Maria del Socorro España Lomeli – Executive Director, ANAFAM, Mexico



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CP Maria del Socorro España Lomeli, executive director of the Mexican generics industry association ANAFAM, discusses the challenges with regard to the 'new rules of the game' in Mexico's healthcare sector since 2018, the willingness of the Mexican pharmaceutical industry to be a trusted ally to the public healthcare system, and the importance of ANAFAM members as the suppliers of up to 70 percent of the public system.

Socorro, having been in the industry for a couple of decades now, what do you think of the ongoing changes in the healthcare sector in Mexico?

Frankly speaking, it has been difficult to adapt to the new rules of the game. This is not because the system is new; the pharmaceutical industry in Mexico has the expertise and ability to adapt rapidly to new situations. The problem has to do with building relationships and having dialogues with the people within the system, in large part due to an unfortunate distrust and lack of confidence in the industry.

Today, there is the stigma of corruption associated with the pharmaceutical industry and many people believe this without any justification or verification. Unfortunately, this has led to a lot of prejudice against the industry, which prevents the different public stakeholders from being willing to get to know the industry and to open the doors to positive dialogue with us.

However, we continue to work tirelessly to engage with public stakeholders. It is very important for there to be dialogue between the public and private sectors because we need each other in order to achieve the healthcare and welfare goals of the country. We have made it very clear that we are extremely open to working with the government. We are adapted to their needs but we need to know exactly what they want from us, with clear rules of engagement. In the past year or so, there has been a lot of changes, and we have sometimes received different signals from different institutions and individuals, which makes it difficult to really understand what the government wants from the industry.

For instance, when it comes to the centralized procurement of medicines and the 'shortages' we are seeing in 2020, I want to emphasize that the Mexican pharmaceutical industry is perfectly prepared to meet the needs of the public sector in terms of medicines and medical supplies. We have done so in previous years and we have the capabilities to continue to do so. There is no need to look outside Mexico for solutions. I am not sure if it is a problem of ignorance or prejudice but we have tried to engage with the government to offer our support and help in resolving this situation.

Indeed, we understand that the different industry associations met with key public institutions including the Secretary of the Interior, Ministry of Health, INSABI, IMSS and ISSSTE a couple of weeks ago. How did this meeting go?

It went well. It was a very strategic meeting because we were able to sit down with all the key decision-makers within the public healthcare sector and open a productive dialogue. It is a start but we have to continue working with all the relevant institutions. It is a complex situation also because there are many layers within the institutions, and sometimes it is not clear to us that the instructions from the top are understood by those at the bottom. But we will continue to insist on opening dialogues with the key actors. We want to have these dialogues not only to share our perspectives but more importantly, to listen to their perspectives and needs in order to work together productively.

Ultimately, what the industry truly wants is to be a good ally of the government in an ethical and transparent way for the benefit and the health of the Mexican population.

How significant is the problem of corruption within the pharmaceutical industry in Mexico?

I have to say that while I do understand the anti-corruption stance the government is taking, I think the problem is that the public sector lacks a good understanding about the pharmaceutical industry, and therefore, they have magnified the problem incorrectly. First and foremost, there is a distinction between pharmaceutical manufacturers and pharmaceutical distributors. We are part of the same value chain but we work in different sectors of the industry.

The pharmaceutical manufacturing industry in Mexico – which ANAFAM represents – has invested in Mexico for many years and decades, supplying not only medicines and health supplies but also jobs and economic value. This is what we want to highlight to the public sector, and we hope that they can learn more about the pharmaceutical manufacturing sector and the contributions that we make to Mexico without being prejudiced by the stigma of corruption.

How is the current situation affecting ANAFAM's members?

The situation is negatively impacting the potential of the Mexican market. There are many opportunities in Mexico but with the current uncertainty, it is difficult for our members to take advantage of them.

For instance, our members are also facing regulatory challenges. When it comes to drug registrations, our members struggle to receive approvals for their generic drugs even after the innovator patents have expired because the approval timelines from COFEPRIS are slow. In comparison with other markets like the US, where generic drugs can be launched in the market a few weeks or even days after the innovator patents expire, Mexico is a bit behind in terms of our regulatory timelines.

In general, ANAFAM has a good relationship with COFEPRIS and we understand that they have an enormous portfolio since they are also responsible for the regulation of food and beverages. They have too few resources for the work they need to do. Unfortunately, I must admit that dialogue with them is becoming more difficult than before, and even after we have meetings, it is not very clear to us if they followed up on the conversations. The regulation of medicines is very critical to healthcare delivery so we are continuing to knock on doors and engage more with COFEPRIS. We really hope that COFEPRIS and other public institutions can take the chance to understand more about the industry and work more closely with us.

We are all committed to the same goal: to secure the supply of all the medicines needed for the health of Mexicans.

At the same time, the private market is also a significant part of the healthcare market in Mexico. How are your members performing in this segment?

So far, the uncertainty in the public sector has temporarily strengthened the private sector because more patients are accessing the private sector in order to access the medicines they need. But this is in the short term. Once the situation in the public system is resolved, things will go back to normal.

Most of ANAFAM's members are generics players and we supply perhaps 60 to 70 percent of the generic medicines available in the public sector. Of course, our members also have a significant percentage of sales in the private market.

In general, generics are an important part of the healthcare system in Mexico and have seen a lot of growth in recent years. As I mentioned above, the problem is the delays in regulatory approval. If we can align our regulatory processes to those of countries like Canada so that generic drugs can be approved very quickly after the expiry of the innovator patents, then it would help increase generic penetration in Mexico, giving Mexican patients more access to affordable medicines.

When we met you in 2015, you highlighted the need for Mexico to develop its own APIs industry. How has this advanced?

This is still a significant challenge for our industry. The majority of the APIs used in Mexico is still imported, typically from China and India, so we still have a huge dependency here. This is a huge problem because it makes it difficult for our pharma manufacturers to be self-sufficient in terms of production. There have been cases where an API supplier lost its regulatory approval and manufacturing facilities in Mexico that depended on that supplier have to find a new one, which is not always easy.

The development of a national API industry is one of the priorities of ANAFAM, and we have a working group specifically focused on this topic. It would take at least 10 to 15 years but I hope that if we start now, we can have some reasonable progress in the development of an API industry in Mexico.

2020 marks the 75th anniversary of ANAFAM. How will you celebrate it this year?

ANAFAM is the oldest healthcare industry association in Mexico and to celebrate our 75th anniversary, we will organize a scientific conference later in the year. We hope to bring together academics, KOLs and industry leaders to share their insights and perspectives on key topics.

Typically, we also organize a business partnering conference called Vector Pharma each year but due to the exceptional circumstances within the industry, we decided not to do it this year.

A final message for our international audience?

Just as there is the Mirena in Mexico, there is also the industry in Mexico! The pharmaceutical industry in Mexico has invested hugely in Mexico over the past decades in terms of medicines, research, manufacturing and employment, and we continue to be committed to raising our standards to international levels. We want to be known for the quality and reputation of our manufacturing and exports. This is our final message.

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