hospital beds in the country.

Could you provide an overview of Kener and its operations? What areas of business is the company involved in?

Kener was established in 1960 by a family that primarily produced tablets and some capsule products, focusing largely on generic drugs for government sales. In 1996, they acquired Precimex, the first local company to manufacture injectables. Subsequently, they sold the company to an individual who relocated the manufacturing sites from Mexico City, near the airport, to Toluca 2000, where we are currently based. However, this move led to bankruptcy. Banamex, now Citibanamex, took over, and the current owners purchased it from the bank.

Was Kener a distressed asset that Banamex held before the current owners took it over?

The current owners were part of Grupo Quan, which, at its peak, comprised many companies primarily within the food industry. They dealt with ice cream, bottled water, and consumer goods distribution. When the M&A expert Patricia Fassi acquired Kener, the owner of Grupo Quan acknowledged their lack of pharmaceutical knowledge. However, Patricia, being a chemist, was sent to manage Kener. She operated the company for six years. During the previous ten years, we achieved multiple GMP certifications, expanded the plant, and invested over USD 50 million to

completely overhaul the facility and launch new products.

Given that you have both solid and injectable products, could you explain the investments made and the layout of your facilities since 2013?

We have invested over USD 50 million in a plant and new products, establishing a new cephalosporin facility, which must be self-contained due to the nature of the products manufactured there. We also have an oral solids plant where we produce tablets and capsules, alongside various injectable lines for ampoules, lyophilised products, and vials. All these operations are based in Toluca 2000.

Our facilities are spread across three lots. One lot houses a warehouse for oral solids and part of our ampoule and vial production. Behind this warehouse is the cephalosporin plant. The second lot contains another warehouse dedicated to injectable products and additional storage. The third lot includes the cafeteria and parking. Despite being on separate lots, it all forms a single site when you visit the plant.

Is the output from these manufacturing sites solely for Kener Laboratories, or do you also engage in contract manufacturing (CMO) for local companies?

We do engage in CMO activities, but only minimally. The main reason is that it is challenging to make a profit from CMO unless you have substantial volumes. If we were producing for the entire Latin American market, it might be worth considering. However, for local companies looking to launch a specific product, it is difficult to achieve a profitable price point.

Are you preparing for international exports, considering the stringent regulatory requirements of bodies like the US FDA, Health Canada, EMEA, and COFEPRIS?

We have harmonized the quality systems from these four agencies into one unified system, preparing for audits and certifications. This positions us well for exporting beyond South America, which we already do, to new markets requiring these stringent quality standards. We are currently working with a few distributors regarding terms and products, among other details. While it is an option worth exploring, we are not considering setting up subsidiaries at the moment.

Injectables account for substantial part of our revenue. We are the second-largest company in Mexico in terms of our injectables portfolio, just after Pisa, with the third company trailing far behind. We cater extensively to hospital needs regarding injectables. Our strategy is to leverage our strengths in this area and expand internationally.

Although there may be some challenges in entering new markets, do you see gaps to fill in Latin America or Europe, especially with the tough competition from Indian companies?

There are definitely opportunities. Competing with Indian companies is challenging due to their scale, but we pride ourselves on the quality of our products. Our products can be tested any day and will pass without issue, which is not always the case for many Indian companies. Once customers recognize the superior quality, the price becomes secondary. We are targeting the private market

rather than the institutional market, which is a different ball game altogether.

Given that many European countries have small private healthcare sectors due to their health insurance systems, do you still see opportunities there?

Despite the small size of private markets in Europe, there are opportunities. We have some attractive combination injectable products, and we believe there is room to grow, even with the strong presence of Indian companies. Their traditional foothold in Europe presents a challenge, but our strategy is a "Mexico plus" approach—expanding our reach while maintaining a strong base in Mexico.

What can you tell us about the Mexican pharma market, its rapid growth, and how you are navigating it?

The Mexican market has indeed seen substantial growth, especially in the pharmaceutical sector, outpacing the general economy. At Kener, we have structured our distribution into three main channels: centralized government, decentralized government, and the private market. Centralized government sales, which include federal purchases, account for a small part of our revenue. Decentralized government sales, involving state governments and institutions like Instituto Nacional de Nutrición, represent around one third. The remaining portion is the private market, split between retail and hospital business.

In retail, we serve all major pharmacy chains and large retailers like Walmart, Comercial Mexicana, and Soriana, even producing some white-label products for them. Strategically, we find this mix advantageous, but we are continually reassessing. Our hospital business is particularly strong, covering 80 percent of private hospital beds in Mexico, and we are experiencing high double-digit growth in this area.

Our focus has been on injectables, which comprise for the largest part of our revenue, making us the second-largest company in Mexico's injectables market. We have invested heavily in state-of-the-art facilities and quality systems, positioning us well for both domestic and international markets. The shift to injectables and the private market stemmed from recognizing the profitability and the complexity involved in these products, which aligns with our expertise in aseptic manufacturing.

While competition from Indian companies is tough, especially in price-sensitive institutional markets, we leverage our high-quality standards to compete in private markets. This strategy of focusing on hard-to-make aseptic products has allowed us to grow robustly and prepare for further expansion.

What about your pipeline? How do you approach sourcing and business development? Do you have a disciplined business development strategy or is it more case-by-case?

We have a dedicated team for this, operating in several areas. Our marketing team closely monitors market trends to identify promising products to develop over the next five to six years. Then the R&D team, comprising 30 people, handles everything from formulation to building a dossier with our regulatory staff. This includes typical analysts and specialists focused solely on new product development.

We have increasingly invested in this area, recognizing it as the lifeline of the company. We pride ourselves on creating hard-to-make products, both in terms of formulation and manufacturing. Maintaining aseptic areas for injectables is particularly challenging, but it is an area where we excel.

When considering future product development, do you rely mostly on internal development, or do you also pursue licensing agreements?

The majority of our product development is internal, although we do engage in some in-licensing. For instance, during my recent trip to Europe, I explored opportunities for in-licensing certain products and bringing them to market as finished formulations. However, our primary focus is on leveraging our past investments and internal capabilities to bring our pipeline to fruition. This approach allows us to maintain control over the development process and ensure products align closely with our strategic objectives.

Are there specific therapeutic areas where Kener is particularly focused, especially considering its expertise in injectables?

While injectables are a significant focus for us, we also concentrate on cardio and ICU medicine, which have specific requirements. During the COVID-19 pandemic, for example, our products played a vital role, particularly those included in the "red cart" found in every hospital, containing essential rescue medications for cardiac arrhythmias, pulmonary distress, and other urgent situations. Additionally, we provide therapies for oncological patients, although we do not have a dedicated oncology site. Recently, we launched a cardio protector product, which we anticipate will have a significant impact, for patients undergoing chemotherapy.

How important are new product launches to your strategy?

As a branded generics company, there is often pressure to launch new products regularly. However, our focus is not solely on the number of launches but rather on the quality of products we introduce to the market. Whether we launch 10 products or two, our priority is on ensuring they are high-quality offerings that make a meaningful impact. We aim for organic sales growth driven by strong products, not just marginal additions to our portfolio. We are strategic in our approach, often targeting niche products with low penetration rates or unique characteristics. These products may be challenging to manufacture, but we are committed to bringing them to market because we see it as a challenge worth pursuing. Additionally, we are meticulous in our analysis, relying on reliable data to inform our decisions and build robust business cases for each new product. Trustworthy data is crucial, especially in emerging markets where data reliability can be a challenge.

With the structured pharmacy chains in Mexico, do you find it easier to penetrate the market?

Today, we have commercial partnerships with hospital chains that provide valuable insights into their purchasing patterns and therapeutic area needs. They share what they are buying and express interest in certain product types. But it is not just about relying on this data; we also leverage market data, government data, and insights from our sales representatives who have close relationships with hospitals.

In the hospital business, our reps have a unique approach. They visit one hospital per day, engaging with multiple stakeholders within, including purchasing departments, pharmacies, ICUs, operating rooms, anaesthesiology, nursing heads, and even hospital managers. This extensive interaction provides rich data that we carefully analyse and filter to produce accurate market reports. While no report is 100 percent perfect, ours are highly accurate, giving us valuable insights into market trends and opportunities.

How crucial is brand recognition in the pharmaceutical industry, particularly in Mexico where there is strong sentiment towards local companies?

Brand recognition is vital, especially as we have entered the hospital business only four years ago, making us relatively new to the scene. However, we are proud to see our brands gaining recognition in the market. We have observed an increasing number of doctors specifically requesting our brand over generics, which adds value both to our products and our company. Around five years ago, we made a strategic decision not to market our products as generics but under the Kener brand instead. This decision has had a positive and continuous impact. It is not just about the products themselves; our teams also play a crucial role in building and maintaining our brand reputation. While we have made many clear-cut decisions to focus on certain areas and strategies, there is always more to do. As for retirement plans, well, I suppose that is still on the agenda, but for now, we remain focused on driving growth and innovation within the company.

Apart from international expansion, are there any other areas you are still keen to develop?

While international expansion is indeed important for the company's growth, I want to emphasize that it is not just about my personal aspirations but rather the vision of the entire company. Our goal is to become a reliable source of injectable products for the hospital market. Achieving this vision requires us to keep our facilities up to date, invest in new machinery, and continually improve our operations.

Over the past few years, we have made significant progress towards this goal despite facing stiff competition. One of our strengths lies in our flexibility—we can quickly adapt and prioritize manufacturing needs as required. Our high fill rates, typically ranging from 95 to 98 percent, demonstrate our commitment to excellent service. This level of performance has earned us the trust and preference of our customers, reinforcing the importance we place on customer service. Moving forward, we will continue to focus on delivering exceptional products and services to solidify our position in the market.

Do you have a final message for our international audience?

Considering our industry, we have both competitors and allies locally and globally. At Kener, as a family-owned company, we are always open to new opportunities. Whether it is partnering with others for product development or seizing market openings, flexibility is key for us. Unlike in larger corporations where decisions often get bogged down in bureaucracy, we pride ourselves on our agility. Here, decisions are made swiftly, typically within this office, with minimal red tape. This approach has enabled us to adapt quickly to market shifts and pursue growth opportunities without delay. And in terms of Mexico's investability, while it may not be the largest market in Latin America, our adaptability and resilience make us stand out. We may be the "tallest of the midgets," as they say, but our determination sets us apart. So, in essence, Mexico presents

unique opportunities for those willing to invest and collaborate.

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