Interview: Cesar Amaro – Director General, Digemid – Peru

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Cesar Amaro, director general of Digemid, highlights the evolution of Peru's recently-established regulatory agency while taking into account the challenges surrounding the institution on a daily basis, like approval times, counterfeit drugs, and adapting to modernity.

What are the main priorities of Digemid today?

I have been running Digemid since 2014. Our institution is in charge of authorization procedures within the entire Peruvian pharma industry; we also supervise the quality of drugs provided to our community, and subsequently ensure the wheels of competition keep turning to the best of our abilities. Again, our main role is to ensure efficacy and safety of the drugs used by Peruvian citizens. Any medical product that is in the process of being commercialized in our country, imported or exported, is thoroughly evaluated by Digemid. Our purpose is to create and maintain a system of quality management based on compliance with ISO 9001:2001 and other legislations.

We also ensure that our population has an ample supply of top-quality medical products through a huge logistics network that includes laboratories, hospitals, pharmacies and drugstores. The main purpose of this network is to ensure that everyone knows their role within a higher strategy and that everyone follows a clear, predictable yet efficient rule set; for example, everyone must know who the authorities are and their role in the bigger picture.

This transparency is vital, especially for entrepreneurs who come to Peru to invest in pharmaceutical companies; they must know the “who is who” within the Peruvian market and have the option to choose between “serious” and “informal” players. Our fundamental objective comes down to ensuring that people have access to safe, effective and quality medicines and that those drugs are rationally used while controlling the market in accordance with the law but without overlooking the need for a competitive environment.

What new regulatory mandates have been implemented to reach this objective?

Theoretically speaking, our network allows everyone to operate within a defined legal and regulatory framework; this is intended to create a lawful, legitimate and stable environment. Nevertheless, there is much to do in practical terms until the market is completely regulated; we also have strict regulations for patents and intellectual property. We also supervise the avoidance of “iatrogenesis”: this refers to any consequence of medical treatment or advice to a patient that can result in harmful reactions or improper usage of any drug.

In addition, new reform took place in 2009 (Law 29459) which focused on transforming an unregulated market into a more secure, quality-based healthcare model. This new law focuses on the regulation of biotechnological and biosimilar products which represent an important area for development. This law also focuses on the interchangeability between brand generics and patent protected drugs.

Finally, we act as a contributor that helps through policies of information and promotion while also being a subsidiary; this means that if a private player does not offer certain benefits, the government will assume that responsibility.

What is the biggest challenge you face today?

One of the biggest challenges that we face is the lack of formality in our market; approximately one-third of the total market is unregulated. This means than many producers are not registered and do things “under the table” without following any proper regulation. There is a recurring tendency and incidence of bad usage of drugs thanks to counterfeit and illegal drugs (many of them are imported). All of this affects both our health and our economy as a country (more people than you think do not comply with our rules and avoid paying taxes).

Companies often wait for several years for product approvals. Why does Digemid have such strict regulations and what measures are you taking to reduce the wait period?

It is true that we are undergoing certain difficulties when talking about the registry of certain medical products; for example, cosmetic products have an extremely agile or even automatic registration process. An enormous number of documents containing administrative formalities and procedures reach Digemid all the time; this is one of the main challenges and distracters that consume much of our energy. Medical devices take about a month, but things can still get difficult, blurry and confusing when talking about drugs. We have thousands of different products in stock waiting to be registered.

My mission as director of Digemid involves finding an answer to these colossal statistics. We are trying to combat this unnecessary time-waster through “results-based” management by working alongside a technical department comprised of experts in the field, using productivity indicators and automatic procedures to guarantee important results. In addition, we are trying to implement simpler regulations to facilitate processes and focus on more important matters. Our productivity ratio for new registrations has increased within the last few months but is still far from ideal; there are many areas to be improved but I am confident that we will reach our goals. A few months ago, I spoke to some counterparts at Cofepris, who recommended us to use Mexico’s outsourcing model to make things easier for ourselves. Unfortunately, that might not be feasible; according to Peruvian law, outsourcing during registration processes is not legal. This means that our own team needs to become more productive and efficient.

How do you become a sustainable entity when speaking about human and financial resources?

The good news is that, financially speaking, we are absolutely sustainable because the national pharmaceutical industry is financing us through all processing and registration fees they are required to pay to us as an authority figure. Similarly, Digemid is currently a strong entity because Peru’s economy is strong and reliable today. There are some difficulties though; Peru is only just starting to experience a transition towards modernity through more agile methods. Certainly, this takes some time because of the public system’s bureaucracy and the clumsiness that it brings. Our current reform process will lead us to becoming more efficient. Automatic procedures will help us focus our energy on the most important issues.

What are your plans for expansion for the future?

Our goal is to become a regional authority, not only in Peru but in other areas in Latin America as well. I want us to become a model for other countries, always following a path for excellence. But first, one must order his own house before going out to the world; this is why we are working

tirelessly to become a modern and efficient institution.

What successes would you like to reach before the end of your term in office?

The most important goal is to become a regional reference authority for other countries in Latin America endorsed by the Pan American Health Organization (PAHO); this will reflect an evolution of our team. We want to be recognized as a productive, well-structured and orderly institution. Also, I would like to have a much more reliable network of pharmaceutical establishments that allow our citizens to receive a better supply of quality drugs. Finally, I would like the Peruvian market to become a highly competitive environment with the aid of recent information technologies that now are at our disposal. Additionally, our market has really outrageous costs for high specialty drugs that need to change. Access to quality drugs is and will always be our priority.

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