Interview: Javier Humberto Guzmán Cruz – Director General, INVIMA, Colombia

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03.07.2017

Tags: Colombia, INVIMA, Association, Regulator, Regulation, Healthcare

In explaining the role of the Colombia National Food and Drug Surveillance Institute (INVIMA) and its impact on the regulatory landscape of the healthcare sector, Javier Guzman, Executive Director, centres the discussion on four key pillars: institutional strengthening, efficiency, transparency and competitiveness. He speaks about his main priorities, the Colombian healthcare landscape, as well as his vision to elevate the organization in the future.

Mr. Guzman, you have held your current position since April 2016. What have been the key priorities in your agenda since your appointment?

Following my formal appointment as Director General of INVIMA in April 2016, I have been centralizing my attention on four key priorities. These four priorities include increasing institutional strengthening, improving efficiency, ensuring transparency and fostering the institution and country's competitiveness. The only way to achieve these priorities is to strengthen our risk-based approach, to invest heavily on information technologies including setting up a modern information and communications technologies system and finally, to work together with other regulatory agencies to avoid duplication and improve the value of what we all do.

Within each of these four priorities we have outlined a 15-point strategic plan of action. Overall, the progress of each priority has been advancing well and we anticipate favorable outcomes moving forward.

INVIMA is well-regarded in the region, most notably for its time-efficient regulatory approval periods. How has INVIMA further strengthened its regulatory timelines to be amongst the top in the region?

Efficiency for INVIMA is a key priority since we thoroughly understand the importance of streamlining regulatory timelines and preempting unnecessary delays. Certainly, there will always be an opportunity to improve the efficiency and efficacy of the operational management of INVIMA and we are constantly working towards that end. In further advancing the time-efficiency of regulatory approval periods, we are making important changes: we are strengthening our IT systems, changing the expert committee that evaluates the entry of new molecules and improving our risk based approach by making low risk transactions automatic (e.g. renewal of marketing authorization when original conditions have not changed and there have not been any issues during post marketing surveillance).

In regards to the new IT systems, we are creating an integrated system where the applicant will input necessary information using a standardized format and the agency will be able to review, follow-up and track an application throughout the entire process. Last year the Ministry of Information Technologies and Communications in Colombia recognized and rewarded Invima for making substantial progress in our automation strategy.

Another significant point worth mentioning is our capacity to impose penalties in order to ensure products comply with set guidelines for safety, quality and effectiveness. The fines levied by INVIMA were inconsequentially low and the system was unable to impose fines in an expedient manner. This communicated a message to product developers that the agency lacked the capacity to fully enforce accountability. In strengthening INVIMA, the penalties imposed on those who fail to comply with health rules and regulations has increased and the timeline for holding product developers accountable has decreased.

Given the widespread reforms in the healthcare sector, what has been the impact on the regulatory landscape?

INVIMA was created in 1993 following the institution of Law 100. Before that, management of the national health care system rested completely with the Colombian government. As such, the Ministry of Health served as the residing regulatory agency. Following article 245 of Law 100, INVIMA was established as the authority responsible for the regulation, supervision and control of products employed by the healthcare sector. In this instance, INVIMA possesses the responsibility for certifying sanitary conditions and generally good practice are upheld.

After the establishment of Law 100, INVIMA started to work in 1995 and just recently celebrated 20 years in 2015. At the outset, INVIMA modestly employed 130 workers. After 20 years in the sector, we have grown to 1,500 employees and have a budget of approximately USD 50 million.

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Moreover, from 2012 onwards, INVIMA has embarked on a process of institutional strengthening that has involved not only a change in infrastructure but expansion into 11 different cities around the country. As such, the agency is increasing its national presence and altogether influence. Since the healthcare reforms, INVIMA has grown its operation in terms of budget, people and infrastructure. The agency will continue to build and maintain a strong presence in Colombia.

The healthcare sector in Colombia and regulatory landscape has been in flux for 20 years and has progressed significantly. Since 1993, the health coverage rate has increased from a meager 17% to reaching universal health coverage.

Subsequently, it is important to mention the instrumental role played by the agency with regards to quality. In 2010, INVIMA was recognized by Icontec certification under NTC GP 1000:2009 and ISO 9001: 2008. These results stem from our risk-based approach that strives to maximize both efficiency and efficacy. When dealing with various products and manufacturers, having the ability to foresee what is likely to happen allows for an approach that aligns with risk. This point is even more significant when considering the wide range of products controlled by INVIMA. These products fall into several groupings including biologics, medical products, phytotherapeutics and dietary supplements. Products such as dietary supplements, phytotherapeutics and homeophatic medicines harbour unique risk profiles that must be taken into account in order for the agency to work efficiently and efficaciously.

In terms of our vigilance in the market, we have integrated a model based on risk that takes into account several variables defining health safety. This model allows us to operate efficiently and efficaciously.

What is your position with respect to the level of integration of the various vigilance agencies across Latin America? What does INVIMA have to learn from such agencies like COFEPRIS In Mexico, or ANVISA in Brazil?

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In 2010, the Pan-American Health Organization (PAHO) certified INVIMA as a reference agency in the Americas, a watershed moment since it recognized our regulatory stance in the region. Today,

8 agencies have been certified as reference agencies and we are currently working to establish convergences and efficiencies in terms of recognizing regulatory decisions. With this, INVIMA allies with COFEPRIS and ANVISA in a reciprocal manner to ensure access to information and to share best practices. For example, in consideration of good manufacturing practices and inspections, the alliance between INVIMA, COFEPRIS and now the Chilean ISP, indicates that a product certified in Mexico or Chile does not have to be inspected and re-certified by the Colombian authority. The certificating documents provided by COFEPRIS AND ISP ensures a product adheres to proper sanitary standards upheld in Colombia.

As a level four regulator, how would you describe INVIMA's role as a development agency in the macroeconomic landscape – for both the country and the region as a whole?

Invima, as a reference agency of the Americas, is now leading the government efforts to open new markets for products manufactured in Colombia and improve the country`s competitiveness. For example, if a product has marketing authorization in Colombia, that market authorization is now recognized throughout Central America by regulatory authorities. In terms of cooperation, Invima is now offering its regulatory expertise to other countries in the region, working towards a system that recognizes regulatory capacities and guarantees that regulatory processes do not have to be repeated across borders. This is a crucial element for the efficiency and competitiveness of the country and the region.

A good example of how this has worked in practice, is the Pacific Alliance agreements on cosmetics and dietary supplements.

What is your overarching vision for an ideal Colombian healthcare landscape?

As the OECD rightly said last year, the Colombian health care system offers "a remarkable example of rapid progress toward universal health coverage that deserves to be better known internationally".

Invima, as the regulatory agency in charge of the safety, efficacy and quality of medicines and medical devises, is part of this positive change with major improvements in the past 5 years.

Despite this progress, the Colombian system still faces important challenges including improving efficacy and transparency and securing sustainability. Invima is playing its role by making steady progress on these areas. For example, Invima is working with the office of the attorney general in the fight against corruption, and is collaborating with the European Union to reinforce a culture of transparency and integrity.

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