Interview: Santiago Salguero – Executive Director, Association of Latin American Pharmaceutical Laboratories in Ecuador (ALAFAR)



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Santiago Salguero, executive director of the Association of Latin American Pharmaceutical Laboratories in Ecuador (ALAFAR), elaborates on the exceptional work done by the association to build the relevant quality of products manufactured by his member companies, additional services the association can provide to its associates as well as the unmatched locational and economic advantages Ecuador has to offer for pharmaceutical laboratories. Finally, he highlights the regulatory obstacles ALAFAR will be looking forward to clear in collaboration with the recently elected national government.

Mr. Salguero, you have been the executive director of ALAFAR since June 2009. Could you briefly introduce yourself to our international readers and the key achievements of the association in recent years?

I have worked in the private and the public sector, being sub secretary and advisor for the Ministry of Industry of Ecuador as well as having managerial positions in industries like petroleum and agribusiness before joining the Association of Latin American Pharmaceutical Laboratories in Ecuador, as its executive director in 2009. In the past ten years, Ecuador's pharmaceutical market has witnessed the same fast paced growth as its Latin American neighbors, and we have been looking to help our members make the most of the opportunities the pharmaceutical market in

Ecuador had to offer.

ALAFAR’s members are Ecuadorian and Latin American pharmaceutical companies operating in Ecuador. These companies have been importing, in some cases producing and constantly bringing high quality medicines in the market for around 30 years in Ecuador and for almost a century in Latin America. With regards to the expertise these companies have built over the course of their existence, we are committed to building the reputation their products deserve from the point of view of quality. As a result of our work, I am proud to say that the medical community, patients and the rest of the sector’s stakeholders have recognized the experience accumulated by our members and placed their trust into products. More specifically, ALAFAR has achieved to gather a group of firms who have a great reputation in affordable quality medicines manufactured by Latin American pharmaceutical companies.

ALAFAR represents the interests of eleven Ecuadorian and Latin American companies operating in Ecuador and accounting for roughly 31 percent of the market’s value in 2017 according to the Ecuadorian Business Committee (CEE). What are the most important challenges your members are facing and how do you help them solve these?

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Looking back, it appears that the industry has faced very difficult times and that ALAFAR’s role has been of great support in this period. ALAFAR has done its best to understand what were the needs of pharmaceutical companies, notably in terms of combining the interests of the private and the public sectors from the point of view of regulations. More specifically, ALAFAR has been looking to shape the regulations to facilitate the operations of its members in the country with regards to marketing, publishing and advertising. For instance, we have been working closely with the National Regulatory Agency for the Control and Surveillance of Medication (ARCSA) as they were looking to improve market access regulations that affected the industry.

In addition, ALAFAR has the ability to help its member companies have a better understanding of some critical regulations related to prices, labeling and intellectual propriety for instance. Our contribution is widely recognized and as a matter of fact, the association represents almost 90 percent of Latin American pharmaceutical companies operating in Ecuador. The association and its members are united in confronting the issues faced by any of the companies in the guild. In fact, we hold regular meetings in which are discussed potential solutions to problems faced by any of our members.

Ecuador’s pharmaceutical market has been consistently growing since 2014 according to IQVIA, and achieving 6.3 percent year-on-year growth in 2017. How attractive is Ecuador for Latin American companies?

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Ecuador is a target country for pharmaceutical companies, notably because the country’s dollarized economy is a protection the economic variations one can witness in other Latin American markets. As a result, Ecuador is often among the first countries targeted by Latin American companies in the process of internationalization. Moreover, Ecuador’s strategic geographical location in the heart of the Andean region makes it an interesting destination for companies eying opportunities in Peru, Colombia or Chile. I believe that Latin American countries see Ecuador as an interesting place to invest and establish a platform for exports.

Having said this, most of our members have not yet made the choice to establish direct manufacturing facilities nor do they use the country as an export platform. In fact, many members use the existing infrastructure of a contract-manufacturing partner to produce in the country. This is a positive element for the domestic industry notably in terms of technological transfer because it allows the Ecuadorian contract manufacturers to reach the standards of good manufacturing practices. In some cases, ALAFAR is in a position to recommend reliable domestics producers to member companies looking to establish a production partnership with an Ecuadorian pharmaceutical company.

What could be done to foster a strong and competitive local productive capacity in Ecuador?

As in the whole world and in Ecuador in particular, pharmaceutical production depends to a large extent on the importation of active ingredients and excipients, which the country is not able to manufacture and probably never will, which leaves little margin for added value that can be given to a medicine. Under these circumstances, the production of medicines should reach very high standards in terms of quality.

Encouraging production in the country would also require the action of our authorities, facilitating and attracting international investment. In fact, with the intention of protecting the economy, the previous one implemented a five percent capital outflow rate, which reduces investment possibilities. In general, the improvement of Ecuador’s regulatory environment should begin with a broad survey of the needs of the pharmaceutical sector and current limitations. Such action seems legitimate in light of its contribution to the economy and human development. The pharmaceutical

industry can only adequately support the health care industry once the government allows real participation of the sector in the formulation of policies.

What do you expect from Moreno's new administration?

Lenin Moreno, our president since May 2017 claims his administration is open to dialogue and looking forward to creating a culture of consensus in the country's political management. In this regard, his political stance is a major improvement in comparison to the previous government's position. We hope this is one of the aspects we can build upon to improve the environment in which pharmaceutical companies operate in Ecuador. Such dialogue has already been initiated and ALAFAR has been given the opportunity to voice the interests of its member companies in the organic code of health's (COS) drafting or regulation. *[A bill to reform this central element to Ecuador's health policies was submitted in January 2018 to the Ecuadorian National Assembly – Ed.]*

Additionally, the current local legislation on biosimilars is extremely unfriendly. ALAFAR and its members are convinced these texts need to be reviewed and regulations inspired by the Colombian authorities' actions in this regard. Indeed, the establishment of innovation friendly regulation, notably in the case of biosimilars, has been a great opportunity for Colombian population to get access to innovative medicine. The same could be said about Ecuadorians provided the government changed its biosimilar regulation. Therefore, we hope that the pharmaceutical industry will be included in the construction of the new governmental policies.

How does Ecuador compare with other countries on the continent in terms of market access, and where do you see growth opportunities for Latin American companies in Ecuador?

Although some aspects of the legislation are similar, we are very different countries. For example, Brazil market access conditions are focused in high quality standards, which the same cannot be said about Ecuador. Nonetheless, I would say that Brazil is facing more problems in terms of market access than Ecuador is, for those who provide low quality products. In comparison to Colombia, Ecuador's pricing policies are similar but stricter. For instance, both countries have decided to focus their pricing controls on the list of most demanded medicines. In Ecuador, the authorities have established a list of so-called strategic medicines in light of the most prevailing diseases in the country. However, the government in 2016 announced a significant decrease for medicines on that list.

Ecuador’s pharmaceutical market’s growth potential in the years to come is undeniable. Indeed, the number of drugs and medical supplies approved in the country is inferior to the one in nations such as Peru and Colombia. Precisely, Ecuador has around 7,000 health products approved, Peru has between 10,000 and 12,000, and Colombia has 18,000. These numbers highlight the fact that Ecuadorian patients and doctors do not have as much choice when choosing a treatment. Undoubtedly, Ecuadorian citizens would see a great improvement in terms of product availability and choice if the regulations were less complicated and a wider range of products was available.

What keeps you motivated after ten years working for ALAFAR?

There are so many challenges and interesting issues to face to improve the market conditions of my members that I never get bored. This is the first time in my professional life that I have naturally been drawn to such a long-term commitment, notably because the pharmaceutical sector and challenges it offers are incomparably exciting.

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