

Juan de Villafranca - Executive Director, AMELAF, Mexico



Our mission is to provide efficient, quality and safe medicines to Mexican patients at reasonable prices

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Juan de Villafranca, executive director of the

Asociacion Mexicana de Laboratorios Farmaceuticos (AMELAF), shares the exciting new initiatives he has launched in the past two years of his term; the importance and strength of AMELAF as the representative association of 44 100 percent Mexican-owned pharmaceutical manufacturers; and the potential and capabilities of the local pharmaceutical industry.

Juan, could you please introduce yourself as the executive director of AMELAF to our international audience?

I have had an extensive career in the government including a number of years at the Ministry of Foreign Affairs and the Ministry of Commerce and Industry Promotion, as well as five years in Singapore as the Mexican Ambassador to Singapore and two years heading the World Intellectual Property Office (WIPO), among other positions. I was appointed as Executive Director of AMELAF in May 2018. I have had some exposure to the pharmaceutical industry during my time in the public sector and I thought it was a very interesting opportunity for me.

AMELAF members are 100 percent Mexican-owned pharmaceutical manufacturers. Our mission is to provide efficient, quality and safe medicines to Mexican patients at reasonable prices. Most of their companies work in generics but some are also advancing up the value chain into biotech

innovation.

Most of our members are second- or third-generation, with some being first-generation companies. They have invested significantly into their companies, managing to thrive and grow over the past years and decades in a rather challenging environment, so they are understandably proud of what they have achieved. In total, AMELAF members have around 67 manufacturing facilities in the country, hiring a total of around 38,000 employees.

AMELAF is also a 100 percent independent association. We are not associated with other industry associations like Cámara Nacional De La Industria Farmacéutica (CANIFARMA), which gives us the strength and autonomy to advocate for our own interests and positions.

In the past two years, I have transformed AMELAF as an organization in a number of aspects. Firstly, we started a campaign to recruit more companies to join AMELAF. This was highly successful: we grew from 18 members in 2018 to the 44 members we currently have. This included retaining some members that were thinking about leaving AMELAF, bringing back old members that had previously left, and of course, recruiting new members. During this process, we also expanded our reach throughout the entire country. Presently, nearly half of our members are based in the state of Jalisco, in Guadalajara (the second-largest city in Mexico, after Mexico City).

With the changing healthcare landscape in Mexico, what do you see as AMELAF's mission today?

Our objective is to strengthen the national pharmaceutical industry. AMELAF and our members are truly, 100 percent, Mexican. We want to be a strong and united association that is truly representative of the local industry and advocates for their interests.

Based on this, we need to outline the strategy and working plan of AMELAF. We must have clear positions based on the interests of members. This is why I ensure that I am in constant communication with our members. I live on the road, travelling across the country to have one-to-one meetings with our members. Last week, for instance, I visited the state of Baja California, where I had 11 one-to-one meetings over two days with our members there.

When we speak about healthcare today, Mexico is like a new country. This is exciting but it is also challenging to navigate. As an industry, we must work with the government while communicating our priorities and positions clearly. At AMELAF, we have to ensure that our positions are positive, logical and realistic, as well as based on the information and insights I receive from our members.

We also have to continue interacting with different healthcare stakeholders, including the Ministry of Health; our regulator, Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS); and other industry members. This is why we also participate in many conferences and workshops to share our views. Recently, we organized a workshop with COFEPRIS and our members regarding regulatory topics.

Another important priority for us is to develop our public image. This is why we are very active in producing and disseminating information to both our members and the public in the form of daily news, position papers, press releases and so on. I personally arrange around six one-to-one meetings a week to speak with the top journalists and columnists in Mexico. This is to ensure that there is information available about our industry. As an independent association, we can share information and opinions very quickly without having to discuss with other industry associations. We also recently updated our logo and website.

What other services does AMELAF pride itself on providing to your members?

Over the past two years, we have really focused on providing value to our members. Firstly, we have revamped our website and there is a members-only section where members can access many different services and resources. We have hired professional legal and regulatory experts to draft guides and documents on key topics. We have also created a directory of service providers approved by AMELAF for our members to browse based on their needs. We have also created marketplaces for the exchange of APIs and manufacturing capacity. If a member has excess manufacturing capacity in his plant, for instance, he can post a listing, and interested parties can bid on it. We have even created an app for our members to access these resources on the go. So far, it is members-only but we are working on making the app public. The digital aspect of our engagement with our members and the larger community is extremely important.

We are also looking at business development opportunities for international imports and exports. Last year, I attended the CPhI worldwide conference in Frankfurt, Germany, where I spoke to a number of API producers. As an association of 44 members, clearly we have far greater clout than individual companies.

Our ability to deliver valuable services is also a reason AMELAF has grown significantly over the past few years. Our members are thus far satisfied with the work that we have done.

We are also a very democratic association. While some associations charge fees based on company size, we charge our members a flat fee. Each company has one vote. Also, since I do not come from the pharma industry myself, our members trust me to be impartial and independent.

What are your members' views on the new healthcare policy changes?

The pharma industry is interesting because it is one of the most regulated industries in the world – regulated, of course, by the government – and at the same time, the government is also the main and single largest customer. It is a delicate balance. About 50 percent of AMELAF members' sales are to the public sector and we also provide 50 percent of the total volume of the public sector.

The most important thing is that we need to have clear rules. AMELAF is working very closely with government authorities to find solutions to the current healthcare challenges such as drug shortages. As an industry, we must bring solutions to the government. At the same time, we also have to be very clear in our position. The decision to import medicines not yet approved by COFEPRIS from overseas is difficult, not only for our members but also for the system. It will not be simple to purchase and import medicines from overseas manufacturers.

With the centralized procurement, it was complicated in December 2019 because companies were only given a short time to prepare their bids and the entire bidding process was done in one day. This made it very difficult for the pharma industry to respond. This is why we are working with the government to plan the 2021 bidding cycle. We would like the bidding process to start sometime in July or August, so that companies have time to prepare their bids as well as manage their manufacturing processes.

Our members are not afraid of competing. They just want to know the rules of the game and have a fair playing field. Many of our members are willing to work with the government. Currently, AMELAF members are only using around 60 percent of our manufacturing capacity. We certainly have the capacity to increase production to resolve these shortages – but we need to have time to plan and execute the manufacturing processes. When we are talking about the needs of the entire country, it is not as simple as going to Walgreens to pick up some medicines! COFEPRIS is a very well-respected regulator and we have a strong regulatory system in place in Mexico. It is not fair if companies in countries with more relaxed regulations or a subsidized industry are able to bypass our regulations to export their drugs more cheaply to Mexico.

In addition, the pharmaceutical industry is one of the few industries in Mexico that has significant growth potential. Last year, Mexico's economy actually shrank by 0.1 percent. But the pharma industry – with the right policies – has the potential to grow four to seven percent. We have the infrastructure and the skills in the country already! Our member companies all have plans to expand their facilities. They have a strong growth mentality – but the ecosystem needs to support them too.

Looking forward, what are your priorities for AMELAF for the next few years?

It is time to consolidate our advancements. We want to continue to improve our services to our members as well as advocate for their interests. Ultimately, AMELAF seeks to work with our members and other healthcare stakeholders to strengthen the local pharmaceutical industry in Mexico.

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