Interview: Juan Carlos Galarza – Executive Director, ARCSA

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Juan Carlos Galarza, executive director of Ecuador's National Health Regulation, Control and Surveillance Agency (ARCSA), discusses the multiple procedural improvements that the Agency has recently implemented with the objective of increasing its international recognition, the benefits of these actions for Ecuadorians - who will have faster and safer access to innovative products - and also how it will help the local industry in terms of exports.

What have been some of the main actions that ARCSA has taken to increase the efficiency of its processes?

Since 2013, the Sanitary Registry process of ARCSA has been carried out through a computer system, called 'Ventanilla Única that allows users to carry out paperwork from any part of the country or the world without the need to provide physical documentation to the Agency. This system continues to mature and in 2017, electronic payment was implemented to further facilitate the activities related to record payments. More specifically, the process has started following the digital submission of a registration request. The Agency's employees verify all elements required to process a sanitary registration in under three days. Either the elements provided by the company are satisfactory and the revision process can start, or the company has an additional five working days to provide the missing elements. If these elements are not provided within this timeframe, the request is abandoned. Once the revision process starts, the requestor has a period of ten days to pay the fees relative to his request. If such payment is not processed in under ten days, the

request is abandoned and any further work on the product in question will have to begin with the verification of the submission of all elements relative to the application. The ‘Ventanilla Única’ program has advantages in terms of transparency and efficiency.

An important change to improve the health record processor has been the implementation of risk profile-based registration. Precisely, three risk profiles have been established and employees work on the sanitary registration applications of a specific risk profile only. As a result, we have been able to fluidize the registration of all types of drugs. As a matter of fact, in 2017 we treated 40 percent more requests in low risk profile drugs than we did in 2016. Computer work has also been carried out to improve the communication channels with the different regulatory authorities, which has allowed us to improve the quality of the analysis of requests.

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We have also implemented a process which is particularly interesting for foreign companies called homologation. This simplified process that Ecuador has carried out since 2010, has the purpose of facilitating the entry of medicines that have previously obtained their sanitary registration in countries that have reference entities in the region or high vigilance worldwide. In other words, products that have already benefitted from such sanitary registration are fast tracked through our system. Unfortunately while this process was imagined with the intention of bringing products that were not available in Ecuador to the country, the legislation has not been restrictive enough to prevent the fast track entrance of products that are not of first necessity, either because they exist in the market or because local companies produce them. Currently, we are analyzing this process and strengthening it in order to recover the initial sense of homologation.

Which aspects of the organization’s services have you improved to guarantee higher levels of transparency?

The role of the Agency is of national interest and Ecuadorian citizens are at the center of the elaboration of our transparency policies. Thus, we have a policy of open doors to dialogue and analysis, and we always prioritize the common interest and mission of the institution, which is to contribute to the protection of the right to health. In fact, Ecuadorian citizens have been given a right to contribute to the creation of health regulations. More specifically, there exists an online platform on which databases and reform projects are accessible to everyone and through which Ecuadorian citizens can formulate suggestions and track the progression of their input to the regulations.

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The second large-scale initiative that we have implemented to increase the dialogue with Ecuadorians, is a mobile application, 'ARCSA Móvil.' This is one of our most powerful tools to contribute to better healthcare conditions in Ecuador in a transparent manner. Indeed the application serves as a host to four main activities. Firstly, it allows the agency to push sanitary alerts to citizens and users of the application. Secondly, it enables the application's users to track the provenance and authenticity of medical products they buy through a photo scan system, thus improving health safety in the retail environment. Thirdly, it allows patients to actively contribute to the surveillance of healthcare dispensaries. Indeed, they can file reviews and complaints in the case of non-compliant medical supply retail situations. Finally, all personnel of ARCSA have signed contracts of confidentiality and conflict of interest.

While it is estimated by the World Health Organization that counterfeit products account for one percent of the medical market's value in developed countries, this can reach up to 15 percent in emerging markets. Ecuador regularly reports cases of counterfeit medication. What do you consider ARCSA's role in this ongoing problem?

The fight against medicine counterfeiting is one of the Pan American Health Organization (PAHO) commitments we have agreed to. Undeniably, Ecuador faces the existence of counterfeit medical products, however I can testify that our administration is uncompromising in its willingness to address this issue. In point of fact, governmental institutions successfully confiscated 18 tons of counterfeit products.

ARCSA is involved in a continuous stream of campaigns to raise awareness on the dangers of purchasing medication outside of an ARCSA-authorized establishments. However, the control of such products cannot be the work of a single entity, rather it requires the collaborative efforts of several state institutions such as the Ministry of Public Health, national health agencies, public prosecutors, police, justice and customs. Interestingly, in 2017 our government chose to form an inter-institutional group to monitor and control counterfeit medicines. That same year, our president of the republic and minister of health reaffirmed their intention to combat this evil until the last of consequences. In my opinion, the participation of pharmaceutical companies and the public in such an initiative could lead to even higher degrees of control.

ARCSA has ambitions to become a nationally and internationally recognized health agency by 2021. What are the elements you are currently focusing on to achieve such recognition?

Just as there are standards to certify companies in terms of quality management systems, in the case of regulatory agencies there is the PAHO guide for reference agencies. Last year, experts from PAHO visited the agency to verify progress and identify the gaps to be addressed in order to reach the level of accreditation of a reference agency (Level Four).

In December 2017, we already delivered our plan of action to PAHO and highlighted the fact that Ecuador would no longer be looking for the status of PAHO priority country as well as our intention of investing efforts and allocating the necessary resources that would lead us to the stated objective. Our short-term ambition is to fully comply with PAHO's requirements and, in the long term, to be a reference entity at the international level. Thus, similarly to any reference agency in the world, we have been focusing on implementing low risk approach organization, increasing our management's transparency, strive for efficiency, and involving the public in our surveillance and control mission.

The government is looking forward to strengthen its local pharmaceutical industry. In what ways can ARCSA become a facilitator of local exports?

Inversely to our implementation of the homologation procedure to fast track the approval of medication already registered by highly recognized health agencies, ARCSA can play a role in increasing the perceived trust in the products it registers. In a nutshell, increasing ARCSA's international recognition should in turn facilitate the approval of local products abroad. Some companies are already successfully exporting their products in high vigilance countries and we are looking forward to participating in the government's political ambition for the domestic industry. Furthermore, the PAHO Level Four recognition progress is a step in this direction.

In addition to the PAHO project, ARCSA has been implementing a number of initiatives such as strengthening the standards of good manufacturing practices expected to register a product, implementing bioequivalence, and engaging into a dialogue with other regulatory entities in the region. For example, ARCSA is in close co-operation with Colombia's National Health Agency, INVIMA. More specifically, the Colombian association is helping us perform quality control tests on products that go beyond our existing scope of expertise. Such collaboration is beneficial on multiple levels. For instance we are building relevant competences by learning from them and contributing to bringing safe innovative drugs to Ecuadorian patients at low levels on investment.

Our collaboration with INVIMA is not the only example of international collaboration. Indeed, we have also decided to join the Uppsala Monitoring Center to increase our registration efficiency. This membership gives us access to an international reference database in which we can consult prior

pharmacovigilance analysis on a specific product.

Do you have a final message for our international audience?

I perceive ARCSA to be an innovative institution that continues to mature and that is well informed, with committed personnel that works in harmony to achieve our main objective, which is to protect the health of our population.

We want to become a Regional Reference Authority, where one feels safe when consuming a product certified by ARCSA. I am confident this will happen soon as our Agency is highly competitive, where men and women work under knowledgeable and tempered leadership.

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