Interview: Socorro España Lomelí – Executive Director, ANAFAM, Mexico

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04.07.2016

Tags: Pharma, Pharmaceuticals, Mexico, ANAFAM, Strategy, Association, Manufacturers, CMO, Manufacturing, Socorro España Lomelí, Export, Interview, Insight, Exclusive, Executive, Free

Socorro España Lomelí, executive director of Mexico's National Association of Drug Manufacturers (ANAFAM), details her strategic priorities with regards to the promotion of the industry's export strategy, the implementation of world-class manufacturing norms, the development of biosimilars and API manufacturing, as well as recognizing the pharmaceutical sector as a strategic industry for Mexico's economy and population.

In June 2016, ANAFAM organized the fifth edition of Vector Pharma, which has been rapidly increasing its line-up to gather up to 80 companies from 27 countries around the globe in 2016, and managed key international experts for its main seminar. How do you explain this overwhelming success?

This success has been accomplished thanks to the great quality of the companies and experts participating in Vector Pharma: we search globally for the best scientists, researchers and industry experts, providing the companies attending our event with key insights on the latest global trends affecting the industry and their suppliers. To fulfill this objective, ANAFAM has been traveling intensively to convince respected experts and to promote our event at an international scale.

This success also demonstrates that the international business community is clearly interested in developing commercial relationships with Mexican drug manufacturers, which is the main objective

of Vector Pharma. This recognition would not have been reachable without COFEPRIS, which has been fostering the expansion of Mexico's pharmaceutical industry by stimulating synergies, creating necessary efficiencies and actively endorsing proper regulations aligned with the highest international standards. Furthermore, Cofepris' recognition as a National Regulatory Authority of Regional Reference by the Pan-American Health Organization (PAHO) and as Functional Regulatory Agency for vaccines by the World Health Organization (WHO), as well as its looming entry in the Pharmaceutical Inspection Convention Scheme (PIC/S) undoubtedly stand as historical milestones that clearly helped Mexican manufacturers broaden our market perspectives and export our products all over the world.

How do you want to see Vector Pharma evolving in the upcoming years?

First of all, we want to see an increasing number of companies and countries participating in the event, while further increasing the number of B2B meetings occurring during the event. Besides fostering new business relationships, the conference part of the event will also be maintained, as we think it is fundamental to ensure the Mexican industry remains up-to-date with global trends and can engage with key international experts.

Our overall objective is to nurture more synergies and international exchange, including between all the laboratories that are part of ANAFAM. We will then continue to support both our large and emerging members to ensure they are ready to join the world scenario and, in this way, bolster more experience, competitiveness and investment.

In 2015, the former Federal Commissioner of COFEPRIS, Mr. Mikel Arriola Peñalosa, outlined that Mexican pharmaceutical exports were set to rise by 46 percent between 2015 and 2018, displaying an annual growth rate of 11.5 percent. What are the key therapeutic areas and geographical destinations that will help sustain this impressive growth?

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We identify great export prospects in a large variety of therapeutic areas. Oncology, for instance, is an area that has been growing significantly from a global standpoint. Metabolic syndrome-related diseases, including cardiovascular, diabetes and obesity are also high on the agenda, and we currently see important investments related to biotech manufacturing in Mexico, as these products are set to become the preferred way to tackle these diseases in the upcoming years. Beside pharmaceutical products, nanotechnologies and medical devices will also be key product categories pushing this rise.

Looking at the most promising export destinations, we have high hopes regarding all the countries which recently signed the Trans-Pacific Partnership (TPP), as well as those who have bounded regulatory agreements with COFEPRIS, like Australia, Japan, Canada, and even Brunei, which is still a developing market. Our top priority will however remain the US market. In this regard, we need COFEPRIS to finally be recognized by the FDA as a sanitary authority implementing stringent-enough regulations and controls, so Mexican manufacturers will ultimately be able to massively export their production to the United States, and no longer proceed by single isolated units.

On the other hand, within the Pacific Alliance, which includes Peru, Chile and Colombia, Mexican products tend to be approved faster than elsewhere, because our standards already stand as the most stringent implemented in the region, which clearly favors our export strategy to these countries.

ANAFAM took part in all meetings of the Trans-Pacific Partnership negotiations, in order to represent the interests of Mexican drug manufacturers. Intellectual property rights and patents on pharmaceutical drugs were among the key issues discussed in those negotiations, as well as biosimilars, doubtlessly one of the fastest growing areas in the Mexican market. How do you think the TPP will affect the development of the Mexican biosimilar industry?

Biotech treatments have been increasingly used in Mexico over the past 20 years, and biosimiliars have been playing a fundamental therapeutic role in saving millions of Mexican lives while preserving the sustainability of our healthcare system. As a result, tremendous investments have been made by the industry over the last few years to foster the development and production of new biosimilars.

As ANAFAM, we strive now to ensure the internal agreements made for the TPP are respected, particularly with regard to data protection, while we see some multinationals still pushing to obtain extended exclusivity rights. Nevertheless, if the intellectual property regulations would eventually be amended in favor of longer exclusivity rights for biotech products, the health outcomes would be catastrophic for Mexico’s eco-system, as it will indisputably restrain the access to affordable drugs for a large part of the Mexican patient population. As a result, the importance of not extending data exclusivity rights goes beyond potential commercial opportunities or economic matters: it is truly a global health issue.

Developing Active Pharmaceutical ingredient (API) manufacturing has been one of the priorities of most of Mexican pharmaceutical stakeholders over the last years. How

ANAFAM is working to favor the development of this essential part of the Pharma manufacturing value chain?

Unfortunately, the Mexican drug manufacturers still highly depend of API imports, as 92 percent of the total APIs used in Mexico are imported. Improving this unsatisfactory situation is getting even more crucial because of the recent depreciation of the Mexican peso, which fell almost 30 percent against the US dollar over the last months, while APIs usually amount to 80 percent of the production cost of a pill. To limit the effect of the peso depreciation, the government only authorized a 3.3 percent price rise in the public (health care system) market. Nevertheless, in 2015, for each dollar of pharmaceutical products we export, we import five dollars in return – and this deficit is largely attributable to API imports.

This situation highlights the extreme necessity to rekindle our national chemical industry, which almost vanished with the implementation of the North American Free Trade Agreement (NAFTA) in 1994. More than ever, we need a strong chemical industry to support our national pharmaceutical industry, decrease our dependence to API imports and bolster the local creation of a renewed productive environment. ANAFAM holds a special section for pharmachemicals through which we started to support and sponsor small local manufacturers outside the country. We are aware this will be a slow process, but the main idea is to help them thrive, while we expect it will in return nurture the growth of a more healthy local market.

We nevertheless dramatically need to attract more investment in this regard, while a proper and updated regulation on pharmachemical production needs to be implemented, and Good Manufacturing Practices (GMPs) should be released faster, so more products can be produced and introduced into the market. Another main challenge we face will be to make the local production of APIs more cost-effective than imports from China or India, which won’t be an easy task considering the initial investments needed to trigger the dawn of local API manufacturers.

ANAFAM plays a key role in advising and training its members to align with the requirements of the Mexican chapter of the FDA. After a couple of years training, do you feel that ANAFAM members are now more prepared to meet FDA requirements?

Our members are now at the cutting edge of what’s going on globally, which sometimes implied substantial investments to align with the recent regulation changes implemented in collaboration between ANAFAM and the related sanitary authorities. Nevertheless, by complying with these new regulations, our members are now truly part of the global market, and, thanks to events like ANAFAM’s Vector Pharma, they can more easily engage business relationships with local and

international suppliers and customers, as well as with research institutions.

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By August 2nd and 3rd 2016, the new versions of the norms NOM 164 (for pharmaceutical) and NOM 59 (medicinal products) will enter in force, while COFEPRIS is about to join the PIC/S, which outlines the strong intent of Mexico's industry to meet the highest international manufacturing standards. The NOM 164 and 59 have been specifically designed to upgrade Mexico's GMPs and ensure Cofepris's entry into PIC/S system. Once again, our members are fully aware that they have to further invest in their production facilities to meet these world-class standards impacting their manufacturing processes. One could estimate that the initial investment that these new norms require may be particularly substantial for some members, but their mid-term impact will be indisputably positive, as it will tremendously foster Mexican exports and then accelerate return on investment. Looking forward, investing in new processes, machinery, and personnel will only make these manufacturers not only a stronger but a better company, from international standards.

In June 2014, Dagoberto Cortés, ANAFAM's Chief Commissioner, stated that over the previous years Mexican manufacturers had invested more than USD 450 million to broaden and modernize their production facilities. Do you see such a level of investment being sustained in the coming years?

In fact, those levels have already significantly increased, as, for instance, the investments made to build new biotech plants in Mexico have been largely progressing since 2014. Developing products can be a slow process, but we know that some of our members are nonetheless opening specific areas in their facilities and making game-changing infrastructure decisions to begin the development and production of new molecules, new processes and new biotech treatments.

We have however reached out to the Ministry of Economy, calling for strong and clear government support to further impulse the competitiveness of our industry. We indeed need the government's endorsement to ease exports, reimbursements, or reduce IRS auditing – and to concretely recognize the pharmaceutical sector as a strategic industry for national development.

In 2014, you indeed mentioned the importance of the Ministry of Economy of Mexico recognizing the country's pharmaceutical industry as a key sector for the country's economy and population. How has the situation evolved since then?

The negotiations concretely started in January 2016, after a meeting with the Ministry of Economy. Nevertheless, we feel that long-awaited developments could happen in the upcoming months. In

this vein, we are fostering the coordinated development and unification of the different industry's clusters and providers, following our overall objective to build a unified industry, and generate a stronger and more direct channel of communication with the government. In this endeavor, we strive to adopt as holistic an approach as possible, including the pharmaceutical market and its suppliers, the patients, and the distributors. Although maintaining prosperous business perspectives and working in close collaboration with the government obviously are of the utmost importance, ANAFAM deeply believes that if the patient eventually is the big winner, the pharmaceutical industry will also largely benefit from this situation, and, ultimately, so will our country.

ANAFAM celebrated its 70th anniversary in 2015. As executive director, what will you consider your main and proudest achievements so far?

First of all, helping build a united industry is a responsibility that is particularly close to my heart. We have been able to tremendously improve the collaboration between all ANAFAM members over the past decade, in order to generate a better and stronger industry eco-system, where all stakeholders acknowledge the necessity to work hand-in-hand.

I am also very proud to be effectively contributing to foster the production of affordable and high-quality medicines that can benefit to a large part of the Mexican population, while ANAFAM is endlessly working with the industry to increase the level of pharmaceutical investments reaching our country.

The pharmaceutical sector is absolutely crucial to improve the health of our population and to effectively ensure we are further increasing the standards of living of our citizens. In this vein, investing in the pharmaceutical industry and in healthcare in general should stand as an utmost a top priority for all leaders in the world, because we are manufacturing drugs that cure, heal and save lives.

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