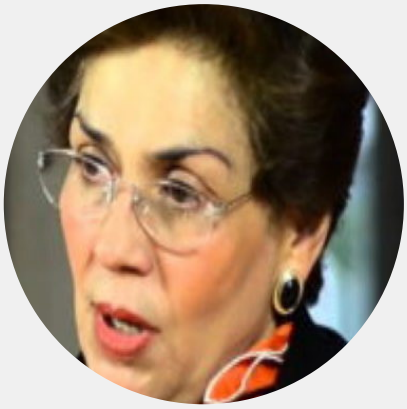
María del Socorro España Lomeli – Executive Director, ANAFAM



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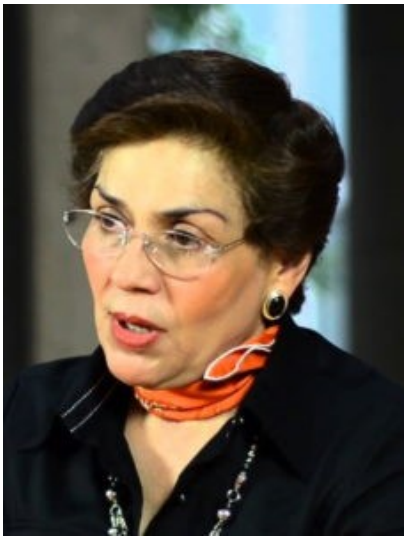
María del Socorro España Lomelí, the executive director of Mexico's National Association of Manufacturers of Medicines (ANAFAM), speaks to PharmaBoardroom about ANAFAM's evolving relationship with the Mexican government and the changes in the country's procurement law, which gave rise to widespread procurement issues. She also discusses ANAFAM member companies' internationalisation ambitions and foreign companies' interest in investing in Mexico.



Can you explain the post-pandemic landscape and how it has affected the pharmaceutical industry, particularly local companies, in Mexico?

Spending almost three years in lockdown radically changed the way we work. However, companies adapted easily to the new system and technologies that had to be implemented in order to continue working. Production facilities never closed or stopped producing, both for pandemic-related needs and other diseases. The context favoured the private market, as the government focused on the pandemic and in many cases stopped treating other diseases and supplying medicines for them, creating a shift in the market and pushing people to buy their medicines for other diseases from private pharmacies.

The market fluctuated greatly, as the production of drugs that were normally manufactured was reduced in order to focus on vaccines and drugs needed to combat the pandemic, not to mention that companies also had to adapt to technologies that allowed them to work over long distances and meet existing targets. It should be noted that the growth of the private market was largely due to the fear people had of becoming infected if they visited hospitals, a very real threat, especially at the beginning, before vaccines were available. The more prominent role of private health has increased confidence in the private sector but has decreased confidence in public hospitals, not only because of the fear of contagion or the lack of medicines due to government budget adjustments, but also because the procurement system made it extremely slow to obtain medicines.

Are the companies affiliated with ANAFAM exclusively Mexican?

In the beginning, almost all of our members were domestic companies, however, for some time now we have also had international companies that joined our association because their objectives are compatible with ours, to continue to increase the range of generic products, both branded and unbranded, but also to invest more resources in research and innovation, since our member companies also have patented products.

How has the market for generics evolved in recent years? What trends are affecting the market?

The market has grown a lot, due to the confidence generated by generic medicines and their prices. It is worth mentioning that there is a government regulation indicating that the purchase of generics should be considered a priority over the purchase of the original brand products. This was an innovative decision because it adds up to savings for the government. Previously this was not

the case, thus patent medicines had to be purchased. The expiry of patents is also a victory for generics as they can meet the demand for many medicines and offer a wide variety of therapeutic alternatives.

Is there much price competition in Mexico or is it limited by the higher segmentation of the private market?

The price war is not as ruthless as in other countries. The price differential between companies is minimal, nothing that would draw the public to buy one product over another based on that factor alone. However, it may be that prices vary more widely in large pharmacy chains. Large pharmacy chains – such as Farmacias Similares – put a lot of pressure on small and medium-sized enterprises (SMEs), and are directly responsible for the demise of many of them. These chains sell a large volume, which is why they are able to charge more affordable prices to customers. By absorbing the market, not only small and medium-sized enterprises disappear, but also all the jobs that SMEs used to generate.

How are ANAFAM's relations with the government after the changes in the market and the new structure of the Federal Commission for the Protection against Health Risks (COFEPRIS)? What issues are expected to be on the agenda?

Unfortunately in 2018 – when the government started – the pharmaceutical industry was hit hard by accusations of alleged corruption in distribution. Although there was no proof of these accusations and no one has been charged, the government has been very reluctant to work with the industry because of them.

Over time, things have changed, but it has been difficult to prove to the government that we are their allies and that we invest in the production of the medicines that Mexicans need, and have we extensive knowledge of health issues. We want to fully meet the needs of the population and we have the necessary infrastructure to export and continue to invest in the country, in order to improve the health system.

Most institutions have not responded as we expected within the industry. At the very least, we had hoped that the procedures and registrations would not take so long and that the authorities would respond in a timely manner so that more therapeutic alternatives would be available to the Mexican population. However, we must recognise that the last commissioner – Alejandro Svarch –

has been working hard to address the situation, and has allowed COFEPRIS to be more open. This move towards openness was hindered by the pandemic as staff cuts were made and employees began working from home, which caused a longer delay in responses. But now with Commissioner Svarch we are working together and that is a great achievement.

Does the Mexican government demand anything in particular from the pharmaceutical industry?

Unfortunately, with the changes made to the Procurement Law, the government's only aim is to keep prices as low as possible, with quality and distribution taking a back seat. The issue of health is simply not a priority for the government. This is evident through the way they minimise many important aspects of the process that allows medicines to reach patients. At times, they make arbitrary changes without understanding the problems in producing medicines and distributing them in a timely manner at the national level.

What is the goal of the Procurement Law you mentioned and what are its most visible parameters?

The government changed the law with the goal of making more medicines available in Mexico and we expected a positive change. But the new law took the task of consolidating the purchase of drugs away from Social Security and eliminated the Seguro Popular – an excellent healthcare system. The Instituto de Salud para el Bienestar (INSABI) replaced Seguro Popular and is now responsible for the purchase of medicines. Far from the positive change we expected, what we are experiencing is a total lack of control, since, in addition to these changes, the government had already changed the Procurement Law. By changing this law, it gave the responsibility for the purchase of medicines to the Ministry of Finance, a body that is not prepared for this function.

When the system collapsed because of these changes, the United Nations Office for Project Services (UNOPS) was contracted to bring in the necessary medicines – including imported ones – in conjunction with a COFEPRIS regulation that quickly granted registration to the suppliers that the organisation required. Such measures were clearly unfair to the established industry in Mexico and fortunately not every medicine that UNOPS proposed was immediately registered. It was then that INSABI decided to eliminate the distribution system we were working with, and we were again on the sidelines of all these changes imposed by the authorities because our voice was not heard. A

new distribution system, chosen by them without any criteria, was put in place.

The distributors, or so-called logistic operators, started to have problems sending the products to the warehouses simply because they did not have the necessary knowledge to properly transport medicines, or the capacity to store such volumes and then distribute them to all the public hospitals. A clear example of these failures is that they had to wait in queues outside of warehouses, suffering robberies and running the risk of the goods being damaged, because they could not offer the fluidity of the previous system.

Although UNOPS had reportedly demonstrated its capacity and experience in other countries, Mexico with its 130 million inhabitants was a challenge it could not successfully address. This failure to some extent benefited the established companies in Mexico, as most of these were the ones that covered the demand for medicines required by the government.

In the two years since it was constituted, INSABI is beginning to demonstrate expertise and show control over all of its functions. There are still some problems with payments, but little by little this problem has been solved. However, despite the debts, companies have remained firm in their work and have not stopped supplying patients with the medicines they need. The pharma companies established in Mexico have met the demand with local, not imported production.

Is expansion into Latin America in the cards for ANAFAM or do its companies still need to consolidate domestically before thinking about going abroad?

With the onset of the pandemic, we were afraid that the importation of active pharmaceutical ingredients (APIs) from China and India would stop. Without APIs we would not be able to produce some drugs, but fortunately, we continued to work. Thankfully, our companies increased their investments and did everything necessary to continue producing what was needed to help the government and the general population in those times of crisis. The private market grew and many migrated to this sector, which helped to meet the needs of public and private hospitals.

With respect to internationalisation, there are several that have been successful in their expansions; among them are Sanfer, Psicofarma, Liomont, Asofarma, Siegfried, to mention a few. Sanfer’s growth in particular is due not only to its factories and plants throughout Latin America, but also to its increased exports.

How do you see the future for your member companies in Mexico, considering that there are still two years left of the current government?

With the current COFEPRIS commissioner, we have had a good understanding, but there are still some latent problems that we have already voiced to him and we hope that he will offer us a good solution. Although the pandemic is now a thing of the past, COVID-19 continues to be an issue that constantly disables many workers, together with influenza during this time of year. This does not help us to make faster progress and keeps us nervous about the possibility of a new strain wreaking more havoc. Pharma companies, as usual, are working continuously in the hope of staying ahead of whatever medical situation the future presents. Goals have been met, perhaps not in the way we had hoped, but working with the government has been possible.

Are international or foreign companies still interested in investing in Mexico?

Yes, ANAFAM is constantly receiving offers not only from Brazil, but also from China and even India. In general, they want to sell and they want us to participate in their markets. We often receive delegations with these intentions, but the biggest limitations for all of them are regulations. In the case of Brazil, the regulations are local and specific to each state, increasing the barriers to penetrate this market. In addition, the issue of registrations does not facilitate entry into new markets, as Mexico does not recognise registrations from other countries, just as other countries do not recognise those from Mexico.

It is important to note that COFEPRIS has joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Companies are working together with the government on the modification that COFEPRIS is carrying out, with the aim of strengthening regulations, adjusting them to the reality of the industry and respecting ICH standards. The adjustments must not slow down the growth due to registrations, as these actions would mean that new products could not be launched on the market and would be acting against the interests of patients.

Have steps been taken to secure Food and Drug Administration (FDA) or European Medicines Agency (EMA) certifications for Mexican plants?

Yes, it is going slowly, but there are companies like Psicofarma that have a plant in Puerto Rico, which obliges them to follow FDA regulations and therefore has the facility to export to other

countries. Laboratories in general are raising their standards to be similar to those of the FDA and EMA.

Do you have any final words for our readers about Mexico?

Firstly, I invite everyone to get to know Mexico, as it is a great country with very hospitable people. Secondly, I would like them to have confidence in the investment that companies have made and confidence in the medicines that our country produces -innovation and generics-. Mexico is a country that does everything for its people and that is why it produces and invests in them. We are also prepared to project ourselves to international levels and continue to grow.

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