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I think 2020 can be a year of opportunities but we need to be creative and optimistic to identify and seize these opportunities

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Francisco Kuri BreÃ±a, director of new developments at local Mexican player Landsteiner, shares the companyâ??s existing positioning as one of the top 10 suppliers of generic medicines to the Mexican government, their exciting pipeline of new projects including in genomic medicine and upcoming plans to invest in medical marijuana once it is legalized in Mexico, and the importance of maintaining creativity and optimism during challenging times.

Francisco, since we had the pleasure to interview you last in 2017, what has changed for Landsteiner?

As you know, we are a Mexican biopharmaceutical company with a diverse portfolio of products and a broad pipeline. We are in the top ten suppliers of generic medicines to the Mexican government. In 2017, 90 percent of our sales came from the public sector but now we have reduced the percentage to 70 percent, with 30 percent of our business now coming from the private sector. We are looking to continue growing in the private sector and expect to equalize the proportion to 50:50 soon. Of course, the public sector will continue to be an important market for us but due to the recent uncertainty in the public sector, we have to look for new growth drivers.

Another very exciting news is the opening of our new manufacturing facility in Toluca, Mexico City. This would be our second manufacturing plant and we actually finished construction in late-2016 but

it took a long time to receive all the necessary approvals. Today, the new plant has been approved for solids and we are in the process of certifying it for injectables, which we expect to take another year or two.

Landsteiner is also in the middle of an investment round though we still intend to remain a majority family-owned company.

You mention the uncertainty in the public sector. Could you share how the new changes implemented by the current administration have affected Landsteiner?

The new changes have placed a lot of pressure on Mexican companies in particular and it is a very complicated situation.

For instance, with the centralization of public procurement of medicines and medical supplies, there is a lot of confusion. Previously, there were three types of tenders in Mexico: open tenders for originator products not manufactured in Mexico; mixed tenders open to both Mexican and foreign companies but only those from countries with pharmaceutical Free Trade Agreements (FTAs) with Mexico, which represented around 80 percent of the market; and national tenders in which only Mexican companies could participate, which represented around five percent of the market.

The tender round held in 2019 was poorly organized. With very little notice, the government demanded fast response times from the industry, which limited participation to companies that already had the products in inventory, since it usually takes a few months to manufacture medications. The prices were also set very low, which some companies agreed to because they wanted to clear their inventories. However, many codes were left with no bidders because the prices were not feasible for many companies. At the same time, the payment term is 90 days after order fulfilment, which is a long time for companies to wait. Also, the tenders used to be held yearly but because of the shortages, we are now seeing monthly tenders.

The government has now opened the Mexican market generally to imports from countries like Canada, Switzerland, the United States, Australia as well as the European Union, even though it is highly implausible that drugs imported from those countries could be cheaper than drugs manufactured locally. They have also allowed the import of any World Health Organization (WHO) prequalified products even though the WHO does not conduct GMP visits, it only prequalifies products based on submitted documentation. Additionally, they have also opened the market to products manufactured in the 53 PIC/S (Pharmaceutical Inspection Co-operation Scheme) countries.

They have also permitted the importing of medicines without the need to receive regulatory approval from COFEPRIS, which also eliminates the need to conduct bioequivalence trials in Mexican populations. This is not fair to local companies because we still have to register our products with COFEPRIS and go through bioequivalence trials against the Mexican reference substances, which may differ from the reference substances used in Europe or Asia. The Mexican population has Native American heritage so our genetics differ from other ethnicities, which affects liver metabolism of some compounds. This is why bioequivalence for generic drugs is critical.

However, the biggest challenge is with the slow reaction times of COFEPRIS. We had to wait a couple of years for the approval of our new manufacturing plants, and even now, we are waiting a long time for things like import permits that we used to be able to apply for online. I think this is because they have decided to centralize the internal processes of COFEPRIS so that all different applications go through one office, which has resulted in a bottleneck and an increasing backlog at the regulator.

Despite these challenges, how is Landsteiner looking to continue growing?

While these changes are making it difficult for Mexican companies to operate in the public sector, we continue to see opportunities in both the public and private sectors. For the public sector, we will continue to invest and develop our high-specialty portfolio, which includes more complex generics and also biosimilars. These are areas where we are still competitive, especially because we have already expanded our manufacturing capabilities. Regarding the tenders, we hope that they might regularize within the year but even then, we do have a history of the sales and consumption of different types of medicines for the Mexican market so we can still anticipate the needs of the market and build a strategy based on historical data.

At the same time, we will expand further into the private market. As I said, we want to achieve 50:50 split in terms of our business to the private and public sectors. We already have strong alliances with most of the pharmacy chains in Mexico so we are looking to increase the sales of parts of our generic portfolio here.

In addition, we are expanding on our partnerships in Mexico to grow into the region. For instance, we have a strong partnership with Medimart pharmacies in Walmart stores in Mexico, and we have just been successfully audited by them in order to sell our products through their stores across Central and South America. This is very exciting for us. We are also in discussion with one of the largest pharmacy chains in the US to register and distribute our products in the US, which would be a great achievement for us.

We are already exporting to Central America including countries like Salvador, Nicaragua and Guatemala but we want to continue our internationalization efforts by exporting to North and South America. In South America, in particular, COFEPRIS has signed agreements with key economics including Argentina, Chile, Colombia and Peru so that products approved in Mexico can receive fast-track approval in these countries within two weeks. This makes Mexico an ideal launch site for exporting pharmaceuticals to South America.

Finally, we are also very excited about the potential of medical marijuana in Mexico. This is something that we have been working on in the past couple of years since the legalization of medical marijuana in Mexico in 2017.

How has Landsteiner started to build your capabilities in medical marijuana? What is the potential of this area for the company?

This is the ace up our sleeves! While medical marijuana was legalized in 2017, no regulations have been outlined for the industry in terms of its use and regulation so the sector has not advanced. However, the Senate has recently agreed to discuss the new laws for not only medical but also recreational marijuana as well as the entire production and distribution value chain so we are optimistic about being able to start working in this field soon.

I do want to emphasize that we want to focus on developing pharmaceuticals with cannabinoid components â?? ethical medical cannabis in conventional medical delivery forms â?? for the treatment of conditions like epilepsy as well as Parkinsonâ??s and other neurodegenerative diseases. As far as we know, we are the only pharma company in Mexico looking into this area, and we are confident in our pharmaceutical capabilities. We will be importing the tetrahydrocannabinol (THC) or cannabidiol (CBD) compounds necessary because we need organic pharmaceutical-grade

compounds derived from greenhouse-grown cannabis. We already have 11 clinical protocols ready to go once clear regulations are defined.

What is helpful also is that for medical marijuana studies, we do not have to conduct Phase I safety trials because cannabis has been used for millennia without negative side effects. Clinical trials are usually a combination of Phase II and Phase III trials to test efficacy for different conditions and optimum dosages, which really accelerates the entire R&D process compared to conventional pharmaceutical R&D.

Is genomic medicine still an area of focus for Landsteiner?

Indeed, our efforts in genomic medicine are my greatest pride! This is mainly done through our sister company in Spain, Landsteiner Genmed, with whom we have worked for the past seven years. We have a number of different projects in the pipeline including an anti-obesity drug in Phase I clinical trials, and in preclinical research, a drug for Alzheimerâ??s disease, a pan-cancer drug and a compound for post-infraction treatment that has been shown to repair the damaged cells of the heart in animal models. We are very excited about the potential in our pipeline.

The focus on genomic medicine is actually one of the factors that convinced me to join Landsteiner in the first place. I have had the opportunity to work with great academics and researchers in Europe. We currently have 11 people on our Scientific Advisory Board and the company works a bit like a virtual company, with different collaborations with hospitals and universities on different research topics. I travel to Spain about once a year and we have teleconference meetings once a month. It is a very interesting and efficient research collaboration model.

A final message for our international audience?

I think 2020 can be a year of opportunities but we need to be creative and optimistic to identify and seize these opportunities. Also, it is always important to enjoy the work that you do because no matter what, there will always be challenging and frustrating times but as long as you truly love what you do, you will be able to work through it.

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