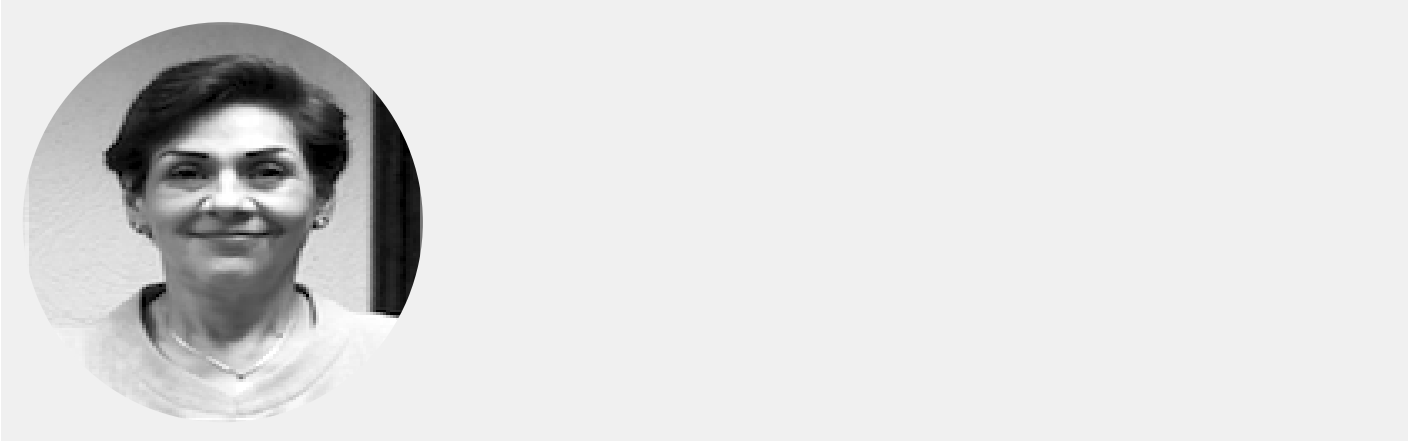
ANAFAM – Socorro España Lomelí, Executive Director – Mexico



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In July 2012 COFEPRIS (the Federal Commission for the Protection against Sanitary Risk) was recognized as a national regulatory authority of regional reference by the PAHO (Pan-American Health Organization), opening the doors to exports for the Mexican pharmaceutical industry. The executive director of the association representing domestic drug manufacturers discusses how companies are now increasingly eyeing foreign markets to expand their business, the challenges they face to start international operations, and what the association is doing to help its membership in this process.

Back in 2012 you told us that generics were going to play an increasing important role in the Mexican market. How much of these expectations come true since we left you?

Since 2012, sales of generic drugs increased 70 percent and the price of drugs dropped up to 90 percent. This was mainly thanks to COFEPRIS, which in the last three years liberated 31 active substances and allowed to register 287 new generics. As a result, Mexico jumped from the 5th to the 2nd market worldwide after UK for production and sales of generic drugs.

In the past generics suffered from a poor image in Mexico. How has this changed over time?

The whole pharmaceutical industry has done a lot to inform patients about bioequivalence, to make sure they understand that a generic drug is the same as an innovative one and that they

represent a cheaper option for treatment. This has been done in collaboration with the government authorities, especially under the current Minister of Health, Mercedes Juan, who has made drug access for Mexican patients a top priority on the government agenda.

In recent years large pharmaceutical companies such as Sanofi-Aventis and Novartis strengthened their generic activities. How much did this help improve the image?

Some of the big drug makers facing the patent cliff decided to make incursions in the generic segment and started aggressively promoting their new product lines, which helped patients increase trust towards generics. Actually, it also aided generic drug manufacturers getting rid of the stigma they had in the past, when generic drugs were considered copycat products of innovative drugs.

An important step was the recognition of COFEPRIS by the PAHO as national regulatory authority of regional reference for medicines and biological products in July 2012. What impact does this recognition have on ANAFAM's membership?

The recognition was a milestone, because today drugs registered with COFEPRIS are recognized at international level. This has helped local companies start exporting to other countries, especially to markets in Central and Latin America. In the past, only larger Mexican drug manufacturers had export activities, because they were the only ones who had the financial capability to comply with the import regulation of each country. We are currently working to make sure regulation is standardized, so the recognition can be broader and can help Mexican companies register their products with the European Medicines Agency and the US Food & Drug Administration.

Are you offering any kind of advisory to your membership to start export operations?

Since July 2014 ANAFAM is working with the Mexican chapter of the FDA and with Rafael Nevarez Nieves, assistant regional director for Latin America, to provide our membership with conferences and training about the drug registration process – and the results have been remarkable. The participation has been impressive, confirming that national manufacturers are interested in exporting to other markets. It's a milestone for an association in Latin America to work that closely with the FDA and we'll continue to offer this kind of training to our membership to make sure they can rely on state-of-the-art know-how.

What markets in Latin America are Mexican companies looking at?

COFEPRIS already relies on mutual recognition agreements with countries such as the US, Australia, New Zealand, Colombia and Canada, and is expected to close new ones with Costa Rica and Panama by the end of 2014. Both countries are interested in signing the agreements to make sure in future they are also recognized by COFEPRIS, thus also at international level, and in the new opportunities the second largest pharmaceutical market in Latin America can offer them. Costa Rica and Panama are small markets on their own, but very interesting as a whole. Especially Panama is an attractive market: the country does not have a pharmaceutical industry, but is a logistic hub for the whole region. Currently it seems we even have a small window open with Brazil, one of the most protectionist markets in the world. I don't think Brazil can continue being as protectionist as it has been in the past, as this inhibits competitiveness. With an eye at foreign markets, Mexico is going exactly the opposite direction.

A further milestone within the Mexican pharmaceutical industry was the approval of a new regulatory framework for biotech drugs in April 2012. How was it welcomed by the industry?

The new guidelines gave the investment community trust to take risks and bet on production of biotech products. Before 2012 drug manufacturers – especially national companies – were facing a very uncertain situation, as everyone was afraid the upcoming law might be too strict or require prohibitive investments to comply with. Fortunately, it was a reasonable regulatory framework, which has not been seen as a barrier by the industry.

Currently ANAFAM is participating in the negotiation process among authorities, multinational companies and national manufacturers to update the regulatory framework for biotech drugs for the years to come. We have had biotech products in Mexico for more than 20 years now, but these drugs were released under different conditions than the current ones. Authorities are aware that the already existing biotech products cannot be taken out of the market, so that's why they are adapting the regulatory framework for new drugs and making sure the old ones can have an extension period to adapt to the new framework. We are sure we'll come to a reasonable agreement for all parties.

What has been the relationship of Enrique Peña Nieto's new government with the pharmaceutical industry and ANAFAM since he took office in December 2012?

Recently we have been working more closely with the government authorities – mainly with the Ministry of Economy– especially since Mexico has been included in the TPP (Trans-Pacific

Partnership) negotiations. We have always had a very close relationship with COFEPRIS and the one with the Ministry of Health is getting better every day.

How is ANAFAM supporting the national pharmaceutical industry in the TPP negotiations?

For the first time in history, someone from ANAFAM is taking part in all meetings of the TPP negotiations to represent the interests of the national manufactures. Our main concern are intellectual property rights and patents on pharmaceutical drugs. Current discussions are supporting the extension of drug patent protection beyond the 20-year limit and the 12 years of regulatory data protection for biologics. This would delay the launch of new generics and mean biosimilar drugs would probably be launched on the Mexican market only until 2025.

We know COFEPRIS' federal commissioner Mikel Arriola and the Minister of Health Mercedes Juan are both very sensitive to these themes, but as spokesperson of the industry we are worried, especially for patients. If intellectual property proposals go ahead, the public sector may not be able to deliver specialized therapies because of the high cost of treatment – this would be catastrophic for Mexico.

What have been ANAFAM's major milestones since the last time we met?

ANAFAM's membership grew to 30 members – it was 22 two years ago – and this has been triggered by the organization of an annual business meeting: Vector Pharma. In 2012, the event brought together 40 manufacturers, which resulted in more than 350 business meetings; in 2013 we had more than 90 companies from Mexico and other 20 different countries; in 2014 we had 1,000 companies from 21 different countries. What started as a one-time event turned a success, so we decided to continue organizing it every year and we are even integrating a committee to organize it.

What are the current challenges faced by ANAFAM's membership?

First of all, the recognition of the national pharmaceutical industry as a key sector for Mexico's economy and population. Drug makers are the most important ally of government and society, because we produce drugs that save lives. Mexican drug manufacturers are investing in the country and are fighting for it – and this should be recognized at national and international level.

Second, the investment required to export. While, a few years ago you could count the companies with international operations on a hand, nowadays 60% of our membership exports and an increasing number of Mexican companies are interested in investing abroad. Some are even

looking for plants to produce – and indeed compete – on foreign markets. There is a lot of collaboration, with large manufacturers supporting smaller ones, but financing export operations still represents a barrier for smaller companies.

What are the priorities of the association for the next two years?

At ANAFAM our priority is to help Mexican companies expand their business to new markets, make sure the national pharmaceutical industry is recognized at local as well as international level, and keep our membership updated about state-of-the-art know-how with trainings. Last but not least, we want to revive the national chemical industry because today most of the raw materials are imported.

Mexico is becoming more competitive, "*Hecho en México*" (Made in Mexico) means quality and excellence, and Mexicans are not lazy as they are often seen. The national pharmaceutical companies are investing in the country and are moving quickly to make sure in the short term Mexico can be one of the top players worldwide in high-quality drug production.

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