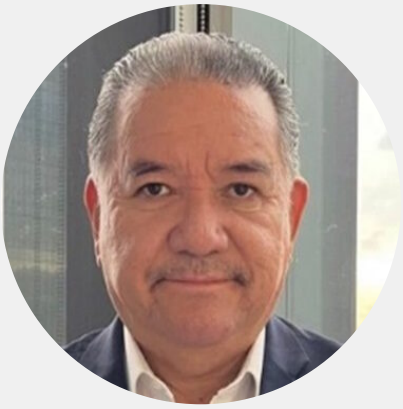
David López García – Director for Mexico and Central America



Every day is an opportunity to make a difference

28.08.2024

Tags: Mexico, LatAm, Rare Diseases

David López García, a pharma industry executive and rare disease expert, discusses the challenges and advancements in treating rare diseases in Mexico. He highlights the importance of public-private partnerships and the growing interest from industry in the rare disease field.

What inspired you to specialize in the field of rare diseases, and how has your career in this area developed?

My specialization in rare diseases began somewhat unexpectedly. Originally, my focus was on oncology, transplants, and other therapeutic areas. However, I was invited to lead a major project at Genzyme, a founder company in the rare disease sector. During that time, Genzyme faced significant challenges with its manufacturing plant due to technical issues, which severely impacted production and resulted in a global supply shortage.

In Mexico, I was tasked with explaining the situation to our customers, social security authorities, and the Ministry of Health. My role involved not only addressing the supply shortfall but also proposing comprehensive, multidisciplinary care solutions for patients. Despite the difficulties, we managed to maintain strong relationships with social security authorities and ensure continued patient care. This initial experience in the rare diseases field was pivotal and has shaped my rewarding career in this area.

How prevalent are rare diseases in Mexico, and how does this compare to global statistics?

The World Health Organization (WHO) defines a rare disease as one that affects no more than five individuals per 10,000 people. This definition is also adopted in Mexico by COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios) and the Consejo de Salubridad. To qualify as an orphan drug in Mexico, a treatment must address a condition with this prevalence threshold.

How many people in Mexico are affected by rare diseases, and which are the most commonly recognized?

Unfortunately, Mexico does not have a formal national registry for rare diseases despite several efforts to establish one. However, estimations from patient associations, government institutions, and companies provide some insights. Gaucher disease is among the most common, with approximately 300 to 400 diagnosed patients in Mexico. Overall, there are about 700 to 800 patients receiving treatment for various rare diseases. However, the actual number of individuals with rare diseases, including those undiagnosed or untreated, is estimated to be around 7,000. For instance, in some rare diseases, there might be 3,000 affected individuals, but only 300 are formally diagnosed, and just 100 receive treatment. This disparity highlights the broader challenges in diagnosing and treating rare diseases in Mexico.

What are the primary challenges in diagnosing rare diseases in Mexico?

The main challenge lies in medical education at universities. It is essential for universities to equip doctors with the knowledge to identify rare diseases, as many of these conditions can be easily mistaken for more common ones due to similar symptoms. For example, Gaucher disease begins with blood issues, which are also common in various other diseases. Historically, medical training on rare diseases has been somewhat limited. In the late 90s, medical students might have encountered only a few publications on rare diseases throughout their education, with perhaps just a single chapter from a book dedicated to the topic.

While there has been notable progress in recent years, with improved educational tools and more comprehensive information, gaps still remain. If doctors are not adequately trained to recognize

rare diseases, they may fail to identify them in clinical practice. Consequently, patients often consult multiple specialists over several years—typically between five to eight—before a rare disease is considered. They are then referred to a geneticist, who is usually the most qualified to diagnose these conditions.

Another significant challenge is the healthcare system itself. When a general practitioner refers a patient to a geneticist, the wait time for an appointment can be as long as nine months to a year. This substantial delay further hinders timely diagnosis and treatment. Therefore, the two main challenges in diagnosing rare diseases in Mexico are insufficient medical education and prolonged waiting times within the healthcare system.

What are the main challenges in accessing treatments for rare diseases in Mexico?

After a diagnosis is established, the next major challenge is navigating the complex process required to access medication. In Mexico, the time from submitting a drug to the Ministry of Health for registration to making it available to patients exceeds five years, according to a recent IQVA study involving 40 laboratories and comparing various Latin American countries. This extensive delay is a significant obstacle, as patients cannot afford to wait that long for essential treatment.

The approval process for reimbursement is particularly arduous. Even after a drug receives full reimbursement approval, each patient must undergo numerous evaluations. These include hospital committee reviews, tests, and assessments by different specialists before the treatment can be administered. This intricate and lengthy pathway significantly hinders timely access to medications, making the journey to treatment for rare diseases exceptionally challenging in Mexico.

What changes or improvements would you recommend for policy and regulation to improve access to treatments for rare diseases?

The most critical improvement would be to streamline the approval process to eliminate redundancies. After a drug receives its initial registration, which ensures the product’s safety and efficacy, it should not require multiple evaluations. Currently, once registered, the product must undergo a Health Technology Assessment (HTA) by the Consejo de Salubridad, which can take six to nine months. Despite this approval, the process continues.

Each payer—such as IMSS (Instituto Mexicano del Seguro Social), ISSSTE (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado), IMSS Bienestar, SEDENA (Secretaría de la Defensa Nacional), etc —requires separate submissions for additional evaluations and approvals. This duplication is inefficient. The past administration initially promised that one approval from the Consejo de Salubridad would suffice to make the product available to patients. However, in reality, each institution independently decides which products to accept, extending the timeline unnecessarily. Simplifying this process to ensure that a single comprehensive approval is recognized across all institutions would significantly expedite patient access to vital medications.

The pharmaceutical industry often stresses the importance of collaboration with the government, peers, and the community. What is your perspective on this, and what role does the pharmaceutical industry play in addressing rare diseases?

I believe we are currently in an excellent position to forge robust alliances with the government and society. There is a prevailing notion that the pharmaceutical industry is solely profit-driven and lacks concern for patient welfare or government cooperation. However, with the recent changes in our Ministry of Health and the appointment of new officials in the health sector, we have a unique opportunity to showcase our commitment to public-private partnerships.

For example, in the realm of diagnostics, companies specializing in rare diseases often provide diagnostic tests at no cost to the government. These tests, which may involve blood, urine, or other fluids, are frequently sent to laboratories in the U.S., or Europe. By covering these expenses, we alleviate the financial burden on the government. Additionally, we play a significant role in medical education. We offer continuous educational programs to hospitals, medical centers, and healthcare professionals to enhance their diagnostic capabilities and multidisciplinary approach for taking care of the diseases management in rare diseases.

These collaborations are highly beneficial as they enable the government to provide better healthcare services, facilitate quicker diagnoses for patients, and ultimately improve public health. While such alliances already exist, there is considerable potential to strengthen and expand them in this new administrative period.

Given the critical role of the pharmaceutical industry in diagnostics and innovation, how does the government perceive the value of these advancements, particularly

considering the high costs and niche focus of treatments for rare diseases?

Historically, the government has often viewed healthcare spending through a cost-effectiveness lens, believing that the funds used to treat one patient with a rare disease could instead benefit multiple patients with more common conditions such as diabetes or hypertension. However, this perspective is evolving. Increasingly, government officials are recognizing that this comparison is inherently unfair.

It is crucial to understand that all patients, whether suffering from common or rare diseases, deserve access to treatment. The value of innovation in rare diseases is becoming more appreciated, particularly because without such advancements, many patients would not survive. Timely treatment is essential, and the role of innovative therapies is critical.

As the government starts to acknowledge the importance of these innovations, the perception of the pharmaceutical industry will improve. The significant investments made by companies in the research and development of treatments for rare diseases are vital for saving lives and enhancing the quality of life for patients.

With 19 years of experience in the rare disease field, what have been the most challenging battles and the most rewarding achievements?

The most challenging battle has been elevating the significance of rare diseases on the public agenda. This ongoing effort involves constantly reminding policymakers, hospital staff, patient associations, and the general public about the critical importance of these diseases. Raising awareness and ensuring that rare diseases receive the attention they deserve has been the most difficult part of my work.

Your efforts over these 19 years have undoubtedly increased awareness of rare diseases. What are your hopes and predictions for the future of rare diseases in Mexico?

We are currently in a promising era. More companies are investing in awareness campaigns, medical education, diagnostics, research, and clinical trials. Fifteen years ago, when I first discussed rare diseases with politicians, many were unfamiliar with the concept. Today, it is common to find policymakers who are aware of and even knowledgeable about rare diseases. This

increased awareness is a very positive development.

The media plays a crucial role in this progress. Media outlets like yours can significantly amplify the conversation around rare diseases. Additionally, societal attitudes are shifting. The increasing focus on inclusion, equality, and health—particularly in the aftermath of the pandemic—has brought health issues to the forefront of public consciousness. We must seize this opportunity to further elevate the importance of rare diseases and ensure they remain a priority in public health discussions.

With almost 20 years working in the field of rare diseases, How do you maintain your motivation, and how do you inspire your team to stay optimistic after all these years?

I often reflect on what keeps me motivated, and the answer is simple. Every morning, I see a new day as an opportunity to make a difference. I strive to be a leader who is first and foremost human, then strategic, and finally effective. This priority guides me daily, ensuring that my actions are grounded in empathy and purpose.

What final message would you like to share with our readers?

I urge everyone not to forget about rare diseases. Look around and consider the profound impact of being involved in this field. There are numerous ways to contribute—by supporting patient organizations, collaborating with authorities, or working alongside doctors. My final objective is to emphasize the importance of collective effort in addressing rare diseases.

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