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The opening of the Mexican Social Security Institute (IMSS) to clinical research is a unique opportunity for Mexico to step up on the international scenario for clinical trials. The CEO of Innovare explains how the company is betting on Mexico to conduct clinical R&D and help companies bring innovative drugs to the market.

Innovare was founded in 1995 to provide contract-manufacturing for generic products, mostly synthetic hormones; in 2008 the company's focus has been driven into high specialty products in the fields of hematology, immunology, and infectious diseases. What was the vision behind this switch?

In the past companies interested in marketing their products on the Mexican market were compelled to have a manufacturing plant in the country. That's how Innovare started, by offering contract-manufacturing services for different pharmaceutical forms, spanning from tablets to injectable products. However, the company did not invest in own developments, so when the mandatory manufacturing requirement was suppressed in 2008, it was not prepared to cope with the new scenario and ended up selling only two products, mainly through government tenders.

I joined the company at the end of 2008, and that's when we started to enrich Innovare's product portfolio. The company had invested in new manufacturing facilities in Mexico City, but I started convincing the new shareholders to move into different medical fields —towards more intangible

assets—yet by keeping a small manufacturing plant. It was hard, but eventually I succeeded. In 2010 we started discussions with the French state-owned company LFB, which specializes in therapeutic proteins and it ended up in 2011 with a distribution contract. LFB is one of the six largest manufacturers of plasma-derived medicinal products in the world and was the only one without a commercial presence in Mexico.

What fascinated me about the company is its commitment to R&D, as the company reinvests nearly 15 percent of its income in research, their amazing platform for recombinant (transgenic) proteins, focusing not only on blood derivative proteins for intensive care, immunology and rare diseases. But we did not want to only market the already developed products on the Mexican market; we wanted to go beyond that – and that's where we started changing the business model. LFB had molecules at a Phase I stage and we wanted to be part of the development and innovation process taking advantage of the authorities' willingness to bring clinical research into the country.

Recently the Mexican Association of Pharmaceutical Research Industries (AMIIF) and the Federal Commission for the Protection against Sanitary Risk (Cofepris) signed an agreement to open the Mexican Social Security Institute (IMSS), the largest public healthcare provider in Latin America, to clinical research. How do you think this agreement is going to benefit the country and what should be the next steps to position Mexico as a clinical hub for the region?

The agreement definitely represents a historic milestone for the Mexican health system. Mexico did not use to have a clinical trial culture and recruitment processes were not well established. This arrangement means having nearly 70 million patients under the same roof – an impressive number and network. IMSS was completely closed in the past, so this agreement opens a goldmine from the clinical research standpoint, even for ultra-rare diseases, and not only for patients but also for the medical community. This is a game changer in terms of R&D in the country.

That being said, now the regulatory authority needs to define good clinical practices to perform clinical research. Cofepris is taking care of this, but I think the pharmaceutical industry should share this responsibility by importing best practices from abroad and investing resources to establish state-of-the-art clinical research centers at IMSS. Today it's like having only crude oil; we need now the infrastructure to refine and get gasoline – and the big pharma definitely needs to participate. That's the next big step that should happen.

A further step should be to create a synergy with the US regulation because it would represent a win-win for all stakeholders –the sponsor, R&D centers, health institutions and the patients. As an

example, in order for a drug to be designated as a breakthrough therapy by the FDA (the relatively new FDASIA signed in 2012), the sponsor needs to present a new molecular entity, a new mechanism of action and – mostly – its demonstrated efficacy. And this is where Mexico can play a synergistic role. After Phase I you know a drug is safe, but you need to prove its efficacy and the vast patient population of the IMSS represents an excellent sample to prove it. Such a synergy would be amazing, but today the communication is not as smooth as it should be. Mexico could be an excellent hub to generate reliable clinical data and even be the first country to launch a drug. It has been happening with some products, such as Ryzodeg® by Novo Nordisk, but it could be much more.

On what new product developments are you currently working on and what challenges are you facing?

We still produce generics to finance operations and investments. We are not interested in entering the biosimilars space, as we think biobetters are the way to go in such a dynamic industry. So why not investing in clinical research, but for innovative products? Today we have one innovative recombinant therapy under assessment by Cofepris for a Phase IIb/III study to be performed in Mexico. What confirmed me Innovare was on the right track was that the authority is currently extremely open to innovation and wants to take you by the hand to get successful clinical trials first, and a successful assessment of the therapeutics later. That’s where we want to go. To do so, Cofepris structured a subcommittee of experts to assess new molecules, and it is something very promising for the country.

The main challenge Innovare is facing today has nothing to do with regulation and marketing, but rather with financing. One of the products we are currently developing is a completely innovative molecule, whose drug substance is manufactured in the US while the final product would be manufactured in Canada. However, in order to invest in the project, Mexican private equity wants to see infrastructure, a manufacturing plant or an already defined five-years product pipeline. When you go and explain intangible assets, it’s incredibly hard to sell a project. Venture capital in Mexico is very immature while more financially developed environments for the biopharmaceutical industry, such as the US, do not know the Mexican financial regulation, so do not want to risk into an unknown environment.

How are you overcoming these challenges?

It’s hard. First, because the science behind the product is incredibly difficult to understand; second, because investors in Mexico do not finance intangible assets. In other countries the situation is

very different. I met a venture capitalist last month, who told me he saw pharmaceutical R&D as an endless consumption of resource – a money drain. Personally, I see it the other way around. Out of five product developments, four will probably never see the light, but the return on investment of the one that will, will be immense and cover the investment for the five of them. Also, for a small biotech company, it's not about getting the product to the market; it's about getting it to a certain stage and then license it out to a bigger player, which is what happens every day in the industry.

We currently have a product under development with the French company MedinCell, which relies on a very interesting drug delivery platform. We are at an early stage, but have found great support from the National Council for Science and Technology (Conacyt), which has recently created a special commission for innovation in healthcare and is very thrilled about the project. This week we are presenting a new project on HIV; it's at a preclinical stage, but we want to make it a breakthrough. The authorities are really pushing to transform Mexico in a hub to launch new therapeutics in the world, and that is a unique opportunity.

What are your future ambitions for the company?

On the one hand I would like to get products at an early stage of development and help our partners in their development process;. LFB has been an amazing companion, both commercially and from a R&D standpoint. Also, we want to start focusing more on the private market. We have a new molecule for Mexico, at a pre-registration stage now, that has been defined a life-saving molecule. But since the process to access government sales in Mexico is so long, we want to start distributing it in the private market through our sales force.

How did you get involved with the company and what do you do to stay ahead of the industry trends?

I'm a chemical engineer, I specialized in organic synthesis and wanted to do my PhD in molecular biology, but the program lasted at least eight years, which made me realize I would be looking for my first job at forty. So I took the chance to join the company –and it was for good, as I love what I do. I believe in continuous education and attend congresses and conferences to stay updated. The company's interest in the HIV field actually started because I had the opportunity to meet a Dutch scientist, who in 2008 was presenting a product development at a congress on gene silencing. He envisioned what we are doing now: in 2008 it was not even in a preclinical stage, today we are coming to see Phase I.

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