Interview: José Luis Hernández – General Manager, Kedrion Mexico



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José Luis Hernández, general manager at Kedrion Mexico, explains the strategy followed by the affiliate in Mexico to obtain success during the past eight years and showcases the added value of plasma-derivate solutions both for patients and government.

What are the primary activities and operations of Kedrion in Mexico?

Kedrion Mexico is a subsidiary of Kedrion Biopharma (Italy) and is specialized in providing the highest quality, plasma-derived products to the Mexican market.

Kedrion established its presence in Mexico in 2008, when it created a Joint Venture with a local partner. We first introduced our human albumin into the market, followed by standard immunoglobulin, hyperimmune globulin, and finally, our human coagulation Factor IX and Factor VIII.

The company has become a significant supplier for the IMSS (Mexican Social Security Institute), ISSSTE (Institute for Social Security and Services for State Workers) as well as the main Public Health Institutes in the country. Kedrion Mexico is proud of its reputation as a trustworthy and reliable partner to Mexico's Healthcare System.

Kedrion products are highly specialized and their manufacturing and distribution processes are long and complicated in order to guarantee the highest standard of safety and quality. It is very

satisfying to know that our work involves accepting vital donations from healthy and noble people to help people whose lives depend on them. Our work gives us great professional pride.

At the global level, Kedrion Biopharma is a group with approximately $700 million in sales, more than 2000 employees, and presence in 100 countries. Some 75 percent of its revenues come from outside its home base of Italy.

Kedrion now ranks fifth in world sales of plasma-derived therapies. What are the main competitive advantages that would make Kedrion the preferred supplier?

We are a very young company compared to our big competitors, but we have been able to exploit opportunities and continually invest in our development, resulting in our international growth. This is undoubtedly one of the reasons we have been able to reach such levels in less than 16 years of history.

Kedrion adopts a fully vertical integrated business model that is capable of managing the entire plasma transformation cycle from supply and production to distribution. This gives us total control over our operations in order to improve efficiency throughout the value chain. In addition, the way we partner with National Health System has been one of our key competitive advantages, positioning Kedrion as one of the most reliable solutions for any government in our field.

How strategically important is the Mexican affiliate to global operations?

After more than eight years operating in this market, Kedrion Mexico is one of the main affiliates and contributors to global revenues.

We opened the subsidiary in Mexico in 2008 and since then I have been in charge of leading the subsidiary’s business operations. I am proud to confirm that the results have been quite positive during these years, increasing the number of our products registered in Mexico and the overall volume distributed into the market.

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Mexico today is the fourth largest market for Kedrion after the US, Italy and Turkey. We expect to continue driving this growth in Latin America, strongly supporting the company’s outstanding global performance.

One key element for this success has been our executive team, with high level experience and strong commitment.

You were named General Manager of Kedrion Mexico in 2008. What have been your biggest achievements so far?

In spite of the economic environment, we have been able to position Kedrion as one of the main players in plasma products in Mexico with a reputation for high reliability and respect from the government and other industry stakeholders. Such brand positioning is the greatest achievement so far.

In Mexico, there are very few entities offering plasma-derived solutions to health institutions to treat Mexican patients suffering from serious or rare diseases such as hemophilia. The demand for these products grows, but it is sometimes limited by healthcare budget constraints and cuts, that, unfortunately, prevent access to care for many patients.

To help reduce this gap in access, Kedrion in Mexico is proposing a program to process residual plasma from hospital transfusions. The products derived from this plasma are then made available to those hospitals at significantly lower cost, increasing availability to a wider patient base. By using their residual plasma, institutions avoid the high cost of procuring plasma from abroad – primarily from the US or the EU.

Kedrion is proud to have created and developed this model in Italy in a very successful way and is very keen to offer its experience, capabilities, technology and know how in Mexico too.

What are the main challenges you have faced in Mexico?

The management of blood products is challenging in all locations. From manufacture through transport and storage to distribution, the plasma must be kept cool and carefully controlled; it is a very precise technique.

Another challenge derives from the complexity of biological production versus standard pharmaceutical production, due to the unique and precious starting point of all our production: the human plasma, rich in proteins so needed by our patients and that we purify in our industrial plants. Therefore, we must be very careful in all the value chain, from supply, planning, production to final supply to our customers, in order to fulfill our commitments to delivery to health entities. This is a complicated and demanding process.

Still, we must continue to develop and to launch new products, formulations and systems to maintain this positive performance in Mexico. National regulations regarding safety and quality standards make this an even greater challenge.

I would like to emphasize that Kedrion invests around 6.7 percent of its revenues in R&D activities to continue offering more efficient and effective value propositions.

In addition, it is important to consider that our main client is the government and it is a reality that National Public Health Institutions are included in recent budget cuts. This obviously has adversely affected our activities and we must carefully adapt ourselves to this situation.

Kedrion produces and distributes human plasma-derived drugs targeting three main therapeutic areas: hemophilia, immunology / neurology, and critical care. What is your income breakdown by therapeutic area and where is the most growth expected?

Immunology treatments are the main contributors to our sales in Mexico, as they are for Kedrion's affiliates around the world. There is still much market to cover in immunology in Mexico, especially in primary immune-deficiencies, due to the often late and difficult diagnosis of such diseases. Such late diagnosis is a national challenge because it increases the cost of treatment for the patient, which in the end is paid by Health Institutions.

Another area of market development is hemophilia, where drugs available on the market are not enough to effectively treat patients suffering from the disease. Unfortunately, the development and availability of these drugs is dependent on the amount of budget resources available in Public Health Institutions. This is a difficult challenge in Mexico, where hemophilia treatment consumption per capita is one of the lowest in Latin America and significantly lower than in the United States or Europe.

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Considering their impact for both patients and the government, what is Kedrion doing in Mexico to communicate the benefits of plasma products?

Kedrion Group participates with other manufacturers in the PPTA (Plasma Protein Therapeutic Association), a leading Association who works globally to: advocate for access to and affordability of therapies for patients, engage in constructive dialogue with regulatory agencies, and collaborate with patient advocacy organizations.

We have been promoting the creation of a national association of producers of plasma products here in Mexico as well, to advocate for better access to care for patients and better awareness of the rare diseases we are treating. We also hope to have a stronger voice in front of the regulators, to help them in updating and improving regulations that monitor and control the use of our medicines.

We have other initiatives, still under development, aimed at disseminating knowledge and therapeutic updates to treating physicians as well as to Patient Associations offering the most authoritative information regarding the diseases of their concern and the associated therapies.

The government has recently announced budget cuts in health spending by 2017. What is your plan of action to overcome this challenge?

As we have already mentioned, Public Health Institutions are our main clients and such a climate creates serious business challenges. Our strategy is to work with our Clients to better understand their needs in terms of volume, stock, supply, and timing, as well as anticipating demand. This approach ensures that we are able to deliver the plasma products in the exact amount and in the precise time requested to avoid waste of resources.

Paolo Marcucci, our global CEO, established Kedrion's strategy to enhance its global role as a strategic partner of National Health Systems in countries aspiring to be self-sufficient in the availability of products derived from their own plasma. We follow this global guide to overcome the budget cuts in Mexican health spending, positioning ourselves as a reliable provider and supporting the government to achieve its goals in this segment.

When we had the pleasure of meeting with Mikel Arriola, he told us that his main objective is to ensure the financial sustainability of the institution and concentrate its efforts on chronic diseases. Proteins derived from plasma are biological medicines widely used in the treatment of rare and chronic diseases. As one of the leading companies in plasma-derived therapies, how is Kedrion helping the Mexican government achieve these goals?

For some pathologies, like immune-deficiencies and hemophilia, early diagnosis and appropriate care, including prophylaxis, while incurring higher treatment costs in the short term, can result clear savings to the healthcare system in the longer term. Such treatments can avoid long-term hospitalizations, emergency room visits, and missed days of work or school. They can also provide significantly enhanced quality of life for patients and their families.

Furthermore, I would like to highlight two very important points that are very specific for our industry vs Big Pharma: the first one is that our sector is very small and a mere niche for the pharmaceutical sector (the plasma industry's global sales represent less than 0.2% of global sales of the pharmaceutical industry), yet our products affect the quality of life of our patients very deeply. The second point is that raw material represents a much higher portion of the production cost of drugs in the plasma industry than in the pharmaceutical industry: 57% vs. 14%, so we do

have to pay maximum attention to our overall costs.

I am fully aware of budgetary constraints but our treatments are crucial to meet the national demand of Mexican patients suffering from serious diseases, disorders and conditions such as those already mentioned. There are no substitutes.

We have very little voice in front of the government if we communicate the benefits of solutions derived from plasma as a single company. This is why we are working with patient associations such as the National Federation of Hemophilia to have a better position vis à vis the authorities.

What are the main goals you would like to achieve in the next three years?

Increase our presence and corporate reputation with patients and health institutions as well as healthcare professionals.

It is not an easy task since they are very different fields with different interests. But we all have a common goal: patients' health.

I want to make sure that we achieve these goals in Mexico by increasing the quality and efficacy of our operations. In fact, we have been able to build a highly efficient company in a very short time, in a difficult market with strong limitations and constraints. We must continue to drive the development of the company in the same direction that we have been following and this is one of my top priorities.

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