Interview: Marisol Sanchez – Executive President, Medical Devices Chamber, ANDI, Colombia



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Marisol Sanchez, executive president of ANDI's Medical Devices Chamber in Colombia, speaks about the opportunities and challenges in the country's medtech sector, the industry's strong ethical code, the key role of the Chamber in supporting its members to navigate the regulatory landscape, as well as the need for a sustainable healthcare system.

When we interviewed you in 2013, you emphasized the need for the importance of a strong ethical code and good commercial practices in the sector. What would you describe as the key developments in the medical devices sector for the last four years?

Firstly, the sector places a strong emphasis on an all-encompassing ethical code that covers multinational, national and distributor companies alike. Our ethical code includes protocols regarding risk analysis in the context of integrity in order to ensure good business practices in our member companies, as well as the checks and balances that are required for manufacturing or commercialization.

In the context of the Colombian medical devices landscape as a whole, one of the key developments within the last four years is the country's participation in the Pacific Alliance. Alongside, Chile, Peru and Mexico, Colombia has joined an agreement that allows for a standardization of sanitary requirements for medical devices, while reducing market access barriers for these products in their respective markets.

Furthermore, in the last four years, the country has made advances in its sanitary regulation framework. An automated sanitary registration protocol has been implemented to optimize the processes in this regard. This major development has been made through a strong collaboration with INVIMA. Currently, Colombia is the only country in the region that has an automated system.

Have any measures been enacted in terms of regulating prices for the sector?

A pilot program, STEN, has been placed for medical devices, especially in regard to cardiological products. There are two main regimes for the program: The first stream is more controlled wherein a price ceiling is set and the other one is a vigilant regime wherein prices are more liberal but they are constantly monitored. The program began in September 2015 and it is still in effect today.

What do you consider to be the principal challenges in the sector?

Currently, our sector faces a lot challenges, including access to new technology, the advancement of sanitary regulation, good manufacturing practices for companies, and semantic standardization for the industry. In the context of access to high-level technology, the government has recently implemented a series of reforms anchored on the Statutory Health Law to create sustainability in the healthcare system.

The decision to join the Pacific Alliance was one of the measures to counter the challenges and implement a gold standard for the industry. We also participate in IMRDF, which stands for the International Medical Forum in Spanish in order to ensure coherence of our standards within the region. Moreover, it was also important for us to establish good manufacturing standards especially as a way to set a benchmark for the rest of the Latin American region. Colombia also supplies large markets such as Mexico and Brazil and therefore it is imperative to set a high-level standard of quality for the country.

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What is the role of the Chamber in helping its members to navigate the challenges in the sector?

Our key priority is to provide a mechanism to anticipate the any sudden changes in the environment of business in the industry and create a stable ecosystem within Colombia, and looking for opportunities in the rest of the world. There is a significant focus on the regulatory environment, especially given the fact that it almost 90 percent of the products in the country are imported, especially from Europe and USA. Sanitary regulations are very strict in the sector, especially given that nature and the dynamics in the industry.

In the context of the Pacific Alliance, recent trade agreements have been reached this year concerning Chile, Colombia, Mexico and Peru for the creation of a single market. What are the advantages and disadvantages of this alliance for Colombia?

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The Pacific Alliance has been mutually beneficial for all the players involved. However, in all the four markets, Colombia is the one that is the most aligned with international standards, especially in terms of the sanitary environment. Our products undergo thorough risk analyses, parred through different environmental variables that can impact their performances. Another key advantage is also in ensuring more efficient timelines when products enter the market. In addition to providing support to the companies, we also work tirelessly to eliminate barriers for market access. Our overarching goal is to be able to provide the most optimal route for commercialization for different products. The two most favorable markets for exports are Peru and Chile especially given the synergies that exist between these countries and Colombia. Moreover, Colombia is well regarded in these countries because of its high level of standards.

Currently, the Pacific Alliance is our main international accord, but given Colombia’s strategic location, we also easily conduct business with many countries in North and South America and even Asia Pacific. Recently, we have even had partnership from markets such as Turkey and Japan.

Given the recent reforms in the healthcare sector, such as the abolition of the POS in the recent months, how has the Colombian medical devices sector been impacted?

The reforms in the healthcare system have forced all actors to change their business strategies. The demonstration of value in the products is very important in the new structure in order to bring more efficiency into the system. Creating sustainability in the healthcare system is of utmost priority. Nevertheless, we also stress the importance of having innovative products in the market and the necessity of your entry with criteria of cost-effectivity. Innovative products shorten hospitalization periods in the majority of cases. New technologies are necessary to be covered in the system because they ameliorate patient outcomes at a much faster rate.

A transactional model for evaluation of medical devices is futile. All elements such as manufacturing costs, engineering costs, as well as the cost for medical education and the medical professionals needed to operate the devices need to be taken into account at the final post-marketing price of the product.

How compatible is the current Colombian hospital infrastructure with high-value medical devices?

As a country that hosts some of the best hospitals in Latin America, there is a high compatibility with the latest medical devices, however, the issue lies with the fact that there are some capabilities that are extremely underutilized. Furthermore, the more pertinent challenge is the fact that there is a need for more streamlined standardization in the industry. Some regions do not have the same level of quality of products and the allocations amongst these areas appear to be arbitrary.

What are your strategic priorities for the organization for the next three years, with 2020 in the horizon?

Access to high technology is the omnipotent priority of the sector. This includes a multifaceted aspect of looking into proper valuation of technology and ensuring that value is created commensurate to the therapeutic value of the devices. Even granular elements such as the terminology used across the industry is another key aspect of focus for us to ensure that the country is aligned with international standards. There needs to be a balance between the cost-effectiveness of the devices used while ensuring access to innovative products in order to create a sustainable medical device sector in Colombia.

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